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Paroxetine

BRL-029060

A Multicenter, Open-label, Six-Month Extension Study to Assess the Long-term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD)

Study 716
Study Initiation Date: 01 May 2000
Study Completion Date: 29 January 2002

Final Clinical Study Report

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Signatory: xxxxxxxxxxx M.D.

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Signature Page

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I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

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Report Synopsis

Study Title: A Multicenter, Open-label, Six-Month Extension Study to Assess the Long-term Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD) (29060/716).

Investigators and Centers: 49 centers in the US and 2 centers in Canada. All investigators were experienced in the treatment of child and adolescent patients. The study center of xxxx xxxxxxxxxxxxxxxxxx (Center 055) was terminated because of significant compliance violations during acute Study 704.

Publication: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx. Interim Results of a 6-month Extension Study to Assess the Long Term Safety and Tolerability of Paroxetine in Children and Adolescents. Poster presented at American Psychiatric Association 155th Annual Meeting, Philadelphia, PA. 22 May 2002.

Study Dates: The first dose of open-label study medication was administered on 13 May 2000. This report includes data for all patients who entered the open-label extension study from acute Studies 701 (patients with MDD), first double-blind dose date 20 March 2000; 704 (patients with OCD), first double-blind dose date 20 January 2000; and 715 (open-label, forced-titration, steady-state pharmacokinetic [PK] evaluation in patients with MDD or OCD), first dose date 15 August 2000. The last dose of Study 716 study medication (including taper) was administered on 06 January 2002.

Objectives: To assess the long-term (6-month) safety of paroxetine in the treatment of children and adolescents with MDD or OCD who completed paroxetine Study 701, 704, or 715, and chose to enter this study.

To monitor the long-term (6-month) efficacy of paroxetine in the treatment of children and adolescents with MDD or OCD who completed paroxetine Study 701, 704, or 715, and chose to enter this study.

Study Design: This was a multicenter, open-label, 6-month extension study in children (aged 7 to 11 years inclusive at acute study entry) and adolescents (aged 12 to 17 years inclusive at acute study entry) who completed acute Study 701 or 704 or PK Study 715, and who chose to enter this study.

Study Population: Children and adolescents who completed Study 701, 704, or 715 and who met all other inclusion and none of the exclusion criteria were eligible to enter this study.

Treatment and Administration: Paroxetine was supplied as white oval film-coated tablets for oral administration once daily. Each tablet contained 10 mg of paroxetine (batch number U00001).

Patients were to receive paroxetine (10 to 50 mg/day) for a period of 24 weeks during the Treatment Phase of Study 716. Patients entering Study 716 from acute Study 701 or 704 were to be started on therapy at 10 mg/day; patients entering Study 716 from PK Study 715 could, at the investigator's discretion, be initiated at a higher dose level (e.g., the dose level achieved at Study 715 endpoint, or 10 mg/day higher or lower).

Starting at Week 2, the dose of paroxetine for any patient could be increased by one dose level (10 mg/day) up to a maximum dose of 50 mg/day, according to clinical response and tolerability. Dose reductions of 10 mg/day at weekly intervals were permitted at the discretion of the investigator. Patients who completed the Treatment Phase or were prematurely withdrawn at a dose of ≥20 mg/day were to be down-titrated at a rate of 10 mg/day per week for a period of up to 4 weeks until they finished one week of Taper Phase dosing at 10 mg/day.

Evaluation Criteria:

Safety Parameters: Safety, of primary interest in this study, was assessed via AE monitoring, vital sign measurements, laboratory evaluations, serum pregnancy tests, electrocardiograms (ECGs), and physical examinations.

Efficacy Parameters: There was no primary efficacy variable in this study.

Secondary efficacy variables were change from baseline in the Children's Depression Rating Scale–Revised (CDRS–R) total score, assessed only in patients with a primary diagnosis of MDD (patients from Study 701 or from Study 715 with MDD as clinically predominant Axis I disorder); change from baseline in the Children's Yale-Brown Obsessive-Compulsive Scale (CY–BOCS) total score, assessed only in patients with a primary diagnosis of OCD (patients from Study 704 or from Study 715 with OCD as clinically predominant Axis I disorder); the proportion of responders based on the Clinical Global Impressions (CGI) Global Improvement item (where response was defined as a score of 1 [very much improved] or 2 [much improved]), assessed in patients with a primary diagnosis of either MDD or OCD (all patients); and change from baseline in the CGI Severity of Illness item score, assessed in patients with a primary diagnosis of either MDD or OCD (all patients).

Statistical Methods: This was an open-label study and no hypothesis testing was performed. Efficacy data were summarized descriptively, both overall and by acute-study treatment group at each visit, with inferences based on the Week 24 observed cases (OC) and last observation carried forward (LOCF) datasets. Categorical data were summarized by counts and percentages. Continuous data were summarized by the mean, median, standard deviation, and range (minimum, maximum). Two patient populations were evaluated. The intention-to-treat (ITT) population consisted of all patients who received at least one dose of open-label medication and for whom at least one valid post-baseline (Study 716, Visit 1) open-label evaluation (including any adverse event) was available. A pure paroxetine (PPX) population was identified for purposes of describing the maintenance effect of paroxetine. It consisted of all ITT patients who received paroxetine in their acute study and were evaluated for key disorder efficacy (i.e., CDRS–R or CY–BOCS) at the conclusion of the acute study. Patients from Study 715 were not part of the PPX population as they had no key disorder efficacy assessments collected at the conclusion of the study.

Patient Disposition and Key Demographic Data:

A total of 265 patients were entered into this open-label study. Of these, 263 patients were included in the ITT population: 133 patients who received paroxetine in their acute or PK study (referred to as acute-study paroxetine patients) and 130 patients who received placebo in their acute study (referred to as acute-study placebo patients). Two patients were not included in the ITT population as they had no post-baseline assessments in this study.

Patient Disposition (All Patients)

Study Stage/ Population	Acute-study Treatment Group: Paroxetine n	Paroxetine %	Placebo n	Placebo %	Total n	Total %
Entered **	135	(100.0)	130	(100.0)	265	(100.0)
Completed *	68	(50.4)	46	(35.4)	114	(43.0)
Early Withdrawal	67	(49.6)	84	(64.6)	151	(57.0)
Intention-to-Treat	133	(98.5)	130	(100.0)	263	(99.2)
Pure Paroxetine	96	(71.1)	–	–	96	(36.2)

* Patients were considered to have completed the study if they completed a Week 24 visit CRF.
** The acute-study paroxetine group includes two patients who entered Study 716 but had no post-baseline assessments and are therefore not included in the ITT population.

In the ITT population, 43.3% (114/263) of patients completed the study and 56.7% (149/263) withdrew early. The primary reasons for withdrawal were "other" (includes unknown and non-study related personal reasons) (13.7%, 36/263), adverse event (13.3%, 35/263), and lack of efficacy (12.2%, 32/263). More patients from the acute-study placebo group withdrew early (64.6%, 84/130) than patients from the acute-study paroxetine group (48.9%, 65/133). The primary reason for withdrawal in patients receiving paroxetine in their acute study was "other" (includes unknown and non-study related personal reasons) (13.5%, 18/133), similar to the number withdrawn for "other" in the placebo group (13.8%, 18/130). Among patients who had received placebo in their acute study, the primary reason for withdrawal was adverse event (18.5%, 24/130), compared to 8.3% (11/133) of patients who had received paroxetine in their acute study. The withdrawal rate was slightly higher for children than adolescents, but was independent of primary diagnosis.

Demographic data were collected at baseline for Studies 701 and 704 and screening for Study 715; efficacy parameters CDRS–R and CY–BOCS are presented for Study 716 baseline. Mean age, height, weight and BMI were similar between acute-study treatment groups for the ITT population. Overall, there were more male patients (57.4%, 151/263) than female patients (42.6%, 112/263). The proportion of males in the acute-study paroxetine group (54.1%, 72/133) was slightly lower than in the acute-study placebo group (60.8%, 79/130).

There were slightly more children than adolescents in the ITT population, 52.9% (139/263) compared to 47.1% (124/263), respectively. This difference occurred only among the patients who received placebo in their acute study.

Demography and Baseline Characteristics (ITT Population)

	Acute-study Treatment Group: Paroxetine	Placebo	Total
Total Patients–Age Group: Total			
Females: Males (%)	45.9:54.1	39.2:60.8	42.6:57.4
Mean age (SD): years	11.7 (2.93)	11.6 (2.82)	11.6 (2.87)
White: n (%)	111 (83.5)	112 (86.2)	223 (84.8)
Total Patients–Age Group: Children			
Females: Males (%)	52.2:47.8	37.5:62.5	44.6:55.4
Mean age (SD): years	9.0 (1.36)	9.4 (1.32)	9.3 (1.34)
White: n (%)	56 (83.6)	63 (87.5)	119 (85.6)
Total Patients–Age Group: Adolescents			
Females: Males (%)	39.4:60.6	41.4:58.6	40.3:59.7
Mean age (SD): years	14.3 (1.54)	14.2 (1.72)	14.2 (1.62)

White: n (%)	55 (83.3)	49 (84.5)	104 (83.9)

Demography and Baseline Characteristics (ITT Population) (continued)

	Acute-study Treatment Group		
	Paroxetine	**Placebo**	**Total**
Patients with MDD–Age Group: Total			
Females: Males (%)	40.7:59.3	43.9:56.1	42.2:57.8
Mean age (SD): years	11.8 (2.85)	11.6 (2.94)	11.7 (2.88)
White: n (%)	65 (80.2)	54 (81.8)	119 (81.0)
716 Baseline CDRS–R Total Score: Mean (SD)	35.5 (13.14)	37.4 (13.93)	36.4 (13.50)
Patients with MDD–Age Group: Children			
Females: Males (%)	48.7:51.3	38.9:61.1	44.0:56.0
Mean age (SD): years	9.3 (1.28)	9.4 (1.29)	9.3 (1.28)
White: n (%)	31 (79.5)	30 (83.3)	61 (81.3)
716 Baseline CDRS–R Total Score: Mean (SD)	33.9 (14.02)	35.3 (12.92)	34.6 (13.39)
Patients with MDD–Age Group: Adolescents			
Females: Males (%)	33.3:66.7	50.0:50.0	40.3:59.7
Mean age (SD): years	14.2 (1.55)	14.3 (1.86)	14.3 (1.68)
White: n (%)	34 (81.0)	24 (80.0)	58 (80.6)
716 Baseline CDRS–R Total Score: Mean (SD)	36.9 (12.36)	39.9 (14.92)	38.1 (13.46)
Patients with OCD–Age Group: Total			
Females: Males (%)	53.8:46.2	34.4:65.5	43.1:56.9
Mean age (SD): years	11.5 (3.22)	11.5 (2.73)	11.5 (2.93)
White: n (%)	46 (88.5)	58 (90.6)	104 (89.7)
716 Baseline CY–BOCS Total Score: Mean (SD)	14.7 (9.21)	19.0 (8.20)	17.1 (8.84)
Patients with OCD–Age Group: Children			
Females: Males (%)	57.1:42.9	36.1:63.9	45.3:54.7
Mean age (SD): years	9.0 (1.48)	9.5 (1.36)	9.3 (1.42)
White: n (%)	25 (89.3)	33 (91.7)	58 (90.6)
716 Baseline CY–BOCS Total Score: Mean (SD)	17.9 (8.10)	21.1 (6.48)	19.7 (7.34)
Patients with OCD–Age Group: Adolescents			
Females: Males (%)	50.0:50.0	32.1:67.9	40.4:59.6
Mean age (SD): years	14.4 (1.56)	14.1 (1.57)	14.2 (1.55)
White: n (%)	21 (87.5)	25 (89.3)	46 (88.5)
716 Baseline CY–BOCS Total Score: Mean (SD)	16.2 (8.78)	20.0 (7.51)	18.3 (8.27)

Safety Results:

Adverse Events: Overall, 75.7% (199/263) of patients reported a gender-non-specific adverse event during the open-label Treatment Phase: 79.7% (106/133) of patients in the acute-study paroxetine group and 71.5% (93/130) of patients in the acute-study placebo group. The most common (≥10%) gender-non-specific adverse events were headache (25.1%), respiratory disorder (18.3%), trauma (13.7%), infection (12.5%), pharyngitis (10.6%), and abdominal pain (10.3%).

In the acute-study paroxetine group, the most common (≥10%) adverse events were headache (29.3%), respiratory disorder and trauma (each 16.5%), pharyngitis (13.5%), infection (12.0%), abdominal pain (11.3%), and nausea (10.5%); the most common adverse events for patients in the acute-study placebo group were headache (20.8%), respiratory disorder (20.0%), infection (13.1%), trauma (10.8%), and nervousness (10.0%). Ten female patients reported a female-specific adverse event during the open-label Treatment Phase. There were no male-specific adverse events emergent during the open-label Treatment Phase.

The overall frequency of gender-non-specific adverse events was slightly higher among children than adolescents. A total of 78.4% (109/139) of children reported gender-non-specific adverse events during the open-label Treatment Phase: 80.6% (54/67) of patients in the acute-study paroxetine group and 76.4% (55/72) of patients in the acute-study placebo group. A total of 72.6% (90/124) of adolescents reported gender-non-specific adverse events during the open-label Treatment Phase: 78.8% (52/66) of patients in the acute-study paroxetine group and 65.5% (38/58) of patients in the acute-study placebo group. Adverse events that occurred in children with an incidence of ≥5% and with an incidence of at least twice that in adolescents were pharyngitis, hyperkinesia, vomiting, otitis media, cough increased, and pain. Adverse events that occurred in adolescents with an incidence of ≥5% and with an incidence of at least twice that in children were allergic reaction, emotional lability, asthenia, somnolence, asthma, and albuminuria.

The overall frequency of gender-non-specific adverse events in patients with a primary diagnosis of MDD was 74.8% (110/147): 81.5% (66/81) of patients in the acute-study paroxetine group and 66.7% (44/66) of patients in the acute-study placebo group. The overall frequency of gender-non-specific adverse events in patients with a primary diagnosis of OCD was 76.7% (89/116): 76.9% (40/52) of patients in the acute-study paroxetine group and 76.6% (49/64) of patients in the acute-study placebo group. Adverse events that occurred in patients with a primary diagnosis of MDD with an incidence of ≥5% and with an incidence of at least twice that in patients with a primary diagnosis of OCD were vomiting (10.9% compared to 0.9%), and emotional lability (6.8% compared to 3.4%). Adverse events that occurred in patients with a primary diagnosis of OCD with an incidence of ≥5% and with an incidence of at least twice that in patients with a primary diagnosis of MDD were hyperkinesia (10.3% compared to 2.0%) and anxiety (5.2% compared to 2.0%).

Overall, 11.8% (31/263) of patients reported a severe gender-non-specific adverse event during the open-label Treatment Phase: 9.8% (13/133) of patients in the acute-study paroxetine group and 13.8% (18/130) of patients in the acute-study placebo group. The only severe adverse events occurring in more than one patient in either acute-study treatment group were emotional lability (4 and 1), hostility (2 and 3), infection (2 and 1), trauma (1 and 2) and urinary incontinence (0 and 2) for patients in the acute-study paroxetine group and acute-study placebo group, respectively. There were no severe gender-specific adverse events. The majority of severe adverse events were considered unrelated to study medication. Two patients from the acute-study paroxetine group and 7 patients from the acute-study placebo group had severe adverse events during the open-label Treatment Phase that were considered by the investigator to be related or possibly related to open-label study medication; the only such event occurring in more than one patient was hostility (1 patient in the acute-study paroxetine group and 2 patients in the acute-study placebo group).

Overall, 49.4% (130/263) of patients reported a gender-non-specific adverse event judged by the investigator to be related or possibly related to open-label study medication during the open-label Treatment Phase: 49.6% (66/133) of patients in the acute-study paroxetine group and 49.2% (64/130) of patients in the acute-study placebo group. The most common (≥5% of patients from either acute-study treatment group) gender-non-specific adverse events judged to be related or possibly related to open-label study medication were headache, nervousness, hyperkinesia, insomnia, weight gain, nausea, and decreased appetite. The only gender-specific adverse event judged to be related or possibly related to open-label study medication was female genital disorders (inorgasmia), which occurred in one adolescent patient in the acute-study placebo group with a primary diagnosis of MDD.

During the Taper Phase or Follow-up Phase, 34.6% (54/156) of patients reported a gender-non-specific emergent adverse event. The most common (≥5%) gender-non-specific adverse events were headache and respiratory disorder.

Serious Adverse Events: There were no deaths during the study, and no deaths have been reported since the completion of the study.

Overall, 5.7% (15/265) of all patients enrolled in Study 716 reported at least one serious adverse event (SAE) during the open-label Treatment Phase or Taper Phase, or within 30 days of the last dose of open-label study medication (including taper). The proportion of patients reporting at least one SAE was similar between the two acute-study treatment groups: 5.9% (8/135) of patients in the acute-study paroxetine group and 5.4% (7/130) of patients in the acute-study placebo group. Of the 18 SAEs reported, 14 occurred during the open-label Treatment Phase. The majority of SAEs were judged moderate or severe in intensity and unrelated to open-label study medication.

The most common SAE was emotional lability, occurring in 2.3% of patients (6/265), 5 of whom were in the acute-study paroxetine group. Verbatim terms for the preferred term of emotional lability were suicidal ideation (2 patients), attempted suicide (2 patients) and suicidal (1 patient) in the acute-study paroxetine group, and hospitalization for suicide attempt in the acute-study placebo group. The only other SAEs occurring in more than one patient were depression and hostility, each occurring in one patient in each acute-study treatment group. No gender-specific SAEs were reported for either acute-study treatment group.

Withdrawals Due to Adverse Events: Overall, 11.8% (31/263) of patients were withdrawn from the study because of an adverse event emergent during the Treatment Phase. The proportion of patients withdrawn because of an adverse event was lower in the acute-study paroxetine group (7.5%, 10/133) than in the acute-study placebo group (16.2%, 21/130). Additionally, 3 patients withdrew during the Treatment Phase for an adverse event that started during the Acute Phase of the prior study, and 2 patients withdrew during the Taper or Follow-up Phase due to an adverse event. Of the 36 patients (12 in the acute-study paroxetine group and 24 in the acute-study placebo group) withdrawn from the study because of an adverse event, 58.3% (21/36) were children and 41.7% (15/36) were adolescents; 52.8% (19/36) had a primary diagnosis of MDD and 47.2% (17/36) had a primary diagnosis of OCD. The majority of the adverse events leading to withdrawal were judged moderate or severe in intensity by the investigator.

Adverse events leading to withdrawal during the open-label Treatment Phase (excluding taper) occurring in more than 1% of the total population were hostility (3.4%, 9/263), emotional lability (1.9%, 5/263), hyperkinesia (1.5%, 4/263) and nervousness (1.1%, 3/263). One male and one female, both in the acute-study placebo group, reported a gender-specific adverse event leading to withdrawal, one of which started in a placebo patient during the acute study.

Vital Signs: Overall, 55 patients (29 patients from the acute-study paroxetine group and 26 patients from the acute-study placebo group) had vital sign values that met the sponsor's definition of potential clinical concern during the open-label Treatment, Taper or Follow-up Phase of the study. The majority of these patients, 19 from the acute-study paroxetine group and 15 from the acute-study placebo group, had an increase in body weight ≥7% from acute-study baseline and above the normal weight range for their age. Eight patients had adverse events associated with the vital sign of concern, 7 for weight gain and one for weight loss. With the exception of weight gain, mean changes in vital sign values from acute-study baseline to Week 24 were generally small for both acute-study treatment groups and age groups and of no clinical concern.

Laboratory Data: In total, 71 patients had laboratory values that met the sponsor's definition of potential clinical concern during the study (36 patients from the acute-study paroxetine group and 35 patients from the acute-study placebo group). The majority of these patients had low hematocrit values of potential clinical concern. Twelve of the 71 patients had adverse events associated with the laboratory value of concern. No remarkable mean changes in laboratory parameters were observed in patients from either acute-study treatment group or age group.

Electrocardiograms: No patients had abnormal ECG assessments at the Study 716 Baseline Visit or Week 24. One acute-study paroxetine patient had an abnormal ECG assessment at Taper End, which was normal on repeat; one acute-study placebo patient had an abnormal ECG assessment at Early Withdrawal that was associated with an adverse event (bundle branch block); and one acute-study paroxetine patient had an abnormal ECG assessment during the Follow-up Phase reported as an adverse event (electrocardiogram abnormal). Both events were considered by the investigator to be of mild intensity and unrelated to study medication.

Efficacy Results:

Datasets: Two datasets were used to summarize the results: an observed case (OC) dataset and a last observation carried forward (LOCF) dataset. For both the ITT population and PPX population, descriptive summaries were produced based on the OC dataset at each visit and the Week 24 LOCF dataset, with primary inferences based on the protocol-defined Week 24 endpoint.

Primary Efficacy Variable: There was no primary efficacy variable defined in this study as this study was not formally designed to assess efficacy.

Secondary Efficacy Variables: Results of the secondary endpoints suggest that MDD and OCD patients who responded during acute treatment generally will continue to respond during long-term (i.e., 6-month) treatment. The mean CDRS–R total score remained substantially decreased from acute-study baseline to the Week 24 OC and Week 24 LOCF endpoints in patients with a primary diagnosis of MDD. Similarly, the mean CY–BOCS total score remained substantially decreased from acute-study baseline to the Week 24 OC and Week 24 LOCF endpoints for patients with a primary diagnosis of OCD.

Among patients with a primary diagnosis of MDD, the majority met the CGI Global Improvement item responder criteria: 93.7% (59/63) of patients in the Week 24 OC dataset and 70.4% (100/142) of patients in the Week 24 LOCF dataset. Among patients with a primary diagnosis of OCD, the majority also met the CGI Global Improvement item responder criteria: 87.8% (43/49) of patients in the Week 24 OC dataset and 67.5% (77/114) of patients in the Week 24 LOCF dataset.

Among patients with a primary diagnosis of MDD, 76.6% (49/64) of patients in the Week 24 OC dataset and 58.0% (83/143) of patients in the Week 24 LOCF dataset were rated as normal or borderline mentally ill according to the CGI–Severity of Illness scale, compared to no patients at acute-study baseline. Among patients with a primary diagnosis of OCD, 53.1% (26/49) of patients in the Week 24 OC dataset and 33.3% (38/114) of patients in the Week 24 LOCF dataset were rated as normal or borderline mentally ill, compared to no patients at acute-study baseline.

Conclusions:

Data from this study demonstrate that paroxetine (10–50 mg/day) is safe and generally well tolerated when used to treat children and adolescents with MDD or OCD for a period of up to 24 weeks. The adverse event profile with long-term dosing was comparable to that observed during acute (short-term) dosing in earlier studies. As was the case in the prior acute studies, the long-term safety data suggest that the common adverse event profile may differ somewhat between children and adolescents.

Although this study was designed primarily to assess safety, the efficacy results suggest that patients who responded in the acute study are likely to continue to respond to paroxetine during long-term administration.

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List of Abbreviations & Definitions

Abbreviation	Unabridged Terms
ADECS	Adverse Drug Experience Coding System (based on COSTART system)
AE	adverse event
ALT	alanine aminotransferase (SGPT)
ART	Adverse Reaction Terminology
AST	aspartate aminotransferase (SGOT)
ATC	Anatomical Therapeutic Chemical
AUC	area under the plasma concentration versus time curve
BMI	body mass index
bpm	beats per minute
BUN	blood urea nitrogen
CDRS–R	Children's Depression Rating Scale–Revised
CFR	Code of Federal Regulation
CGI	Clinical Global Impression
CGI–I	Clinical Global Impression–Global Improvement
CGI–S	Clinical Global Impression–Severity of Illness
Cmax	highest concentration in plasma
COSTART	Coding Symbols for a Thesaurus of Adverse Reaction Terms
CRF	case report form
CV	Curriculum Vitae
CY–BOCS	Children's Yale-Brown Obsessive Compulsive Scale
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, fourth edition
ECDEU	Early Clinical Drug Evaluation Unit
ECG	electrocardiogram
GAD	Generalized Anxiety Disorder
GCP	Good Clinical Practice
HCG	human chorionic gonadotropin
HDPE	high-density polyethylene
ICH	International Conference on Harmonization
IND	Investigative New Drug application
IRB	Institutional Review Board
ITT	Intention-to-Treat
IU	International Unit
kg	kilogram
L	liter
LOCF	last observation carried forward
LOE	lack of efficacy
MDD	Major Depressive Disorder
mmol	millimole

Abbreviation	Unabridged Terms
mg	milligrams
mmHg	millimeters of mercury
mU	milliunit
N (n)	number in population (sample)
NOS	not otherwise specified
OC	observed cases
OCD	Obsessive Compulsive Disorder
PPX	pure paroxetine population
PTSD	Posttraumatic Stress Disorder
RAP	Reporting and Analysis Plan
RBC	red blood cell
SAE	serious adverse event
SAS	Statistical Analysis System
SB	SmithKline Beecham (a GlaxoSmithKline Company)
SD	standard deviation
SGOT	serum glutamic oxaloacetic transaminase (AST)
SGPT	serum glutamic pyruvic transaminase (ALT)
sNDA	Supplemental New Drug Application
SOPs	Standard Operating Procedures
SSRI	selective serotonin reuptake inhibitor
STP	study medication stopped
TSH	thyroid stimulating hormone
umol	micromole
unk	unknown
WBC	white blood cell
WHO	World Health Organization
wk	week
WRC-GCP	Worldwide Regulatory Compliance-GCP
yrs	years

1 Introduction

Paroxetine (Paxil®, Seroxat®, Deroxat®, Aropax®), a phenylpiperidine compound, is a selective serotonin reuptake inhibitor (SSRI) registered for use in adults in the treatment of Obsessive-Compulsive Disorder (OCD), Major Depressive Disorder (MDD), Panic Disorder, Social Anxiety Disorder, Generalized Anxiety Disorder (GAD), and Posttraumatic Stress Disorder (PTSD). Because of the success of paroxetine in the treatment of these psychiatric disorders in adults, studies have been conducted in children and adolescents with MDD, OCD, or Social Anxiety Disorder.

Major Depressive Disorder (MDD) is one of the behavioral disorders that can emerge during childhood and adolescence. Depression in children can lead to school failure, alcohol or other drug use, and even suicide. The prevalence of MDD is estimated to be approximately 2% in children and 4% to 8% in adolescents [1].

Studies 329, 377 and 701 assessed the safety and efficacy of paroxetine in children and adolescent patients with depression. Studies 329 (93 intention-to-treat [ITT] patients randomized to paroxetine) and 377 (182 ITT patients randomized to paroxetine) were randomized, double-blind, placebo-controlled studies in adolescent patients, 13 to 18 years of age and 12 to 18 years, respectively, with unipolar major depression [2] [3] [4]. These studies yielded equivocal results. Study 329 suggested that paroxetine was efficacious, achieving statistical significance on four of eight secondary measures of efficacy, but there was little evidence of benefit in Study 377. The third study, Study 701 (49 children and 52 adolescent ITT patients randomized to paroxetine), was a randomized 8-week double-blind, placebo-controlled study in children and adolescents 7 to 17 years of age with MDD [5]. This study failed to provide evidence that paroxetine was more efficacious than placebo in treating pediatric patients with MDD.

Obsessive-Compulsive Disorder (OCD) is a severe and chronically disabling condition characterized by recurrent ritualized thought patterns (obsessions) and associated repetitive, intentional behavior patterns (compulsions) performed in response to the obsession. The obsessions and compulsions cause marked distress, are time-consuming, and may significantly interfere with the person's normal routine, occupational or school functioning, usual social activities, or relationships. Children and adolescents are frequently affected by OCD, and in fact the disorder

usually emerges during childhood or adolescence, underscoring the importance of developing effective treatments for use in the pediatric population.[6]

Studies 453 and 704 assessed the safety and efficacy of paroxetine in children and adolescent patients with OCD. Study 453 (168 children and 167 adolescents in the ITT population taking open-label paroxetine for up to 16 weeks; 49 children and 46 adolescents randomized to double-blind paroxetine for up to 16 additional weeks) was a multicenter, two-phase, 32-week, relapse-prevention study in children and adolescents, 8 to 17 years of age, with moderate to severe OCD [7]. The mean reduction from baseline in Children's Yale-Brown Obsessive Compulsive Scale (CY–BOCS) total score for the 16-week flexible-dose (10 to 60 mg/day paroxetine) open-label phase was 13.0. The majority of patients enrolled who had data available (68.7%, 226/329) met both response criteria (Clinical Global Impression–Global Improvement item [CGI–I] score of 1 or 2 and CY–BOCS reduction of ≥25% from open-label baseline) at open-label Week 16 LOCF Endpoint and therefore were eligible to enter the double-blind relapse-prevention phase. The proportion of patients who met the criteria for relapse during the 16-week randomized (placebo or 10-60 mg/day paroxetine) relapse-prevention phase was lower in the paroxetine group (34.7%, 33/95) than in the group of patients switched to placebo (43.9%, 43/98), suggesting that paroxetine is beneficial in the treatment of children and adolescents with OCD.

Study 704 (58 children and 40 adolescents randomized to paroxetine) was a 10-week multicenter, randomized, double-blind, placebo-controlled, flexible-dose (placebo or 10 to 50 mg/day paroxetine) study in children and adolescents (7 to 17 years of age) with OCD [8]. A statistically significant difference was demonstrated in favor of paroxetine for the primary variable, change from baseline in CY–BOCS total score at the Week 10 LOCF endpoint. This finding was supported by statistically significant results for three of the six secondary efficacy variables, and numerical results indicating a benefit of paroxetine over placebo for all other secondary efficacy variables.

Study 715 (27 children and 35 adolescents dosed with paroxetine) was a multicenter open-label, repeat-dose, dose-rising study to assess the pharmacokinetics of paroxetine following repeat-dose administration in children (7-11 years of age) and adolescents (12 to 17 years of age) with OCD and/or MDD [9]. Each patient received paroxetine orally starting at 10 mg/day with forced up-titration over 42 days to a dose of 30 mg/day and a 2-week down-titration period. The Cmax and AUC (0-24) data confirmed that, at each dose level, paroxetine steady-state systemic exposure was higher in children than in

adolescents. However, for both parameters, the differences diminished with increasing dose.

An additional study conducted in children and adolescents assessed safety for 16 weeks, as well as efficacy, in patients with Social Anxiety Disorder. Study 676 (46 children and 117 adolescents in the ITT population randomized to paroxetine) was a multicenter, randomized, double-blind, placebo-controlled, flexible-dose (placebo or 10 to 50 mg/day paroxetine) study in children and adolescents (8 to 17 years of age) [10].

Overall, safety data from pediatric studies 329, 377, 701, 704, 715, and 676 indicate that paroxetine is safe and generally well tolerated when used in children (180 patients) and adolescents (519 patients) for up to 16 weeks over the dosage range of 10-50 mg/day. There were no unexpected adverse events or findings in laboratory tests, vital signs, or ECGs. In general, more paroxetine patients than placebo patients withdrew due to adverse events, and more children than adolescents withdrew due to AEs in the paroxetine group. The safety profile appeared similar to that previously reported for adults except that there were few gender-specific adverse events. There was some indication that the AE profile in children may differ slightly from that in adolescents.

However, there is limited information on the long-term safety and efficacy of paroxetine in the pediatric population. Psychiatric disorders may occur in childhood and continue into adulthood, requiring long-term treatment. It is therefore imperative that studies assessing the long-term safety of SSRIs in children and adolescents be undertaken. A review of the long-term safety data from Study 329, which included a 6-month extension phase, and Study 453, which was a 32-week study, indicates that there were no significant new or unexpected adverse events emerging upon long-term dosing. However, additional long-term safety data in children and adolescents are needed.

This 6-month, open-label extension study was conducted to assess the long-term safety and efficacy of paroxetine in the treatment of children and adolescents with MDD or OCD. Children and adolescents 7 to 17 years of age meeting DSM-IV criteria for either MDD or OCD and who completed Studies 701, 704, or 715 were eligible for entry into Study 716. Interim results were reported in January 2002 [11] [12]. This final report supersedes the interim report.

2 Objectives

2.1 Primary Objective

The primary objective of this study was to assess the long-term (6-month) safety of paroxetine in the treatment of children and adolescents with MDD or OCD who completed paroxetine Study 701, 704, or 715.

2.2 Secondary Objective

The secondary objective was to monitor the long-term (6-month) efficacy of paroxetine in the treatment of children and adolescents with MDD or OCD who completed paroxetine Study 701, 704, or 715.

3 Methodology

3.1 Study Design

This was a multicenter, open-label, 6-month extension study. Children and adolescents who completed Study 701, 704, or 715 and who chose to enter this study were considered eligible if they met all the inclusion criteria and none of the exclusion criteria (Sections 3.4.1 and 3.4.2).

Eligibility was assessed at the Study 716 Baseline Visit (Day 0). For patients who entered a Taper Phase upon completing Study 701, 704 or 715, the Taper End visit was the Study 716 Baseline Visit. For patients who did not enter a Taper Phase upon completion of Study 701, 704 or 715, the treatment end visit was the Study 716 Baseline Visit.

Paroxetine was administered according to a flexible-dose regimen (10 to 50 mg/day). Patients entering Study 716 from Study 701 or 704 were to be started on therapy at 10 mg/day (however, several patients started at a higher dose; see Section 4.7.2, Titration of Dose). Patients entering Study 716 from Study 715 could, at the investigator's discretion, be initiated at a higher dose level (e.g., the dose level achieved at Study 715 endpoint, or 10 mg/day higher or lower). For all patients, the Study 716 starting dose could thereafter be increased at each clinic visit by 10 mg/day no more frequently than every 7 days. Dose increases were at the discretion of the investigator, and were based on clinical response and tolerability. The maximum dose allowed was 50 mg/day.

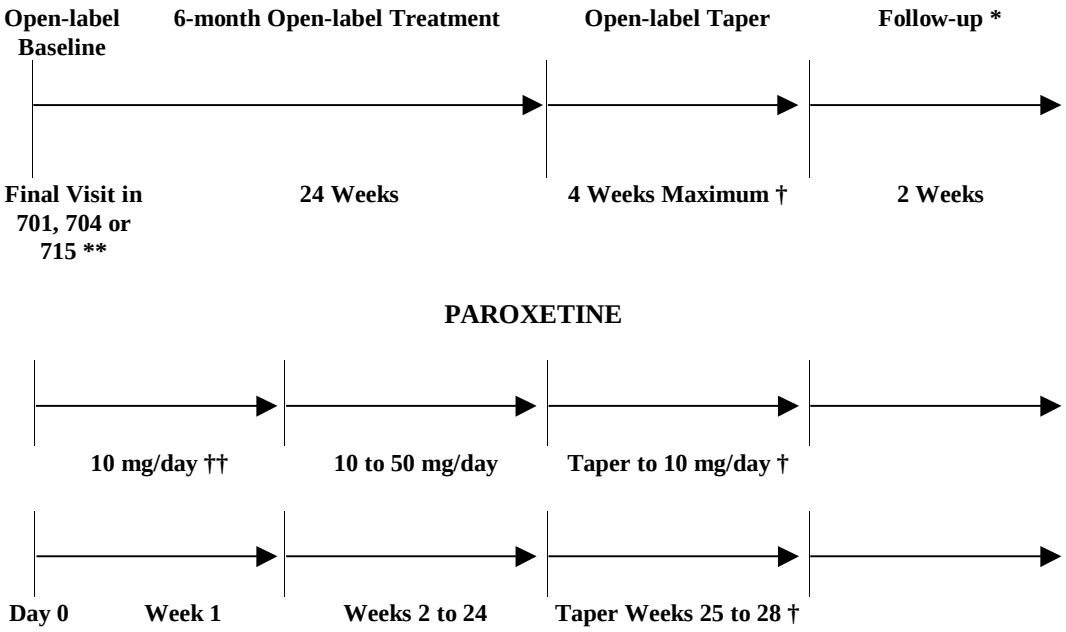
Dose reductions of 10 mg/day at weekly intervals were permitted at the discretion of the investigator. Patients unable to tolerate a paroxetine dose of 10 mg/day were withdrawn from the study. It was recommended that dose reductions be initiated at clinic visits. If the dose reduction was due to an adverse event, the patient could return to the previous dose level upon resolution of the adverse event.

Gradual reduction of dosing for patients who completed the 6-month open-label Treatment Phase or were prematurely withdrawn was required for all patients except for those who terminated at the 10 mg/day dose level. Patients were down-titrated at a rate of 10 mg/day each week until they finished one week of Taper Phase dosing at 10 mg/day. The duration of the Taper Phase, therefore, varied for each patient, depending on the dose level upon completion of the open-label

Treatment Phase. A Follow-up Visit was scheduled 14 days (± 3 days) after the last dose of study medication (including any Taper Phase dosing).

An overview of the study design is presented in Figure 1.

Figure 1 Study Design for Study 716



*14 days (± 3 days) after the last dose of study medication
** Study 701: Week 8 or Taper End; Study 704: Week 10 or Taper End; Study 715: Day 42 or end of optional taper
† Or corresponding weeks 1, 2, 3 or 4 following Early Withdrawal. The duration of the Taper Phase was dependent on the final dose level at Week 24 or Early Withdrawal.
†† Patients entering from open-label Study 715 may have started at a higher dose level at the investigator's discretion.

Patients in Study 716 who took paroxetine in Study 701, 704, or 715 are referred to in this report as acute-study paroxetine patients; patients who took placebo in either Study 701 or 704 are referred to as acute-study placebo patients (no patients took placebo in Study 715).

3.1.1 Protocol Amendments

No amendments were made to the protocol.

3.2 Investigators

A total of 49 centers in the United States and 2 centers in Canada participated in this study. A list of principal investigators, their center numbers, affiliated institutions and geographic locations are provided in Table 1. Appendix A, Study Information and Administration, contains copies of the curricula vitae (CVs) of all principal investigators, which provide details of the investigators' qualifications and experience.

Investigators were selected based on previous experience with the patient population under study, their ability to recruit eligible patients, and their ability to conduct the study according to Good Clinical Practice (GCP).

The study site (Center 055) of xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx, who entered 9 patients in Study 716, was terminated by the sponsor following an internal audit during Study 704 that detected significant compliance violations for Study 704. Of the 9 patients enrolled at Center 55 in Study 716, 7 were withdrawn from the study when the site was closed and 2 were previously withdrawn due to protocol violations (including non-compliance). No patient at this site completed Study 716, and the longest duration of treatment was 16 weeks. Results presented in this report include xxxxxxxxxxxx's patients.

The study site (Center 171) of xxxxxxxxxxxxxxxxxxxxxxxxx , who entered 1 patient, was closed because the principal investigator moved out of state. The single patient enrolled was withdrawn from the study after receiving study medication for 120 days.

Table 1 Investigators, the Assigned Center Number and the Investigator Hospital or University Affiliation and Location

Investigator	Center	Affiliated Institute	City/State
United States			
			Minneapolis, MN
		Minnesota	
			Dallas, TX
		Center of Dallas	
	005		
	006		Charlotte, NC
			Eugene, OR
		Inc.	
	009		Piscataway, NJ
			Lake Jackson, TX
		Inc.	
			Madison, WI
			Baltimore, MD
		Institutions	
			Phoenix, AZ
		Hospital	
			Cincinnati, OH
			Galveston, TX
	020		Gainesville, FL
		Florida	

Source: Appendix A, Investigator CVs
* xxxxxxxxx was superseded as Principal Investigator by xxxxxxx

Table continues

Table 1 (Continued) Investigators, the Assigned Center Number and the Investigator Hospital or University Affiliation and Location

Investigator	Center	Affiliated Institute	City/State
United States (continued)			
			Medina, OH
			Washington, DC
	028		Richmond, VA
		Inc.	
	040		Baltimore MD
		Inc.	
			Clearwater, FL
		West Florida	
			Maitland, FL
			Elkins Park, PA
		Advanced Clinical Research	
	049		Hershey, PA
	055		New Orleans, LA
MD		of New Orleans	
	148	Albuquerque	Albuquerque, NM
MD			
			Cleveland, OH
			Charleston, SC
		South Carolina	
			Lake Oswego, OR
			Columbia, MO
		Columbia	
			Long Beach, CA
		Institute	
	167		
MD			

Source: Appendix A, Investigator CVs
xxxxxxx was superseded as Principal Investigator by xxxxxxx

Table continues

Table 1 (Continued) Investigators, the Assigned Center Number and the Investigator Hospital or University Affiliation and Location

Investigator	Center	Affiliated Institute	City/State
United States			
	168		Seattle, WA
		Mental Health	
			Lynn, MA
		North Shore	
	170		Atlanta, GA
MD			
			GA
	176		
MD			KS
			Philadelphia, PA
		Philadelphia	
			Orlando, FL
			Houston, TX
	186		
	201		Cleveland, OH
PhD			
			Boston, MA
		Hospital	
			Salt Lake City, UT
			Shreveport, LA
Canada			
	031		Halifax, Nova Scotia
			Halifax, Nova
		Center	Scotia

Source: Appendix A, Investigator CVs
*xxxxxxx was superseded as Principal Investigator by xxxxx xxxxx

3.3 Ethics

This study was conducted in accordance with GCP, the Declaration of Helsinki as amended in Somerset West, Republic of South Africa (1996), and US 21 CFR (Code of Federal Regulations) for studies filed to the US IND. The protocol and statement of informed consent and/or assent were approved by an Institutional Review Board (IRB) before each center's initiation[1]. The IRB was to be informed by the investigator of protocol amendments and of serious or unexpected adverse events occurring during the study that were likely to affect the safety of the patients or the conduct of the study.

Written informed consent by parent (or legal guardian), or by patient if emancipated minor, and assent by minor patient (when required), were obtained before any study procedures were conducted. Case report forms (CRFs) were provided for each patient's data to be recorded. A sample CRF is provided in Appendix A, Study Information and Administration.

3.4 Eligibility Criteria

This study enrolled male and female outpatients who completed Study 701, 704, or 715 and chose to enter the open-label extension study. Children and adolescents 7 to 17 years of age at acute-study screening meeting DSM IV criteria for either MDD or OCD [2] as their predominant psychiatric diagnosis were eligible for entry into the acute Studies 701 or 704, respectively. Patients participating in the paroxetine forced-titration open-label pharmacokinetic study (715) could meet diagnostic criteria for either MDD or OCD. Written informed consent by parent (or legal guardian), or by patient if emancipated minor, and assent by minor patient (when required), were obtained before participation in Study 716 and the preceding study. The inclusion and exclusion criteria for Study 716 are listed in Section 3.4.1 and Section 3.4.2, respectively.

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[1] A sample informed consent / assent is provided in the protocol, which may be found in Appendix A, Study Information and Administration.

[2] The DSM-IV Diagnostic Criteria for Major Depressive Disorder, Single Episode (296.2) or Recurrent (296.3), and for Obsessive-Compulsive Disorder (300.30) may be found in Appendices E, F, and H, respectively, of the protocol.

3.4.1 Inclusion Criteria

Patients were considered eligible for the study if they satisfied all of the following inclusion criteria:

- children or adolescents completing Study 701 (MDD), 704 (OCD) or 715 (pharmacokinetic study in patients with OCD or MDD)
- patients who were otherwise determined medically healthy by physical examination, medical history and laboratory screening
- written informed consent of parent (or legal guardian) and assent of patient (where required) before any specific study procedures.

3.4.2 Exclusion Criteria

Patients were considered ineligible for the study if they met any of the following exclusion criteria:

- patients not completing Study 701, 704 or 715
- patients who posed a current suicidal or homicidal risk in the investigator's judgment
- patients who in the opinion of the investigator would be non-compliant with the visit schedule or other study procedures
- patients with clinically significant abnormalities in hematology, blood chemistry, ECG or physical examination at acute-study endpoint that had not resolved
- patients who in the opinion of the investigator had a serious medical condition that would preclude the administration of paroxetine
- female patients who had a positive dipstick or serum human chorionic gonadotropin (HCG) pregnancy test at acute-study endpoint or who were lactating
- sexually active female patients who were not using a reliable method of contraception (e.g., oral contraception, condom in conjunction with spermicidal foam).

3.5 Study Medication and Administration

3.5.1 Study Medication

Open-label medication was supplied as oval, white, film-coated tablets containing 10 mg of paroxetine (batch number U00001). All paroxetine tablets were identical in appearance. A certificate of analysis is provided in Appendix A, Study Information and Administration.

All open-label study medication was provided in white opaque high-density polyethylene (HDPE) bottles with white opaque plastic child-resistant caps with a coated polyester film bonded aluminum foil inner seal. Each bottle contained 34 tablets. Open-label study medication was dispensed at Study 716 Baseline and at each scheduled visit during the Treatment Phase, with medication for the Taper Phase dispensed at the Week 24 or Early Withdrawal visit. The total number of bottles dispensed at any given visit was dependent on the patient's dose level and the protocol-stipulated time interval before the next scheduled visit.

All open-label study medication bottles were labeled according to the protocol. The label text contained the following information: protocol number, job number, batch and lot number, contents, medication number, tablets strength, dosage directions, storage instructions, "Keep out of reach of children," "FOR CLINICAL TRIAL USE ONLY," sponsor's address, and any other information required by local law. The tear-off portion of the label was affixed to the patient's CRF.

All study medication was to be stored in a secure (locked) area at ambient temperature (15 to 30°C).

3.5.2 Drug Accountability

Study medication was dispensed according to the protocol to enrolled patients under the supervision of the investigator or his/her designee. Records of all study medication shipped to the center, dispensed to the patients, returned by patients, and returned to the sponsor were to be maintained at each study center. Unused study medication was to be returned to SmithKline Beecham (a GlaxoSmithKline company) at the end of the study.

3.5.3 Dosage and Administration

Patients, under parental supervision, were instructed to take from 1 to 5 (dependent on dose) 10-mg paroxetine tablets each morning, with food, throughout the Treatment Phase of the study (Weeks 1–24), and the Taper Phase

if necessary (Weeks 25–28). Written dosage instructions were to be provided on the label of each bottle since the number of 10-mg paroxetine tablets to be taken per day varied as each patient's daily dose was increased or decreased based on clinical response and tolerability.

Patients were to receive paroxetine (10 to 50 mg/day) for a period of 24 weeks during the open-label Treatment Phase of Study 716, starting at a daily dosage of 10mg/day. Patients entering Study 716 from open-label Study 715 could, at the investigator's discretion, be initiated at the dose level achieved at Study 715 endpoint or at one dose level higher or lower. Patients entering Study 716 from double-blind Study 701 or 704 were to be started on therapy at 10 mg/day, as noted above; however, exceptions were made for several patients to start at a higher dose (see Section 4.7.2, Titration of Dose). Starting at Week 2, at the discretion of the investigator, the dose of paroxetine could be increased by 10 mg/day at weekly intervals up to a maximum dose of 50 mg/day, according to clinical response and tolerability. It was recommended that dose increases be initiated at clinic visits.

Dose reductions of 10 mg/day at weekly intervals were also permitted at the discretion of the investigator. Patients unable to tolerate a paroxetine dose of 10 mg/day were withdrawn from the study. It was recommended that dose reductions were initiated at clinic visits. If the dose reduction was due to an adverse event, the patient could return to the previous dose level upon resolution of the adverse event.

During the Taper Phase, open-label study medication was reduced by 10 mg/day each week for a period of up to 4 weeks for patients who completed the Treatment Phase or were prematurely withdrawn at a dose of ≥20 mg/day. Patients completing or withdrawing at 10 mg/day did not enter the Taper Phase. Patients completing or withdrawing at ≥20 mg/day commenced Taper Phase dosing at a dose of 10 mg/day below the dose of their final open-label Treatment Phase dose and ended the Taper Phase as shown in Table 2.

Table 2 Study Medication Dosing Instructions During the Taper Phase

Dose *	Week 25 **	Week 26 **	Week 27 **	Week 28 **
10 mg	**No taper medication**			
20 mg	10 mg	**No further taper medication**		
30 mg	20 mg	10 mg	**No further taper medication**	
40 mg	30 mg	20 mg	10 mg	**No further taper medication**
50 mg	40 mg	30 mg	20 mg	10 mg

* Dose at the end of the 6-month open-label Treatment Phase
** Or corresponding Weeks 1, 2, 3 or 4 following early withdrawal

All open-label study medication for the Taper Phase was dispensed at the Week 24 or Early Withdrawal visit. Written dosage instructions were provided on the label of each bottle since the number of 10-mg paroxetine tablets to be taken per day was dependent on the dose of paroxetine at the end of the open-label Treatment Phase.

3.5.4 Blinding

There was no blinding as this was an open-label study. All 10-mg paroxetine tablets were identical in appearance and packaged in bottles containing 34 tablets.

3.6 Compliance with Study Medication

Every effort was made to encourage patient compliance with the dosing regimen as per protocol. All patients were instructed to return their medication bottles, with any unused study medication, to the investigator at their next clinic visit. All medication dispensed to the patient, taken by the patient, and returned by the patient was recorded in the patient's CRF at each visit.

If, in the opinion of the investigator, there were any significant irregularities in compliance, the patient was to be withdrawn from the study. Patients who missed more than three consecutive days of medication on more than one occasion were to be withdrawn from the study.

3.7 Concomitant Medication

All concomitant medications taken during the study were to be recorded in the patient's CRF with the total daily dose, route of administration, indication, start date, and end date or notation that medication was continuing.

The concomitant use of psychotropic drugs, other than open-label study medication, was contraindicated during this study. Exceptions were allowed if the investigator obtained approval from the Medical Monitor.

3.8 Study Procedures

3.8.1 Schedule of Assessments

An overview of the schedule of assessments and study procedures is presented in Table 3.

All patients were assessed at the open-label Baseline Visit (Day 0), which coincided with the Taper End visit in Studies 701 and 704 (and Study 715 for patients who underwent the optional taper) or with the last Treatment Phase visit if there was no Taper Phase. The open-label Treatment Phase started on the first day that open-label study medication was administered (Day 1) and continued through to completion of the Week 24 visit (or Early Withdrawal visit). The open-label Taper Phase started following the Week 24 visit or the Early Withdrawal visit, and continued for a maximum of 4 weeks. The length of the Taper Phase was dependent on the dose at the Week 24 or Early Withdrawal visit. The Follow-up Visit was scheduled for 14 days (± 3 days) after the last dose of study medication (including Taper Phase dosing) for all patients.

Table 3 Outline of Study Procedures for Study 29060/716

	Baseline (Day 0)	Week 1	2	3	4	6	8	12	16	20	24	Early Withdrawal	Taper Phase End	Follow-up Visit [a]
Screen/Baseline Evaluations														
Informed Consent/Assent	X													
Inclusion/Exclusion Criteria	X													
Efficacy Parameters														
CDRS–R [b]	X										X	X		
CY–BOCS [b]	X										X	X		
CGI–S [c]	X	X	X	X	X		X	X	X	X	X	X		
CGI–I [c]	X	X	X	X	X		X	X	X	X	X	X		
Safety Evaluations														
12-lead ECG	X [d]										X	X	X [e]	X [e]

(a) Follow-up Visit was completed 14 days (± 3 days) after the last dose of study medication including taper for all patients.
(b) Children's Depression Rating Scale–Revised (CDRS–R) assessed for patients from Study 701, or from Study 715 with a primary diagnosis of MDD; Children's Yale-Brown Obsessive-Compulsive Scale (CY–BOCS) assessed for patients from Study 704, or from Study 715 with a primary diagnosis of OCD. CDRS-R and CY-BOCS assessments were not repeated for Study 701/704 patients whose treatment end visit in the acute study coincided with Study 716 baseline visit.
(c) CGI–S = Clinical Global Impression–Severity of Illness; CGI–I = Clinical Global Impression–Global Improvement
(d) Last laboratory assessments, ECG, and physical examination from the previous acute or PK study (within 3 weeks and with no clinically significant abnormalities) were taken as baseline data for Study 716.
(e) Repeat laboratory evaluations or ECG assessments were performed only if results were clinically significantly abnormal at previous visit, and with the investigator's agreement.
(f) 3-minute sitting systolic and diastolic blood pressure and heart rate
(g) Hematology (hemoglobin, hematocrit, WBC with differential, RBC, and platelet count); blood chemistry (creatinine, BUN, total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT [AST], electrolytes); dipstick urinalysis (if positive for blood or protein, full microscopy was performed)
(h) Dipstick and HCG serum pregnancy test for females of child-bearing potential; not repeated if the patient’s treatment end visit in the acute study coincided with Study 716 baseline visit.
(i) Taper medication dispensed for all patients ending open-label Treatment Phase or withdrawing at a dose of 20 to 50 mg/day

Table continues

Table 3 (Continued) Outline of Study Procedures for Study 29060/716

	Baseline (Day 0)	Week 1	2	3	4	6	8	12	16	20	24	Early Withdrawal	Taper Phase End	Follow-up Visit [a]
Safety Evaluations (continued)														
Vital Signs [f]	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Height and Weight	X							X			X	X		
Adverse Events	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Laboratory Evaluations [g]	X [d]				X			X			X	X	X [e]	X [e]
Physical Examination	X [d]										X	X		
Pregnancy Dipstick/Serum Test [h]	X [h]							X			X	X		

(a) Follow-up Visit was completed 14 days (± 3 days) after the last dose of study medication including taper for all patients.
(b) Children's Depression Rating Scale–Revised (CDRS–R) assessed for patients from Study 701, or from Study 715 with a primary diagnosis of MDD; Children's Yale-Brown Obsessive-Compulsive Scale (CY–BOCS) assessed for patients from Study 704, or from Study 715 with a primary diagnosis of OCD. CDRS-R and CY-BOCS assessments were not repeated for Study 701/704 patients whose treatment end visit in the acute study coincided with Study 716 baseline visit.
(c) CGI–S = Clinical Global Impression–Severity of Illness; CGI–I = Clinical Global Impression–Global Improvement
(d) Last laboratory assessments, ECG, and physical examination from the previous acute or PK study (within 3 weeks and with no clinically significant abnormalities) were taken as baseline data for Study 716.
(e) Repeat laboratory evaluations or ECG assessments were performed only if results were clinically significantly abnormal at previous visit, and with the investigator's agreement.
(f) 3-minute sitting systolic and diastolic blood pressure and heart rate
(g) Hematology (hemoglobin, hematocrit, WBC with differential, RBC, and platelet count); blood chemistry (creatinine, BUN, total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT [AST], electrolytes); dipstick urinalysis (if positive for blood or protein, full microscopy was performed)
(h) Dipstick and HCG serum pregnancy test for females of child-bearing potential; not repeated if the patient's treatment end visit in the acute study coincided with Study 716 baseline visit.
(i) Taper medication dispensed for all patients ending open-label Treatment Phase or withdrawing at a dose of 20 to 50 mg/day

Table continues

Table 3 (Continued) Outline of Study Procedures for Study 29060/716

	Baseline (Day 0)	Week 1	2	3	4	6	8	12	16	20	24	Early Withdrawal	Taper Phase End	Follow-up Visit [a]
Miscellaneous Records														
Concomitant Medications	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Dispense Study Medication	X	X	X	X	X	X	X	X	X	X	X [i]	X [i]		
Medical Procedures Record	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Study Medication Record		X	X	X	X	X	X	X	X	X	X	X	X	
Study Conclusion Record											X	X		

(a) Follow-up Visit was completed 14 days (± 3 days) after the last dose of study medication including taper for all patients.
(b) Children's Depression Rating Scale–Revised (CDRS–R) assessed for patients from Study 701, or from Study 715 with a primary diagnosis of MDD; Children's Yale-Brown Obsessive-Compulsive Scale (CY–BOCS) assessed for patients from Study 704, or from Study 715 with a primary diagnosis of OCD. CDRS-R and CY-BOCS assessments were not repeated for Study 701/704 patients whose treatment end visit in the acute study coincided with Study 716 baseline visit.
(c) CGI–S = Clinical Global Impression–Severity of Illness; CGI–I = Clinical Global Impression–Global Improvement
(d) Last laboratory assessments, ECG, and physical examination from the previous acute or PK study (within 3 weeks and with no clinically significant abnormalities) were taken as baseline data for Study 716.
(e) Repeat laboratory evaluations or ECG assessments were performed only if results were clinically significantly abnormal at previous visit, and with the investigator's agreement.
(f) 3-minute sitting systolic and diastolic blood pressure and heart rate
(g) Hematology (hemoglobin, hematocrit, WBC with differential, RBC, and platelet count); blood chemistry (creatinine, BUN, total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT [AST], electrolytes); dipstick urinalysis (if positive for blood or protein, full microscopy was performed)
(h) Dipstick and HCG serum pregnancy test for females of child-bearing potential; not repeated if the patient's treatment end visit in the acute study coincided with Study 716 baseline visit.
(i) Taper medication dispensed for all patients ending open-label Treatment Phase or withdrawing at a dose of 20 to 50 mg/day

3.8.2 Baseline Visit (Day 0)

The open-label Study 716 Baseline Visit (Day 0) coincided with the final visit in Studies 701 and 704, and PK Study 715. Baseline values for efficacy assessments were determined at baseline for Studies 701 and 704 and at Screening for Study 715. They will be referred in this report as acute-study baseline values.

Those patients meeting all the inclusion criteria and none of the exclusion criteria were administered open-label paroxetine. The following assessments and procedures were performed at the Study 716 Baseline Visit.

- written informed consent by parent (or legal guardian), or by patient if emancipated minor, and assent by minor patient (when required), obtained before any study procedures were conducted
- assessment with respect to all other inclusion/exclusion criteria (Section 3.4.1 and Section 3.4.2)
- CDRS–R for patients from Study 701, or from Study 715 with a primary diagnosis of MDD
- CY–BOCS for patients from Study 704, or from Study 715 with a primary diagnosis of OCD
- Clinical Global Impression–Severity of Illness (CGI–S)
- Clinical Global Impression–Global Improvement item (CGI–I) (based on comparison to acute-study baseline
- vital signs (3-minute sitting systolic and diastolic blood pressure and heart rate). Blood pressure was measured in the same arm and, where possible, by the same person throughout the study
- physical examination (the last assessment from the acute or PK study was acceptable if taken within 3 weeks of the Study 716 baseline assessment and not clinically significant)
- height (cm) and weight (kg) measurements without shoes
- 12-lead ECG (the last assessment from the acute or PK study was acceptable if taken within 3 weeks of the Study 716 baseline assessment and not clinically significant)

- pregnancy urine dipstick test and serum HCG pregnancy test for females of child-bearing potential. Patients with confirmatory positive results from serum HCG pregnancy test were withdrawn from the study
- laboratory evaluations (last assessments from the acute or PK study were acceptable if taken within 3 weeks of the Study 716 baseline assessment and not clinically significant). Laboratory evaluations consisted of hematology (hemoglobin, hematocrit, red blood cells, white blood cells with differential, and platelet count); blood chemistry (creatinine, blood urea nitrogen [BUN], total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT [AST] and electrolytes); and dipstick urinalysis (if dipstick method was positive for blood or protein, full microscopy was performed). Laboratory evaluations were interpreted and deemed clinically non-significant by the investigator.
- concomitant medications
- Medical Procedures Record completed
- adverse events
- study medication dispensed.

3.8.3 Open-label Treatment Phase (Weeks 1–24)

Study assessments during the open-label Treatment Phase were scheduled for Weeks 1 to 4, 6, 8, 12, 16, 20, and 24 or at Early Withdrawal. An investigator could schedule a clinic visit outside the protocol-defined visit schedule for handling a dose adjustment. Each study visit included the following evaluations unless otherwise specified:

- vital signs (3-minute sitting systolic and diastolic blood pressure and heart rate)
- height (cm) and weight (kg) measurements without shoes at the 12- and 24-week visits (or Early Withdrawal visit)
- CGI–Global Improvement item at the Week 1, 2, 3, 4, 8, 12, 16, 20, and 24 visits (or Early Withdrawal visit)
- CGI–Severity of Illness item at the Week 1, 2, 3, 4, 8, 12, 16, 20, and 24 visits (or Early Withdrawal visit)

- CDRS–R at the Week 24 visit (or Early Withdrawal visit) for patients from the acute Study 701, or from Study 715 with a primary diagnosis of MDD

- CY–BOCS at the Week 24 visit (or Early Withdrawal visit) for patients from the acute Study 704, or from Study 715 with a primary diagnosis of OCD

- adverse events

- concomitant medications

- open-label study medication dispensed. At the open-label Study 716 baseline and at Weeks 1, 2, and 3, a supply of open-label treatment medication sufficient for a 1-week period was dispensed; at Weeks 4 and 6, open-label treatment medication sufficient for a 2-week period was dispensed; at Weeks 8, 12, 16, and 20, open-label treatment medication sufficient for a 4-week period was dispensed; and at Week 24 or Early Withdrawal, all open-label taper medication, if necessary, was dispensed

- physical examination at Week 24 (or Early Withdrawal visit)

- pregnancy urine dipstick test and serum HCG pregnancy test for females of child-bearing potential at Weeks 12 and 24 (or Early Withdrawal visit). Patients with confirmatory positive results from serum HCG pregnancy test were withdrawn from the study

- laboratory evaluations at Weeks 4, 12, and 24 (or Early Withdrawal visit). Laboratory evaluations consisted of hematology (hemoglobin, hematocrit, red blood cells, white blood cells with differential, and platelet count); blood chemistry (creatinine, BUN, total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT [AST] and electrolytes); and dipstick urinalysis (if dipstick method was positive for blood or protein, full microscopy was performed)

- 12-lead ECG at Week 24 (or Early Withdrawal visit)

- Study Medication Record completed

- Medical Procedures Record completed

- Study Conclusion Record completed at Week 24 (or Early Withdrawal visit).

3.8.4 Open-label Taper Phase (Weeks 25–28)

For patients on ≥20 mg/day paroxetine at completion of the open-label Treatment Phase or at Early Withdrawal, study medication was gradually reduced by 10 mg/day at intervals of approximately 7 days during the Taper Phase. All patients completed the Taper Phase at 10 mg/day.

3.8.5 Taper End Visit

Following completion of the Taper Phase, patients returned to the clinic for a Taper End visit. Study medication was returned and patients underwent a safety evaluation, which was planned to coincide with the last study medication dose taken in the Taper Phase. The following evaluations were performed at the Taper End visit:

- vital signs
- adverse events
- concomitant medications
- repeat laboratory evaluation or 12-lead ECG, if clinically significantly abnormal values were noted at previous visit
- Taper Medication Record completed
- Medical Procedures Record completed.

3.8.6 Follow-up Visit

All patients returned for a safety Follow-up Visit 14 days (± 3 days) after the last dose of study medication (including Taper Phase medication). The following evaluations were performed at the Follow-up visit:

- vital signs
- adverse events
- concomitant medications

- repeat laboratory evaluation or 12-lead ECG if clinically significantly abnormal values were noted at previous visit
- Medical Procedures Record completed.

3.9 Patient Completion and Early Withdrawal

3.9.1 Definition

Patients were considered to have completed the study if they completed the Week 24 visit. Any patient who did not complete the Week 24 visit was considered to have withdrawn prematurely.

3.9.2 Reasons for Withdrawal

Patients could withdraw or be withdrawn from the study at any time. The primary reason for withdrawal was categorized as one of the following:

- adverse event
- lack of efficacy
- protocol deviation (including non-compliance)
- lost to follow-up
- other (reason specified).

The reason for withdrawal was recorded in the study conclusion section of the patient's CRF. If a patient withdrew, every attempt was made to carry out the assessments scheduled for the Week 24 visit at the patient's final Treatment Phase visit.

3.10 Efficacy Assessments

There was no primary efficacy parameter in this open-label study. The following instruments were used to monitor the severity of the patient's MDD or OCD symptoms, the patient's overall clinical condition, and the patient's response to open-label medication:

- CDRS–R total score for patients from Study 701, or from Study 715 with a primary diagnosis of MDD

- CY–BOCS total score for patients from Study 704, or from Study 715 with a primary diagnosis of OCD
- CGI–Severity of Illness item for all patients
- CGI–Global Improvement item for all patients.

Descriptions of the efficacy assessments are provided in Section 3.10.1 to Section 3.10.3. Copies of the CDRS–R, CY–BOCS, CGI–Severity of Illness, and CGI–Global Improvement are provided in the protocol in Appendix G, Appendix I, Appendix J, and Appendix K, respectively.

All the efficacy assessments were to be conducted by a psychiatrist, clinical psychologist or psychometrician with 2–3 years of experience with pediatric patients. For consistency, it was recommended that the same person, where possible, should perform the assessments on individual patients.

Baseline values for efficacy assessments were determined at baseline for Studies 701 and 704 and at Screening for Study 715.

3.10.1 Children's Depression Rating Scale–Revised (CDRS–R)

The CDRS–R is a clinician-rated instrument initially designed to measure the severity of depression in children aged 6 to 12 years. It has also been used successfully in adolescents in measuring the severity of depression. The CDRS–R has high inter-rater reliability, good test-retest reliability, good internal consistency, and good convergent and discriminant validity [13]. The CDRS–R captures slight but notable changes in a child's symptoms, thus making the scale useful for monitoring symptoms during illness or remission.

The CDRS–R assesses 17 symptom areas, including those that serve as the criteria in the DSM-IV [14] for the diagnosis of depressive disorders. It can be administered by a clinician or trained rater in a semi-standard fashion to the child or adolescent, parent(s), teacher, or guardian in approximately 30 minutes. The first 14 items of the scale are rated on the basis of the patient’s verbal responses to interview questions. The remaining 3 symptom areas of the CDRS–R (depressed facial affect, listless speech, and hypoactivity) are rated by the clinician on the basis of the patient’s nonverbal behavior for signs of depression. Fifteen of the symptom areas are rated on a 7-point scale and two on a 5-point scale. Following separate CDRS–R evaluation sessions with the patient and parent or guardian, the clinician summarizes the best overall description of the patient and enters the data on the patient’s CRF.

For the CDRS–R summary score, the highest possible score is 113, which represents the most severe measure of depression, and the lowest is 17, for a patient without depression. A summary score of 45 or above on the CDRS–R is a strong indicator of the presence of or potential for MDD. Although the score of 45 is a reliable indicator of depression, it should serve as a heuristic, not as a criterion by which the child is diagnosed with MDD or not.

CDRS–R raters were required to attend the training sessions offered at the investigator meeting before the start of acute Study 701 and PK Study 715 or to complete follow-up training requirements (see Section 3.13, Data Quality Assurance). Follow-up training for raters included reviewing the scoring conventions for the CDRS–R and assessing an MDD patient on video through completion of the CDRS–R score sheet. The rater's scores were then compared with an acceptable score range set for the MDD patient. This documentation was reviewed by the sponsor. Confirmation of an acceptable passing score was sent to the rater.

Treatment of missing values in the calculation of CDRS–R total scores was handled as detailed in the Reporting and Analysis Plan (RAP) and is summarized below. For the individual items of the scale, the raw data values were listed. Any subtotals or total scores which were listed and/or used in the summaries were adjusted to include the relevant imputations outlined below.

The CDRS-R total score is the sum of the responses to the 17 questions as recorded in the CRF. If only approximately 90% of the questions (minimum 15 questions answered) making up the score were present at a particular timepoint, the missing values were allowed for by calculating the total score as:

$$\text{Observed Total Score} * \left(1 + \frac{\text{Sum of Denominator(s) of the missing value(s)}}{\text{Sum of Denominators of the non - missing values}}\right)$$

Note: Denominator refers to the maximum possible value for a question (either 5 or 7).

As the Total Score was imputed when there were 1 or 2 missing values only, the above formula was simplified for the five following possible scenarios:

One missing question:

1. Missing answer for a 5-item question: Observed total score * (1 + 5/108)

2. Missing answer for a 7-item question: Observed total score * (1 + 7/106)

Two missing questions:

1. Missing answer for a 5-item question and for a 7-item question: Observed total score * (1 + 12/101)

2. Missing answer for two 5-item questions: Observed total score * (1 + 10/103)

3. Missing answer for two 7-item questions: Observed total score * (1 + 14/99)

If the calculation resulted in a fractional value, it was rounded to the nearest whole number.

If fewer than 15 questions were answered for a patient at a particular timepoint, then that patient's data were excluded from the summary tables for the variable at that timepoint.

Change in CDRS-R total score is the difference between CDRS-R total score at the timepoint being summarized and baseline. In the OC dataset, efficacy data were summarized only at the timepoint when they were collected; no data were carried forward to estimate missing data points. For the LOCF summary, the last known non-missing post-baseline score was carried forward.

3.10.2 Children's Yale-Brown Obsessive-Compulsive Scale (CY–BOCS)

The CY–BOCS is a clinician-rated scale designed to rate the severity of obsessive and compulsive symptoms in children and adolescents [15]. It is identical in form and scoring to the widely used adult Yale-Brown Obsessive Compulsive Scale, except that the questions are slightly modified for age appropriateness.

The clinician or rater first reviews the definitions of obsessions and compulsions with the parent(s) or guardian and the patient. The clinician or rater then proceeds with detailed questioning about the patient's symptoms using the obsessions checklist and compulsions checklist as guides. Following completion of the obsessions and compulsions checklists, the four most severe obsessions and four most severe compulsions are listed on the target symptom lists.

The clinician then reviews the severity of the symptoms. For both obsessions (items 1 to 5) and compulsions (items 6 to 10), the specific questions relate to time spent with obsessions or compulsions, interference due to obsessions or

compulsions, distress associated with the obsessions or compulsions, resistance against obsessions or compulsions, and degree of control over obsessions or compulsions. These items are rated on a severity scale ranging from 0 (“none,” “no symptoms.” “always resists,” or “complete control”) to 4 (“extreme,” “extremely short,” “completely yields,” or “no control”). Scores for these items reflect the rater's best estimate from all available information from the past week, with special emphasis on the target symptoms.

The total CY–BOCS score is the sum of items 1–10 (not including items 1b or 6b); the obsession and compulsion subtotals are the sums of items 1–5 and 6–10, respectively (not including items 1b and 6b). The total CY–BOCS score ranges from 0 to 40, with a score of 20 indicating moderate severity of obsessive and compulsive symptoms and a score of 10 or below indicating subclinical OCD.

CY–BOCS raters were required to attend the training sessions offered at the investigator meeting before the start of acute Study 704 and PK Study 715 or to complete follow-up training requirements (see Section 3.13, Data Quality Assurance). Follow-up training for raters included reviewing the scoring conventions for the CY–BOCS and assessing an OCD patient on video through completion of the CY–BOCS score sheet. The rater's scores were then compared with an acceptable score range set for the OCD patient. This documentation was reviewed by the sponsor. Confirmation of an acceptable passing score was sent to the rater.

Treatment of missing values in the calculation of CY–BOCS scores was handled as detailed in the RAP and is summarized below.

If only nine of the 10 questions making up the total CY-BOCS score were present at a particular timepoint, the missing value was allowed for by calculating the total score as follows:

$$\frac{(Sum\ of\ the\ scores\ for\ items\ present)\times 10}{9}$$

If the calculation resulted in a fractional value, it was rounded to the nearest whole number.

If fewer than 9 of the questions were answered for a patient at a particular timepoint, then that patient's data were excluded from the summary tables for the variable at that timepoint.

Change in CY-BOCS total score is the difference between CY-BOCS total score at the timepoint being summarized and baseline. In the OC dataset, efficacy data were summarized only at the timepoint when they were collected; no data were carried forward to estimate missing data points. For the LOCF summary, the last known non-missing post-baseline score was used to estimate missing data points.

3.10.3 Clinical Global Impression (CGI)–Severity of Illness and Global Improvement Items

The CGI is a widely accepted measure of clinical improvement in a variety of psychiatric disorders. These items have been extensively used in psychopharmacologic trials since their introduction into the Early Clinical Drug Evaluation Unit (ECDEU) Assessment Manual for Psychopharmacologic Trials published by the US National Institute of Mental Health [16].

The CGI–I is rated on a 1 to 7 scale. Based on all information available at the time of rating, the clinicians indicate their assessment of the patients' total improvement or worsening compared to their condition at entry into the acute or PK study, whether or not that improvement or worsening is judged to be due to study medication, according to the following:

0 = Not assessed
1 = Very much improved
2 = Much improved
3 = Minimally improved
4 = No change
5 = Minimally worse
6 = Much worse
7 = Very much worse

Patients with a 0 value (i.e., not assessed) at baseline or the timepoint being summarized were considered as missing. For the LOCF summary, the last non-zero post-baseline score was carried forward.

Patients were categorized as responders if they were rated either as 1 (very much improved) or 2 (much improved) at a particular endpoint compared to Baseline.

The proportion of responders based on the global improvement item is defined as:

$$\frac{\text{Number of patients with a response of 1 or 2 at the visit}}{\text{Total number of patients with a CGI assessment at that visit *}}$$

*i.e., the sum of responders and non-responders.

*i.e., the sum of responders and non-responders.

For the CGI–Severity of Illness item, clinicians indicate their assessment of the patients' severity of illness considering their total clinical experience with the particular patient population being studied, based on all information available at the time of rating. The assessment of the patient's severity of illness is based on a 1 to 7 scale according to the following:

0 = Not assessed
1 = Normal, not at all ill
2 = Borderline mentally ill
3 = Mildly ill
4 = Moderately ill
5 = Markedly ill
6 = Severely ill
7 = Among the most extremely ill patients

Patients with a 0 value (i.e., not assessed) at baseline or the timepoint being summarized were considered as missing. For the LOCF summary, the last non-zero post-baseline score was carried forward.

3.11 Safety Assessments

Safety was assessed primarily through routine adverse event monitoring, vital sign determinations (systolic and diastolic blood pressure and heart rate), physical examination (including height and weight), clinical laboratory evaluations (hematology, blood chemistry, and urinalysis), urine dipstick and serum HCG pregnancy tests (where applicable), and 12-lead ECGs.

3.11.1 Adverse Events

An adverse event (AE) was any noxious, pathological or unintended change in anatomical, physiological or metabolic functions as indicated by physical signs, symptoms and/or laboratory changes occurring in any phase of the clinical study and whether or not considered to be related to study medication. This included exacerbation of a pre-existing condition or event, intercurrent illness, drug interaction or the significant worsening of the disease under investigation that was not recorded elsewhere in the CRF under specific efficacy assessments. Anticipated day-to-day fluctuations of pre-existing conditions, including the disease under study, that did not represent a clinically significant exacerbation or

worsening were not considered adverse events. Discrete episodes of chronic conditions occurring during the study were reported as adverse events in order to assess changes in frequency or severity.

All serious and non-serious adverse events, whether observed by the investigator or reported by the patient, parent or legal guardian, were evaluated by the investigator and recorded in the AE section of the patient's CRF. Adverse events were elicited by the investigator asking the patient (or parent or legal guardian, as appropriate) a non-leading question such as, "Do you [or Does your child] feel different in any way since starting the new treatment or since the last visit?" If the response was "yes," details of the adverse event and its severity, including any change in study medication administration, investigator attribution to study medication, any corrective therapy given, and outcome status, were documented in the CRF.

The maximum severity of an adverse event was assigned to one of the following categories:

Mild:	An adverse event that was easily tolerated, caused minimal discomfort and did not interfere with everyday activities.
Moderate:	An adverse event that was sufficiently discomforting to interfere with normal everyday activities.
Severe:	An adverse event that prevented normal everyday activities.

Every effort was made to explain each adverse event and assess its relationship, if any, to study medication. Causality was assessed using the following categories:

Unrelated:	The adverse event was definitely not related to the study medication.
Probably unrelated:	Cause and effect relationship between the study medication and the adverse event was not demonstrated, was improbable but not impossible.
Possibly related:	A direct cause and effect relationship between the study medication and the adverse event was not demonstrated but was possible or likely.
Related:	There was a direct cause and effect relationship between the adverse event and the study medication.

All adverse events were coded from the verbatim term according to the World Health Organization (WHO) Adverse Reaction Terminology (ART) dictionary and

then mapped by body system and preferred term according to the COSTART-based Adverse Drug Experiences Coding System (ADECS).

3.11.2 Serious Adverse Events

A serious adverse event (SAE) was any event that was fatal, life threatening, or disabling/incapacitating, or resulted in hospitalization, prolonged a hospital stay, or was associated with congenital abnormality, cancer or overdose (either accidental or intentional). In addition, any event that the investigator regarded as serious or that suggested any significant hazard, contraindication, side effect or precaution that was associated with the use of the study medication was documented as an SAE. Pregnancy was captured as a serious adverse event for the purpose of tracking the status of pregnancies to term.

Any SAE that occurred at any time during the study or within 30 days of receiving the last dose of study medication, whether or not related to study medication, was to be reported to the sponsor within 24 hours. Instances of death, cancer or congenital abnormality occurring after 30 days, if brought to the attention of the investigator and considered by the investigator to be possibly related to study medication, were to be reported to the sponsor.

Serious adverse events were documented on an SAE form, and the event captured on the SAE page of the patient's CRF.

In the safety tabulations, serious adverse events were coded by the WHO ART dictionary and mapped by ADECS for preferred term. In the separate database used for preparing the clinical narratives, serious adverse events were coded by the WHO ART dictionary.

Elective surgery or routine clinical procedures that required hospitalization but were not the result of an AE, and were completed without complication as planned, were not to be considered as adverse events and were to be recorded on the medical procedures page of the patient's CRF.

3.11.3 Physical Examination

Physical examinations were conducted at the open-label Study 716 Baseline Visit (the last assessment from Study 701, 704, or 715 was acceptable if taken within 3 weeks of the open-label baseline assessment and no clinically significant abnormalities were found) and Week 24 or Early Withdrawal. The physical examination included height (cm) and weight (kg) measurements plus any other examination deemed necessary by the investigator. Height and weight were also

assessed at Week 12. Any adverse changes were to be recorded in the adverse event section of the patient's CRF.

3.11.4 Vital Signs

Vital signs consisted of systolic and diastolic blood pressure and heart rate. Vital sign readings were taken after the patient had been sitting for at least 3 minutes. Readings were taken at each visit. Any clinically significant adverse changes were to be recorded in the adverse event section of the patient's CRF.

3.11.5 Electrocardiograms (ECGs)

An electrocardiogram (ECG) was conducted at the open-label Study 716 Baseline Visit (the last assessment from Study 701, 704 or 715 was acceptable if taken within 3 weeks of the open-label baseline assessment and was not clinically significantly abnormal), and the Week 24 or Early Withdrawal visit. Any clinically significant adverse changes were to be recorded in the adverse event section of the patient's CRF. If an ECG assessment revealed a clinically significant finding, a repeat ECG was required.

3.11.6 Laboratory Values

Laboratory evaluations were assessed at the open-label Study 716 Baseline Visit (the last assessment from Study 701, 704, or 715 was acceptable if taken within 3 weeks of the open-label baseline assessment and was not clinically significantly abnormal), and at Weeks 4, 12, and 24 (or Early Withdrawal visit). The laboratory evaluation consisted of hematology (hemoglobin, hematocrit, red blood cells, white blood cells with differential, and platelet count), blood chemistry (BUN, creatinine, total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT [AST], and electrolytes), and dipstick urinalysis (if dipstick method was positive for blood or protein, a full microscopy was performed).

Any abnormalities considered clinically significant were to be recorded in the adverse event pages of the patient's CRF. Laboratory assessments were to be repeated if clinically significant abnormalities were detected and followed up until the abnormality had resolved or stabilized.

All laboratory assessments were carried out centrally by Quest Diagnostics Clinical Trials, 7600 Tyrone Avenue, Van Nuys, CA, USA (central laboratory for protocol-specified procedures) or the local laboratory at the site(s) in the event of an urgent safety laboratory test.

3.11.7 Pregnancy Tests

Pregnancy urine dipstick and serum HCG pregnancy tests were performed at the open-label Baseline Visit (only if the Study 701, 704 or 715 treatment phase endpoint visit did not coincide with the Study 716 Baseline Visit) and at Weeks 12 and 24 (or Early Withdrawal) for patients of child-bearing potential.

Patients who became pregnant during the study were to be withdrawn from the study immediately. Patients were instructed to notify the investigator if it was determined after completion of the study that they became pregnant either during the study or within 30 days of the last dose of study medication (including Taper Phase medication). Whenever possible, a pregnancy was to be followed to term, any premature terminations were to be reported, and the status of the mother and child was to be reported to GlaxoSmithKline after delivery.

3.12 Pharmacokinetic Assessments

No pharmacokinetic assessments were made in this study.

3.13 Data Quality Assurance

To ensure that study procedures were correctly and consistently carried out across all investigator sites, the protocol, CRFs and safety reporting were reviewed with the investigator and his/her personnel responsible for the conduct of the study by a GlaxoSmithKline representative at the investigator site. In addition, a multicenter Investigators' meeting was held on 24-25 February 2000 in xxxxxx, xxxxx, xxxx, for Study 701; on 08-09 December 1999 in xxxx, xxxx, xxxx, for Study 704; and on 26 April 2000 in xxxx, xxxx, xxxx, for Study 715. Information about procedures for Study 716 was also presented at these meetings.

Adherence to the protocol requirements and verification of data generation accuracy was achieved through monitoring visits to each study site by sponsor personnel at periodic intervals during the study and at the completion of the study. The monitor verified CRF entries by comparing them with the source documents (hospital/clinic/office records). Subsequent data handling and reporting processes were subject to in-process quality control. All the above procedures were performed according to methodologies detailed in SmithKline Beecham (a GlaxoSmithKline company) Standard Operating Procedures (SOPs).

This study was subject to audit by GlaxoSmithKline's department of Worldwide Regulatory Compliance–GCP (WRC–GCP). To date no study-specific audits have been performed for this study.

3.14 Statistical Evaluation

The study center of xxxxxxxx xx xxxx, xxxx, who entered 9 patients, was terminated by the sponsor following an internal audit during acute Study 704 that detected significant compliance violations for Study 704 (see Section 3.2, Investigators). All 9 patients enrolled at this site in Study 716 were included in the ITT population.

3.14.1 Target Sample Size

No sample size calculations were performed for this study. Sample size was determined by the number of patients who completed Studies 701, 704, or 715 and continued into this extension study. It was estimated that approximately 250 patients would complete their acute study and choose to enter this extension study.

3.14.2 Method of Randomization

There was no randomization as this was an open-label extension study and all patients took paroxetine.

3.14.3 Population/Datasets To Be Evaluated

Two patient populations were evaluated:

- The intention-to-treat (ITT) population consisted of all patients who received at least one dose of open-label medication and for whom at least one valid post-baseline (Study 716, Visit 1) open-label evaluation (including any adverse event) was available. Primary inference was based on the OC and LOCF datasets at the protocol-defined Week 24 endpoint. The summaries using the ITT population are intended to describe the long-term effect of paroxetine.

- The pure paroxetine (PPX) population, a subset of the ITT population, consisted of all ITT patients who received paroxetine in their acute study and were evaluated for key disorder efficacy at the conclusion of the acute study. The summaries using the PPX population are intended to describe

the maintenance effect of paroxetine. Patients from Study 715 are excluded from the PPX population because key disorder efficacy parameters (i.e., CDRS-R and CY-BOCS) were not conducted in Study 715 other than at the Screening visit, and final Treatment-Phase assessment is considered as baseline for comparisons involving the PPX population. Therefore, the PPX population consists of all ITT patients in Study 716 who took paroxetine in Study 701 or 704. Primary inference was based on the OC and LOCF datasets at the protocol-defined Week 24 endpoint.

No per-protocol population was identified for this study.

3.14.4 Planned Efficacy Evaluations

As this was an open-label extension study, no formal hypothesis testing was performed. Descriptive summaries were provided for the observed case (OC) dataset at each visit and the Week 24 last observation carried forward (LOCF) dataset, with primary inference based on the protocol-defined Week 24 endpoint. In the OC dataset, efficacy data were assessed at the timepoint at which they were collected; no data were carried forward to estimate missing data. In the LOCF datasets for change in CY–BOCS total score and change in CDRS–R total score, the last known non-missing post-baseline score for each patient was carried forward to estimate missing data points. In the LOCF datasets for change in CGI–Severity of Illness and proportion of responders based on the CGI–Global Improvement item, the last non-zero post-baseline score for each patient was carried forward to estimate missing data points. The LOCF dataset contains all data from the Week 24 visit plus the last on-treatment assessment for patients who withdrew before Week 24.

In acute Studies 701 and 704, baseline values for efficacy parameters were established at the Baseline Visit. For PK Study 715, baseline values for efficacy parameters were established at the Screening Visit. These are the values (referred to as acute-study baseline values) from which changes from baseline are calculated.

Based on the primary diagnosis from the acute or PK study, the following instruments were used in this study in order to monitor the intensity of the patient's MDD or OCD symptoms, the patient's overall clinical condition, and the patient's response to open-label treatment:

- CDRS–R at Study 716 baseline and Week 24 (or Early Withdrawal) for patients from Study 701 and 715 (if primary diagnosis was MDD)

- CY–BOCS at Study 716 baseline and Week 24 (or Early Withdrawal) for patients from Study 704 and 715 (if primary diagnosis was OCD)

- CGI–Severity of Illness item at Study 716 baseline and Weeks 1, 2, 3, 4, 8, 12, 16, 20, and 24 (or Early Withdrawal) for all patients

- CGI–Global Improvement item at Study 716 baseline and Weeks 1, 2, 3, 4, 8, 12, 16, 20, and 24 (or Early Withdrawal) (relative to acute-study baseline condition) for all patients.

3.14.4.1 Primary Efficacy Variable

There was no primary measure of efficacy in this study.

3.14.4.2 Secondary Efficacy Variables

The following efficacy variables were summarized descriptively for the ITT and PPX populations, except for the CGI Global Improvement item, which was summarized for the ITT population only since the improvement score is relative to the acute-study baseline:

- change from baseline in the CDRS–R total score at the Week 24 visit (OC and LOCF) for patients entering Study 716 from Study 701 and from Study 715 if primary diagnosis was MDD

- change from baseline in the CY–BOCS total score at the Week 24 visit (OC and LOCF) for patients entering Study 716 from Study 704 and from Study 715 if primary diagnosis was OCD

- proportion of responders based on the CGI–Global Improvement item at the Week 24 visit (OC and LOCF) for patients entering Study 716 from Study 701, 704, or 715 (separately by indication, MDD or OCD). Global improvement was rated by comparing the patient's condition at a particular visit to the patient's condition at the acute-study baseline. Response was defined as a score of 1 (very much improved) or 2 (much improved)

- change from baseline in the CGI–Severity of Illness item score at the Week 24 visit (OC and LOCF) for patients entering Study 716 from Study 701, 704 or 715 (separately by indication, MDD or OCD).

For comparisons involving the ITT population, the baseline assessment was defined as the patient's acute-study Baseline Visit (or Screening Visit in Study

715). For comparisons involving the PPX population, the baseline assessment was defined as the patient's final on-treatment assessment (excluding Taper Phase medication) in the acute study. (See Section 3.14.3, Population/Datasets To Be Evaluated.)

3.14.4.3 Other Variables of Interest

The following efficacy variables were summarized by acute-study treatment group and dose level at the end of the acute-study Treatment Phase (pre-taper). These summaries are intended to describe the effect of taper in patients treated with paroxetine:

- for all patients entering Study 716 from Study 701, the change from Study 701 Treatment Phase endpoint to Study 716 Visit 1 (pre- to post-taper) in CDRS–R total score. Patients who completed the acute Study 701 at dose level 1 (or 10 mg/day) were excluded from this evaluation as their Treatment Phase endpoint was on the same day as their Study 716 Visit 1 assessment.

- for all patients entering Study 716 from Study 704, the change from Study 704 Treatment Phase endpoint to Study 716 Visit 1 (pre- to post-taper) in CY–BOCS total score. Patients who completed the acute Study 704 at dose level 1 (or 10 mg/day) were excluded from this evaluation as their Treatment Phase endpoint was on the same day as their Study 716 Visit 1 assessment.

3.14.5 Methods of Analyses

This was an open-label study and no hypothesis testing was performed. Efficacy data were summarized descriptively, both overall and by acute-study treatment group. Categorical data were summarized by counts and percentages. Continuous data were summarized by the mean, median, standard deviation and range (minimum, maximum).

3.14.6 Safety Evaluations

The safety population was identical to the ITT population. All patients who received at least one dose of open-label study medication and who had at least one valid post-dose assessment (including any adverse events) were included in the safety population and assessed for clinical safety and tolerability. All safety evaluations were assessed relative to the baseline assessment of the acute study.

3.14.6.1 Adverse Events

Adverse events were coded from the verbatim term using the WHO adverse reaction WHO ART dictionary, and then mapped to the ADECS (COSTART based) classification to give a body system and preferred term. Serious adverse events were coded from the verbatim term according to the WHO ART dictionary and mapped by ADECS for preferred term and body system.

Adverse event data were listed by acute-study treatment group, age group and patient number. The number (%) of patients with treatment-emergent adverse events were summarized for overall incidence by acute-study treatment group and by body system and preferred term. Tables of adverse events are presented for the pre-acute-study Treatment Phase, acute-study Treatment Phase adverse events ongoing into Study 716, open-label Treatment Phase, Taper Phase and Follow-up Phase. The number (%) of adverse events are presented by primary diagnosis and age group for each diagnosis subgroup and overall.

Numbers and percentages are also presented for patients with adverse events by severity, adverse events by relationship to study medication, adverse events leading to withdrawal, and serious adverse events.

Adverse events were summarized in five phases as follows:

- *Pre-acute-study Treatment Phase adverse events* were defined as all adverse events where the onset date was before the first day of acute-study treatment. All pre-acute-study treatment adverse events were classified as Screening-emergent.

- *Acute-study Treatment (including Taper) Phase adverse events* were defined as all adverse events where the onset date was on or after the first day of acute-study treatment and before the first day of open-label study treatment. Adverse events that started and stopped in this phase were reported in the acute study only.

- *Open-label Treatment Phase adverse events* were defined as all adverse events where the onset date was on or after the first day of open-label treatment and before or on the last day of open-label treatment (excluding taper medication).

- *Taper Phase adverse events* were defined as all adverse events where the onset date was on or after the first day of taper medication and on

or before last day of taper medication. (Some patients may not have this phase.)

- *Follow-up Phase adverse events* were defined as all adverse events where the onset date was after the last date of open-label treatment (or taper medication) but less than 14 days (or 30 days if a serious adverse event) after this date.

In addition, a post-Follow-up Phase was defined for the listing of serious adverse events where the onset date was >30 days after the last date of open-label medication (or taper medication).

Adverse events were categorized as emergent according to International Conference on Harmonization (ICH) E9 guidelines, which gives the following definition of a treatment-emergent adverse event: " An event that emerges during treatment having been absent pre-treatment, or worsens relative to the pre-treatment state."

However, this is an open-label treatment study and is divided into 5 phases: pre-acute-study treatment, acute-study treatment (including taper), open-label treatment, taper and follow-up. Hence the definition has been modified to, "An event that emerges during the open-label Treatment Phase having been absent pre-acute-study treatment, or worsens relative to the pre-acute-study treatment state."

3.14.6.2 Vital Signs

Vital signs data were listed by acute-study treatment group, age group and patient number. Summary statistics by acute-study treatment group were produced for changes from acute-study baseline for blood pressure, heart rate, weight, height and body mass index (BMI). In addition, the number and percentage of patients with a significant increase or decrease in any vital sign from acute-study baseline that was of potential clinical concern during the study was tabulated by parameter by acute-study treatment group. Table 4 shows these pre-defined levels of potential clinical concern for vital signs.

Table 4 Criteria for Assessment of Vital Signs

Parameter	Age *	Absolute Value of Clinical Concern	Change from Acute-study Baseline of Clinical Concern	
			Decrease	Increase
Systolic BP (mmHg)	all	<95 or >145	≥ 30	≥ 40
Diastolic BP (mmHg)	all	<50 or >85	≥ 20	≥ 30
Pulse Rate (bpm)	7–12	<65 or >115	≥ 30	≥ 30
	13–18	<55 or >110	≥ 30	≥ 30
Weight (kg)** (Boys)	7–8	<18.2 or >36.8	≥ 7%	≥ 7%
	9	<20.0 or >41.8	≥ 7%	≥ 7%
	10	<21.8 or >47.2	≥ 7%	≥ 7%
	11	<24.5 or >53.6	≥ 7%	≥ 7%
	12	<27.2 or >60.4	≥ 7%	≥ 7%
	13	<31.3 or >67.2	≥ 7%	≥ 7%
	14	<35.9 or >74.5	≥ 7%	≥ 7%
	15	<40.9 or >81.3	≥ 7%	≥ 7%
	16	<45.4 or >89.9	≥ 7%	≥ 7%
	17–18	<49.0 or >93.5	≥ 7%	≥ 7%
Weight (kg)** (Girls)	7–8	<17.3 or >36.8	≥ 7%	≥ 7%
	9	<19.5 or >42.7	≥ 7%	≥ 7%
	10	<21.8 or >49.5	≥ 7%	≥ 7%
	11	<25.0 or >56.3	≥ 7%	≥ 7%
	12	<28.1 or >63.1	≥ 7%	≥ 7%
	13	<31.8 or >69.5	≥ 7%	≥ 7%
	14	<35.4 or >75.4	≥ 7%	≥ 7%
	15	<38.6 or >79.9	≥ 7%	≥ 7%
	16	<40.9 or >83.1	≥ 7%	≥ 7%
	17–18	<42.2 or >84.4	≥ 7%	≥ 7%

* Age used to determine concern values for vital signs during Study 716 was the age at Study 716 baseline.

** For weight, the last pre-acute-study treatment value was considered to be the acute-study baseline value

3.14.6.3 Electrocardiograms (ECGs)

ECG assessments were listed by acute-study treatment group, age group and patient number. ECGs were repeated at Taper End and/or Follow-up if results at Week 24 or Early Withdrawal were clinically significantly abnormal. The number and percentage of patients with an abnormal ECG and those with a normal ECG are tabulated for acute-study screening, acute-study baseline, open-label Study 716 baseline, last Study 716 treatment/Early Withdrawal, taper and follow-up.

3.14.6.4 Laboratory Values

Laboratory data (hematology, blood chemistry and urinalysis) were listed by acute-study treatment group and patient number. Summary statistics for the changes from acute-study baseline to endpoint in laboratory values for the overall population are presented by parameter by acute-study treatment group. Baseline for laboratory data was defined as the last acute-study baseline assessment. Endpoint was defined as the last on-treatment open-label laboratory assessment, including the Taper Phase. Follow-up was the last open-label laboratory assessment up to 14 days after the last open-label treatment date (including taper).

The number and percentage of patients with a significant increase or decrease in any laboratory parameter from acute-study baseline that was of potential clinical concern was tabulated by parameter by acute-study treatment group. Table 5 shows these pre-defined levels of potential clinical concern for laboratory values. In addition, the number and percentage of patients with transitions (e.g., from normal to abnormal) from baseline to endpoint and/or Follow-up were tabulated by parameter by acute-study treatment group.

Table 5 Laboratory Values of Potential Clinical Concern

Laboratory Parameters	Sex/Age *	Units	Values of Potential Clinical Concern
Hematology			
Hemoglobin	Males	g/L	<115
	Females	g/L	<95
Hematocrit	6–11 years	%	<35
	12–17 years	%	<36
	Males 18–64 years	%	<35
	Females 18–64 years	%	<41
RBC	Males	x 10^{12}/L	>8
	Females	x 10^{12}/L	>10
WBC	All	x 10^{9}/L	<2.8 or >16
Lymphocytes	All	x 10^{9}/L	<0.53 or >4.43
Monocytes	All	x 10^{9}/L	>1.38
Basophils	All	x 10^{9}/L	>0.40
Eosinophils	All	x 10^{9}/L	>0.79
Neutrophil	All	x 10^{9}/L	<1.58 or >8.64
Platelet Count	All	x 10^{9}/L	<75 or >700
Liver Function			
AST (SGOT)	All	IU/L	>150
ALT (SGPT)	All	IU/L	>165
Total Bilirubin	All	umol/L	>34.2
Renal Function			
Creatinine	All	umol/L	>176.8
BUN	All	mmol/L	>10.71
Others			
Sodium	All	mmol/L	<126 or >156
Potassium	All	mmol/L	<3 or >6
TSH	All	mU/L	>10

* Age used to determine concern values for hematocrit in Study 716 was the age at Study 716 baseline.
Source: Table 15.3.2, Section 12

3.14.7 Defined Visit Timepoints

The protocol stipulated that patients' visits during the open-label Treatment Phase were to occur at specific timepoints. However, because of schedule problems, patient visits could not always occur on the exact day specified. Therefore, where

possible, data were slotted into the following time windows depending on the frequency with which the assessment was recorded as per protocol, with days relative to the first dose of open-label medication. Unscheduled visits were also slotted according to the visit windows specified in Table 6.

Table 6 Visit Windows

Visit	Proposed Day Relative to the First Dose of Open-label Medication	Visit Window
716 Baseline (Visit 1)	0	–
Week 1 (Visit 2)	7	Days 1* to 10
Week 2 (Visit 3)	14	Days 11 to 17
Week 3 (Visit 4)	21	Days 18 to 24
Week 4 (Visit 5)	28	Days 25 to 35
Week 6 (Visit 6)	42	Days 36 to 49
Week 8 (Visit 7)	56	Days 50 to 70
Week 12 (Visit 8)	84	Days 71 to 98
Week 16 (Visit 9)	112	Days 99 to 126
Week 20 (Visit 10)	140	Days 127 to 154
Week 24 (Visit 11)	168	Days 155 to 196
Post-week 24	—	Greater than 196 days

* Day 1 is included as open-label baseline (Visit 1) if data were recorded before open-label study medication was taken; however, Day 1 is included as Week 1 (visit 2) if data were recorded after open-label study medication was taken.

Baseline (Visit 1) data are all data that were collected on the baseline page of the Study 716 CRF, before the first dose of open-label medication.

Data recorded at specific visits only were slotted according to the intervals given above. All data were listed, but only data slotted into intervals corresponding to the protocol-defined assessment time were tabulated. For example, only CDRS–R and CY–BOCS assessments that fell into baseline and Week 24 intervals were tabulated; however, all data are displayed in the listings.

If more than one assessment occurred in the same time window, then the latest assessment was used in the data summaries; however, all assessments are displayed in the listings.

Where efficacy data were recorded at the Early Withdrawal visit, they were handled in the same way as scheduled data and were slotted using the pre-defined visit windows. Thus, for example, if a patient withdrew at Week 8, the final

CDRS–R data would not be tabulated since Week 8 was not a scheduled visit for collection of this endpoint. However, these data were listed and contributed to the LOCF summary statistics.

Efficacy assessments performed more than 7 days after the last dose of open-label medication (excluding Taper Phase) and safety assessments performed more than 14 days after the last dose of taper medication, or more than 14 days after the last dose of open-label study medication if the patient did not enter the Taper Phase, were excluded from the summary tables. However, all data were listed.

3.14.8 Phases of the Study

3.14.8.1 Baseline

All safety evaluations were assessed relative to the baseline assessment of the acute study. For efficacy comparisons involving the ITT population, the baseline assessment was defined as the value at the patient's acute-study Baseline Visit for Studies 701 and 704 and Screening Visit for Study 715, referred to in this report as acute-study baseline values. For efficacy comparisons involving the PPX population, the baseline assessment was defined as the patient's final on-treatment assessment (excluding taper period medication) from the acute study.

3.14.8.2 Open-label Treatment Phase

An efficacy assessment was defined as occurring during the open-label Treatment Phase if the assessment date was on or after the first dose of open-label study medication and up to and including 7 days after the last dose of open-label study medication, as long as it was before the start of open-label taper medication. For all other data, the open-label Treatment Phase started on the date of the first dose of open-label study medication and ended on either of the following dates:

- the date of the last dose of open-label study medication, if no open-label taper medication was taken
- the day before the date of first open-label taper medication taken.

Once the Taper Phase commenced, no assessments after the last dose of open-label study medication were classified as occurring during the open-label Treatment Phase.

3.14.8.3 Open-label Taper Phase

The open-label Taper Phase was defined as from the first dose date of taper medication to the last dose date of taper medication. No efficacy assessments were made during the open-label Taper Phase.

3.14.8.4 Follow-up Phase

The Follow-up Phase was defined as any evaluable data that were collected after the last dose of study medication (including taper). No efficacy assessments were made during the Follow-up Phase.

3.14.9 Interim Analysis

An interim report for this study was completed on 28 January 2002 in order to meet FDA reporting obligations for an sNDA for paroxetine pediatric use.

3.14.10 Data Irregularities

In Table 13.10.1, Section 10, and Listing 13.10.1, Appendix B, patients 716.176.27170, 716.201.00102 and 716.020.25461 had "unknown" entered at some visits for compliance question "missed >3 consecutive days of study medication." The compliance was listed in Listing 13.10.1 as "unk" and treated the same as missing data.

Table 13.10.1, Patients Who Missed More Than 3 Consecutive Days of Study Medication, Section 10, counts patients with missing compliance at a visit and duration of study medication >3 days at that visit as having missed >3 consecutive days for that visit. Therefore, it contains more patients as having missed more than 3 consecutive days medication than Listing 13.10.1, Appendix B, which is based solely on the investigators' reporting of patients who missed more than 3 consecutive days of study medication.

In Listing 15.1.1 (AEs on therapy) and Listing 15.1.4 (AE withdrawals), patient 716.015.25464 (acute-study placebo group) has an AE of manic reaction coded STP (study medication stopped); patient 716.010.25371 (acute-study placebo group) has an AE of abnormal ejaculation coded STP; and patient 716.008.25644 (acute-study paroxetine group) has an AE of somnolence coded STP. However, the AEs started 18 days, 16 days, and 40 days before the start of open-label study medication, respectively. The patients do not appear in Table 15.1.5.1, adverse events leading to withdrawal, as this table includes only treatment-emergent AEs.

In Table 13.3.1b (reasons for withdrawal), the patients are coded as having withdrawn due to an adverse event.

In Listing 15.1.2 (AEs in Taper, Follow-up and Post-Follow-up Phases), Appendix D, adverse events during the Follow-up Phase, Patient 716.028.27685, in the acute-study placebo group, had an adverse event with a verbatim of "elevated liver enzymes," which, following a query, was coded to "SGOT increased." Patient 716.006.25418, also in the acute-study placebo group, also had an adverse event during the Follow-up Phase with a verbatim of "elevated liver enzymes," which coded to "Liver function tests abnormal." The enhancement in regard to SGOT (AST) does not appear in the listing.

Patient 716.013.00702 had an AE of hyperkinesia that started on Day 0 and is recorded in Listing 15.1.1, Appendix D, as leading to a dose reduction. The reduction, from 20 mg to 10 mg per day, occurred on Day 50. This adverse event is not included in Table 15.1.8 (Dose Decreases due to Adverse Events) because it was not emergent during the open-label Treatment Phase.

Patient 716.006.25420 appears in Listing 15.1.1, Appendix D, as having dose decreases for two episodes of insomnia. One of them has no dose at onset and no onset date, and the patient appears only once in Table 15.1.8, Section 12, Dose Decreases due to Adverse Events.

If a patient's age was 11 years at acute-study baseline and 12 years at Study 716 baseline, the patient was still counted as a child in Study 716 listings and tabulations. Age at Study 716 baseline was used to determine the reference ranges and concern values for laboratory values and vital signs in Study 716 (Listing 15.2.1, Appendix E; 15.3.1, 15.3.2, and 15.3.3, Appendix F). However, for the interim report, age at acute-study baseline was used to determine reference ranges and concern values for vital signs.

Five patients had paroxetine listed as a concomitant medication during the open-label treatment phase (Table 13.9.2, Concomitant Medication, Excluding Taper Phase, Section 10). Three of these patients (716.017.00002, 716.206.00606, and 176.208.00806, all in the acute-study paroxetine group) started taking paroxetine as a concomitant medication on the day that they stopped taking open-label medication in the Treatment Phase instead of entering the Taper Phase as specified in the protocol. Because of the apparent overlap in medication dates, these are captured as on-treatment concomitant medication. The other 2 patients (716.019.25751 and 716.159.25628, both in the acute-study placebo group) did

take concomitant paroxetine for 1 day and 5 days respectively (see Section 4.6, Concomitant Medications).

Patient 716.169.25781 in the acute-study placebo group and patient 716.009.25504 in the acute-study paroxetine group each completed the Week 24 visit CRF, but because the visits occurred less than 155 days after the first dose of open-label study medication, completion of the study for each patient was slotted to Week 20. Patient 716.044.27138 in the acute-study placebo group completed the Week 24 visit CRF, but because the visit occurred more than 196 days after the first dose of open-label study medication, completion of the study was slotted to Post-Week 24.

Patient 716.004.27702 withdrew due to a protocol violation on Day 197; because the withdrawal occurred more than 196 days after the first dose of open-label study medication, the withdrawal was slotted to Post-Week 24 and he was considered to be still in the study at Week 24 (see Section 3.14.7, Defined Visit Timepoints).

Patient 716.201.00108, a child with a primary diagnosis of OCD, did not have any information for Week 1. Therefore this patient is not included at Week 1 in any tables that tabulate data by visit.

Patient 716.004.27003 in the acute-study placebo group had a final visit slotted to Week 20. However, per Listing 13.3.1b, the patient's final visit is reported as Week 16, because the Week 20 visit occurred less than 126 days after the first dose of open-label study medication (see Section 3.14.7, Defined Visit Timepoints).

In Listing 13.10.1, Appendix B, start and stop days for changed doses of study medication were recorded as occurring at separate visits in order to track compliance. If a patient changed the dose of study medication between visits, the next scheduled visit was recorded twice as occurring on the same date, once for each dose level. In some cases, the count for tablets returned at the "second visit" is a negative number because no tablets were dispensed to match that visit. The total for the two "visits" added together gives the correct tablet count.

Patient 716.183.25901, in the acute-study placebo group, had an adverse event with the verbatim "decreased libido inorgasmia." The decreased libido coded to "Libido decreased," a gender-non-specific adverse event. The inorgasmia coded to "Female genital disorders," a gender-specific adverse event. This event appears in

Table 15.1.5.1, Section 12, as a gender-non-specific adverse event and also as a gender-specific adverse event.

All laboratory parameters and vital signs that were assessed more than 14 days after the last dose of study medication (including taper), even if they occurred at a properly scheduled visit (14 days ± 3 days after the last dose of study medication) were listed but not tabulated.

4 Study Population

This report includes data for all patients who entered the open-label extension study from acute Studies 701, 704 and 715.

4.1 Study Dates

The first dose of open-label study medication was administered on 13 May 2000. The last dose of open-label study medication (including taper) was administered on 06 January 2002. The date of the last visit for the last patient was 29 January 2002.

4.2 Patient Disposition

4.2.1 Number and Distribution of Patients

A total of 265 patients were entered into this open-label extension study: 117 patients from Study 701, 111 patients from Study 704, and 37 patients (31 with a primary diagnosis of MDD and 6 with a primary diagnosis of OCD) from Study 715. A total of 148 patients had a primary diagnosis of MDD and 117 had a primary diagnosis of OCD. All patients who had baseline evaluations for Study 716 entered the study, including one patient who failed the inclusion/exclusion criteria but was entered into the study (Table 13.3.1a, Section 10) (see Section 4.3, Protocol Violations). A summary of the number and disposition of patients by primary diagnosis (OCD or MDD), age group (child or adolescent), and acute-study treatment group (paroxetine or placebo) is presented in Table 7.

The ITT population consisted of all patients who received at least one dose of open-label medication and who had at least one valid post-baseline (Study 716, Visit 1) open-label evaluation (including any adverse event). Two patients who entered Study 716, both adolescents and both of whom received paroxetine in their acute study, are not included in the ITT population (Listing 13.1.1, Appendix B). One patient (716.020.25462) from acute Study 704 moved to another state and one patient (716.154.25767) from acute Study 701 was lost to follow-up; both patients had no post-baseline assessments in Study 716.

The ITT population, therefore, consisted of 263 patients: 133 patients who received paroxetine in acute Study 701 or 704 or in PK Study 715 (referred to as

acute-study paroxetine patients) and 130 patients who received placebo in their acute Study 701 or 704 (referred to as acute-study placebo patients).

The PPX population consisted of all patients in the ITT population who received paroxetine in their acute study and were evaluated for key efficacy parameters (CDRS-R and CY-BOCS) at the conclusion of the acute study. Therefore, patients from Study 715 were not part of the PPX population. The PPX population consisted of 96 acute-study paroxetine patients, 50 from Study 701 (MDD) and 46 from Study 704 (OCD) (see Section 3.14.3, Population/Datasets To Be Evaluated).

In the ITT population, 55.9% (147/263) had a primary diagnosis of MDD and 44.1% (116/263) had a primary diagnosis of OCD. Of those with MDD, 51.0% (75/147) were children and 49.0% (72/147) were adolescents; 55.1% (81/147) had received paroxetine in their acute study and 44.9% (66/147) had received placebo in their acute study. Of those with OCD, 55.2% (64/116) were children and 44.8% (52/116) were adolescents; 44.8% (52/116) had received paroxetine in their acute study and 55.2% (64/116) had received placebo in their acute study.

A total of 43.0% (114/265) of patients completed the study and 57.0% (151/265) withdrew early. More patients from the acute-study placebo group withdrew early (64.6%, 84/130) than patients from the acute-study paroxetine group (49.6%, 67/135). Further, more children (61.9%, 86/139) withdrew early than adolescents (51.6%, 65/126). The number of early withdrawals was similar in patients with MDD (55.4%, 82/148) and OCD (59.0%, 69/117).

Table 7 Number (%) and Disposition of Patients by Primary Diagnosis, Age Group, and Acute-study Treatment Group (All Patients)

	Acute-study Treatment Group																	
	Paroxetine *						Placebo						Total					
Study Stage /	Total		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents	
Population	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Primary Diagnosis: Total	**(N = 135)**		**(N = 67)**		**(N = 68)**		**(N = 130)**		**(N = 72)**		**(N = 58)**		**(N = 265)**		**(N = 139)**		**(N = 126)**	
716 Baseline Only	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–
Number Entered	135	(100.0)	67	(100.0)	68	(100.0)	130	(100.0)	72	(100.0)	58	(100.0)	265	(100.0)	139	(100.0)	126	(100.0)
Completed **	68	(50.4)	31	(46.3)	37	(54.4)	46	(35.4)	22	(30.6)	24	(41.4)	114	(43.0)	53	(38.1)	61	(48.4)
Early Withdrawal	67	(49.6)	36	(53.7)	31	(45.6)	84	(64.6)	50	(69.4)	34	(58.6)	151	(57.0)	86	(61.9)	65	(51.6)
ITT Population	133	(98.5)	67	(100.0)	66	(97.1)	130	(100.0)	72	(100.)	58	(100.0)	263	(99.2)	139	(100.0)	124	(98.4)
PPX Population	96	(71.1)	50	(74.6)	46	(67.6)	–	–	–	–	–	–	96	(36.2)	50	(36.0)	46	(36.5)
Primary Diagnosis: MDD	**(N = 82)**		**(N = 39)**		**(N = 43)**		**(N = 66)**		**(N = 36)**		**(N = 30)**		**(N = 148)**		**(N = 75)**		**(N = 73)**	
Number Entered	82	(100.0)	39	(100.0)	43	(100.0)	66	(100.0)	36	(100.0)	30	(100.0)	148	(100.0)	75	(100.0)	73	(100.0)
Completed †	42	(51.2)	17	(43.6)	25	(58.1)	24	(36.4)	11	(30.6)	13	(43.3)	66	(44.6)	28	(37.3)	38	(52.1)
Early Withdrawal	40	(48.8)	22	(56.4)	18	(41.9)	42	(63.6)	25	(69.4)	17	(56.7)	82	(55.4)	47	(62.7)	35	(47.9)
ITT Population	81	(98.8)	39	(100.0)	42	(97.7)	66	(100.0)	36	(100.0)	30	(100.0)	147	(99.3)	75	(100.0)	72	(98.6)
PPX Population	50	(61.0)	25	(64.1)	25	(58.1)	–	–	–	–	–	–	50	(33.8)	25	(33.3)	25	(34.2)

Source: Table 13.1.1, Section 10; Listings 13.1.1, 13.1.2 and 13.3.1b, Appendix B.

* The acute-study paroxetine group includes two patients (716.020.25462 from acute Study 704 and 716.154.25767 from acute Study 701) who entered Study 716 but had no post-baseline assessments and are therefore not included in the ITT population.

** Patients were considered to have completed the study if they completed a Week 24 visit CRF. Three patients who completed the study had their completion visit slotted to weeks other than Week 24; they are counted in this table as completers (see Section 3.14.10, Data Irregularities).

Table continues

Table 7 (Continued) Number (%) and Disposition of Patients by Primary Diagnosis, Age Group, and Acute-study Treatment Group (All Patients)

Study Stage / Population	Acute-study Treatment Group																	
	Paroxetine *						Placebo						Total					
	Total		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Primary Diagnosis: OCD	**(N = 53)**		**(N = 28)**		**(N = 25)**		**(N = 64)**		**(N = 36)**		**(N = 28)**		**(N = 117)**		**(N = 64)**		**(N = 53)**	
Number Entered	53	(100.0)	28	(100.0)	25	(100.0)	64	(100.0)	36	(100.0)	28	(100.0)	117	(100.0)	64	(100.0)	53	(100.0)
Completed **	26	(49.1)	14	(50.0)	12	(48.0)	22	(34.4)	11	(30.6)	11	(39.3)	48	(41.0)	25	(39.1)	23	(43.4)
Early Withdrawal	27	(50.9)	14	(50.0)	13	(52.0)	42	(65.6)	25	(69.4)	17	(60.7)	69	(59.0)	39	(60.9)	30	(56.6)
ITT Population	52	(98.1)	28	(100.0)	24	(96.0)	64	(100.0)	36	(100.0)	28	(100.0)	116	(99.1)	64	(100.0)	52	(98.1)
PPX Population	46	(86.8)	25	(89.3)	21	(84.0)	–	–	–	–	–	–	46	(39.3)	25	(39.1)	21	(39.6)

Source: Table 13.1.1, Section 10; Listings 13.1.1, 13.1.2 and 13.3.1b, Appendix B.

* The acute-study paroxetine group includes two patients (716.020.25462 from acute Study 704 and 716.154.25767 from acute Study 701) who entered Study 716 but had no post-baseline assessments and are therefore not included in the ITT population.

** Patients were considered to have completed the study if they completed a Week 24 visit CRF. Three patients who completed the study had their completion visit slotted to weeks other than Week 24; they are counted in this table as completers (see Section 3.14.10, Data Irregularities).

The number and disposition of patients by age group and acute-study treatment group are presented by country (US or Canada) in Table 13.1.2, Section 11.

Table 8 presents the number of patients entered and completed by center. Investigator names at each center and affiliation may be found in Table 1, Section 3.2, Investigators. The number of patients enrolled per center ranged from a single patient at 10 centers to 18 patients at Center 025. A total of 14 centers each entered at least 8 patients.

Table 8 Number (%) of Patients Entered and Completed by Center and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group											
	Paroxetine (N = 133)				Placebo (N = 130)				Total (N = 263)			
Center	Entered		Completed*		Entered		Completed*		Entered		Completed*	
No.	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
002	1	(0.8)	1	(0.8)	2	(1.5)	1	(0.8)	3	(1.1)	2	(0.8)
004	3	(2.3)	2	(1.5)	3	(2.3)	0	–	6	(2.3)	0	–
005	4	(3.0)	1	(0.8)	4	(3.1)	2	(1.5)	8	(3.0)	3	(1.1)
006	3	(2.3)	3	(2.3)	1	(0.8)	0	–	4	(1.5)	3	(1.1)
008	3	(2.3)	0	–	1	(0.8)	0	–	4	(1.5)	0	–
009	1	(0.8)	1	(0.8)	1	(0.8)	1	(0.8)	2	(0.8)	2	(0.8)
010	6	(4.5)	4	(3.0)	7	(5.4)	3	(2.3)	13	(4.9)	7	(2.7)
012	1	(0.8)	1	(0.8)	0	–	0	–	1	(0.4)	1	(0.4)
013	7	(5.3)	3	(2.3)	0	–	0	–	7	(2.7)	3	(1.1)
014	3	(2.3)	1	(0.8)	6	(4.6)	2	(1.5)	9	(3.4)	3	(1.1)
015	3	(2.3)	1	(0.8)	3	(2.3)	0	–	6	(2.3)	1	(0.4)
016	4	(3.0)	4	(3.0)	5	(3.8)	0	–	9	(3.4)	4	(1.5)
017	5	(3.8)	3	(2.3)	0	–	0	–	5	(1.9)	3	(1.1)
019	4	(3.0)	1	(0.8)	5	(3.8)	1	(0.8)	9	(3.4)	2	(0.8)
020	4	(3.0)	3	(2.3)	6	(4.6)	2	(1.5)	10	(3.8)	5	(1.9)
025	7	(5.3)	5	(3.8)	11	(8.5)	4	(3.1)	18	(6.8)	9	(3.4)
026	1	(0.8)	0	–	2	(1.5)	0	–	3	(1.1)	0	–
027	1	(0.8)	0	–	2	(1.5)	2	(1.5)	3	(1.1)	2	(0.8)
028	3	(2.3)	1	(0.8)	6	(4.6)	2	(1.5)	9	(3.4)	3	(1.1)
031	0	–	0	–	3	(2.3)	2	(1.5)	3	(1.1)	2	(0.8)
040	1	(0.8)	0	–	1	(0.8)	1	(0.8)	2	(0.8)	1	(0.4)
043	3	(2.3)	2	(1.5)	1	(0.8)	0	–	4	(1.5)	2	(0.8)

Source: Table 13.4.1, Section 10; Listing 13.3.1b, Appendix B

* Patients were considered to have completed the study if they completed the Week 24 visit CRF.

Table continues

Table 8 (Continued) Number (%) of Patients Entered and Completed by Center and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group											
	Paroxetine (N = 133)				Placebo (N = 130)				Total (N = 263)			
Center	Entered		Completed*		Entered		Completed*		Entered		Completed*	
No.	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
044	2	(1.5)	1	(0.8)	5	(3.8)	3	(2.3)	7	(2.7)	4	(1.5)
047	1	(0.8)	0	–	2	(1.5)	0	–	3	(1.1)	0	–
049	2	(1.5)	1	(0.8)	3	(2.3)	2	(1.5)	5	(1.9)	3	(1.1)
052	0	–	0	–	1	(0.8)	0	–	1	(0.4)	0	–
055	4	(3.0)	0	–	5	(3.8)	0	–	9	(3.4)	0	–
148	1	(0.8)	0	–	0		0	–	1	(0.4)	0	–
151	0	–	0	–	2	(1.5)	1	(0.8)	2	(0.8)	1	(0.4)
154	1	(0.8)	0	–	0		0	–	1	(0.4)	0	–
159	3	(2.3)	1	(0.8)	5	(3.8)	3	(2.3)	8	(3.0)	4	(1.5)
164	1	(0.8)	0	–	1	(0.8)	0	–	2	(0.8)	0	–
165	0	–	0	–	2	(1.5)	0	–	2	(0.8)	0	–
167	1	(0.8)	1	(0.8)	2	(1.5)	2	(1.5)	3	(1.1)	3	(1.1)
168	4	(3.0)	1	(0.8)	3	(2.3)	1	(0.8)	7	(2.7)	2	(0.8)
169	0	–	0	–	1	(0.8)	1	(0.8)	1	(0.4)	1	(0.4)
170	1	(0.8)	0	–	2	(1.5)	1	(0.8)	3	(1.1)	1	(0.4)
171	0	–	0	–	1	(0.8)	0	–	1	(0.4)	0	–
172	1	(0.8)	1	(0.8)	0		0	–	1	(0.4)	1	(0.4)
173	1	(0.8)	1	(0.8)	0		0	–	1	(0.4)	1	(0.4)
176	6	(4.5)	4	(3.0)	8	(6.2)	4	(3.1)	14	(5.3)	8	(3.0)
179	0	–	0	–	1	(0.8)	1	0.8)	1	(0.4)	1	(0.4)
180	2	(1.5)	0	–	1	(0.8)	0	–	3	(1.1)	0	–
183	4	(3.0)	3	(2.3)	8	(6.2)	2	(1.5)	12	(4.6)	5	(1.9)
186	3	(2.3)	2	(1.5)	3	(2.3)	1	(0.8)	6	(2.3)	3	(1.1)
192	3	(2.3)	2	(1.5)	4	(3.1)	1	(0.8)	7	(2.7)	3	(1.1)
201	9	(6.8)	2	(1.5)	0		0	–	9	(3.4)	2	(0.8)
202	1	(0.8)	1	(0.8)	0	–	0	–	1	(0.4)	1	(0.4)
205	4	(3.0)	3	(2.3)	0	–	0	–	4	(1.5)	3	(1.1)
206	2	(1.5)	1	(0.8)	0	–	0	–	2	(0.8)	1	(0.4)
208	8	(6.0)	6	(4.5)	0	–	0	–	8	(3.0)	6	(2.3)
Total	133		68		130		46		263		114	

Source: Table 13.4.1, Section 10, Listing 13.3.1b Appendix B

* Patients were considered to have completed the study if they completed the Week 24 visit CRF.

4.2.2 Number of Patients Present at Each Visit

Table 9 presents the number and percentage of patients remaining in this study at the conclusion of each study visit. The percentages shown in this table are based on the number of patients in the ITT population. A total of 111 patients completed Study 716 (completed the Week 24 visit measurements) at Week 24. Two additional patients (716.009.25504, acute-study paroxetine group, and 716.169.25781, acute-study placebo group) took their last dose of non-taper study medication before relative day 155 and thus the completion was slotted to Week 20. One further additional patient (716.044.27138) in the acute-study placebo group took the last dose of non-taper study medication after relative day 196 and thus had the completion visit slotted to Post-week 24 (see Section 3.14.7, Defined Visit Timepoints, and Section 3.14.10, Data Irregularities). Therefore, 43.3% of the ITT patients (114/263) completed this study, 68 patients in the acute-study paroxetine group and 46 patients in the acute-study placebo group.

Withdrawals occurred with similar frequency throughout the study in both acute-study treatment groups, although there were slightly more in the acute-study placebo group from Week 6 onwards.

Table 9 Number (%) of Patients Remaining in the Study at Each Visit by Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group					
	Paroxetine (N = 133)		Placebo (N = 130)		Total (N = 263)	
Visit	n	(%) *	n	(%) *	n	(%) *
716 Baseline	133	(100.0)	130	(100.0)	263	(100.0)
Week 1	128	(96.2)	125	(96.2)	253	(96.2)
Week 2	127	(95.5)	122	(93.8)	249	(94.7)
Week 3	124	(93.2)	117	(90.0)	241	(91.6)
Week 4	117	(88.0)	108	(83.1)	225	(85.6)
Week 6	112	(84.2)	93	(71.5)	205	(77.9)
Week 8	100	(75.2)	81	(62.3)	181	(68.8)
Week 12	88	(66.2)	70	(53.8)	158	(60.1)
Week 16	77	(57.9)	59	(45.4)	136	(51.7)
Week 20	70	(52.6)	47	(36.2)	117	(44.5)
Completed Wk 20 **	1	(0.8)	1	(0.8)	2	(0.8)
Week 24 †	0	–	2	(1.5)	2	(0.8)
Completed Wk 24 ††	67	(50.4)	44	(33.8)	111	(42.2)
Completed Post-Wk 24 ‡	0	–	1	(0.8)	1	(0.4)

Source: Table 13.3.2, Section 10; Listing 13.3.1b, Appendix B.
Completed = Patients who completed a week 24 visit CRF.
* Percentages for patients still in the study at each visit are based on the total number of patients at Study 716 baseline.
** Two patients (716.009.25504, acute-study paroxetine group, and 716.169.25781, acute-study placebo group) took their last dose of non-taper study medication before relative day 155 and thus the completion was slotted to Week 20 (see Section 3.14.10, Data Irregularities).
† In addition to the patient who completed the study post-Week 24, patient 716.004.27702 was considered to be still in the study at Week 24 as he withdrew due to a protocol violation on Day 197, which was slotted to Post-Week 24 (see Section 3.14.10, Data Irregularities).
†† These numbers represent patients who completed the study at the Week 24 visit window and do not include 3 patients whose completion was slotted to other visits (see Section 3.14.10, Data Irregularities).
‡ One patient (716.044.27138) in the acute-study placebo group took the last dose of non-taper study medication after relative day 196 and thus the completion was slotted to Post-Week 24 (see Section 3.14.10, Data Irregularities).

4.2.3 Withdrawal Reasons

A summary of the number and percentage of patients not completing the study and the reason for withdrawal by primary diagnosis, age group, and acute-study treatment group is presented in Table 10. A total of 56.7% (149/263) of ITT patients were withdrawn during the open-label Treatment Phase of Study 716.

The primary reasons for withdrawal were “other” (includes unknown and non-study related personal reasons) (13.7%, 36/263), adverse event (13.3%, 35/263), and lack of efficacy (12.2%, 32/263). The “other” reasons included the following (Listing 13.3.1b, Appendix B):

- withdrew consent (13 patients)
- site was prematurely closed (7 patients)
- scheduling conflict (2 patients)
- family wanted to seek additional treatment (1 patient)
- patient choice (1 patient)
- did not want to give blood (1 patient)
- patient’s mother wanted the patient off all medication before beginning therapy (1 patient)
- mother and child desired to withdraw from the study (1 patient)
- issues at school override therapeutic effects of study (1 patient)
- patient needed to take excluded medication (1 patient)
- early withdrawal (1 patient)
- patient/family decision (1 patient)
- moved (1 patient)
- early termination as principal investigator moving out of state (1 patient) (see Section 3.2, Investigators)
- did not want to continue (1 patient)
- patient wished to withdraw due to lack of time (1 patient)
- patient refused to come to further appointments (1 patient).

Among patients receiving paroxetine in their acute study, the primary reason for withdrawal was also “other” (includes unknown and non-study related personal reasons) (13.5%, 18/133), similar to the number withdrawn for “other” in the

acute-study placebo group (13.8%, 18/130). Among patients who had received placebo in their acute study, the primary reason for withdrawal was adverse event (18.5%, 24/130), compared to 8.3% (11/133) of patients who had received paroxetine in their acute study.

Withdrawal rates among children (61.9%, 86/139) were higher than among adolescents (50.8%, 63/124). Among children, the primary reasons for withdrawal were adverse event (13.7%, 19/139), lack of efficacy (12.9%, 18/139) and lost to follow-up (12.2%, 17/139). Among adolescents, the primary reasons for withdrawal were adverse event (12.9%, 16/124) and lack of efficacy (11.3%, 14/124). The primary reasons for withdrawal among children in the acute-study paroxetine group were "lost to follow-up" and "other" (each 13.4%, 9/67). The primary reasons for withdrawal among children in the acute-study placebo group were adverse event and "other" (each 19.4%, 14/72). The primary reason for withdrawal among adolescents was "other" in the acute-study paroxetine group (13.6%, 9/66 patients) and adverse event in the acute-study placebo group (17.2%, 10/58 patients).

Overall, 55.1% (81/147) of patients with a primary diagnosis of MDD were withdrawn during the open-label Treatment Phase of the study. Among MDD patients receiving paroxetine in their acute study, the primary reasons for withdrawal were lack of efficacy, lost to follow-up, and adverse event (each 11.1%, 9/81 patients). Among MDD patients receiving placebo in their acute study, the primary reasons for withdrawal were lack of efficacy and "other" (each 16.7%, 11/66 patients). More children with MDD in both acute-study treatment groups withdrew for "other" reasons (17.3%, 13/75) than adolescents (4.2%, 3/72).

Overall, 58.6% (68/116) of patients with a primary diagnosis of OCD were withdrawn during the open-label Treatment Phase of the study. Among OCD patients receiving paroxetine in their acute study, the primary reason for withdrawal was "other" (25.0%, 13/52, compared to 7/64 (10.9%) for acute-study placebo patients). Among OCD patients receiving placebo in their acute study, the primary reason for withdrawal was adverse event (21.9%, 14/64, compared to 3.8% (2/52) receiving paroxetine in their acute study). The reasons for withdrawal among children and adolescents were similar.

Table 10 indicates that 35 patients were withdrawn from the study due to adverse events, whereas Table 40 indicates that 31 patients were withdrawn from the study due to adverse events. This difference is due to the different data sources for these tables. Table 10 is based on Data Source Table 13.3.1b, which is derived from a

checkbox in the CRF where the investigator supplies the reason for withdrawal. Table 40 is based on Data Source Table 15.1.5.1, which includes adverse events with drug action coded as STP (study medication stopped).

Table 10 Number (%) of Patients Who Completed the Study or Were Withdrawn from the Study by Reason for Withdrawal by Primary Diagnosis, Age Group, and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group																	
	Paroxetine						Placebo						Total					
	Total		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents	
Study Stage/Population	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Primary Diagnosis: Total	(N = 133)		(N = 67)		(N = 66)		(N = 130)		(N = 72)		(N = 58)		(N = 263)		(N = 139)		(N = 124)	
Completed Study *	68	(51.1)	31	(46.3)	37	(56.1)	46	(35.4)	22	(30.6)	24	(41.4)	114	(43.3)	53	(38.1)	61	(49.2)
Adverse Event	11	(8.3)	5	(7.5)	6	(9.1)	24	(18.5)	14	(19.4)	10	(17.2)	35	(13.3)	19	(13.7)	16	(12.9)
Lack of Efficacy	13	(9.8)	8	(11.9)	5	(7.6)	19	(14.6)	10	(13.9)	9	(15.5)	32	(12.2)	18	(12.9)	14	(11.3)
Protocol Deviation (Including Non-compliance)	9	(6.8)	5	(7.5)	4	(6.1)	9	(6.9)	4	(5.6)	5	(8.6)	18	(6.8)	9	(6.5)	9	(7.3)
Lost to Follow-up	14	(10.5)	9	(13.4)	5	(7.6)	14	(10.8)	8	(11.1)	6	(10.3)	28	(10.6)	17	(12.2)	11	(8.9)
Other **	18	(13.5)	9	(13.4)	9	(13.6)	18	(13.8)	14	(19.4)	4	(6.9)	36	(13.7)	23	(16.5)	13	(10.5)
Total withdrawn	65	(48.9)	36	(53.7)	29	(43.9)	84	(64.6)	50	(69.4)	34	(58.6)	149	(56.7)	86	(61.9)	63	(50.8)
Primary Diagnosis: MDD	(N = 81)		(N = 39)		(N = 42)		(N = 66)		(N = 36)		(N = 30)		(N = 147)		(N = 75)		(N = 72)	
Completed Study *	42	(51.9)	17	(43.6)	25	(59.5)	24	(36.4)	11	(30.6)	13	(43.3)	66	(44.9)	28	(37.3)	38	(52.8)
Adverse Event	9	(11.1)	4	(10.3)	5	(11.9)	10	(15.2)	6	(16.7)	4	(13.3)	19	(12.9)	10	(13.3)	9	(12.5)
Lack of Efficacy	9	(11.1)	6	(15.4)	3	(7.1)	11	(16.7)	5	(13.9)	6	(20.0)	20	(13.6)	11	(14.7)	9	(12.5)
Protocol Deviation (Including Non-compliance)	7	(8.6)	3	(7.7)	4	(9.5)	3	(4.5)	1	(2.8)	2	(6.7)	10	(6.8)	4	(5.3)	6	(8.3)
Lost to Follow-up	9	(11.1)	6	(15.4)	3	(7.1)	7	(10.6)	3	(8.3)	4	(13.3)	16	(10.9)	9	(12.0)	7	(9.7)
Other **	5	(6.2)	3	(7.7)	2	(4.8)	11	(16.7)	10	(27.8)	1	(3.3)	16	(10.9)	13	(17.3)	3	(4.2)
Total withdrawn	39	(48.1)	22	(56.4)	17	(40.5)	42	(63.6)	25	(69.4)	17	(56.7)	81	(55.1)	47	(62.7)	34	(47.2)

Source: Table 13.3.1b, Section 10; Listing 13.3.1b, Appendix B

* Patients were considered to have completed the study if they completed a Week 24 visit CRF. Three patients who completed the study had their completion visit slotted to weeks other than Week 24; they are counted in this table as completers (see Section 3.14.10, Data Irregularities).

** Includes unknown and non-study related personal reasons.

Table continues

Table 10 (Continued) Number (%) of Patients Who Completed the Study or Were Withdrawn from Study by Reason for Withdrawal Primary Diagnosis, Age Group, and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group																	
	Paroxetine						Placebo						Total					
	Total		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents	
Study Stage/Population	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Primary Diagnosis: OCD	**(N = 52)**		**(N = 28)**		**(N = 24)**		**(N = 64)**		**(N = 36)**		**(N = 28)**		**(N = 116)**		**(N = 64)**		**(N = 52)**	
Completed Study *	26	(50.0)	14	(50.0)	12	(50.0)	22	(34.4)	11	(30.6)	11	(39.3)	48	(41.4)	25	(39.1)	23	(44.2)
Adverse Event	2	(3.8)	1	(3.6)	1	(4.2)	14	(21.9)	8	(22.2)	6	(21.4)	16	(13.8)	9	(14.1)	7	(13.5)
Lack of Efficacy	4	(7.7)	2	(7.1)	2	(8.3)	8	(12.5)	5	(13.9)	3	(10.7)	12	(10.3)	7	(10.9)	5	(9.6)
Protocol Deviation (Including Non-compliance)	2	(3.8)	2	(7.1)	0	–	6	(9.4)	3	(8.3)	3	(10.7)	8	(6.9)	5	(7.8)	3	(5.8)
Lost to Follow-up	5	(9.6)	3	(10.7)	2	(8.3)	7	(10.9)	5	(13.9)	2	(7.1)	12	(10.3)	8	(12.5)	4	(7.7)
Other **	13	(25.0)	6	(21.4)	7	(29.2)	7	(10.9)	4	(11.1)	3	(10.7)	20	(17.2)	10	(15.6)	10	(19.2)
Total withdrawn	26	(50.0)	14	(50.0)	12	(50.0)	42	(65.6)	25	(69.4)	17	(60.7)	68	(58.6)	39	(60.9)	29	(55.8)

Source: Table 13.3.1b, Section 10; Listing 13.3.1b, Appendix B

* Patients were considered to have completed the study if they completed a Week 24 visit CRF. Three patients who completed the study had their completion visit slotted to weeks other than Week 24; they are counted in this table as completers (see Section 3.14.10, Data Irregularities).

** Includes unknown and non-study related personal reasons.

The reasons for withdrawal for patients in the PPX population are presented in Table 13.3.1d, Section 10. The proportions of completers and reasons for withdrawal are similar to the proportions in the corresponding age groups among paroxetine patients with a primary diagnosis of MDD and OCD, respectively, in Table 10.

Table 11 presents a cumulative summary of patients withdrawing from the study by acute-study treatment group, visit, and reason for withdrawal for both age groups combined as well as for children and adolescents separately.

More than half of all patients who withdrew did so before or at Week 8, and the greatest percentage of withdrawals occurred at Week 8. The predominant reason for withdrawal in the first 8 weeks for both acute-study treatment groups combined was “other” (includes protocol deviation [including non-compliance], lost to follow-up, unknown, and non-study related personal reasons) (16.3%, 43/263). Of the 35 patients who withdrew due to an adverse event, 25 withdrew on or before Week 8.

Table 11 Cumulative Number (%) of Patient Withdrawals by Reason and by Visit, Age Group and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group																							
	Paroxetine (N = 133)								Placebo (N = 130)								Total (N = 263)							
	AE		LOE		Other *		Total		AE		LOE		Other *		Total		AE		LOE		Other *		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Total																								
Wk 1	0	–	1	0.8	4	3.0	5	3.8	1	0.8	1	0.8	3	2.3	5	3.8	1	0.4	2	0.8	7	2.7	10	3.8
Wk 2	0	–	1	0.8	5	3.8	6	4.5	2	1.5	2	1.5	4	3.1	8	6.2	2	0.8	3	1.1	9	3.4	14	5.3
Wk 3	2	1.5	1	0.8	6	4.5	9	6.8	4	3.1	2	1.5	7	5.4	13	10.0	6	2.3	3	1.1	13	4.9	22	8.4
Wk 4	2	1.5	2	1.5	12	9.0	16	12.0	8	6.2	2	1.5	12	9.2	22	16.9	10	3.8	4	1.5	24	9.1	38	14.4
Wk 6	5	3.8	3	2.3	13	9.8	21	15.8	13	10.0	4	3.1	20	15.4	37	28.5	18	6.8	7	2.7	33	12.5	58	22.1
Wk 8	7	5.3	6	4.5	20	15.0	33	24.8	18	13.8	8	6.2	23	17.7	49	37.7	25	9.5	14	5.3	43	16.3	82	31.2
Wk 12	7	5.3	10	7.5	28	21.1	45	33.8	20	15.4	14	10.8	26	20.0	60	46.2	27	10.3	24	9.1	54	20.5	105	39.9
Wk 16	11	8.3	12	9.0	33	24.8	56	42.1	20	15.4	17	13.1	34	26.2	71	54.6	31	11.8	29	11.0	67	25.5	127	48.3
Wk 20	11	8.3	13	9.8	38	28.6	62	46.6	24	18.5	19	14.6	39	30.0	82	63.1	35	13.3	32	12.2	77	29.3	144	54.8
Wk 24	11	8.3	13	9.8	41	30.8	65	48.9	24	18.5	19	14.6	40	30.8	83	63.8	35	13.3	32	12.2	81	30.8	148	56.3
Post-Wk 24 **	11	8.3	13	9.8	41	30.8	65	48.9	24	18.5	19	14.6	41**	31.5	84	64.6	35	13.3	32	12.2	82	31.2	149	56.7

Source: Table 13.3.3, Section 10; Listing 13.3.1b, Appendix B

AE: adverse event; LOE: lack of efficacy

* "Other" includes protocol deviations, including non-compliance, lost to follow-up, unknown, and non-study related personal reasons

** One patient (716.004.27702), a child in the acute-study placebo group, was withdrawn during the post-Week 24 visit window (see Section 3.14.10, Data Irregularities).

Table continues

Table 11 (Continued) Cumulative Number (%) of Patient Withdrawals by Reason and by Visit, Age Group and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group																							
	Paroxetine (N = 67)								Placebo (N = 72)								Total (N = 139)							
	AE		LOE		Other *		Total		AE		LOE		Other *		Total		AE		LOE		Other *		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Children																								
Wk 1	0	–	1	1.5	3	4.5	4	6.0	0	–	0	–	2	2.8	2	2.8	0	–	1	0.7	5	3.6	6	4.3
Wk 2	0	–	1	1.5	3	4.5	4	6.0	0	–	0	–	3	4.2	3	4.2	0	–	1	0.7	6	4.3	7	5.0
Wk 3	1	1.5	1	1.5	3	4.5	5	7.5	2	2.8	0	–	5	6.9	7	9.7	3	2.2	1	0.7	8	5.8	12	8.6
Wk 4	1	1.5	2	3.0	6	9.0	9	13.4	5	6.9	0	–	8	11.1	13	18.1	6	4.3	2	1.4	14	10.1	22	15.8
Wk 6	3	4.5	2	3.0	7	10.4	12	17.9	8	11.1	1	1.4	12	16.7	21	29.2	11	7.9	3	2.2	19	13.7	33	23.7
Wk 8	4	6.0	4	6.0	14	20.9	22	32.8	11	15.3	3	4.2	13	18.1	27	37.5	15	10.8	7	5.0	27	19.4	49	35.3
Wk 12	4	6.0	7	10.4	19	28.4	30	44.8	12	16.7	8	11.1	16	22.2	36	50.0	16	11.5	15	10.8	35	25.2	66	47.5
Wk 16	5	7.5	7	10.4	19	28.4	31	46.3	12	16.7	9	12.5	20	27.8	41	56.9	17	12.2	16	11.5	39	28.1	72	51.8
Wk 20	5	7.5	8	11.9	21	31.3	34	50.7	14	19.4	10	13.9	24	33.3	48	66.7	19	13.7	18	12.9	45	32.4	82	59.0
Wk 24	5	7.5	8	11.9	23	34.3	36	53.7	14	19.4	10	13.9	25	34.7	49	68.1	19	13.7	18	12.9	48	34.5	85	61.2
Post-Wk 24 **	5	7.5	8	11.9	23	34.3	36	53.7	14	19.4	10	13.9	26**	36.1	50	69.4	19	13.7	18	12.9	49	35.3	86	61.9

Source: Table 13.3.3, Section 10; Listing 13.3.1b, Appendix B

AE: adverse event; LOE: lack of efficacy

* "Other" includes protocol deviations, including non-compliance, lost to follow-up, unknown, and non-study related personal reasons

** One patient (716.004.27702), a child in the acute-study placebo group, was withdrawn during the post-Week 24 visit window (see Section 3.14.10, Data Irregularities).

Table continues

Table 11 (Continued) Cumulative Number (%) of Patient Withdrawals by Reason and by Visit, Age Group and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group																							
	Paroxetine (N = 66)								Placebo (N = 58)								Total (N = 124)							
	AE		LOE		Other *		Total		AE		LOE		Other *		Total		AE		LOE		Other *		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Adolescents																								
Wk 1	0	–	0	–	1	1.5	1	1.5	1	1.7	1	1.7	1	1.7	3	5.2	1	0.8	1	0.8	2	1.6	4	3.2
Wk 2	0	–	0	–	2	3.0	2	3.0	2	3.4	2	3.4	1	1.7	5	8.6	2	1.6	2	1.6	3	2.4	7	5.6
Wk 3	1	1.5	0	–	3	4.5	4	6.1	2	3.4	2	3.4	2	3.4	6	10.3	3	2.4	2	1.6	5	4.0	10	8.1
Wk 4	1	1.5	0	–	6	9.1	7	10.6	3	5.2	2	3.4	4	6.9	9	15.5	4	3.2	2	1.6	10	8.1	16	12.9
Wk 6	2	3.0	1	1.5	6	9.1	9	13.6	5	8.6	3	5.2	8	13.8	16	27.6	7	5.6	4	3.2	14	11.3	25	20.2
Wk 8	3	4.5	2	3.0	6	9.1	11	16.7	7	12.1	5	8.6	10	17.2	22	37.9	10	8.1	7	5.6	16	12.9	33	26.6
Wk 12	3	4.5	3	4.5	9	13.6	15	22.7	8	13.8	6	10.3	10	17.2	24	41.4	11	8.9	9	7.3	19	15.3	39	31.5
Wk 16	6	9.1	5	7.6	14	21.2	25	37.9	8	13.8	8	13.8	14	24.1	30	51.7	14	11.3	13	10.5	28	22.6	55	44.4
Wk 20	6	9.1	5	7.6	17	25.8	28	42.4	10	17.2	9	15.5	15	25.9	34	58.6	16	12.9	14	11.3	32	25.8	62	50.0
Wk 24	6	9.1	5	7.6	18	27.3	29	43.9	10	17.2	9	15.5	15	25.9	34	58.6	16	12.9	14	11.3	33	26.6	63	50.8
Post-Wk 24	6	9.1	5	7.6	18	27.3	29	43.9	10	17.2	9	15.5	15	25.9	34	58.6	16	12.9	14	11.3	33	26.6	63	50.8

Source: Table 13.3.3, Section 10; Listing 13.3.1b, Appendix B

AE: adverse event; LOE: lack of efficacy

* "Other" includes protocol deviations, including non-compliance, lost to follow-up, unknown, and non-study related personal reasons

** One patient (716.004.27702), a child in the acute-study placebo group, was withdrawn during the post-Week 24 visit window (see Section 3.14.10, Data Irregularities).

4.3 Protocol Violations

Protocol violations were not defined for this open-label extension study, and therefore a per-protocol population was not identified.

4.4 Demographic and Baseline Characteristics

4.4.1 Demographic Characteristics

The demographic characteristics of the ITT population are summarized for the overall population and by acute-study treatment group, primary diagnosis, and age group in Table 12. All demographic data were collected at acute-study baseline (PK Study Screening). If a patient's age was 11 years at acute-study baseline and 12 years at Study 716 baseline, the patient was still counted as a child in Study 716.

There were more male patients (57.4%, 151/263) than female patients (42.6%, 112/263). However, among children in the acute-study paroxetine group, there were more females (52.2%, 35/67) than males (47.8%, 32/67). The proportion of females in the acute-study paroxetine group (45.9%, 61/133) was higher than in the acute-study placebo group (39.2%, 51/130).

There were slightly more children than adolescents in the ITT population, 52.9% (139/263) compared to 47.1% (124/263), respectively. This slight imbalance occurred only in the patients who received placebo in their acute study. The mean ages of children in both acute-study treatment groups were similar (9.0 years and 9.4 years in the paroxetine and placebo groups, respectively), as were mean ages of adolescents (14.3 years and 14.2 years in the paroxetine and placebo groups, respectively), with an overall mean age of 11.6 years (SD 2.87). The mean height, weight and BMI of children were generally comparable in both acute-study treatment groups, as were mean height, weight and BMI of adolescents.

Overall, 84.8% (223/263) of patients were white, 8.0% (21/263) were black and 7.2% (19/263) were categorized as "other": 11 Hispanic; 1 mixed Hispanic and white; 2 American Indian; 1 Indian; and 4 biracial/mixed patients.

The demographic characteristics of the population of patients with a primary diagnosis of MDD were similar to the population of patients with a primary diagnosis of OCD.

Table 12 Demographic Characteristics by Primary Diagnosis, Age Group and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group								
	Paroxetine			Placebo			Total		
Primary Diagnosis: Total	**Total (N = 133)**	**Children (N = 67)**	**Adolescents (N = 66)**	**Total (N = 130)**	**Children (N = 72)**	**Adolescents (N = 58)**	**Total (N = 263)**	**Children (N = 139)**	**Adolescents (N = 124)**
Gender, n (%)									
Female	61 (45.9)	35 (52.2)	26 (39.4)	51 (39.2)	27 (37.5)	24 (41.4)	112 (42.6)	62 (44.6)	50 (40.3)
Male	72 (54.1)	32 (47.8)	40 (60.6)	79 (60.8)	45 (62.5)	34 (58.6)	151 (57.4)	77 (55.4)	74 (59.7)
Age (years)									
Mean (SD)	11.7 (2.93)	9.0 (1.36)	14.3 (1.54)	11.6 (2.82)	9.4 (1.32)	14.2 (1.72)	11.6 (2.87)	9.3 (1.34)	14.2 (1.62)
Range	6-17	6-11	12-17	7-17	7-11	12-17	6-17	6-11	12-17
Race, n (%)									
White	111 (83.5)	56 (83.6)	55 (83.3)	112 (86.2)	63 (87.5)	49 (84.5)	223 (84.8)	119 (85.6)	104 (83.9)
Black	10 (7.5)	5 (7.5)	5 (7.6)	11 (8.5)	7 (9.7)	4 (6.9)	21 (8.0)	12 (8.6)	9 (7.3)
Oriental	0	0	0	0	0	0	0	0	0
Other *	12 (9.0)	6 (9.0)	6 (9.1)	7 (5.4)	2 (2.8)	5 (8.6)	19 (7.2)	8 (5.8)	11 (8.9)
Height (cm)									
Mean (SD)	153.2 (16.61)	140.84 (11.98)	165.7 (9.93)	150.9 (16.45)	138.9 (10.20)	166.0 (8.37)	152.0 (16.54)	139.8 (11.10)	165.8 (9.20)
Range	114.5-188.0	114.5-165.0	139.5-188.0	115.6-180.3	115.6-161.0	149.9-180.3	114.5-188.0	114.5-165.0	139.5-188.0
Weight (kg)**									
Mean (SD)	55.69 (23.25)	41.93 (15.52)	69.67 (21.43)	51.54 (22.21)	38.77 (14.42)	67.68 (19.73)	53.65 (22.80)	40.29 (14.99)	68.75 (20.60)
Range	20.4-141.0	20.4-79.5	30.1-141.0	20.5-131.4	20.5-104.0	38.2-131.4	20.4-141.0	20.4-104.0	30.1-141.0
BMI (kg/m^2)									
Mean (SD)	22.86 (6.53)	20.57 (5.29)	25.19 (6.87)	21.79 (6.18)	19.70 (5.22)	24.43 (6.32)	22.33 (6.37)	20.12 (5.25)	24.83 (6.61)
Range	13.9-45.9	13.9-32.8	13.9-45.9	13.6-45.4	13.6-40.1	16.4-45.4	13.6-45.9	13.6-40.1	13.9-45.9

Source: Tables 13.5.1b and 13.5.2b, Section 10; Listings 13.5.1, Appendix B, and 15.2.1, Appendix E

Height, weight and BMI data are missing for patient 716.049.28150 (acute-study placebo, adolescent, primary diagnosis OCD).

* Other race includes Hispanic (11 patients), Hispanic/white (1 patient), American Indian (2 patients), Indian (1 patient), and mixed or biracial (4 patients).

** Weight measured in pounds was converted to kilograms using the conversion 1 lb. = 0.454 kg

Table continues

Table 12 (Continued) Demographic Characteristics by Primary Diagnosis, Age Group and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group								
	Paroxetine			Placebo			Total		
Diagnosis: MDD	**(N = 81)**	**(N = 39)**	**(N = 42)**	**(N = 66)**	**(N = 36)**	**(N = 30)**	**(N = 147)**	**(N = 75)**	**(N = 72)**
Gender, n (%)									
Female	33 (40.7)	19 (48.7)	14 (33.3)	29 (43.9)	14 (38.9)	15 (50.0)	62 (42.2)	33 (44.0)	29 (40.3)
Male	48 (59.3)	20 (51.3)	28 (66.7)	37 (56.1)	22 (61.1)	15 (50.0)	85 (57.8)	42 (56.0)	43 (59.7)
Age (years)									
Mean (SD)	11.8 (2.85)	9.3 (1.28)	14.2 (1.55)	11.6 (2.94)	9.4 (1.29)	14.3 (1.86)	11.7 (2.88)	9.3 (1.28)	14.3 (1.68)
Range	7-17	7-11	12-17	7-17	7-11	12-17	7-17	7-11	12-17
Race, n (%)									
White	65 (80.2)	31 (79.5)	34 (81.0)	54 (81.8)	30 (83.3)	24 (80.0)	119 (81.0)	61 (81.3)	58 (80.6)
Black	7 (8.6)	3 (7.7)	4 (9.5)	7 (10.6)	4 (11.1)	3 (10.0)	14 (9.5)	7 (9.3)	7 (9.7)
Oriental	0	0	0	0	0	0	0	0	0
Other *	9 (11.1)	5 (12.8)	4 (9.5)	5 (7.6)	2 (5.6)	3 (10.0)	14 (9.5)	7 (9.3)	7 (9.7)
Height (cm)									
Mean (SD)	153.8 (15.85)	140.9 (11.34)	165.72 (8.22)	150.2 (16.36)	138.0 (10.36)	164.73 (8.21)	152.2 (16.13)	139.5 (10.91)	165.3 (8.17)
Range	120.0-181.6	120.0-165.0	143.5-181.6	119.4-180.3	119.4-160.0	143.5-181.6	119.4-181.6	119.4-165.0	143.5-181.6
Weight (kg)**									
Mean (SD)	57.51 (23.93)	42.90 (14.35)	71.08 (23.12)	52.91 (23.53)	40.20 (14.81)	68.15 (23.14)	55.44 (23.78)	41.60 (14.53)	69.86 (23.01)
Range	24.9-141.0	24.9-74.0	40.9-141.0	21.8-131.4	21.8-89.0	40.0-131.4	21.8-141.0	21.8-89.0	40.0-141.0
BMI (kg/m^2)									
Mean (SD)	23.51 (6.67)	21.20 (5.16)	25.65 (7.23)	22.56 (6.63)	20.68 (5.62)	24.83 (7.12)	23.08 (6.64)	20.95 (5.35)	25.31 (7.15)
Range	15.0-45.9	15.0-31.0	16.8-45.9	13.6-45.4	13.6-34.8	16.9-45.4	13.6-45.9	13.6-34.8	16.8-45.9

Source: Tables 13.5.1b and 13.5.2b, Section 10; Listings 13.5.1, Appendix B, and 15.2.1, Appendix E

Height, weight and BMI data are missing for patient 716.049.28150 (acute-study placebo, adolescent, primary diagnosis OCD).

* Other race includes Hispanic (11 patients), Hispanic/white (1 patient), American Indian (2 patients), Indian (1 patient) , and mixed or biracial (4 patients).

** Weight measured in pounds was converted to kilograms using the conversion 1 lb. = 0.454 kg

Table continues

Table 12 (Continued) Demographic Characteristics by Primary Diagnosis, Age Group and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group								
	Paroxetine			Placebo			Total		
Gender, n (%)									
Female	28 (53.8)	16 (57.1)	12 (50.0)	22 (34.4)	13 (36.1)	9 (32.1)	50 (43.1)	29 (45.3)	21 (40.4)
Male	24 (46.2)	12 (42.9)	12 (50.0)	42 (65.6)	23 (63.9)	19 (67.9)	66 (56.9)	35 (54.7)	31 (59.6)
Age (years)									
Mean (SD)	11.5 (3.08)	9.0 (1.48)	14.4 (1.56)	11.5 (2.71)	9.5 (1.36)	14.1 (1.57)	11.5 (2.87)	9.3 (1.42)	14.2 (1.55)
Range	6-17	6-11	12-17	7-17	7-11	12-17	6-17	6-11	12-17
Race, n (%)									
White	46 (88.5)	25 (89.3)	21 (87.5)	58 (90.6)	33 (91.7)	25 (89.3)	104 (89.7)	58 (90.6)	46 (88.5)
Black	3 (5.8)	2 (7.1)	1 (4.2)	4 (6.3)	3 (8.3)	1 (3.6)	7 (6.0)	5 (7.8)	2 (3.8)
Oriental	0	0	0	0	0	0	0	0	0
Other *	3 (5.8)	1 (3.6)	2 (8.3)	2 (3.1)	–	2 (7.1)	5 (4.3)	1 (1.6)	4 (7.7)
Height (cm)									
Mean (SD)	152.3 (17.86)	140.7 (13.04)	165.7 (12.58)	151.6 (16.63)	139.8 (10.01)	167.3 (8.49)	151.9 (17.12)	140.2 (11.39)	166.6 (10.53)
Range	114.5-188.0	114.5-161.3	139.5-188.0	115.6-180.3	115.6-161.0	151.3-180.3	114.5-188.0	114.5-161.3	139.5-188.0
Weight (kg)**									
Mean (SD)	52.87 (22.08)	40.58 (17.21)	67.21 (18.30)	50.11 (20.83)	37.33 (14.08)	67.16 (15.49)	51.36 (21.36)	38.75 (15.48)	67.18 (16.70)
Range	20.4-110.9	20.4-79.5	30.1-110.9	20.5-104.0	20.5-104.0	38.2-100.9	20.4-110.9	20.4-104.0	30.1-110.9
BMI (kg/m^2)									
Mean (SD)	21.85 (6.24)	19.69 (5.45)	24.38 (6.25)	20.97 (5.60)	18.72 (4.66)	23.98 (5.40)	21.37 (5.89)	19.14 (5.00)	24.17 (5.76)
Range	13.9-41.9	13.9-32.8	13.9-41.9	13.7-40.1	13.7-40.1	16.4-37.7	13.7-41.9	13.7-40.1	13.9-41.9

Source: Tables 13.5.1b and 13.5.2b, Section 10; Listings 13.5.1, Appendix B, and 15.2.1, Appendix E

Height, weight and BMI data are missing for patient 716.049.28150 (acute-study placebo, adolescent, primary diagnosis OCD).

* Other race includes Hispanic (11 patients), Hispanic/white (1 patient), American Indian (2 patients), Indian (1 patient) , and mixed or biracial (4 patients).

** Weight measured in pounds was converted to kilograms using the conversion 1 lb. = 0.454 kg

The demographic characteristics for patients in the PPX population are presented in Tables 13.5.1d and 13.5.2d, Section 10, and Listings 13.5.1, Appendix B, and 15.2.1, Appendix E. The proportions of patients with each demographic characteristic were similar to those in the ITT population in the corresponding age groups among paroxetine patients with a primary diagnosis of MDD and OCD, respectively, in Table 12.

4.4.2 Baseline Characteristics

Summary statistics for CDRS–R total scores at Study 716 baseline by acute-study treatment group and age group (patients from Studies 701 and 715 with a primary diagnosis of MDD) are presented in Table 13. At the Study 716 baseline, the mean CDRS–R total scores were similar irrespective of acute-study treatment group or age group. The overall mean CDRS–R total score was 36.4 (SD 13.50), indicative of relatively mild depressive symptomatology.

Summary statistics for CY–BOCS total scores at Study 716 baseline by acute-study treatment group and age group (patients from Studies 704 and 715 with a primary diagnosis of OCD) are presented in Table 14. At the Study 716 baseline, patients who had received paroxetine in their acute study had lower mean CY–BOCS scores than patients who had received placebo in their acute study, reflecting the statistically significant positive effect of paroxetine demonstrated in Study 704. The mean CY–BOCS total score for patients who had received paroxetine in their acute study was 16.2 (SD 8.78) and for patients who had received placebo in their acute study was 20.0 (SD 7.51). Scores for children were consistently lower than for adolescents, regardless of acute-study treatment group, for both parameters.

Table 13 Summary Statistics for CDRS–R Total Scores at Study 716 Baseline by Acute-study Treatment Group and Age Group (ITT Population with Primary Diagnosis of MDD)

	Acute-study Treatment Group											
	Paroxetine (N = 81)				Placebo (N = 66)				Total (N = 147)			
716 Baseline	**n ***	**Mean**	**(SD)**	**Range**	**n ***	**Mean**	**(SD)**	**Range**	**n ***	**Mean**	**(SD)**	**Range**
CDRS–R Total Scores												
Children	35	33.9	14.02	18-75	36	35.3	12.92	17-68	71	34.6	13.39	17-75
Adolescents	41	36.9	12.36	20-72	29	39.9	14.92	19-73	70	38.1	13.46	19-73
Total	76	35.5	13.14	18-75	65	37.4	13.93	17-73	141	36.4	13.50	17-75

Source: Table 13.6.1b, Section 10; Listing 14.1.1, Appendix C

* 5 acute-study paroxetine patients and 1 acute-study placebo patient either were missing data at Study 716 baseline or had insufficient data to calculate total.

Table 14 Summary Statistics for CY–BOCS Total Scores at Study 716 Baseline by Acute-study Treatment Group and Age Group (ITT Population with Primary Diagnosis of OCD)

	Acute-study Treatment Group											
	Paroxetine (N = 52)				Placebo (N = 64)				Total (N = 116)			
716 Baseline	**n ***	**Mean**	**(SD)**	**Range**	**n ***	**Mean**	**(SD)**	**Range**	**n ***	**Mean**	**(SD)**	**Range**
CY–BOCS Total Scores												
Children	27	14.7	9.21	0-35	35	19.0	8.20	0-34	62	17.1	8.84	0-35
Adolescents	22	17.9	8.10	1-34	28	21.1	6.48	0-35	50	19.7	7.34	0-35
Total	49	16.2	8.78	0-35	63	20.0	7.51	0-35	112	18.3	8.27	0-35

Source: Table 13.7.1b, Section 10; Listing 14.2.1, Appendix C

* 3 acute-study paroxetine patients and 1 acute-study placebo patient either were missing data at Study 716 baseline or had insufficient data to calculate total.

Summary statistics for CDRS–R total scores at Study 716 baseline for the PPX population are presented in Table 13.6.1d, Section 10, and Listing 14.1.1, Appendix C. The mean scores for adolescents in the PPX population (35.8 [SD 11.55]) were similar to those in the ITT population among paroxetine patients with a primary diagnosis of MDD (36.9 [SD 12.36]); however, the mean CDRS–R scores for children were slightly higher in the PPX population (mean of 37.8 [SD 15.12]) than in the ITT population (33.9 [SD 14.02]).

Summary statistics for CY–BOCS total scores at Study 716 baseline for the PPX population are presented in Table 13.7.1d, Section 10, and Listing 14.2.1, Appendix C. The mean scores were similar to those in the ITT population in the corresponding age groups among paroxetine patients with a primary diagnosis of OCD (Table 14).

The number and percentage of patients in each category of the CGI–Severity of Illness item at Study 716 baseline by primary diagnosis, age group, and acute-study treatment group are presented in Table 15.

For patients with a primary diagnosis of MDD (patients from Studies 701 and 715 with a primary diagnosis of MDD), the majority of patients in both acute-study treatment groups and both age groups were rated as mildly ill (28.1%, 41/146) or moderately ill (30.8%, 45/146) at Study 716 baseline. The greatest proportion of patients in the acute-study paroxetine group were mildly ill (37.5%, 30/80), while the greatest proportion of patients in the acute-study placebo group were moderately ill (42.4%, 28/66).

For patients with a primary diagnosis of OCD (patients from Studies 704 and 715 with a primary diagnosis of OCD), the greatest proportion of patients in both acute-study treatment groups were rated as moderately ill at Study 716 baseline (40.4% [21/52] and 49.2% [31/63] of patients receiving paroxetine or placebo, respectively, in their acute study). However, there was a greater percentage of normal or borderline mentally ill patients in the acute-study paroxetine group (25.0%, 13/52) than in the acute-study placebo group (6.3%, 4/63). Further, there were no severely ill patients in the acute-study paroxetine group, but 6.3% (4/63) of patients in the acute-study placebo group were rated as severely ill.

There were also notable differences in CGI–Severity of Illness scores at Study 716 baseline between children and adolescents with OCD. A greater percentage of children (20.6%, 13/63) were normal or borderline mentally ill than adolescents (7.7%, 4/52).

Table 15 Number (%) of Patients in Each Category of the CGI Severity of Illness Item Score at Study 716 Baseline by Primary Diagnosis, Age Group, and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group																	
	Paroxetine						Placebo						Total					
	Total		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Primary Diagnosis: MDD	**(N = 81)**		**(N = 39)**		**(N = 42)**		**(N = 66)**		**(N = 36)**		**(N = 30)**		**(N = 147)**		**(N = 75)**		**(N = 72)**	
Normal, not at all ill	17	(21.3)	10	(26.3)	7	(16.7)	10	(15.2)	5	(13.9)	5	(16.7)	27	(18.5)	15	(20.3)	12	(16.7)
Borderline mentally ill	11	(13.8)	6	(15.8)	5	(11.9)	14	(21.2)	7	(19.4)	7	(23.3)	25	(17.1)	13	(17.6)	12	(16.7)
Mildly ill	30	(37.5)	12	(31.6)	18	(42.9)	11	(16.7)	5	(13.9)	6	(20.0)	41	(28.1)	17	(23.0)	24	(33.3)
Moderately ill	17	(21.3)	7	(18.4)	10	(23.8)	28	(42.4)	17	(47.2)	11	(36.7)	45	(30.8)	24	(32.4)	21	(29.2)
Markedly ill	4	(5.0)	2	(5.3)	2	(4.8)	3	(4.5)	2	(5.6)	1	(3.3)	7	(4.8)	4	(5.4)	3	(4.2)
Severely ill	1	(1.3)	1	(2.6)	0	–	0	–	0	–	0	–	1	(0.7)	1	(1.4)	0	–
Among the most extremely ill	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–
Total	80	(100.0)	38	(100.0)	42	(100.0)	66	(100.0)	36	100.0)	30	100.0)	146	(100.0)	74	(100.0)	72	(100.0)
Primary Diagnosis: OCD	**(N = 52)**		**(N = 28)**		**(N = 24)**		**(N = 64)**		**(N = 36)**		**(N = 28)**		**(N = 116)**		**(N = 64)**		**(N = 52)**	
Normal, not at all ill	4	(7.7)	3	(10.7)	1	(4.2)	3	(4.8)	2	(5.7)	1	(3.6)	7	(6.1)	5	(7.9)	2	(3.8)
Borderline mentally ill	9	(17.3)	7	(25.0)	2	(8.3)	1	(1.6)	1	(2.9)	0	–	10	(8.7)	8	(12.7)	2	(3.8)
Mildly ill	10	(19.2)	3	(10.7)	7	(29.2)	10	(15.9)	7	(20.0)	3	(10.7)	20	(17.4)	10	(15.9)	10	(19.2)
Moderately ill	21	(40.4)	11	(39.3)	10	(41.7)	31	(49.2)	15	(42.9)	16	(57.1)	52	(45.2)	26	(41.3)	26	(50.0)
Markedly ill	8	(15.4)	4	(14.3)	4	(16.7)	14	(22.2)	7	(20.0)	7	(25.0)	22	(19.1)	11	(17.5)	11	(21.2)
Severely ill	0	–	0	–	0	–	4	(6.3)	3	(8.6)	1	(3.6)	4	(3.5)	3	(4.8)	1	(1.9)
Among the most extremely ill	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–
Total	52	(100.0)	28	(100.0)	24	(100.0)	63	(100.0)	35	(100.0)	28	(100.0)	115	(100.0)	63	(100.0)	52	(100.0)

Source: Table 13.8.1b, Section 10; Listing 14.4.1, Appendix C

Note: Percentages are based on the total number of patients assessed in one of the categories.

4.5 Adverse Events Occurring Prior to the Open-label Baseline

Listing 15.1.1, Appendix D, presents all adverse events for each patient that were emergent pre-acute study, emergent during the acute study (including taper) and ongoing into Study 716, or emergent during the open-label Treatment Phase. Patients are listed by acute-study treatment group and age group, and details are provided of the onset, severity, relationship to study medication, and duration of the events.

Table 15.1.1.0.1, Section 12, summarizes adverse events occurring before the start of acute-study treatment by body system, preferred term, and acute-study treatment group. Overall, 15.2% (40/263) of patients reported one or more gender-non-specific adverse events before the start of acute-study treatment, 15.8% (21/133) of acute-study paroxetine patients and 14.6% (19/130) of acute-study placebo patients. No gender-specific adverse events were reported before the start of acute-study treatment. The most frequent adverse event was headache, which occurred in 4.5% (6/133) of acute-study paroxetine patients and 3.1% (4/130) of acute-study placebo patients.

Among patients with a primary diagnosis of MDD, 11.1% (9/81) of acute-study paroxetine patients and 12.1% (8/66) of acute-study placebo patients reported one or more gender-non-specific adverse events before the start of acute-study treatment. Among patients with a primary diagnosis of OCD, 23.1% (12/52) of acute-study paroxetine patients and 17.2% (11/64) of acute-study placebo patients reported one or more gender-non-specific adverse events before the start of acute-study treatment.

Table 15.1.1.0.2, Section 12, summarizes adverse events occurring before the start of acute-study treatment and continuing into Study 716 by body system, preferred term, and acute-study treatment group. A total of 1.9% (5/263) of patients reported one or more gender-non-specific adverse events before the start of acute-study treatment that were ongoing at the Study 716 baseline, 1.5% (2/133) of acute-study paroxetine patients and 2.3% (3/130) of acute-study placebo patients. All adverse events were reported by only one patient each. No gender-specific AEs were reported as occurring before the start of acute-study treatment and continuing into Study 716.

Among patients with a primary diagnosis of MDD, 1.2% (1/81) of acute-study paroxetine patients and 1.5% (1/66) of acute-study placebo patients reported one or more gender-non-specific adverse events before the start of acute-study

treatment that were ongoing at the Study 716 baseline. Among patients with a primary diagnosis of OCD, 1.9% (1/52) of acute-study paroxetine patients and 3.1% (2/64) of acute-study placebo patients reported one or more gender-non-specific adverse events before the start of acute-study treatment that were ongoing at the Study 716 baseline.

Table 15.1.1.0.3, Section 12, summarizes adverse events occurring during the acute-study Treatment Phase (including taper) and ongoing into Study 716 by body system, preferred term, and acute-study treatment group. A total of 24.3% (64/263) of patients reported one or more gender-non-specific adverse events during the acute-study Treatment Phase (including taper) that were ongoing at the Study 716 baseline, 30.1% (40/133) of acute-study paroxetine patients and 18.5% (24/130) of acute-study placebo patients. The most frequently reported adverse events were somnolence (4.5% [6/133] of acute-study paroxetine patients and 2.3% [3/130] of acute-study placebo patients) and nervousness (3.0% [4/133] of acute-study paroxetine patients and 1.5% [2/130] of acute-study placebo patients). Two patients reported gender-specific adverse events during the acute-study Treatment Phase (including taper) that were ongoing at the Study 716 baseline. One female patient in the acute-study paroxetine group (716.180.25641) with a primary diagnosis of MDD had delayed menstruation/irregular menstruation; one male patient in the acute-study placebo group (716.010.25371) with a primary diagnosis of OCD had delayed ejaculation.

Among patients with a primary diagnosis of MDD, 29.6% (24/81) of acute-study paroxetine patients and 16.7% (11/66) of acute-study placebo patients reported one or more gender-non-specific adverse events during the acute-study Treatment Phase (including taper) that were ongoing at the Study 716 baseline. The most frequently reported adverse event was somnolence, which occurred in 4.9% (4/81) of acute-study paroxetine patients and 4.5% (3/66) of acute-study placebo patients.

Among patients with a primary diagnosis of OCD, 30.8% (16/52) of acute-study paroxetine patients and 20.3% (13/64) of acute-study placebo patients reported one or more gender-non-specific adverse events during the acute-study Treatment Phase (including taper) that were ongoing at the Study 716 baseline. The most frequently reported adverse event was nervousness, which occurred in 5.8% (3/52) of acute-study paroxetine patients and 3.1% (2/64) of acute-study placebo patients.

In addition, 20 patients (13 in the acute-study paroxetine group and 7 in the acute-study placebo group) had one or more gender-non-specific adverse events during

their acute-study Treatment Phase (including taper) that were ongoing at the Study 716 baseline but were not entered into the Study 716 database. The convention was that any unresolved ongoing adverse event was to be transcribed from the acute-study CRF to the applicable baseline 716 CRF page. Adverse events for these patients were not transcribed by the investigators onto the Study 716 CRF from the acute-study CRF and therefore are not included in Table 15.1.1.0.3, Section 12 (AEs emergent during the acute study and ongoing into Study 716) or Listing 15.1.1, Appendix D (AEs excluding Taper, Follow-up, and post-treatment) (see Section 13, Errata). However, these events were included in the data output and reports for the respective acute studies. Data Source Table 15.1.1.1 (treatment-emergent AEs) is correct since none of these 20 omitted AEs, by definition, were treatment-emergent in Study 716 (e.g., worsened in Study 716). These events are summarized in Table 16.

Table 16 Summary of Number (%) of Patients with Acute-Study Treatment Phase-emergent Adverse Events Ongoing into Study 716 but Omitted from the Database, by Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group					
	Paroxetine (N = 133)		Placebo (N = 130)		Total (N = 263)	
AE Preferred Term	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least One Continuing AE	13	(9.8)	7	(5.4)	20	(7.6)
Somnolence	3	(2.3)	0	–	3	(1.1)
Dry mouth	2	(1.5)	1	(0.8)	3	(1.1)
Allergic reaction	2	(1.5)	0	–	2	(0.8)
Asthenia	1	(0.8)	1	(0.8)	2	(0.8)
Infection	1	(0.8)	1	(0.8)	2	(0.8)
Nausea	1	(0.8)	1	(0.8)	2	(0.8)
Rhinitis	1	(0.8)	1	(0.8)	2	(0.8)
Abnormal dreams	1	(0.8)	0	–	1	(0.4)
Anemia	1	(0.8)	0	–	1	(0.4)
Asthma	1	(0.8)	0	–	1	(0.4)
Decreased appetite	1	(0.8)	0	–	1	(0.4)
Neurosis	1	(0.8)	0	–	1	(0.4)
Pharyngitis	1	(0.8)	0	–	1	(0.4)
Photosensitivity	1	(0.8)	0	–	1	(0.4)
Sweating	1	(0.8)	0	–	1	(0.4)
Vasodilatation	1	(0.8)	0	–	1	(0.4)
Myoclonus	0	–	1	(0.8)	1	(0.4)
Withdrawal syndrome	0	–	1	(0.8)	1	(0.4)

Sorted by decreasing frequency in the total group

Duration of these events is unknown except for 2 patients. Per-patient details of all adverse events ongoing from the acute study and omitted from the Study 716 database may be found in Appendix I, Patients with Acute-Study Treatment Phase-emergent Adverse Events Ongoing into Study 716 but Omitted from the Database.

Three of the 20 patients with unreported ongoing adverse events had the same event reported as a new adverse event in Study 716:

- Patient 716.159.25798, in the acute-study placebo group, had an adverse event of mild Withdrawal syndrome (verbatim: Serotonin discontinuation syndrome) reported as ongoing with an onset on Day 56 (last day of study medication) of acute Study 701, considered by the investigator to be

related to study medication. It was reported twice as an adverse event in Study 716, once on Day 2 with a duration of 3 days (moderate, related), and on Day 60 with a duration of 2 days (moderate, possibly related).

- Patient 716.008.25375, in the acute-study paroxetine group, had an adverse event of mild Photosensitivity (verbatim: Increased sensitivity to sun) reported as ongoing with an onset on Day 68 (3 days before the last day of study medication) of acute Study 704, considered possibly related to study medication. It was reported twice as an adverse event in Study 716 as Trauma (verbatim: sunburn; moderate, possibly related), once on Day 20 with a duration of 4 days, and on Day 29, reported as continuing.

- Patient 716.016.27021, in the acute-study placebo group, had an adverse event of mild Myoclonus (verbatim: Tics) reported as ongoing with an onset on Day 22 (59 days before the last day of study medication) of acute Study 704, considered by the investigator to be probably unrelated to study medication. It was reported as an adverse event in Study 716 as Myoclonus (verbatim: increase in tics; mild, unrelated), on Day 13 with a duration of 14 days.

4.6 Concomitant Medications

Table 17 presents a summary of the most frequently reported (≥5%) concomitant medications taken during the open-label Treatment Phase by therapeutic class. A total of 65.8% (173/263) of the ITT population were reported to have taken at least one concomitant medication, 69.2% (92/133) of patients from the acute-study paroxetine group and 62.3% (81/130) of patients from the acute-study placebo group. The proportion of patients taking each medication by therapeutic class was generally similar between the acute-study treatment groups.

The most frequently reported concomitant medications by therapeutic class were OTC central nervous system agents (primarily paracetamol and ibuprofen) for pain, and respiratory agents (primarily pseudoephedrine hydrochloride, diphenhydramine hydrochloride, loratadine, paracetamol, and dextromethorphan hydrochloride) for cold and flu symptoms and allergies (Table 13.9.1 Section 10). The most frequent single medication used was paracetamol, taken by 38.3% (51/133) of patients in the acute-study paroxetine group and 19.2% (25/130) of patients in the acute-study placebo group (Table 13.9.2, Section 10).

The concomitant use of any psychotropic drug, other than study-supplied paroxetine study medication, was contraindicated. Five patients had paroxetine listed as a concomitant medication during the open-label Treatment Phase. Three of these patients (716.017.00002, 716.206.00606, and 716.208.00806, all in the acute-study paroxetine group) started taking paroxetine as a prescription medication on the day that they stopped taking open-label medication in the Treatment Phase instead of entering the Taper Phase as specified in the protocol. Because of the apparent overlap in medication dates, paroxetine is captured as an on-treatment concomitant medication (Section 3.14.10, Data Irregularities). The other 2 patients, both in the acute-study placebo group, both took paroxetine as a concomitant medication. Patient 716.019.25751 took a prescribed dose of 20 mg for one day while being treated for a compound fracture of the arm on Day 45 of open-label study medication (indication reported as MDD). Patient 716.159.25628 took 20 mg paroxetine instead of 10 mg per day without the knowledge or consent of the investigator for 5 days starting on Day 3 of the Study 701 Taper Phase, continuing until Day 2 of Study 716, as self-medication for a moderate AE of acute exacerbation of major depression.

Other medications with potential psychotropic effect taken by ≥2% of patients were dextromethorphan (3.0%, 8/263), chlorpheniramine maleate (2.3%, 6/263), and doxylamine succinate (2.3%, 6/263).

A complete summary by WHO ATC generic names and the Level I drug classification system may be found in Table 13.9.1, Section 10, in which medications that are part of combination products may be counted in more than one ATC level. A complete summary by generic name in order of decreasing frequency may be found in Table 13.9.2, Section 10, in which components are counted only once. Per-patient details, including dosage, indication, and starting and ending days relative to start and end of open-label study medication may be found in Listing 13.9.1, Appendix B.

Table 17 Frequently Reported (≥5%) Concomitant Medications During the Open-label Treatment Phase (Excluding Taper Phase) by Therapeutic Class and Acute-study Treatment Group (ITT Population)

Therapeutic Class and Medication *	Acute-study Treatment Group: Paroxetine (N = 133) n	(%)	Placebo (N = 130) n	(%)	Total (N = 263) n	(%)
Total **	92	(69.2)	81	(62.3)	173	(65.8)
Alimentary tract/metabolic	29	(21.8)	30	(23.1)	59	(22.4)
Vitamins NOS	10	(7.5)	6	(4.6)	16	(6.1)
Anti-infectives, systemic	37	(27.8)	30	(23.1)	67	(25.5)
Amoxicillin	7	(5.3)	3	(2.3)	10	(3.8)
Azithromycin	5	(3.8)	8	(6.2)	13	(4.9)
Central Nervous System	64	(48.1)	55	(42.3)	119	(45.2)
Acetylsalicylic acid	12	(9.0)	5	(3.8)	17	(6.5)
Caffeine	9	(6.8)	2	(1.5)	11	(4.2)
Paracetamol	51	(38.3)	25	(19.2)	76	(28.9)
Ibuprofen	31	(23.3)	27	(20.8)	58	(22.1)
Pseudoephedrine hydrochloride	8	(6.0)	5	(3.8)	13	(4.9)
Dermatologicals	26	(19.5)	34	(26.2)	60	(22.8)
Diphenhydramine hydrochloride	9	(6.8)	11	(8.5)	20	(7.6)
Musculoskeletal	36	(27.1)	29	(22.3)	65	(24.7)
Ibuprofen	31	(23.3)	27	(20.8)	58	(22.1)
Respiratory	51	(38.3)	57	(43.8)	108	(41.1)
Chlorphenamine maleate	7	(5.3)	4	(3.1)	11	(4.2)
Phenylpropanolamine	7	(5.3)	2	(1.5)	9	(3.4)
Salbutamol	7	(5.3)	7	(5.4)	14	(5.3)
Pseudoephedrine hydrochloride	19	(14.3)	12	(9.2)	31	(11.8)
Diphenhydramine hydrochloride	10	(7.5)	13	(10.0)	23	(8.7)
Loratadine	12	(9.0)	10	(7.7)	22	(8.4)
Paracetamol	14	(10.5)	9	(6.9)	23	(8.7)
Dextromethorphan hydrobromide	12	(9.0)	5	(3.8)	17	(6.5)

Source: Table 13.9.1, Section 10; Listing 13.9.1, Appendix B

Medications sorted by descending frequency in the total group within each therapeutic class.

* Medications can be counted in more than one class

** Total patients with a concomitant medication. Patients taking multiple concomitant medications are counted only once.

During the Taper and Follow-up Phases, concomitant medication usage was reported for 98.7% (154/156) of patients (Table 13.9.3, Section 10, by Level I classification and generic name, and Table 13.9.4, Section 10, by generic name in order of decreasing frequency; Listing 13.9.1, Appendix B). These tables may include concomitant medication usage for some patients who did not enter the Follow-up Phase but had a concomitant medication that was started before the last dose of open-label study/taper medication and had a missing stop date. The medication most frequently used during the Taper or Follow-up Phase, excluding physician-prescribed paroxetine, was ibuprofen, taken by 16.7% (26/156) of patients, 15.4% (12/78) of patients in the acute-study paroxetine group and 17.9% (14/78) of patients in the acute-study placebo group. Other frequently used medications (≥10% of patients in either acute-study treatment group) were paracetamol (12.2%, 19/156), and vitamins NOS (10.3%, 16/156).

A total of 34.6% (54/156) of patients, 42.3% (33/78) of patients in the acute-study paroxetine group and 26.9% (21/78) of patients in the acute-study placebo group, were reported as taking paroxetine as a concomitant medication during the Taper or Follow-up Phase (Table 13.9.3, Section 10, Listing 13.9.1, Appendix B):

- Of these 54 patients, 44 patients did not taper and started taking prescribed paroxetine in the Follow-up Phase following the open-label Treatment Phase. The indication for paroxetine for these patients was either depression or OCD.

- Two patients (716.004.25400 and 716.004.27004) appear to have taken prescribed paroxetine for OCD in addition to taper medication.

- Four patients tapered and started taking prescribed paroxetine during the Follow-up Phase following the Taper Phase; the indication was either depression or OCD.

- In one case paroxetine was administered because a patient (716.159.25629) had an adverse event of withdrawal syndrome (verbatim: serotonin discontinuation syndrome) 4 days after the last dose of study medication

- Three patients had an apparent one-day overlap of the last dose of study medication and the first dose of post-treatment prescribed paroxetine because of the way the medication start and stop dates were recorded.

4.7 Treatment Compliance and Titration

4.7.1 Treatment Compliance

Investigators recorded at each visit whether the patients had missed more than 3 consecutive days study medication. A summary of compliance by each visit interval is presented in Table 18. For the summary tables, patients with unknown compliance and a duration of study medication of >3 days at a visit were considered to have missed more than 3 consecutive days of study medication for that visit. Two patients who had a total duration of ≤3 days in the study (716.055.28189 and 716.201.00107) were not included in these summaries. The majority of patients (75.5%, 197/261) did not miss >3 consecutive days of study medication at any time during the study.

The percentage of patients who missed >3 consecutive days study medication at any time was slightly greater in the acute-study paroxetine group, 28.0% (37/132) of patients, than in the acute-study placebo group, 20.9% (27/129) of patients. This slight imbalance was more pronounced among adolescents: 30.3% (20/66) of patients in the acute-study paroxetine group missed >3 consecutive days study medication at any time during the study, compared to 17.2% (10/58) in the acute-study placebo group. The corresponding proportions in children were 25.8% (17/66) of patients in the acute-study paroxetine group compared to 23.9% (17/71) of patients in the acute-study placebo group (Table 18).

Patients missing >3 consecutive days of dosing on more than one occasion were to be withdrawn from the study. Of the 44 patients reported by the investigator as missing >3 consecutive days of dosing, 4 patients did so on more than one occasion (Listing 13.10.1, Appendix B). However, only 1 of these patients was withdrawn from the study for non-compliance. Patient 716.004.27003 in the acute-study placebo group was listed as non-compliant at the Week 16 visit and Week 20 visit. This patient was withdrawn due to a protocol violation (including non-compliance) at the Week 20 visit. Patient 716.055.28133, in the acute-study paroxetine group, withdrew early for site closure; patients 716.049.28152 and 159.25629, both in the acute-study placebo group, completed the study.

Table 13.10.1, Section 10, counts patients with missing compliance at a visit and duration of study medication >3 days at that visit as non-compliant for that visit (Table 18). Therefore, it contains 20 more patients as having missed more than 3 consecutive days medication than Listing 13.10.1, Appendix B, which is based solely on the investigators' reporting of patients who missed more than 3 consecutive days study medication (see Section 3.14.10, Data Irregularities).

Table 18 Summary of Patients Missing >3 Consecutive Days Open-label Study Medication at Each Visit and Overall, Excluding Taper Phase, by Age Group and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group											
	Paroxetine				Placebo				Total			
Missed >3 Consecutive	No		Yes		No		Yes		No		Yes	
Days *	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Total	(N = 133)				(N = 130)				(N = 263)			
Week 1	125	(95.4)	6	(4.6)	127	(98.4)	2	(1.6)	252	(96.9)	8	(3.1)
Week 2	121	(99.2)	1	(0.8)	120	(98.4)	2	(1.6)	241	(98.8)	3	(1.2)
Week 3	116	(93.5)	8	(6.5)	115	(95.8)	5	(4.2)	231	(94.7)	13	(5.3)
Week 4	116	(96.7)	4	(3.3)	107	(97.3)	3	(2.7)	223	(97.0)	7	(3.0)
Week 6	114	(97.4)	3	(2.6)	104	(98.1)	2	(1.9)	218	(97.8)	5	(2.2)
Week 8	104	(93.7)	7	(6.3)	89	(94.7)	5	(5.3)	193	(94.1)	12	(5.9)
Week 12	96	(94.1)	6	(5.9)	80	(94.1)	5	(5.9)	176	(94.1)	11	(5.9)
Week 16	82	(94.3)	5	(5.7)	70	(93.3)	5	(6.7)	152	(93.8)	10	(6.2)
Week 20	73	(98.6)	1	(1.4)	59	(96.7)	2	(3.3)	132	(97.8)	3	(2.2)
Week 24	66	(93.0)	5	(7.0)	45	(93.8)	3	(6.3)	111	(93.3)	8	(6.7)
Overall **	95	(72.0)	37	(28.0)	102	(79.1)	27	(20.9)	197	(75.5)	64	(24.5)

Source: Table 13.10.1, Section 10; Listing 13.10.1, Appendix B

Percentages at each visit are based on the number of patients with study medication information for that visit

* Patients with unknown compliance and a duration of open-label study medication of >3 days at a visit were considered to have missed more than 3 consecutive days of study medication for that visit.

** Overall number of patients who missed >3 consecutive days at any point in the study. Patients missing >3 consecutive days on more than one occasion were counted only once. Two children (716.055.28189, in the acute-study placebo group, and 716.201.00107, in the acute-study paroxetine group) had a total duration of ≤3 days in the study, and thus do not appear in these summaries.

Table continues

Table 18 (Continued) Summary of Patients Missing >3 Consecutive Days Open-label Study Medication at Each Visit and Overall, Excluding Taper Phase by Age Group and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group											
	Paroxetine				Placebo				Total			
Missed >3 Consecutive	No		Yes		No		Yes		No		Yes	
Days *	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Children	(N = 67)				(N = 72)				(N = 139)			
Week 1	62	(95.4)	3	(4.6)	71	(100.0)	0	–	133	(97.8)	3	(2.2)
Week 2	58	(100.0)	0	–	68	(98.6)	1	(1.4)	126	(99.2)	1	(0.8)
Week 3	60	(96.8)	2	(3.2)	64	(95.5)	3	(4.5)	124	(96.1)	5	(3.9)
Week 4	58	(96.7)	2	(3.3)	59	(96.7)	2	(3.3)	117	(96.7)	4	(3.3)
Week 6	56	(96.6)	2	(3.4)	58	(98.3)	1	(1.7)	114	(97.4)	3	(2.6)
Week 8	50	(92.6)	4	(7.4)	49	(94.2)	3	(5.8)	99	(93.4)	7	(6.6)
Week 12	43	(91.5)	4	(8.5)	43	(91.5)	4	(8.5)	86	(91.5)	8	(8.5)
Week 16	35	(94.6)	2	(5.4)	37	(94.9)	2	(5.1)	72	(94.7)	4	(5.3)
Week 20	33	(100.0)	0		31	(96.9)	1	(3.1)	64	(98.5)	1	(1.5)
Week 24	31	(93.9)	2	(6.1)	22	(91.7)	2	(8.3)	53	(93.0)	4	(7.0)
Overall **	49	(74.2)	17	(25.8)	54	(76.1)	17	(23.9)	103	(75.2)	34	(24.8)

Source: Table 13.10.1, Section 10; Listing 13.10.1, Appendix B

Percentages at each visit are based on the number of patients with study medication information for that visit

* Patients with unknown compliance and a duration of open-label study medication of >3 days at a visit were considered to have missed more than 3 consecutive days of study medication for that visit.

** Overall number of patients who missed >3 consecutive days at any point in the study. Patients missing >3 consecutive days on more than one occasion were counted only once. Two children (716.055.28189, in the acute-study placebo group, and 716.201.00107, in the acute-study paroxetine group) had a total duration of ≤3 days in the study, and thus do not appear in these summaries.

Table continues

Table 18 (Continued) Summary of Patients Missing >3 Consecutive Days Open-label Study Medication at Each Visit and Overall, Excluding Taper Phase by Age Group and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group											
	Paroxetine				Placebo				Total			
Missed >3 Consecutive Days *	No		Yes		No		Yes		No		Yes	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Adolescents	(N = 66)				(N = 58)				(N = 124)			
Week 1	63	(95.5)	3	(4.5)	56	(96.6)	2	(3.4)	119	(96.0)	5	(4.0)
Week 2	63	(98.4)	1	(1.6)	52	(98.1)	1	(1.9)	115	(98.3)	2	(1.7)
Week 3	56	(90.3)	6	(9.7)	51	(96.2)	2	(3.8)	107	(93.0)	8	(7.0)
Week 4	58	(96.7)	2	(3.3)	48	(98.0)	1	(2.0)	106	(97.2)	3	(2.8)
Week 6	58	(98.3)	1	(1.7)	46	(97.9)	1	(2.1)	104	(98.1)	2	(1.9)
Week 8	54	(94.7)	3	(5.3)	40	(95.2)	2	(4.8)	94	(94.9)	5	(5.1)
Week 12	53	(96.4)	2	(3.6)	37	(97.4)	1	(2.6)	90	(96.8)	3	(3.2)
Week 16	47	(94.0)	3	(6.0)	33	(91.7)	3	(8.3)	80	(93.0)	6	(7.0)
Week 20	40	(97.6)	1	(2.4)	28	(96.6)	1	(3.4)	68	(97.1)	2	(2.9)
Week 24	35	(92.1)	3	(7.9)	23	(95.8)	1	(4.2)	58	(93.5)	4	(6.5)
Overall **	46	(69.7)	20	(30.3)	48	(82.8)	10	(17.2)	94	(75.8)	30	(24.2)

Source: Table 13.10.1, Section 10; Listing 13.10.1, Appendix B

Percentages at each visit are based on the number of patients with study medication information for that visit

* Patients with unknown compliance and a duration of open-label study medication of >3 days at a visit were considered to have missed more than 3 consecutive days of study medication for that visit.

** Overall number of patients who missed >3 consecutive days at any point in the study. Patients missing >3 consecutive days on more than one occasion were counted only once. Two children (716.055.28189, in the acute-study placebo group, and 716.201.00107, in the acute-study paroxetine group) had a total duration of <3 days in the study, and thus do not appear in these summaries.

For each patient, counts of tablets dispensed and returned were recorded at each visit. Tablet accountability for each visit was determined according to the following calculation:

$$\left(\frac{\textit{No. of Tablets Dispensed - No. of Tablets Returned}}{\textit{No. of Days} \times \textit{No. of Tablets per Day}}\right) \times 100$$

If patients had a dose change between visits, tablet accountability was summarized according to the following calculation:

$$\left(\frac{\textit{Total No. of Tablets Dispensed for the Visit - Total No. of Tablets Returned for the Visit}}{\textit{Sum for Each Record in the CRF Corresponding to the Visit (No. of Days} \times \textit{No. of Tablets per Day)}}\right) \times 100$$

Overall tablet accountability was summarized according to the following calculation:

$$\left(\frac{\textit{Total No. of Tablets Dispensed - Total No. of Tablets Returned}}{\textit{Sum for Each Visit (No. of Days} \times \textit{No. of Tablets per Day)}}\right) \times 100$$

If any of the data required to calculate tablet accountability were missing, accountability was not calculated.

Patients were tabulated according to whether or not the results of these calculations were ≥80% and ≤120% (Table 13.10.2, Section 10).

Overall accountability was high, with 92.9% (158/170) of patients within the range of ≥80% to ≤120% accountability. Between 79.4% and 90.2% of patients in the acute-study paroxetine group and between 83.5% and 91.2% of patients in the acute-study placebo group fell within the range of ≥80% to ≤ 120% accountability at each visit (Table 19). Although accountability was higher at most timepoints in the acute-study placebo group, overall accountability was higher in the acute-study paroxetine group (94.0% compared to 91.9%).

The pattern of accountability was similar among acute-study paroxetine patients and acute-study placebo patients in both age groups with the following exceptions: Among children, at Week 16, accountability rose to 94.3% (33/35) in the acute-study paroxetine group compared to 85.3% (29/34) for children in the acute-study placebo group, and at Week 20, accountability fell to 82.8% (24/29) in the acute-study paroxetine group compared to 93.3% (28/30) in the acute-study placebo group. Among adolescents, at Week 6, accountability fell to 82.8% (48/58) in the acute-study paroxetine group compared to 93.2% (41/44) for adolescents in the acute-study placebo group, and at Week 12, accountability fell to 79.2% (42/53) in

the acute-study paroxetine group compared to 88.2% (30/34) in the acute-study placebo group. Among children, overall accountability was higher in the acute-study paroxetine group (94.9%, 37/39) than in the acute-study placebo group (87.2%, 41/47). Among adolescents, overall accountability was higher in the acute-study placebo group (97.4%, 38/39) than in the acute-study paroxetine group (93.3%, 42/45).

Table 19 Tablet Accountability (Number [%] of Patients) at Each Visit and Overall by Age Group and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group											
	Paroxetine (N = 133)				Placebo (N = 130)				Total (N = 263)			
	Accountable*		Non-accountable		Accountable*		Non-accountable		Accountable*		Non-accountable	
Age Group: Total	**n**	**(%) ****	**n**	**(%) ****	**n**	**(%) ****	**n**	**(%) ****	**n**	**(%) ****	**n**	**(%) ****
Week 1	107	(86.3)	17	(13.7)	107	(84.9)	19	(15.1)	214	(85.6)	36	(14.4)
Week 2	95	(81.2)	22	(18.8)	104	(86.7)	16	(13.3)	199	(84.0)	38	(16.0)
Week 3	104	(88.1)	14	(11.9)	101	(89.4)	12	(10.6)	205	(88.7)	26	(11.3)
Week 4	97	(84.3)	18	(15.7)	88	(83.8)	17	(16.2)	185	(84.1)	35	(15.9)
Week 6	89	(81.7)	20	(18.3)	89	(86.4)	14	(13.6)	178	(84.0)	34	(16.0)
Week 8	81	(79.4)	21	(20.6)	76	(83.5)	15	(16.5)	157	(81.3)	36	(18.7)
Week 12	79	(83.2)	16	(16.8)	67	(87.0)	10	(13.0)	146	(84.9)	26	(15.1)
Week 16	74	(90.2)	8	(9.8)	61	(89.7)	7	(10.3)	135	(90.0)	15	(10.0)
Week 20	58	(86.6)	9	(13.4)	52	(91.2)	5	(8.8)	110	(88.7)	14	(11.3)
Week 24	54	(83.1)	11	(16.9)	39	(88.6)	5	(11.4)	93	(85.3)	16	(14.7)
Overall †	79	(94.0)	5	(6.0)	79	(91.9)	7	(8.1)	158	(92.9)	12	(7.1)

Source: Table 13.10.2, Section 10; Listing 13.10.1, Appendix B

Note: Accountability and overall accountability were calculated only if all data required were present.

* Accountability at each visit is defined as the result of the following calculation falling between 80% and 120%: [(no. of tablets dispensed at the visit - no. of tablets returned at the visit) / (sum for each record in the CRF corresponding to a visit ([no. of days x no. of tablets per day])] x 100.

** Percentages at each visit are based on the number of patients with study medication information for that visit (no. accountable + no. non-accountable).

† Accountability overall is defined as the result of the following calculation falling between 80% and 120%: [(total no. of tablets dispensed - total no. of tablets returned) / (sum for each visit [number of days x no. of tablets per day])] x 100

Table continues

Table 19 (Continued) Tablet Accountability (Number [%] of Patients) at Each Visit and Overall by Age Group and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group											
	Paroxetine (N = 67)				Placebo (N = 72)				Total (N = 139)			
	Accountable*		Non-accountable		Accountable*		Non-accountable		Accountable*		Non-accountable	
Age Group: Children	**n**	**(%) ****	**n**	**(%) ****	**n**	**(%) ****	**n**	**(%) ****	**n**	**(%) ****	**n**	**(%) ****
Week 1	57	(90.5)	6	(9.5)	63	(92.6)	5	(7.4)	120	(91.6)	11	(8.4)
Week 2	49	(86.0)	8	(14.0)	61	(91.0)	6	(9.0)	110	(88.7)	14	(11.3)
Week 3	54	(91.5)	5	(8.5)	57	(89.1)	7	(10.9)	111	(90.2)	12	(9.8)
Week 4	48	(85.7)	8	(14.3)	49	(83.1)	10	(16.9)	97	(84.3)	18	(15.7)
Week 6	41	(80.4)	10	(19.6)	48	(81.4)	11	(18.6)	89	(80.9)	21	(19.1)
Week 8	38	(77.6)	11	(22.4)	40	(81.6)	9	(18.4)	78	(79.6)	20	(20.4)
Week 12	37	(88.1)	5	(11.9)	37	(86.0)	6	(14.0)	74	(87.1)	11	(12.9)
Week 16	33	(94.3)	2	(5.7)	29	(85.3)	5	(14.7)	62	(89.9)	7	(10.1)
Week 20	24	(82.8)	5	(17.2)	28	(93.3)	2	(6.7)	52	(88.1)	7	(11.9)
Week 24	24	(85.7)	4	(14.3)	19	(90.5)	2	(9.5)	43	(87.8)	6	(12.2)
Overall **	37	(94.9)	2	(5.1)	41	(87.2)	6	(12.8)	78	(90.7)	8	(9.3)

Source: Table 13.10.2, Section 10; Listing 13.10.1, Appendix B

Note: Accountability and overall accountability were calculated only if all data required were present

* Accountability at each visit is defined as the result of the following calculation falling between 80% and 120%: [(no. of tablets dispensed at the visit - no. of tablets returned at the visit) / (sum for each record in the CRF corresponding to a visit ([no. of days x no. of tablets per day])] x 100.

** Percentages at each visit are based on the number of patients with study medication information for that visit (no. accountable + no. non-accountable).

† Accountability overall is defined as the result of the following calculation falling between 80% and 120%: [(total no. of tablets dispensed - total no. of tablets returned) / (sum for each visit [number of days x no. of tablets per day])] x 100

Table continues

Table 19 (Continued) Tablet Accountability (Number [%] of Patients) at Each Visit and Overall by Age Group and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group											
	Paroxetine (N = 66)				Placebo (N = 58)				Total (N = 124)			
	Accountable*		Non-accountable		Accountable*		Non-accountable		Accountable*		Non-accountable	
Age Group: Adolescents	**n**	**(%) ****	**n**	**(%) ****	**n**	**(%) ****	**n**	**(%) ****	**n**	**(%) ****	**n**	**(%) ****
Week 1	50	(82.0)	11	(18.0)	44	(75.9)	14	(24.1)	94	(79.0)	25	(21.0)
Week 2	46	(76.7)	14	(23.3)	43	(81.1)	10	(18.9)	89	(78.8)	24	(21.2)
Week 3	50	(84.7)	9	(15.3)	44	(89.8)	5	(10.2)	94	(87.0)	14	(13.0)
Week 4	49	(83.1)	10	(16.9)	39	(84.8)	7	(15.2)	88	(83.8)	17	(16.2)
Week 6	48	(82.8)	10	(17.2)	41	(93.2)	3	(6.8)	89	(87.3)	13	(12.7)
Week 8	43	(81.1)	10	(18.9)	36	(85.7)	6	(14.3)	79	(83.2)	16	(16.8)
Week 12	42	(79.2)	11	(20.8)	30	(88.2)	4	(11.8)	72	(82.8)	15	(17.2)
Week 16	41	(87.2)	6	(12.8)	32	(94.1)	2	(5.9)	73	(90.1)	8	(9.9)
Week 20	34	(89.5)	4	(10.5)	24	(88.9)	3	(11.1)	58	(89.2)	7	(10.8)
Week 24	30	(81.1)	7	(18.9)	20	(87.0)	3	(13.0)	50	(83.3)	10	(16.7)
Overall **	42	(93.3)	3	(6.7)	38	(97.4)	1	(2.6)	80	(95.2)	4	(4.8)

Source: Table 13.10.2, Section 10; Listing 13.10.1, Appendix B

Note: Accountability and overall accountability were calculated only if all data required were present

* Accountability at each visit is defined as the result of the following calculation falling between 80% and 120%: [(no. of tablets dispensed at the visit - no. of tablets returned at the visit) / (sum for each record in the CRF corresponding to a visit ([no. of days x no. of tablets per day])] x 100.

** Percentages at each visit are based on the number of patients with study medication information for that visit (no. accountable + no. non-accountable).

† Accountability overall is defined as the result of the following calculation falling between 80% and 120%: [(total no. of tablets dispensed - total no. of tablets returned) / (sum for each visit [number of days x no. of tablets per day])] x 100

4.7.2 Titration of Dose

Following double-blind down-titration (if applicable) in acute Studies 701 and 704, patients entering Study 716 were to be started on therapy at 10 mg/day. At the investigators' discretion, patients entering Study 716 from Study 715 could be started on therapy at the dose they were taking at the end of Study 715 instead of down-titrating to a dose of 10 mg/day, or one dose level higher or lower. Thirty-three patients from Study 715 were entered at doses higher than 10 mg: 12 at 20 mg/day and 21 at 30 mg/day. In addition, exceptions occurred for 9 patients from Study 701 and 5 patients from Study 704 to start therapy in Study 716 at a dose higher than 10 mg/day. Seven patients from Study 701 entered at 20 mg/day and one each at 30 and 40 mg/day. The 5 patients from Study 704 entered Study 716 at 20 mg/day (Table 13.10.3, Section 10).

Starting at Week 2, the dose of paroxetine could be increased at weekly intervals by 10 mg/day up to a maximum dose of 50 mg/day, according to clinical response and tolerability. It was recommended that dose increases were initiated at clinic visits. Dose reductions of 10 mg/day at weekly intervals were also permitted at the discretion of the investigator.

Patient 716.043.27694 received a dose of 15 mg/day at Week 20. The dose was listed in Listing 13.10.1 as 15 mg, and 15 mg was included in the tablet accountability Table 13.10.2. In dosing Table 13.10.3, this 15-mg dose has been excluded from the table and shows no dosing for this patient for Week 20. In Table 13.10.6, the 15-mg dose has been included (see Section 13, Errata).

The number and percentage of patients by maximum daily dose of open-label study medication taken at any time during the study is presented by primary diagnosis and age group for the ITT population in Table 20. In the overall population, 14.8% (39/263) of patients took a maximum dose of 50 mg/day. Among adolescents, 21.0% (26/124) took a maximum dose of 50 mg/day paroxetine for at least one dosing period compared to 9.4% (13/139) of children. More adolescents than children were exposed to daily doses of paroxetine ≥40 mg/day: 43.5% (54/124) of adolescents compared to 21.6% (30/139) of children.

For patients with a primary diagnosis of MDD, 8.2% (12/147) of patients took a maximum dose of 50 mg/day. There was no notable difference between age groups. For patients with a primary diagnosis of OCD, 23.3% (27/116) of patients took a maximum dose of 50 mg/day, 9.4% (6/64) of children and 40.4% (21/52) of adolescents.

Table 20 Number (%) of Patients by Maximum Daily Dose of Open-label Study Medication by Primary Diagnosis and Age Group (ITT Population)

	Age Group					
	Children		Adolescents		Total	
Paroxetine Dosage	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Primary Diagnosis: Total	**(N = 139)**		**(N = 124)**		**(N = 263)**	
10 mg/day	15	(10.8)	9	(7.3)	24	(9.1)
20 mg/day	44	(31.7)	22	(17.7)	66	(25.1)
30 mg/day	50	(36.0)	39	(31.5)	89	(33.8)
40 mg/day	17	(12.2)	28	(22.6)	45	(17.1)
50 mg/day	13	(9.4)	26	(21.0)	39	(14.8)
Primary Diagnosis: MDD	**(N = 75)**		**(N = 72)**		**(N = 147)**	
10 mg/day	12	(16.0)	6	(8.3)	18	(12.2)
20 mg/day	20	(26.7)	15	(20.8)	35	(23.8)
30 mg/day	29	(38.7)	29	(40.3)	58	(39.5)
40 mg/day	7	(9.3)	17	(23.6)	24	(16.3)
50 mg/day	7	(9.3)	5	(6.9)	12	(8.2)
Primary Diagnosis: OCD	**(N = 64)**		**(N = 52)**		**(N = 116)**	
10 mg/day	3	(4.7)	3	(5.8)	6	(5.2)
20 mg/day	24	(37.5)	7	(13.5)	31	(26.7)
30 mg/day	21	(32.8)	10	(19.2)	31	(26.7)
40 mg/day	10	(15.6)	11	(21.2)	21	(18.1)
50 mg/day	6	(9.4)	21	(40.4)	27	(23.3)

Source: Table 13.10.4, Section 10; Listing 13.10.1, Appendix B

A summary of the number and percentage of patients with a primary diagnosis of MDD exposed to each dose of paroxetine by visit and age group is presented in Table 21. A total of 63.9% (94/147) of patients received a dose higher than 20 mg/day. Slightly more than half of the children (57.3%, 43/75) took a dose higher than 20 mg/day compared to 70.8% (51/72) of adolescents.

Table 21 Summary of the Number (%) of Patients with a Primary Diagnosis of MDD Exposed to Each Dose of Paroxetine by Visit and Age Group (ITT Population)

		Paroxetine									
		10 mg		20 mg		30 mg		40 mg		50 mg	
Daily Dose	**N**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Age Group: Total											
Week 1	147	110	(74.8)	17	(11.6)	19	(12.9)	1	(0.7)	0	–
Week 2	139	44	(31.7)	72	(51.8)	19	(13.7)	4	(2.9)	0	–
Week 3	136	27	(19.9)	61	(44.9)	43	(31.6)	5	(3.7)	0	–
Week 4	131	23	(17.6)	56	(42.7)	44	(33.6)	8	(6.1)	0	–
Week 6	126	18	(14.3)	54	(42.9)	44	(34.9)	7	(5.6)	3	(2.4)
Week 8	117	15	(12.8)	44	(37.6)	45	(38.5)	13	(11.1)	0	–
Week 12	108	12	(11.1)	40	(37.0)	40	(37.0)	14	(13.0)	2	(1.9)
Week 16	96	11	(11.5)	33	(34.4)	39	(40.6)	9	(9.4)	4	(4.2)
Week 20	79	9	(11.4)	28	(35.4)	22	(27.8)	16	(20.3)	4	(5.1)
Week 24	72	9	(12.5)	28	(38.9)	21	(29.2)	8	(11.1)	6	(8.3)
Maximum *	147	18	(12.2)	35	(23.8)	58	(39.5)	24	(16.3)	12	(8.2)
Age Group: Children											
Week 1	75	59	(78.7)	7	(9.3)	8	(10.7)	1	(1.3)	0	–
Week 2	71	29	(40.8)	32	(45.1)	7	(9.9)	3	(4.2)	0	–
Week 3	69	19	(27.5)	28	(40.6)	20	(29.0)	2	(2.9)	0	–
Week 4	66	16	(24.2)	26	(39.4)	19	(28.8)	5	(7.6)	0	–
Week 6	64	13	(20.3)	25	(39.1)	19	(29.7)	6	(9.4)	1	(1.6)
Week 8	58	11	(19.0)	20	(34.5)	20	(34.5)	7	(12.1)	0	–
Week 12	52	9	(17.3)	18	(34.6)	17	(32.7)	7	(13.5)	1	(1.9)
Week 16	44	8	(18.2)	14	(31.8)	16	(36.4)	2	(4.5)	4	(9.1)
Week 20	34	5	(14.7)	11	(32.4)	10	(29.4)	5	(14.7)	3	(8.8)
Week 24	33	6	(18.2)	12	(36.4)	10	(30.3)	1	(3.0)	4	(12.1)
Maximum *	75	12	(16.0)	20	(26.7)	29	(38.7)	7	(9.3)	7	(9.3)

Source: Tables 13.10.3 and 13.10.4, Section 10; Listing 13.10.1, Appendix B

N = number of patients in the study who were dispensed study medication at each visit; percentages are based on N

* Represents the number (%) of patients for whom the dose was the maximum dose during the study

Table continues

Table 21 (Continued) Summary of the Number (%) of Patients with a Primary Diagnosis of MDD Exposed to Each Dose of Paroxetine by Visit and Age Group (ITT Population)

		Paroxetine									
		10 mg		20 mg		30 mg		40 mg		50 mg	
Daily Dose	**N**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Age Group: Adolescents											
Week 1	72	51	(70.8)	10	(13.9)	11	(15.3)	0	–	0	–
Week 2	68	15	(22.1)	40	(58.8)	12	(17.6)	1	(1.5)	0	–
Week 3	67	8	(11.9)	33	(49.3)	23	(34.3)	3	(4.5)	0	–
Week 4	65	7	(10.8)	30	(46.2)	25	(38.5)	3	(4.6)	0	–
Week 6	62	5	(8.1)	29	(46.8)	25	(40.3)	1	(1.6)	2	(3.2)
Week 8	59	4	(6.8)	24	(40.7)	25	(42.4)	6	(10.2)	0	–
Week 12	56	3	(5.4)	22	(39.3)	23	(41.1)	7	(12.5)	1	(1.8)
Week 16	52	3	(5.8)	19	(36.5)	23	(44.2)	7	(13.5)	0	–
Week 20	45	4	(8.9)	17	(37.8)	12	(26.7)	11	(24.4)	1	(2.2)
Week 24	39	3	(7.7)	16	(41.0)	11	(28.2)	7	(17.9)	2	(5.1)
Maximum *	72	6	(8.3)	15	(20.8)	29	(40.3)	17	(23.6)	5	(6.9)

Source: Tables 13.10.3 and 13.10.4, Section 10; Listing 13.10.1, Appendix B
N = number of patients in the study who were dispensed study medication at each visit; percentages are based on N
* Represents the number (%) of patients for whom the dose was the maximum dose during the study

A summary of the number and percentage of patients with a primary diagnosis of OCD exposed to each dose of paroxetine by visit and age group is presented in Table 22. A total of 68.1% (79/116) of patients received a dose higher than 20 mg/day. Slightly more than half of the children (57.8%, 37/64) took a dose higher than 20 mg/day compared to 80.8% (42/52) of adolescents. Adolescents also reached higher doses earlier than children, with 55.1% (27/49) of adolescents receiving at least 30 mg/day at Week 3 compared to 28.3% (17/60) of children.

Table 22 Summary of the Number (%) of Patients with a Primary Diagnosis of OCD Exposed to Each Dose of Paroxetine by Visit and Age Group (ITT Population)

		Paroxetine									
		10 mg		20 mg		30 mg		40 mg		50 mg	
Daily Dose	**N**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Age Group: Total											
Week 1	115	105	(91.3)	7	(6.1)	3	(2.6)	0	–	0	–
Week 2	106	24	(22.6)	70	(66.0)	12	(11.3)	0	–	0	–
Week 3	109	13	(11.9)	52	(47.7)	38	(34.9)	6	(5.5)	0	–
Week 4	103	10	(9.7)	37	(35.9)	34	(33.0)	16	(15.5)	6	(5.8)
Week 6	100	8	(8.0)	29	(29.0)	30	(30.0)	20	(20.0)	13	(13.0)
Week 8	90	8	(8.9)	23	(25.6)	27	(30.0)	17	(18.9)	15	(16.7)
Week 12	79	5	(6.3)	23	(29.1)	21	(26.6)	13	(16.5)	17	(21.5)
Week 16	68	5	(7.4)	21	(30.9)	18	(26.5)	10	(14.7)	14	(20.6)
Week 20	59	6	(10.2)	18	(30.5)	13	(22.0)	10	(16.9)	12	(20.3)
Week 24	50	4	(8.0)	16	(32.0)	12	(24.0)	7	(14.0)	11	(22.0)
Maximum *	116	6	(5.2)	31	(26.7)	31	(26.7)	21	(18.1)	27	(23.3)
Age Group: Children											
Week 1	63	59	(93.7)	3	(4.8)	1	(1.6)	0	–	0	–
Week 2	57	18	(31.6)	34	(59.6)	5	(8.8)	0	–	0	–
Week 3	60	11	(18.3)	32	(53.3)	15	(25.0)	2	(3.3)	0	–
Week 4	57	7	(12.3)	28	(49.1)	15	(26.3)	5	(8.8)	2	(3.5)
Week 6	54	7	(13.0)	21	(38.9)	16	(29.6)	7	(13.0)	3	(5.6)
Week 8	48	7	(14.6)	14	(29.2)	18	(37.5)	4	(8.3)	5	(10.4)
Week 12	42	4	(9.5)	16	(38.1)	13	(31.0)	5	(11.9)	4	(9.5)
Week 16	34	4	(11.8)	14	(41.2)	9	(26.5)	5	(14.7)	2	(5.9)
Week 20	31	5	(16.1)	13	(41.9)	8	(25.8)	4	(12.9)	1	(3.2)
Week 24	27	4	(14.8)	12	(44.4)	8	(29.6)	3	(11.1)	0	–
Maximum *	75	12	(16.0)	20	(26.7)	29	(38.7)	7	(9.3)	7	(9.3)

Source: Tables 13.10.3 and 13.10.4, Section 10; Listing 13.10.1, Appendix B

N = number of patients in the study who were dispensed study medication at each visit; percentages are based on N

* Represents the number (%) of patients for whom the dose was the maximum dose during the study

Table continues

Table 22 (Continued) Summary of the Number (%) of Patients with a Primary Diagnosis of OCD Exposed to Each Dose of Paroxetine by Visit and Age Group (ITT Population)

		Paroxetine									
		10 mg		20 mg		30 mg		40 mg		50 mg	
Daily Dose	**N**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Age Group: Adolescents											
Maximum *	64	3	(4.7)	24	(37.5)	21	(32.8)	10	(15.6)	6	(9.4)
Week 1	52	46	(88.5)	4	(7.7)	2	(3.8)	0	–	0	–
Week 2	49	6	(12.2)	36	(73.5)	7	(14.3)	0	–	0	–
Week 3	49	2	(4.1)	20	(40.8)	23	(46.9)	4	(8.2)	0	–
Week 4	46	3	(6.5)	9	(19.6)	19	(41.3)	11	(23.9)	4	(8.7)
Week 6	46	1	(2.2)	8	(17.4)	14	(30.4)	13	(28.3)	10	(21.7)
Week 8	42	1	(2.4)	9	(21.4)	9	(21.4)	13	(31.0)	10	(23.8)
Week 12	37	1	(2.7)	7	(18.9)	8	(21.6)	8	(21.6)	13	(35.1)
Week 16	34	1	(2.9)	7	(20.6)	9	(26.5)	5	(14.7)	12	(35.3)
Week 20	28	1	(3.6)	5	(17.9)	5	(17.9)	6	(21.4)	11	(39.3)
Week 24	23	0	–	4	(17.4)	4	(17.4)	4	(17.4)	11	(47.8)
Maximum *	52	3	(5.8)	7	(13.5)	10	(19.2)	11	(21.2)	21	(40.4)

Source: Tables 13.10.3 and 13.10.4, Section 10; Listing 13.10.1, Appendix B
N = number of patients in the study who were dispensed study medication at each visit; percentages are based on N
* Represents the number (%) of patients for whom the dose was the maximum dose during the study

The mean daily dose of paroxetine is presented for each visit and overall by primary diagnosis and age group for the ITT population in Table 23. The overall mean daily dose of paroxetine to which patients were exposed was 22.9 mg/day. The mean daily dose of paroxetine to which children were exposed was 20.9 mg/day and the mean daily dose of paroxetine to which adolescents were exposed was 25.0 mg/day.

For patients with a primary diagnosis of MDD, the overall mean daily dose of paroxetine was 21.7 mg/day, and the mean dose at the Week 24 LOCF endpoint was 26.4 mg/day. For patients with a primary diagnosis of OCD, the overall mean daily dose of paroxetine was 24.3 mg/day and the mean dose at the Week 24 LOCF endpoint was 28.6 mg/day. There was a greater difference between age groups in the OCD patients than in the MDD patients.

Overall duration of exposure to study medication may be found in Table 24, Section 5.1, Extent of Exposure, and Tables 13.10.5.1b (excluding taper) and 13.10.5.2b (including taper), Section 10.

Table 23 Mean Daily Dose of Paroxetine by Primary Diagnosis and Age Group (ITT Population)

	Total			Children			Adolescents		
Visit	**N**	**Mean (mg/day)**	**(SD)**	**N**	**Mean (mg/day)**	**(SD)**	**N**	**Mean (mg/day)**	**(SD)**
Primary Diagnosis: Total									
Week 1	262 *	12.7	(6.24)	138 *	12.2	(5.92)	124	13.2	(6.57)
Week 2	245	18.8	(6.76)	128	17.7	(7.12)	117	20.0	(6.16)
Week 3	245	22.6	(7.81)	129	21.0	(7.89)	116	24.3	(7.37)
Week 4	234	24.7	(9.46)	123	23.0	(9.23)	111	26.7	(9.37)
Week 6	226	26.6	(10.59)	118	24.5	(10.09)	108	29.0	(10.67)
Week 8	207	27.4	(10.69)	106	25.4	(10.44)	101	29.6	(10.58)
Week 12	187	28.3	(11.08)	94	26.0	(10.51)	93	30.6	(11.21)
Week 16	164	28.1	(11.16)	78	25.8	(10.99)	86	30.2	(10.95)
Week 20	139	28.6	(11.90)	66	25.7	(11.02)	73	31.2	(12.13)
Week 24	122	28.3	(12.04)	60	24.7	(10.65)	62	31.8	(12.35)
Overall Mean **	263 *	22.9	(8.03)	139 *	20.9	(7.66)	124	25.0	(7.91)

Source: Table 13.10.6 and 13.10.7, Section 10; Listing 13.10.1, Appendix B

* Patient 716.201.00108 did not have dosing information for Week 1 (see Section 3.14.10, Data Irregularities).

** The Week 24 LOCF endpoint corresponds to the visit making up each patient's LOCF assessment for CDRS–R or CY–BOCS total score, thus is shown only when the table is split by primary diagnosis.

Table continues

Table 23 (Continued) Mean Daily Dose of Paroxetine by Primary Diagnosis and Age Group (ITT Population)

	Total			Children			Adolescents		
Visit	**N**	**Mean (mg/day)**	**(SD)**	**N**	**Mean (mg/day)**	**(SD)**	**N**	**Mean (mg/day)**	**(SD)**
Primary Diagnosis: MDD									
Week 1	147	13.9	(7.36)	75	13.5	(7.26)	72	14.4	(7.48)
Week 2	139	18.8	(7.47)	71	17.7	(7.96)	68	19.9	(6.80)
Week 3	136	21.9	(7.94)	69	20.7	(8.28)	67	23.1	(7.43)
Week 4	131	22.8	(8.25)	66	22.0	(8.98)	65	23.7	(7.41)
Week 6	126	23.9	(8.85)	64	23.3	(9.60)	62	24.5	(8.03)
Week 8	117	24.8	(8.57)	58	24.0	(9.35)	59	25.6	(7.72)
Week 12	108	25.7	(9.19)	52	24.8	(10.00)	56	26.6	(8.37)
Week 16	96	26.0	(9.57)	44	25.5	(11.30)	52	26.5	(7.89)
Week 20	80	27.1	(10.75)	35	26.7	(11.69)	45	27.3	(10.09)
Week 24	72	26.4	(11.04)	33	25.5	(12.01)	39	27.2	(10.25)
Overall Mean	147	21.7	(7.34)	75	20.6	(7.86)	72	22.8	(6.63)
Week 24 LOCF *	101	26.4	(11.63)	50	25.8	(12.63)	51	27.1	(10.64)

Source: Table 13.10.6 and 13.10.7, Section 10; Listing 13.10.1, Appendix B

* Patient 716.201.00108 did not have dosing information for Week 1 (see Section 3.14.10, Data Irregularities).

** The Week 24 LOCF endpoint corresponds to the visit making up each patient's LOCF assessment for CDRS–R or CY–BOCS total score, thus is shown only when the table is split by primary diagnosis.

Table continues

Table 23 (Continued) Mean Daily Dose of Paroxetine by Primary Diagnosis and Age Group (ITT Population)

	Total			Children			Adolescents		
Visit	**N**	**Mean (mg/day)**	**(SD)**	**N**	**Mean (mg/day)**	**(SD)**	**N**	**Mean (mg/day)**	**(SD)**
Primary Diagnosis: OCD									
Week 1	115 *	11.1	(3.92)	63 *	10.8	(3.26)	52	11.5	(4.60)
Week 2	106	18.9	(5.74)	57	17.7	(5.98)	49	20.2	(5.20)
Week 3	109	23.4	(7.60)	60	21.3	(7.47)	49	25.9	(7.05)
Week 4	103	27.2	(10.33)	57	24.2	(9.44)	46	30.9	(10.29)
Week 6	100	30.1	(11.59)	54	25.9	(10.55)	46	35.0	(10.90)
Week 8	90	30.9	(12.15)	48	27.1	(11.48)	42	35.2	(11.53)
Week 12	79	31.8	(12.48)	42	27.4	(11.06)	37	36.8	(12.26)
Week 16	68	31.0	(12.59)	34	26.2	(10.74)	34	35.9	(12.58)
Week 20	59	30.7	(13.11)	31	24.5	(10.28)	28	37.5	(12.66)
Week 24	50	31.0	(12.98)	27	23.7	(8.84)	23	39.6	(11.86)
Overall Mean	116 *	24.3	(8.63)	64 *	21.3	(7.47)	52	28.1	(8.57)
Week 24 LOCF *	70	28.6	(12.89)	38	22.6	(8.28)	32	35.6	(13.90)

Source: Table 13.10.6 and 13.10.7, Section 10; Listing 13.10.1, Appendix B

* Patient 716.201.00108 did not have dosing information for Week 1 (see Section 3.14.10, Data Irregularities).

** The Week 24 LOCF endpoint corresponds to the visit making up each patient's LOCF assessment for CDRS–R or CY–BOCS total score, thus is shown only when the table is split by primary diagnosis.

5 Safety Results

Patients in the safety population were assessed for clinical safety and tolerability. For this study, the safety population is identical to the ITT population, which includes all patients who received at least one dose of open-label study medication and who had at least one valid post-dose assessment (including any adverse events). The safety data summarized all adverse events, vital signs, laboratory data, and ECGs.

5.1 Extent of Exposure

The overall duration of exposure to open-label study medication (excluding taper medication) is presented by acute-study treatment group for the ITT population in Table 24. The overall mean number of days of exposure to open-label study medication (excluding taper medication) was 116.2 days (range 2 to 204 days): 125.1 days for patients in the acute-study paroxetine group and 107.2 days for patients in the acute-study placebo group. The range of overall duration of exposure was similar between acute-study treatment groups. Overall mean duration of exposure was higher among adolescents than among children (122.4 days for adolescents, 110.7 days for children). As in the overall population, among children, the acute-study paroxetine group had a higher overall mean duration (paroxetine, 117.2 days; placebo, 104.7 days). Similarly, among adolescents, the acute-study paroxetine group had a higher overall mean duration (paroxetine, 133.0 days; placebo, 110.3 days).

Table 24 Overall Duration of Exposure to Open-label Study Medication (Excluding Taper Medication) by Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group					
Paroxetine Exposure	**Paroxetine**		**Placebo**		**Total**	
(Days)	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Age Group: Total	**(N=133)**		**(N=130)**		**(N=263)**	
≥1	133	(100.0)	130	(100.0)	263	(100.0)
>7	130	(97.7)	128	(98.5)	258	(98.1)
>14	128	(96.2)	123	(94.6)	251	(95.4)
>21	124	(93.2)	119	(91.5)	243	(92.4)
>28	123	(92.5)	116	(89.2)	239	(90.9)
>42	114	(85.7)	102	(78.5)	216	(82.1)
>56	109	(82.0)	90	(69.2)	199	(75.7)
>70	100	(75.2)	81	(62.3)	181	(68.8)
>84	96	(72.2)	77	(59.2)	173	(65.8)
>112	82	(61.7)	67	(51.5)	149	(56.7)
>140	74	(55.6)	53	(40.8)	127	(48.3)
>168	44	(33.1)	33	(25.4)	77	(29.3)
>182	11	(8.3)	8	(6.2)	19	(7.2)
Overall Mean	125.1		107.2		116.2	
Range	2–195		2–204		2–204	
Age Group: Children	**(N=67)**		**(N=72)**		**(N=139)**	
≥1	67	(100.0)	72	(100.0)	139	(100.0)
>7	65	(97.0)	71	(98.6)	136	(97.8)
>14	63	(94.0)	69	(95.8)	132	(95.0)
>21	62	(92.5)	66	(91.7)	128	(92.1)
>28	62	(92.5)	64	(88.9)	126	(90.6)
>42	56	(83.6)	57	(79.2)	113	(81.3)
>56	53	(79.1)	50	(69.4)	103	(74.1)
>70	45	(67.2)	45	(62.5)	90	(64.7)
>84	42	(62.7)	41	(56.9)	83	(59.7)
>112	36	(53.7)	35	(48.6)	71	(51.1)
>140	35	(52.2)	27	(37.5)	62	(44.6)
>168	22	(32.8)	17	(23.6)	39	(28.1)
>182	6	(9.0)	6	(8.3)	12	(8.6)
Overall Mean	117.2		104.7		110.7	
Range	2–195		2–197		2–197	

Source: Tables 13.10.5.1b, Section 10; Listing 13.10.1, Appendix B.
Note: Day 1 = Study 716 Baseline

Table continues

Table 24 (Continued) Overall Duration of Exposure to Open-label Study Medication (Excluding Taper Medication) by Acute-study Treatment Group (ITT Population) by Acute-study Treatment Group (ITT Population)

Paroxetine Exposure (Days)	Acute-study Treatment Group: Paroxetine n	(%)	Placebo n	(%)	Total n	(%)
Age Group: Adolescents	**(N=66)**		**(N=58)**		**(N=124)**	
≥1	66	(100.0)	58	(100.0)	124	(100.0)
>7	65	(98.5)	57	(98.3)	122	(98.4)
>14	65	(98.5)	54	(93.1)	119	(96.0)
>21	62	(93.9)	53	(91.4)	115	(92.7)
>28	61	(92.4)	52	(89.7)	113	(91.1)
>42	58	(87.9)	45	(77.6)	103	(83.1)
>56	56	(84.8)	40	(69.0)	96	(77.4)
>70	55	(83.3)	36	(62.1)	91	(73.4)
>84	54	(81.8)	36	(62.1)	90	(72.6)
>112	46	(69.7)	32	(55.2)	78	(62.9)
>140	39	(59.1)	26	(44.8)	65	(52.4)
>168	22	(33.3)	16	(27.6)	38	(30.6)
>182	5	(7.6)	2	(3.4)	7	(5.6)
Overall Mean	133.0		110.3		122.4	
Range	2-187		2-204		2-204	

Source: Tables 13.10.5.1b, Section 10; Listing 13.10.1, Appendix B.
Note: Day 1 = Study 716 Baseline

The overall duration of exposure to open-label study medication including taper medication is presented by acute-study treatment group for the ITT population in Table 13.10.5.2b, Section 10. The overall mean number of days of exposure to open-label study medication including taper was 119.9 (range 2 to 225). The mean number of days of exposure to open-label study medication including taper was 129.0 for patients in the acute-study paroxetine group and 110.5 for patients in the acute-study placebo group. Among children, the acute-study paroxetine group had a higher overall mean duration (paroxetine, 120.6 days; placebo, 108.2 days). Similarly, among adolescents, the acute-study paroxetine group had a higher overall mean duration (paroxetine, 137.6 days; placebo, 113.5 days).

The overall duration of exposure to paroxetine study medication (excluding acute-study taper medication and open-label taper medication) is presented for the PPX population (patients from Studies 701 or 704 who had taken paroxetine in the

acute study) in Table 13.10.5.1d, Section 10. The overall mean number of days of exposure to paroxetine during the acute-study Treatment Phase and open-label study Treatment Phase (excluding taper) was 191.8 days (range 58 to 264 days). The mean number of days of exposure to paroxetine was slightly greater among adolescents (197.3 days) than among children (186.7 days).

The overall duration of exposure to paroxetine study medication (including all taper medication) is presented for the PPX population in Table 13.10.5.2d, Section 10. The overall mean number of days of exposure to paroxetine was 210.3 days (range 65 to 304). The mean number of days of exposure to paroxetine was 202.5 days in children and 218.7 days in adolescents.

5.2 Adverse Events

All adverse events were coded from the verbatim term according to the WHO ART dictionary and then mapped by body system and preferred term according to the COSTART-based ADECS. Adverse events were summarized according to the phase of the study in which they initially occurred (see Section 3.14.6.1, Adverse Events). Adverse events occurring in the pre-acute-study Treatment Phase and acute-study Treatment Phase if ongoing into Study 716 are discussed in Section 4.5, Adverse Events Occurring Prior to the Open-label Baseline. Open-label Treatment Phase, Taper Phase, and Follow-up Phase AEs are presented in this section.

For completeness, the sponsor also prepared tables that summarize all adverse events that occurred during either the open-label Treatment Phase or Taper Phase, i.e., while the patient was actively taking open-label study medication. These summaries combine data from the two phases. Tables were also prepared that combined Taper Phase and Follow-up Phase; and open-label Treatment Phase, Taper Phase and Follow-up Phase.

Adverse events that occurred after the last dose of open-label study medication, even if the patient was still considered by the investigator to be on therapy (e.g., the patient came in for the Week 24 or Early Withdrawal visit one or more days after the last dose of study medication), were coded as occurring during the Follow-up Phase if the patient did not enter the Taper Phase, and as occurring during the Taper Phase if the patient did enter the Taper Phase. Adverse events that occurred after the last dose of taper medication were coded as occurring during the Follow-up Phase.

Summaries of all adverse events during the open-label Treatment Phase, Taper Phase, and Follow-up Phase may be found in Section 12: Tables 15.1.1.1 and 15.1.1.1.X for open-label Treatment Phase-emergent adverse events; 15.1.1.2 and 15.1.1.2.X for Taper Phase-emergent adverse events; 15.1.1.3 and 15.1.1.3.X for combined open-label Treatment Phase-emergent and Taper Phase-emergent adverse events; 15.1.1.4 and 15.1.1.4.X for Follow-up Phase-emergent adverse events; 15.1.1.5 and 15.1.1.5.X for combined Taper Phase-emergent and Follow-up Phase-emergent adverse events; and 15.1.1.6 and 15.1.1.6.X for combined open-label Treatment Phase-emergent, Taper Phase-emergent and Follow-up Phase-emergent adverse events by body system and preferred term, and in descending order for AEs occurring in ≥1% of the population, respectively. Individual patient listings of adverse events may be found in Listings 15.1.1, Appendix D (Pre-Treatment and Treatment Phase) and 15.1.2, Appendix D (Taper, Follow-up, and Post-Follow-up Phases).

The incidence of adverse events was determined for serious and non-serious combined, regardless of investigator-deemed relationship to study medication.

There is a discrepancy in some cases between the dose at onset for an AE and the dosage at the time of the event per the dosing listings. The discrepancies occurred because the dose at the last scheduled visit was used to determine the dose at AE onset, even if the AE occurred after a dose change between visits (Listing 13.10.1, Appendix B; Listing 15.1.4, Appendix D). (See Section 13, Errata.)

5.2.1 Open-label Treatment Phase-emergent Adverse Events

Table 25 presents a summary of the most frequently reported (≥5% in the total population or in either acute-study treatment group within either age group) open-label Treatment Phase-emergent gender-non-specific adverse events, regardless of treatment attribution, for both age groups combined and separately. Open-label Treatment Phase-emergent adverse events are summarized in Tables 15.1.1.1, Section 12 (by body system and preferred term), and 15.1.1.1.X, Section 12 (by preferred term occurring in 1% or more of the population in descending order).

Overall, 75.7% (199/263) of patients reported a gender-non-specific emergent adverse event during the open-label Treatment Phase. The most common (≥10%) gender-non-specific adverse events were headache (25.1%, 66/263), respiratory disorder (18.3%, 48/263), trauma (13.7%, 36/263), infection (12.5%, 33/263), pharyngitis (10.6%, 28/263), and abdominal pain (10.3%, 27/263). The proportion of patients reporting at least one gender-non-specific adverse event during the open-label Treatment Phase was slightly higher in the acute-study

paroxetine group (79.7%, 106/133) than in the acute-study placebo group (71.5%, 93/130). Overall, the most common (≥10%) gender-non-specific adverse events for patients in the acute-study paroxetine group were headache (29.3%, 39/133), respiratory disorder and trauma (each 16.5%, 22/133), pharyngitis (13.5%, 18/133), infection (12.0%, 16/133), abdominal pain (11.3%, 15/133), and nausea (10.5%, 14/133), while the most common adverse events for patients in the acute-study placebo group were headache (20.8%, 27/130), respiratory disorder (20.0%, 26/130), infection (13.1%, 17/130), trauma (10.8%, 14/130), and nervousness (10.0%, 13/130).

Five adverse events occurred with an incidence of ≥5% in the acute-study paroxetine group and with an incidence of at least twice that in the acute-study placebo group: vomiting (9.8% [13/133] compared to 3.1% (4/130)], sinusitis (8.3% [11/133] compared to 1.5% [2/130]), emotional lability (7.5% [10/133] compared to 3.1% (4/130)], diarrhea (6.8% [9/133] compared to 2.3% [3/130]), and albuminuria (6.0% [8/133] compared to 1.5% [2/130]). In the paroxetine group, the verbatim terms for the 10 occurrences of emotional lability were 2 suicidal ideation, 2 attempted suicide, and one each wound right hand self-inflicted with pencil, consumed 10 tabs of Aleve, suicidal, heightened emotions, increased weeping, and unstable mood. In the placebo group, the verbatim terms for the 4 occurrences of emotional lability were mood swing, mood swings/patient cut on self wrist/cut on self upper thighs bilateral, hospitalization for suicide attempt, and emotional crisis. No adverse event occurred with an incidence of ≥5% in the acute-study placebo group and with an incidence of at least twice that in the acute-study paroxetine group.

The overall frequency of gender-non-specific adverse events was slightly higher among children than adolescents. A total of 78.4% (109/139) of children reported gender-non-specific adverse events during the open-label Treatment Phase: 80.6% (54/67) of patients in the acute-study paroxetine group and 76.4% (55/72) of patients in the acute-study placebo group. A total of 72.6% (90/124) of adolescents reported gender-non-specific adverse events during the open-label Treatment Phase: 78.8% (52/66) of patients in the acute-study paroxetine group and 65.5% (38/58) of patients in the acute-study placebo group.

The nature of the adverse events was generally similar between children and adolescents but there were some differences in the rates of occurrence of individual AEs. Adverse events that occurred in children with an incidence of ≥5% and with an incidence of at least twice that in adolescents were pharyngitis (14.4% [20/139] compared to 6.5% [8/124]), hyperkinesia (8.6% [12/139] compared to 2.4% [3/124]), vomiting (8.6% [12/139] compared to 4.0% [5/124]), otitis media

(5.8% [8/139] compared to 1.6% [2/124]), and cough increased and pain (each 5.0% [7/139] compared to 1.6% [2/124]).

Adverse events that occurred in adolescents with an incidence of ≥5% and with an incidence of at least twice that in children were allergic reaction (8.9% [11/124] compared to 4.3% [6/139]), emotional lability (9.7% [12/124] compared to 1.4% [2/139]), asthenia (8.9% [11/124] compared to 2.9% [4/139]), somnolence (7.3% [9/124] compared to 2.9% [4/139]), asthma (6.5% [8/124] compared to 1.4% [2/139]), and albuminuria (5.6% [7/124] compared to 2.2% [3/139]).

Table 25 Most Frequent (≥5% in the Total Population or in Either Acute-study Treatment Group within Either Age Group) Open-label Treatment Phase-emergent Gender-non-specific Adverse Events by Age Group and Acute-study Treatment Group (ITT Population)

	Age Group: Total						Age Group: Children						Age Group: Adolescents					
	Paroxetine		Placebo		Total		Paroxetine		Placebo		Total		Paroxetine		Placebo		Total	
AE Preferred Term	(N = 133)		(N = 130)		(N = 263)		(N = 67)		(N = 72)		(N = 139)		(N = 66)		(N = 58)		(N = 124)	
Patients with AEs	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least One AE	106	(79.7)	93	(71.5)	199	(75.7)	54	(80.6)	55	(76.4)	109	(78.4)	52	(78.8)	38	(65.5)	90	(72.6)
Headache	39	(29.3)	27	(20.8)	66	(25.1)	18	(26.9)	12	(16.7)	30	(21.6)	21	(31.8)	15	(25.9)	36	(29.0)
Respiratory disorder	22	(16.5)	26	(20.0)	48	(18.3)	11	(16.4)	14	(19.4)	25	(18.0)	11	(16.7)	12	(20.7)	23	(18.5)
Trauma	22	(16.5)	14	(10.8)	36	(13.7)	15	(22.4)	8	(11.1)	23	(16.5)	7	(10.6)	6	(10.3)	13	(10.5)
Infection	16	(12.0)	17	(13.1)	33	(12.5)	8	(11.9)	12	(16.7)	20	(14.4)	8	(12.1)	5	(8.6)	13	(10.5)
Pharyngitis	18	(13.5)	10	(7.7)	28	(10.6)	13	(19.4)	7	(9.7)	20	(14.4)	5	(7.6)	3	(5.2)	8	(6.5)
Abdominal pain	15	(11.3)	12	(9.2)	27	(10.3)	9	(13.4)	8	(11.1)	17	(12.2)	6	(9.1)	4	(6.9)	10	(8.1)
Nausea	14	(10.5)	11	(8.5)	25	(9.5)	6	(9.0)	3	(4.2)	9	(6.5)	8	(12.1)	8	(13.8)	16	(12.9)
Nervousness	10	(7.5)	13	(10.0)	23	(8.7)	6	(9.0)	9	(12.5)	15	(10.8)	4	(6.1)	4	(6.9)	8	(6.5)
Rhinitis	13	(9.8)	9	(6.9)	22	(8.4)	8	(11.9)	7	(9.7)	15	(10.8)	5	(7.6)	2	(3.4)	7	(5.6)
Insomnia	10	(7.5)	11	(8.5)	21	(8.0)	4	(6.0)	5	(6.9)	9	(6.5)	6	(9.1)	6	(10.3)	12	(9.7)
Vomiting	13	(9.8)	4	(3.1)	17	(6.5)	8	(11.9)	4	(5.6)	12	(8.6)	5	(7.6)	0	–	5	(4.0)
Allergic reaction	11	(8.3)	6	(4.6)	17	(6.5)	3	(4.5)	3	(4.2)	6	(4.3)	8	(12.1)	3	(5.2)	11	(8.9)
Fever	11	(8.3)	6	(4.6)	17	(6.5)	8	(11.9)	3	(4.2)	11	(7.9)	3	(4.5)	3	(5.2)	6	(4.8)
Dyspepsia	9	(6.8)	7	(5.4)	16	(6.1)	6	(9.0)	4	(5.6)	10	(7.2)	3	(4.5)	3	(5.2)	6	(4.8)
Weight gain	7	(5.3)	9	(6.9)	16	(6.1)	4	(6.0)	6	(8.3)	10	(7.2)	3	(4.5)	3	(5.2)	6	(4.8)
Hyperkinesia	8	(6.0)	7	(5.4)	15	(5.7)	7	(10.4)	5	(6.9)	12	(8.6)	1	(1.5)	2	(3.4)	3	(2.4)
Asthenia	6	(4.5)	9	(6.9)	15	(5.7)	2	(3.0)	2	(2.8)	4	(2.9)	4	(6.1)	7	(12.1)	11	(8.9)
Hostility	6	(4.5)	9	(6.9)	15	(5.7)	5	(7.5)	5	(6.9)	10	(7.2)	1	(1.5)	4	(6.9)	5	(4.0)

Source: Table 15.1.1.1 and 15.1.1.1.X, Section 12, Listing 15.1.1, Appendix D
Sorted by decreasing frequency in the total age group, total acute-study treatment groups

Table continues

Table 25 (Continued) Most Frequent (≥5% in the Total Population or in Either Acute-study Treatment Group within Either Age) Open-label Treatment Phase-emergent Gender-non-specific Adverse Events by Age Group and Acute-study Treatment Group (ITT Population)

	Age Group: Total						Age Group: Children						Age Group: Adolescents					
AE Preferred Term	**Paroxetine (N = 133)**		**Placebo (N = 130)**		**Total (N = 263)**		**Paroxetine (N = 67)**		**Placebo (N = 72)**		**Total (N = 139)**		**Paroxetine (N = 66)**		**Placebo (N = 58)**		**Total (N = 124)**	
Patients with AEs	**n**	**(%)**	**n**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Emotional lability	10	(7.5)	4	(3.1)	14	(5.3)	2	(3.0)	0	–	2	(1.4)	8	(12.1)	4	(6.9)	12	(9.7)
Sinusitis	11	(8.3)	2	(1.5)	13	(4.9)	5	(7.5)	2	(2.8)	7	(5.0)	6	(9.1)	0	–	6	(4.8)
Somnolence	7	(5.3)	6	(4.6)	13	(4.9)	1	(1.5)	3	(4.2)	4	(2.9)	6	(9.1)	3	(5.2)	9	(7.3)
Diarrhea	9	(6.8)	3	(2.3)	12	(4.6)	5	(7.5)	1	(1.4)	6	(4.3)	4	(6.1)	2	(3.4)	6	(4.8)
Dizziness	6	(4.5)	5	(3.8)	11	(4.2)	1	(1.5)	3	(4.2)	4	(2.9)	5	(7.6)	2	(3.4)	7	(5.6)
Decreased appetite	4	(3.0)	7	(5.4)	11	(4.2)	3	(4.5)	3	(4.2)	6	(4.3)	1	(1.5)	4	(6.9)	5	(4.0)
Albuminuria	8	(6.0)	2	(1.5)	10	(3.8)	2	(3.0)	1	(1.4)	3	(2.2)	6	(9.1)	1	(1.7)	7	(5.6)
Otitis media	6	(4.5)	4	(3.1)	10	(3.8)	5	(7.5)	3	(4.2)	8	(5.8)	1	(1.5)	1	(1.7)	2	(1.6)
Asthma	5	(3.8)	5	(3.8)	10	(3.8)	1	(1.5)	1	(1.4)	2	(1.4)	4	(6.1)	4	(6.9)	8	(6.5)
Agitation	4	(3.0)	6	(4.6)	10	(3.8)	2	(3.0)	3	(4.2)	5	(3.6)	2	(3.0)	3	(5.2)	5	(4.0)
Cough increased	6	(4.5)	3	(2.3)	9	(3.4)	5	(7.5)	2	(2.8)	7	(5.0)	1	(1.5)	1	(1.7)	2	(1.6)
Pain	6	(4.5)	3	(2.3)	9	(3.4)	5	(7.5)	2	(2.8)	7	(5.0)	1	(1.5)	1	(1.7)	2	(1.6)
Anxiety	3	(2.3)	6	(4.6)	9	(3.4)	1	(1.5)	4	(5.6)	5	(3.6)	2	(3.0)	2	(3.4)	4	(3.2)
Acne	5	(3.8)	3	(2.3)	8	(3.0)	3	(4.5)	0	–	3	(2.2)	2	(3.0)	3	(5.2)	5	(4.0)
Rash	1	(0.8)	5	(3.8)	6	(2.3)	1	(1.5)	4	(5.6)	5	(3.6)	0	–	1	(1.7)	1	(0.8)
Urinary incontinence	1	(0.8)	4	(3.1)	5	(1.9)	1	(1.5)	4	(5.6)	5	(3.6)	0	–	0	–	0	–

Source: Table 15.1.1.1 and 15.1.1.1.X, Section 12, Listing 15.1.1, Appendix D

Sorted by decreasing frequency in the total age group, total acute-study treatment groups

Table 26 presents a summary of the most frequently reported (≥5% in the total population or in either acute-study treatment group within either primary diagnosis) open-label Treatment Phase-emergent gender-non-specific adverse events, regardless of treatment attribution, by primary diagnosis. Treatment Phase-emergent adverse events are summarized in Tables 15.1.1.1, Section 12 (by body system and preferred term), and 15.1.1.1.X, Section 12 (by preferred term occurring in 1% or more of the population in descending order).

The overall frequency of gender-non-specific adverse events in patients with a primary diagnosis of MDD was 74.8% (110/147): 81.5% (66/81) of patients in the acute-study paroxetine group and 66.7% (44/66) of patients in the acute-study placebo group. The overall frequency of gender-non-specific adverse events in patients with a primary diagnosis of OCD (76.7%, 89/116) was similar to those with MDD, and the frequency was similar between the two acute-study treatment groups: 76.9% (40/52) of patients in the acute-study paroxetine group and 76.6% (49/64) of patients in the acute-study placebo group.

Adverse events that occurred in patients with a primary diagnosis of MDD with an incidence of ≥5% and with an incidence of at least twice that in patients with a primary diagnosis of OCD were vomiting (10.9% [16/147] compared to 0.9% [1/116]) and emotional lability (6.8% [10/147] compared to 3.4% [4/116]).

Adverse events that occurred in patients with a primary diagnosis of OCD with an incidence of ≥5% and with an incidence of at least twice that in patients with a primary diagnosis of MDD were hyperkinesia (10.3% [12/116] compared to 2.0% [3/147]) and anxiety (5.2% [6/116] compared to 2.0% [3/147]).

Table 26 Most Frequent (≥5% in the Total Population or in Either Acute-study Treatment Group within Either Primary Diagnosis) Open-label Treatment Phase-emergent Gender-non-specific Adverse Events by Primary Diagnosis and Acute-study Treatment Group (ITT Population)

	Primary Diagnosis: Total						Primary Diagnosis: MDD						Primary Diagnosis: OCD					
AE Preferred Term	**Paroxetine (N = 133)**		**Placebo (N = 130)**		**Total (N = 263)**		**Paroxetine (N = 81)**		**Placebo (N = 66)**		**Total (N = 147)**		**Paroxetine (N = 52)**		**Placebo (N = 64)**		**Total (N = 116)**	
Patients with AEs	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least One AE	106	(79.7)	93	(71.5)	199	(75.7)	66	(81.5)	44	(66.7)	110	(74.8)	40	(76.9)	49	(76.6)	89	(76.7)
Headache	39	(29.3)	27	(20.8)	66	(25.1)	20	(24.7)	10	(15.2)	30	(20.4)	19	(36.5)	17	(26.6)	36	(31.0)
Respiratory disorder	22	(16.5)	26	(20.0)	48	(18.3)	16	(19.8)	13	(19.7)	29	(19.7)	6	(11.5)	13	(20.3)	19	(16.4)
Trauma	22	(16.5)	14	(10.8)	36	(13.7)	17	(21.0)	6	(9.1)	23	(15.6)	5	(9.6)	8	(12.5)	13	(11.2)
Infection	16	(12.0)	17	(13.1)	33	(12.5)	8	(9.9)	11	(16.7)	19	(12.9)	8	(15.4)	6	(9.4)	14	(12.1)
Pharyngitis	18	(13.5)	10	(7.7)	28	(10.6)	12	(14.8)	5	(7.6)	17	(11.6)	6	(11.5)	5	(7.8)	11	(9.5)
Abdominal pain	15	(11.3)	12	(9.2)	27	(10.3)	10	(12.3)	4	(6.1)	14	(9.5)	5	(9.6)	8	(12.5)	13	(11.2)
Nausea	14	(10.5)	11	(8.5)	25	(9.5)	8	(9.9)	4	(6.1)	12	(8.2)	6	(11.5)	7	(10.9)	13	(11.2)
Nervousness	10	(7.5)	13	(10.0)	23	(8.7)	8	(9.9)	1	(1.5)	9	(6.1)	2	(3.8)	12	(18.8)	14	(12.1)
Rhinitis	13	(9.8)	9	(6.9)	22	(8.4)	8	(9.9)	4	(6.1)	12	(8.2)	5	(9.6)	5	(7.8)	10	(8.6)
Insomnia	10	(7.5)	11	(8.5)	21	(8.0)	4	(4.9)	5	(7.6)	9	(6.1)	6	(11.5)	6	(9.4)	12	(10.3)
Vomiting	13	(9.8)	4	(3.1)	17	(6.5)	12	(14.8)	4	(6.1)	16	(10.9)	1	(1.9)	0	–	1	(0.9)
Allergic reaction	11	(8.3)	6	(4.6)	17	(6.5)	7	(8.6)	2	(3.0)	9	(6.1)	4	(7.7)	4	(6.3)	8	(6.9)
Fever	11	(8.3)	6	(4.6)	17	(6.5)	8	(9.9)	3	(4.5)	11	(7.5)	3	(5.8)	3	(4.7)	6	(5.2)
Dyspepsia	9	(6.8)	7	(5.4)	16	(6.1)	7	(8.6)	4	(6.1)	11	(7.5)	2	(3.8)	3	(4.7)	5	(4.3)
Weight gain	7	(5.3)	9	(6.9)	16	(6.1)	5	(6.2)	6	(9.1)	11	(7.5)	2	(3.8)	3	(4.7)	5	(4.3)
Hyperkinesia	8	(6.0)	7	(5.4)	15	(5.7)	2	(2.5)	1	(1.5)	3	(2.0)	6	(11.5)	6	(9.4)	12	(10.3)

Source: Table 15.1.1.1 and 15.1.1.1.X, Section 12, Listing 15.1.1, Appendix D

Sorted by decreasing frequency in the total primary diagnosis group, total acute study treatment groups

Table continues

Table 26 (Continued) Most Frequent (≥5% in the Total Population or in Either Acute-study Treatment Group within Either Primary Diagnosis) Open-label Treatment Phase-emergent Gender-non-specific Adverse Events by Primary Diagnosis and Acute-study Treatment Group (ITT Population)

	Primary Diagnosis: Total						Primary Diagnosis: MDD						Primary Diagnosis: OCD					
	Paroxetine		Placebo		Total		Paroxetine		Placebo		Total		Paroxetine		Placebo		Total	
AE Preferred Term	(N = 133)		(N = 130)		(N = 263)		(N = 81)		(N = 66)		(N = 147)		(N = 52)		(N = 64)		(N = 116)	
Patients with AEs	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Asthenia	6	(4.5)	9	(6.9)	15	(5.7)	3	(3.7)	5	(7.6)	8	(5.4)	3	(5.8)	4	(6.3)	7	(6.0)
Hostility	6	(4.5)	9	(6.9)	15	(5.7)	4	(4.9)	2	(3.0)	6	(4.1)	2	(3.8)	7	(10.9)	9	(7.8)
Emotional lability	10	(7.5)	4	(3.1)	14	(5.3)	7	(8.6)	3	(4.5)	10	(6.8)	3	(5.8)	1	(1.6)	4	(3.4)
Sinusitis	11	(8.3)	2	(1.5)	13	(4.9)	6	(7.4)	1	(1.5)	7	(4.8)	5	(9.6)	1	(1.6)	6	(5.2)
Somnolence	7	(5.3)	6	(4.6)	13	(4.9)	5	(6.2)	3	(4.5)	8	(5.4)	2	(3.8)	3	(4.7)	5	(4.3)
Diarrhea	9	(6.8)	3	(2.3)	12	(4.6)	5	(6.2)	2	(3.0)	7	(4.8)	4	(7.7)	1	(1.6)	5	(4.3)
Dizziness	6	(4.5)	5	(3.8)	11	(4.2)	3	(3.7)	2	(3.0)	5	(3.4)	3	(5.8)	3	(4.7)	6	(5.2)
Decreased appetite	4	(3.0)	7	(5.4)	11	(4.2)	2	(2.5)	3	(4.5)	5	(3.4)	2	(3.8)	4	(6.3)	6	(5.2)
Albuminuria	8	(6.0)	2	(1.5)	10	(3.8)	3	(3.7)	2	(3.0)	5	(3.4)	5	(9.6)	0	–	5	(4.3)
Otitis media	6	(4.5)	4	(3.1)	10	(3.8)	3	(3.7)	1	(1.5)	4	(2.7)	3	(5.8)	3	(4.7)	6	(5.2)
Pain	6	(4.5)	3	(2.3)	9	(3.4)	3	(3.7)	2	(3.0)	5	(3.4)	3	(5.8)	1	(1.6)	4	(3.4)
Anxiety	3	(2.3)	6	(4.6)	9	(3.4)	1	(1.2)	2	(3.0)	3	(2.0)	2	(3.8)	4	(6.3)	6	(5.2)
Neurosis	4	(3.0)	1	(0.8)	5	(1.9)	1	(1.2)	0	–	1	(0.7)	3	(5.8)	1	(1.6)	4	(3.4)
Vasodilatation	0	–	4	(3.1)	4	(1.5)	0	–	0	–	0	–	0	–	4	(6.3)	4	(3.4)

Source: Table 15.1.1.1 and 15.1.1.1.X, Section 12, Listing 15.1.1, Appendix D

Sorted by decreasing frequency in the total primary diagnosis group, total acute study treatment groups

Adverse events that occurred in children with a primary diagnosis of MDD with an incidence of ≥5% and with an incidence of at least twice that in adolescents with a primary diagnosis of MDD were infection (18.7% [14/75] compared to 6.9% [5/72]), pharyngitis (16.0% [12/75] compared to 6.9% [5/72]), vomiting (14.7% [11/75] compared to 6.9% [5/72]), abdominal pain (13.3% [10/75] compared to 5.6% [4/72]), hostility (6.7% [5/75] compared to 1.4% [1/72]), and pain (5.3% [4/75] compared to 1.4% [1/72]) (Table 15.1.1.1, Section 12).

In adolescents with a primary diagnosis of MDD, adverse events that occurred with an incidence of ≥5% and with an incidence of at least twice that in children with a primary diagnosis of MDD were nausea (12.5% [9/72] compared to 4.0% [3/75]), emotional lability (12.5% [9/72] compared to 1.3% [1/75]), somnolence (9.7% [7/72] compared to 1.3% [1/75]), asthma (6.9% [5/72] compared to 1.3% [1/75]), albuminuria (5.6% [4/72] compared to 1.3% [1/75]), dizziness (5.6% [4/72] compared to 1.3% [1/75]), and bronchitis (5.6% [4/72] compared to 1.3% [1/75]) (Table 15.1.1.1, Section 12).

Adverse events that occurred in children with a primary diagnosis of OCD with an incidence of ≥5% and with an incidence of at least twice that in adolescents with a primary diagnosis of OCD were nervousness (15.6% [10/64] compared to 7.7% [4/52]), hyperkinesia (14.1% [9/64] compared to 5.8% [3/52]), pharyngitis (12.5% [8/64] compared to 5.8% [3/52])], and rhinitis (12.5% [8/64] compared to 3.8% [2/52]), and otitis media (7.8% [5/64] compared to 1.9% [1/52]) (Table 15.1.1.1, Section 12).

In adolescents with a primary diagnosis of OCD, adverse events that occurred with an incidence of ≥5% and with an incidence of at least twice that in children with a primary diagnosis of OCD were allergic reaction (13.5% [7/52] compared to 1.6% [1/64]), asthenia (13.5% [7/52] compared to none), neurosis (7.7% [4/52] compared to none), arthralgia (5.8% [3/52] compared to none), emotional lability (5.8% [3/52] compared to 1.6% [1/64]), acne (5.8% [3/52] compared to 1.6% [1/64]), and asthma (5.8% [3/52] compared to 1.6% [1/64]) (Table 15.1.1.1, Section 12).

No patients reported a male-specific emergent adverse event starting during the open-label Treatment Phase. Ten patients reported a female-specific emergent adverse event during the open-label Treatment Phase: dysmenorrhea (11.5% [7/61] of females in the acute-study paroxetine group compared to 2.0% [1/51] of females in the acute-study placebo group) and female genital disorders, menstrual disorder, and uterus disorders (each 2.0% [1/51] of females in

the acute-study placebo group and none in the acute-study paroxetine group) (Table 15.1.1.1, Section 12).

5.2.1.1 Open-label Treatment Phase-emergent Adverse Events by Investigator-Assessed Intensity

Investigators assessed the intensity of all open-label Treatment Phase-emergent AEs as mild, moderate, or severe (Section 3.11.1, Adverse Events). These AEs are summarized by intensity in Tables 15.1.3.1, Section 12 (by body system and preferred term), and 15.1.3.1.X, Section 12 (by preferred term occurring in 1% or more of the population in descending order). In addition, open-label Treatment Phase-emergent adverse events are summarized by maximum intensity by body system and preferred term in Table 15.1.7.1, Section 12. The majority of open-label Treatment Phase-emergent adverse events were mild or moderate in intensity.

Severe gender-non-specific open-label Treatment Phase-emergent adverse events are presented by acute-study treatment group in Table 27. Overall, 11.8% (31/263) of patients reported a severe gender-non-specific adverse event during the open-label Treatment Phase. The proportion of patients reporting at least one severe gender-non-specific adverse event during the open-label Treatment Phase was 9.8% (13/133) of patients in the acute-study paroxetine group compared to 13.8% (18/130) of patients in the acute-study placebo group. The only severe adverse events occurring in more than one patient in either acute-study treatment group were emotional lability, hostility, infection, trauma and urinary incontinence. All severe adverse events of emotional lability were considered serious (see Section 5.4, Serious Adverse Events). There were no severe gender-specific adverse events.

Table 27 Summary of Number (%) of Patients with Open-label Treatment Phase-emergent Severe Adverse Events by Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group					
	Paroxetine (N = 133)		Placebo (N = 130)		Total (N = 263)	
AE Preferred Term	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least One Severe AE	13	(9.8)	18	(13.8)	31	(11.8)
Emotional lability	4	(3.0)	1	(0.8)	5	(1.9)
Hostility	2	(1.5)	3	(2.3)	5	(1.9)
Infection	2	(1.5)	1	(0.8)	3	(1.1)
Trauma	1	(0.8)	2	(1.5)	3	(1.1)
Agitation	1	(0.8)	1	(0.8)	2	(0.8)
Urinary incontinence	0	–	2	(1.5)	2	(0.8)
Abscess	1	(0.8)	0	–	1	(0.4)
Back pain	1	(0.8)	0	–	1	(0.4)
Depression	1	(0.8)	0	–	1	(0.4)
Lack of emotion	1	(0.8)	0	–	1	(0.4)
Neurosis	1	(0.8)	0	–	1	(0.4)
Pharyngitis	1	(0.8)	0	–	1	(0.4)
Somnolence	1	(0.8)	0	–	1	(0.4)
Abdominal pain	0	–	1	(0.8)	1	(0.4)
Anxiety	0	–	1	(0.8)	1	(0.4)
Asthma	0	–	1	(0.8)	1	(0.4)
Euphoria	0	–	1	(0.8)	1	(0.4)
Hallucinations	0	–	1	(0.8)	1	(0.4)
Hyperkinesia	0	–	1	(0.8)	1	(0.4)
Migraine	0	–	1	(0.8)	1	(0.4)
Nausea	0	–	1	(0.8)	1	(0.4)
Nervousness	0	–	1	(0.8)	1	(0.4)
Otitis media	0	–	1	(0.8)	1	(0.4)
Paralysis	0	–	1	(0.8)	1	(0.4)
Rash	0	–	1	(0.8)	1	(0.4)
Syncope	0	–	1	(0.8)	1	(0.4)
Tooth caries	0	–	1	(0.8)	1	(0.4)
Weight gain	0	–	1	(0.8)	1	(0.4)

Source: Table 15.1.3.1 Section 12; Listing 15.1.1, Appendix D
Sorted by decreasing frequency in the total group

The proportion of patients reporting severe gender-non-specific open-label Treatment Phase-emergent adverse events was similar in children (12.2%, 17/139) and adolescents (11.3%, 14/124) (Table 15.1.3.1, Section 12). Among children, 7.5% (5/67) of patients in the acute-study paroxetine group and 16.7% (12/72) of patients in the acute-study placebo group reported severe gender-non-specific open-label Treatment Phase-emergent adverse events. Among adolescents, 12.1% (8/66) of patients in the acute-study paroxetine group and 10.3% (6/58) of patients in the acute-study placebo group reported severe gender-non-specific open-label Treatment Phase-emergent adverse events.

The proportion of patients reporting severe gender-non-specific open-label Treatment Phase-emergent adverse events was slightly higher in patients with a primary diagnosis of MDD (13.6%, 20/147) than in patients with a primary diagnosis of OCD (9.5%, 11/116) (Table 15.1.3.1, Section 12). Among patients with a primary diagnosis of MDD, 11.1% (9/81) of patients in the acute-study paroxetine group and 16.7% (11/66) of patients in the acute-study placebo group reported severe gender-non-specific open-label Treatment Phase-emergent adverse events. Among patients with a primary diagnosis of OCD, 7.7% (4/52) of patients in the acute-study paroxetine group and 10.9% (7/64) of patients in the acute-study placebo group reported severe gender-non-specific open-label Treatment Phase-emergent adverse events.

Patients with severe Treatment Phase-emergent adverse events considered related or possibly related to study medication are discussed in Section 5.2.1.2, Open-label Treatment Phase-emergent Adverse Events by Relationship to Study Medication, and are presented in Table 29.

5.2.1.2 Open-label Treatment Phase-emergent Adverse Events by Relationship to Study Medication

Patients with adverse events judged by the investigator to be related or possibly related to open-label study medication are summarized in Tables 15.1.4.1, Section 12 (by body system and preferred term), and 15.1.4.1.X, Section 12 (by preferred term occurring in 1% or more of the population in descending order).

A summary of the most frequent (incidence ≥5% in the total population or in either acute-study treatment group) gender-non-specific open-label Treatment Phase-emergent adverse events that were judged by the investigator to be related or possibly related to open-label study medication are presented in Table 28 by acute-study treatment group.

Overall, 49.4% (130/263) of patients reported a gender-non-specific adverse event judged by the investigator to be related or possibly related to open-label study medication during the open-label Treatment Phase. The most common (≥5% of patients) adverse events judged to be related or possibly related were headache (11.8%, 31/263), nervousness (7.2%, 19/263), hyperkinesia, insomnia, and weight gain (each 5.7%, 15/263), and nausea (5.3%, 14/263). A total of 49.6% (66/133) of patients in the acute-study paroxetine group and 49.2% (64/130) of patients in the acute-study placebo group reported a gender-non-specific adverse event judged by the investigator to be related or possibly related to open-label study medication during the open-label Treatment Phase. The most common events in each group were similar to those in the population as a whole, except that more patients from the acute-study paroxetine group had nausea, and more patients from the acute-study placebo group had nervousness and decreased appetite.

Table 28 Summary of Number (%) of Patients with Open-label Treatment Phase-emergent Adverse Events Considered Related or Possibly Related to Study Medication Occurring in ≥3% of Patients in Either Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group					
	Paroxetine (N = 133)		Placebo (N = 130)		Total (N = 263)	
AE Preferred Term	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least One Related or Possibly Related AE	66	(49.6)	64	(49.2)	130	(49.4)
Headache	18	(13.5)	13	(10.0)	31	(11.8)
Nervousness	7	(5.3)	12	(9.2)	19	(7.2)
Hyperkinesia	8	(6.0)	7	(5.4)	15	(5.7)
Insomnia	7	(5.3)	8	(6.2)	15	(5.7)
Weight gain	7	(5.3)	8	(6.2)	15	(5.7)
Nausea	9	(6.8)	5	(3.8)	14	(5.3)
Somnolence	5	(3.8)	6	(4.6)	11	(4.2)
Decreased appetite	4	(3.0)	7	(5.4)	11	(4.2)
Hostility	5	(3.8)	5	(3.8)	10	(3.8)
Abdominal pain	4	(3.0)	5	(3.8)	9	(3.4)
Agitation	3	(2.3)	5	(3.8)	8	(3.0)
Asthenia	3	(2.3)	5	(3.8)	8	(3.0)
Anxiety	2	(1.5)	4	(3.1)	6	(2.3)
Vasodilatation	0	–	4	(3.1)	4	(1.5)
Tremor	0	–	4	(3.1)	4	(1.5)

Source: Table 15.1.4.1 and 15.1.4.1.X, Section 12; Listing 15.1.1, Appendix D
Sorted by decreasing frequency in the total group

More children (53.2% [74/139] than adolescents (45.2% [56/124]) had gender-non-specific open-label Treatment Phase-emergent adverse events judged related or possibly related to study medication (Table 15.1.4.1, Section 12). In the acute-study paroxetine group, a slightly higher proportion of children (55.2%, 37/67) reported adverse events judged related or possibly related to study medication than adolescents (43.9%, 29/66). In the acute-study placebo group, the proportions were similar: 51.4% (37/72) of children and 46.6% (27/58) of adolescents.

The proportion of patients reporting gender-non-specific open-label Treatment Phase-emergent adverse events judged related or possibly related to study

medication occurred less frequently in patients with a primary diagnosis of MDD (43.5% [64/147]) than in patients with a primary diagnosis of OCD (56.9% [66/116]) (Table 15.1.4.1, Section 12). Among patients with a primary diagnosis of MDD, 45.7% (37/81) of patients in the acute-study paroxetine group and 40.9% (27/66) of patients in the acute-study placebo group reported adverse events judged related or possibly related to study medication. Among patients with a primary diagnosis of OCD, 55.8% (29/52) of patients in the acute-study paroxetine group and 57.8% (37/64) of patients in the acute-study placebo group reported adverse events judged related or possibly related to study medication.

The only gender-specific adverse event judged to be related or possibly related to open-label study medication was female genital disorder, which occurred in one adolescent patient in the acute-study placebo group with a primary diagnosis of MDD.

The majority of severe open-label Treatment Phase-emergent adverse events were considered unrelated to study medication. Two patients in the acute-study paroxetine group and 7 patients in the acute-study placebo group had severe adverse events during the open-label Treatment Phase that were considered by the investigator to be related or possibly related to open-label study medication (Table 29). As a result of a severe adverse event considered to be related or possibly related to open-label study medication, 1 acute-study paroxetine patient and 4 acute-study placebo patients were withdrawn from the study. None of the severe adverse events considered related or possibly related to open-label study medication was reported as a serious adverse event. Hostility was experienced by 1 acute-study paroxetine patient and 2 acute-study placebo patients; the other events were experienced by one patient each.

Table 29 Open-label Treatment Phase-emergent Severe Adverse Events Considered Related or Possibly Related to Study Medication (ITT Population)

Patient Number	Gender (M/F)	Age (yrs)	Dose at Onset	AE Preferred Term (Verbatim Term)	Relationship	Study Medication Action	Day of Onset *	Duration (days)
Acute-study Paroxetine Group								
716.168.27077	F	15	30	Neurosis (impulsivity)	Possibly related	None	13 [100] (-41)	Ongoing
716.201.00110	M	9	10	Hostility (increased behavior problems)	Possibly related	Stopped	30 [73] (-8)	Ongoing
Acute-study Placebo Group								
716.010.25840	F	11	30	Urinary incontinence (bed wetting)	Possibly related	None	78 (-6)	13
716.016.25447	M	7	20	Hostility (aggression)	Possibly related	Stopped	47 (-2)	8
716.016.25450	F	11	20	Nervousness (irritability)	Possibly related	Stopped	45 (-2)	6
716.016.27021	M	8	20	Hyperkinesia (hyperactivity)	Related	Stopped	27 (-3)	8
716.016.27017	M	12	20	Hostility (oppositional behavior)	Related	Stopped	52 (-7)	10
716.168.27075	F	12	40	Abdominal pain (stomach discomfort)	Possibly related	None	23 (-96)	37
716.176.27171	F	10	20	Weight gain (weight gain)	Possibly related	None	30 (-140)	Ongoing

Source: Tables 15.1.3.1 and 15.1.4.1, Section 12; Listing 13.5.1, Appendix B; Listing 15.1.1, Appendix D; Listing 13.14.1, Study 701; Listing 13.13.1, Study 704; Table DS33, Study 715

* Relative to the first day of open-label study medication [relative to the first dose of paroxetine in the acute study, including acute-study taper] (relative to the last day of open-label medication, excluding taper)

5.2.1.3 Open-label Treatment Phase-emergent Adverse Events by Time of First Occurrence

A summary of all open-label Treatment Phase-emergent adverse events by the time of first occurrence by preferred term is presented in Table 15.1.6.1.X, Section 12. Table 30 summarizes the most frequently occurring open-label Treatment Phase-emergent adverse events (i.e., those occurring in ≥5% of patients in either acute-study treatment group) by the time of first occurrence for each treatment group. In both treatment groups, the time to first occurrence for the most frequent adverse events was generally spread across the course of the open-label Treatment Phase, except that for some adverse events the majority of first occurrences was during the first 3 weeks: headache, nervousness, diarrhea, insomnia, and somnolence in the acute-study paroxetine group; and nervousness, abdominal pain, insomnia, pharyngitis, decreased appetite, and dyspepsia in the acute-study placebo group.

No adverse events had the first occurrence more often in the last 12 weeks of the study than in the first 12 weeks of the study. The only adverse events that had the time to first occurrence more often from Week 8 onwards were weight gain in both acute-study treatment groups, and trauma and vomiting in the acute-study paroxetine group. However, the numbers are generally too small to make detailed conclusions.

Table 30 Number (%) of Patients with the Most Frequent (≥5%) Open-label Treatment Phase-emergent Adverse Events by Time of First Occurrence and Acute-study treatment group (ITT Population)

	Time of First Occurrence (Week) *																					
Acute Study	**1**		**2**		**3**		**4**		**6**		**8**		**12**		**16**		**20**		**24**		**Total**	
Treatment Group	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Paroxetine (N = 133)																						
Headache	11	(8.3)	4	(3.0)	6	(4.5)	1	(0.8)	4	(3.0)	5	(3.8)	1	(0.8)	2	(1.5)	3	(2.3)	2	(1.5)	39	(29.3)
Respiratory disorder	4	(3.0)	1	(0.8)	1	(0.8)	2	(1.5)	4	(3.0)	1	(0.8)	2	(1.5)	2	(1.5)	3	(2.3)	2	(1.5)	22	(16.5)
Trauma	0	–	3	(2.3)	3	(2.3)	1	(0.8)	3	(2.3)	0	–	8	(6.0)	2	(1.5)	2	(1.5)	0	–	22	(16.5)
Pharyngitis	3	(2.3)	1	(0.8)	2	(1.5)	0	–	3	(2.3)	4	(3.0)	2	(1.5)	2	(1.5)	0	–	1	(0.8)	18	(13.5)
Infection	1	(0.8)	0	–	1	(0.8)	2	(1.5)	3	(2.3)	3	(2.3)	3	(2.3)	1	(0.8)	0	–	2	(1.5)	16	(12.0)
Abdominal pain	0	–	3	(2.3)	3	(2.3)	0	–	5	(3.8)	1	(0.8)	1	(0.8)	0	–	2	(1.5)	0	–	15	(11.3)
Nausea	1	(0.8)	1	(0.8)	2	(1.5)	2	(1.5)	1	(0.8)	1	(0.8)	3	(2.3)	0	–	3	(2.3)	0	–	14	(10.5)
Rhinitis	2	(1.5)	2	(1.5)	1	(0.8)	1	(0.8)	1	(0.8)	3	(2.3)	0	–	1	(0.8)	1	(0.8)	1	(0.8)	13	(9.8)
Vomiting	2	(1.5)	1	(0.8)	1	(0.8)	0	–	0	–	2	(1.5)	4	(3.0)	0	–	1	(0.8)	2	(1.5)	13	(9.8)
Allergic reaction	0	–	3	(2.3)	0	–	2	(1.5)	3	(2.3)	0	–	2	(1.5)	1	(0.8)	0	–	0	–	11	(8.3)
Fever	0	–	1	(0.8)	1	(0.8)	1	(0.8)	3	(2.3)	3	(2.3)	0	–	0	–	0	–	2	(1.5)	11	(8.3)
Sinusitis	1	(0.8)	3	(2.3)	1	(0.8)	0	–	0	–	3	(2.3)	2	(1.5)	0	–	0	–	1	(0.8)	11	(8.3)
Emotional lability	0	–	0	–	0	–	1	(0.8)	4	(3.0)	2	(1.5)	0	–	3	(2.3)	0	–	0	–	10	(7.5)
Nervousness	4	(3.0)	2	(1.5)	1	(0.8)	0	–	1	(0.8)	2	(1.5)	0	–	0	–	0	–	0	–	10	(7.5)
Diarrhea	4	(3.0)	0	–	1	(0.8)	0	–	0	–	2	(1.5)	0	–	1	(0.8)	0	–	1	(0.8)	9	(6.8)
Dyspepsia	0	–	2	(1.5)	0	–	3	(2.3)	0	–	2	(1.5)	0	–	0	–	2	(1.5)	0	–	9	(6.8)
Insomnia	3	(2.3)	4	(3.0)	0	–	0	–	0	–	2	(1.5)	0	–	0	–	0	–	0	–	9	(6.8)
Albuminuria	0	–	0	–	0	–	2	(1.5)	2	(1.5)	0	–	3	(2.3)	0	–	0	–	1	(0.8)	8	(6.0)
Hyperkinesia	2	(1.5)	0	–	1	(0.8)	1	(0.8)	2	(1.5)	0	–	2	(1.5)	0	–	0	–	0	–	8	(6.0)
Somnolence	2	(1.5)	2	(1.5)	0	–	0	–	0	–	1	(0.8)	2	(1.5)	0	–	0	–	0	–	7	(5.3)
Weight gain	1	(0.8)	0	–	0	–	0	–	0	–	0	–	4	(3.0)	0	–	1	(0.8)	1	(0.8)	7	(5.3)

Source: Table 15.1.6.1.X, Section 12; Listing 15.1.1, Appendix D

* No adverse events fell in the post-Week 24 time interval

Table continues

Table 30 (Continued) Number (%) of Acute-study Placebo Patients with the Most Frequent (≥5%) Open-label Treatment Phase-emergent Adverse Events by Time of First Occurrence (ITT Population)

	Time of First Occurrence (Week) *																			
Acute Study	**1**		**2**		**3**		**4**		**6**		**8**		**12**		**16**		**20**		**24**		**Total**	
Treatment Group	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Placebo (N = 130)																						
Headache	6	(4.6)	4	(3.1)	3	(2.3)	2	(1.5)	2	(1.5)	5	(3.8)	1	(0.8)	2	(1.5)	1	(0.8)	1	(0.8)	27	(20.8)
Respiratory disorder	5	(3.8)	2	(1.5)	3	(2.3)	2	(1.5)	6	(4.6)	3	(2.3)	1	(0.8)	0	–	4	(3.1)	0	–	26	(20.0)
Infection	1	(0.8)	4	(3.1)	2	(1.5)	0	–	2	(1.5)	2	(1.5)	4	(3.1)	2	(1.5)	0	–	0	–	17	(13.1)
Trauma	2	(1.5)	1	(0.8)	1	(0.8)	1	(0.8)	3	(2.3)	0	–	1	(0.8)	2	(1.5)	0	–	3	(2.3)	14	(10.8)
Nervousness	3	(2.3)	0	–	4	(3.1)	1	(0.8)	3	(2.3)	1	(0.8)	1	(0.8)	0	–	0	–	0	–	13	(10.0)
Abdominal pain	2	(1.5)	3	(2.3)	3	(2.3)	0	–	0	–	1	(0.8)	0	–	3	(2.3)	0	–	0	–	12	(9.2)
Insomnia	3	(2.3)	3	(2.3)	0	–	2	(1.5)	1	(0.8)	0	–	0	–	2	(1.5)	0	–	0	–	11	(8.5)
Nausea	3	(2.3)	1	(0.8)	1	(0.8)	0	–	2	(1.5)	2	(1.5)	2	(1.5)	0	–	0	–	0	–	11	(8.5)
Pharyngitis	3	(2.3)	3	(2.3)	0	–	1	(0.8)	1	(0.8)	0	–	0	–	0	–	2	(1.5)	0	–	10	(7.7)
Asthenia	2	(1.5)	2	(1.5)	0	–	1	(0.8)	0	–	1	(0.8)	1	(0.8)	0	–	1	(0.8)	1	(0.8)	9	(6.9)
Hostility	0	–	0	–	3	(2.3)	3	(2.3)	2	(1.5)	0	–	0	–	0	–	1	(0.8)	0	–	9	(6.9)
Rhinitis	1	(0.8)	2	(1.5)	0	–	1	(0.8)	2	(1.5)	2	(1.5)	1	(0.8)	0	–	0	–	0	–	9	(6.9)
Weight gain	1	(0.8)	0	–	0	–	1	(0.8)	1	(0.8)	0	–	4	(3.1)	1	(0.8)	1	(0.8)	0	–	9	(6.9)
Decreased Appetite	4	(3.1)	1	(0.8)	0	–	0	–	1	(0.8)	1	(0.8)	0	–	0	–	0	–	0	–	7	(5.4)
Dyspepsia	2	(1.5)	1	(0.8)	2	(1.5)	0	–	0	–	1	(0.8)	1	(0.8)	0	–	0	–	0	–	7	(5.4)
Hyperkinesia	0	–	2	(1.5)	0	–	2	(1.5)	1	(0.8)	1	(0.8)	1	(0.8)	0	–	0	–	0	–	7	(5.4)

Source: Table 15.1.6.1.X, Section 12; Listing 15.1.1, Appendix D

* No adverse events fell in the post-Week 24 time interval

5.2.1.4 Dose Reductions for Open-label Treatment Phase-emergent Adverse Events

Dose reductions of 10 mg/day no more frequently than every 7 days were permitted at the discretion of the investigator. It was recommended that dose reductions were to be initiated at clinic visits. Dose reductions were permitted more than once. If the dose reduction was due to an adverse event, the patient could return to the previous dose level upon resolution of the adverse event. A summary of the number and percentage of patients with a decrease in open-label medication dose due to an open-label Treatment Phase-emergent adverse event by body system and preferred term is presented in Table 15.1.8, Section 12. Adverse events leading to dose reduction occurred with the greatest frequency in the Nervous System body system.

The number and proportion of patients whose dose of open-label study medication was decreased during the open-label Treatment Phase because of an adverse event is summarized in Table 31. Overall, 13.3% (35/263) of patients had dose reductions because of a gender-non-specific adverse event during the open-label Treatment Phase, with similar numbers of patients in both acute-study treatment groups (12.8% [17/133] of patients in the acute-study paroxetine group and 13.8% [18/130] of patients in the acute-study placebo group). The adverse events that most frequently resulted in a dose reduction in the acute-study paroxetine group were nervousness (3.8%, 5/133), hyperkinesia (3.8%, 5/133), and hostility (3.0%, 4/130). In the acute-study placebo group, the adverse events that most frequently resulted in a dose reduction were nervousness (3.8%, 5/130) and hostility (3.1%, 4/130). The proportion of patients reporting gender-non-specific open-label Treatment Phase-emergent adverse events that required dose reduction was higher in children (20.9%, 29/139) than in adolescents (10.5%, 13/124) (Table 15.1.8, Section 12). Among children, 17.9% (12/67) of patients in the acute-study paroxetine group and 23.6% (17/72) of patients in the acute-study placebo group had at least one adverse event that resulted in a dose reduction. Among adolescents, 12.1% (8/66) of patients in the acute-study paroxetine group and 8.6% (5/58) of patients in the acute-study placebo group had at least one adverse event that resulted in a dose reduction.

There were no gender-specific adverse events that resulted in a dose reduction.

Table 32 presents a listing of patients who had an adverse event identified as leading to a dose reduction. All adverse events that resulted in a dose reduction were either mild or moderate in intensity.

Table 31 Open-label Treatment Phase-emergent Adverse Events That Led to Dose Reductions by Body System and Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group					
	Paroxetine (N = 133)		Placebo (N = 130)		Total (N = 263)	
	n	(%)	n	(%)	n	(%)
Total Patients with a Dose Reduction Due to an AE *	17	(12.8)	18	(13.8)	35	(13.3)
Nervous System						
Nervousness	5	(3.8)	5	(3.8)	10	(3.8)
Hostility	4	(3.0)	4	(3.1)	8	(3.0)
Hyperkinesia	5	(3.8)	2	(1.5)	7	(2.7)
Agitation	2	(1.5)	2	(1.5)	4	(1.5)
Anxiety	2	(1.5)	2	(1.5)	4	(1.5)
Insomnia	2	(1.5)	2	(1.5)	4	(1.5)
Somnolence	2	(1.5)	1	(0.8)	3	(1.1)
Tremor	0	–	2	(1.5)	2	(0.8)
Manic reaction	1	(0.8)	0	–	1	(0.4)
Neurosis	1	(0.8)	0	–	1	(0.4)
Dyskinesia	0	–	1	(0.8)	1	(0.4)
Emotional lability	0	–	1	(0.8)	1	(0.4)
Lack of emotion	0	–	1	(0.8)	1	(0.4)
Body as a Whole	4	(3.0)	3	(2.3)	7	(2.7)
Abdominal pain	1	(0.8)	2	(1.5)	3	(1.1)
Headache	1	(0.8)	2	(1.5)	3	(1.1)
Asthenia	2	(1.5)	0	–	2	(0.8)
Digestive System	2	(1.5)	3	(2.3)	5	(1.9)
Dyspepsia	1	(0.8)	1	(0.8)	2	(0.8)
Nausea	1	(0.8)	1	(0.8)	2	(0.8)
Vomiting	1	(0.8)	1	(0.8)	2	(0.8)
Decreased appetite	0	–	1	(0.8)	1	(0.4)
Metabolic and Nutritional Disorders	0	–	3	(2.3)	3	(1.1)
Weight gain	0	–	2	(1.5)	2	(0.8)
Weight loss	0	–	1	(0.8)	1	(0.4)
Urogenital System	1	(0.8)	1	(0.8)	2	(0.8)
Urinary incontinence	1	(0.8)	1	(0.8)	2	(0.8)

Source: Table 15.1.8., Section 12; Listing 15.1.1, Appendix D
Sorted by total number of AEs within each body system
* A patient may have more than one AE that led to a dose reduction.

Table 32 Open-label Treatment Phase-emergent Adverse Events That Led to Dose Reductions by Acute-study treatment group (ITT Population)

Patient Number	Gender (M/F)	Age (Yrs)	Day of Onset *	Dose at Onset (mg/day)	AE Preferred Term (Verbatim)	Intensity	Relationship
Paroxetine							
716.005.25414	F	10	21 [102] (-25)	20	Headache (headache)	Mild	Possibly related
716.006.25420	F	14	19 [109] (-147)	20	Asthenia (daytime tiredness)	Moderate	Probably unrelated
			19 [109] (-147)	20	Anxiety (increased anxiety)	Moderate	Probably unrelated
			19 [109] (-147)	20	Insomnia (restless sleep) **	Mild	Probably unrelated
			17 [107](-149)	20	Nervousness (increased irritability)	Moderate	Probably unrelated
716.006.27177	F	9	28 [119] (-154)	30	Hyperkinesia (hyperactivity)	Moderate	Possibly related
716.013.00702	F	11	0 [43] (-195)	– †	Hyperkinesia (hyperactivity)	Moderate	Related
716.013.00704	M	9	65 [106] (-98)	30	Nervousness (irritability)	Moderate	Possibly related
716.013.00705	M	9	6 [48] (-81)	30	Asthenia (decreased energy)	Moderate	Probably unrelated
716.013.00708	F	8	1 [43] (-147)	30	Hyperkinesia (hyperactive)	Moderate	Possibly related
716.016.25448	F	11	81 [174] (-105)	30	Hyperkinesia (hyperactive)	Moderate	Possibly related
716.016.27016	F	14	89 [183] (-94)	40	Hostility (hyperactive defiant)	Moderate	Related
			89 [183] (-94)	40	Hyperkinesia (hyperactive defiant)	Moderate	Related
716.028.25962	F	15	83 [140] (-6)	40	Nausea (nausea)	Mild	Possibly related
			83 [140] (-6)	40	Vomiting (vomiting)	Mild	Possibly related
			81 [138] (-8)	40	Somnolence (sedation)	Mild	Possibly related

Source: Table 15.1.8, Section 12; Listings 13.5.1 and 13.10.1, Appendix B; Listing 15.1.1, Appendix D

* Relative to the first day of open-label study medication [relative to the first dose of paroxetine in the acute study, including acute-study taper] (relative to the last day of open-label medication, excluding taper)

** In Listing 15.1.1, AEs, patient 716.006.25420 is listed as having dose decreases for 2 episodes of insomnia. One of them has no dose at onset and no onset date, and does not appear in Table 15.1.8, Dose Decreases due to AEs (see Section 3.14.10, Data Irregularities).

† AE started on Day 0 and is not included in Table 15.1.8, Section 12 (see Section 3.14.10, Data Irregularities).

†† Dose at onset of AE was different in Listing 13.10.1, Appendix B, and Listing 15.1.4, Appendix D (see Section 13, Errata).

Table continues

Table 32 (Continued) Open-label Treatment Phase-emergent Adverse Events That Led to Dose Reductions by Acute-study treatment group (ITT Population)

Patient Number	Gender (M/F)	Age (Yrs)	Day of Onset *	Dose at Onset (mg/day)	AE Preferred Term (Verbatim)	Intensity	Relationship
Paroxetine (continued)							
716.028.25962	F	15	83 [140] (-6)	40	Nausea (nausea)	Mild	Possibly related
			83 [140] (-6)	40	Vomiting (vomiting)	Mild	Possibly related
			81 [138] (-8)	40	Somnolence (sedation)	Mild	Possibly related
716.043.27694	M	9	76 [133] (-94)	30	Hostility (anger)	Moderate	Possibly related
716.148.27658	F	10	22 [77] (-28)	30	Nervousness (restlessness)	Moderate	Possibly related
716.159.25799	M	10	36 [101] (-57)	40	Hostility (aggression)	Moderate	Possibly related
			36 [101] (-57)	40	Nervousness (irritability)	Moderate	Possibly related
716.168.27072	F	10	43 [128] (-88)	50	Hyperkinesia (hyperactivity)	Moderate	Possible related
716.168.27077	F	15	23 [110] (-31)	50	Manic reaction (mood cycling)	Moderate	Possibly related
716.172.25619	M	10	130 [192] (-45)	40	Dyspepsia (gastrointestinal upset)	Mild	Possibly related
			130 [192] (-45)	40	Agitation (psychomotor agitation, hyper)	Moderate	Possibly related
			130 [192] (-45)	40	Urinary incontinence (enuresis daily)	Moderate	Possibly related
716.180.25641	F	14	57 [119] (-49)	30	Somnolence (sedation)	Moderate	Possibly related
716.186.25992	F	15	17 [73](-162)	20	Nervousness (restlessness)	Mild	Possibly related

Source: Table 15.1.8, Section 12; Listings 13.5.1 and 13.10.1, Appendix B; Listing 15.1.1, Appendix D

* Relative to the first day of open-label study medication [relative to the first dose of paroxetine in the acute study, including acute-study taper] (relative to the last day of open-label medication, excluding taper)

** In Listing 15.1.1, AEs, patient 716.006.25420 is listed as having dose decreases for 2 episodes of insomnia. One of them has no dose at onset and no onset date, and does not appear in Table 15.1.8, Dose Decreases due to AEs (see Section 3.14.10, Data Irregularities).

† AE started on Day 0 and is not included in Table 15.1.8, Section 12 (see Section 3.14.10, Data Irregularities).

†† Dose at onset of AE was different in Listing 13.10.1, Appendix B, and Listing 15.1.4, Appendix D (see Section 13, Errata).

Table continues

Table 32 (Continued) Open-label Treatment Phase-emergent Adverse Events That Led to Dose Reductions by Acute-study treatment group (ITT Population)

Patient Number	Gender (M/F)	Age (Yrs)	Day of Onset *	Dose at Onset (mg/day)	AE Preferred Term (Verbatim)	Intensity	Relationship
Paroxetine (continued)							
716.201.00110	M	9	1 [44](-37)	30	Hostility (intermittent increased roughness with siblings/disobedience)	Moderate	Probably unrelated
			1 [44](-37)	30	Neurosis (intermittent disinhibition)	Mild	Probably unrelated
			6 [49] (-32)	30	Hostility (intermittent increased anger)	Moderate	Probably unrelated
716.205.00506	M	12	19 [78] (-155)	20	Abdominal pain (intermittent GI distress/pain)	Moderate	Possibly related
716.205.00510	M	12	5 [48] (-162)	30	Agitation (worsening anxious/agitated)	Moderate	Possibly related
			6 [49] (-161)	20	Anxiety (worsening anxious/agitated)	Moderate	Possibly related
			6 [49] (-161)	20	Insomnia (sleep disturbance)	Moderate	Possibly related
Placebo							
716.002.25443	M	11	84 (-48)	50	Weight gain (weight gain)	Moderate	Possibly related
716.005.25412	M	11	20 (-62)	30	Dyskinesia (shoulder shrug)	Mild	Possibly related
			20 (-62)	30	Tremor (tremor)	Mild	Possibly related
			20 (-62)	30	Nervousness (restless)	Moderate	Possibly related

Source: Table 15.1.8, Section 12; Listings 13.5.1 and 13.10.1, Appendix B; Listing 15.1.1, Appendix D

* Relative to the first day of open-label study medication [relative to the first dose of paroxetine in the acute study, including acute-study taper] (relative to the last day of open-label medication, excluding taper)

** In Listing 15.1.1, AEs, patient 716.006.25420 is listed as having dose decreases for 2 episodes of insomnia. One of them has no dose at onset and no onset date, and does not appear in Table 15.1.8, Dose Decreases due to AEs (see Section 3.14.10, Data Irregularities).

† AE started on Day 0 and is not included in Table 15.1.8, Section 12 (see Section 3.14.10, Data Irregularities).

†† Dose at onset of AE was different in Listing 13.10.1, Appendix B, and Listing 15.1.4, Appendix D (see Section 13, Errata).

Table continues

Table 32 (Continued) Open-label Treatment Phase-emergent Adverse Events That Led to Dose Reductions by Acute-study treatment group (ITT Population)

Patient Number	Gender (M/F)	Age (Yrs)	Day of Onset *	Dose at Onset (mg/day)	AE Preferred Term (Verbatim)	Intensity	Relationship
Placebo (continued)							
716.009.25505	M	10	98 (-81)	40	Weight gain (weight gain)	Mild	Possibly related
			98 (-81)	40	Somnolence (sleepiness)	Mild	Possibly related
716.010.25741	F	17	5 (-163)	10	Agitation (restlessness and agitation)	Moderate	Related
			19 (-149)	30	Agitation (restlessness and agitation)	Moderate	Related
			5 (-163)	10	Nervousness (restlessness and agitation)	Moderate	Related
			19 (-149)	30	Nervousness (restlessness and agitation)	Moderate	Related
716.015.27042	M	7	31 (-40)	20	Abdominal pain (stomach ache)	Moderate	Related
			31 (-40)	20	Hostility (disruptive behavior)	Mild	Related
716.016.25447	M	7	9 (-40)	20	Headache (headache)	Moderate	Possibly related
			20 (-29)	30	Hostility (aggression)	Moderate	Possibly related
716.016.25450	F	11	29 (-18)	30	Hyperkinesia (hyperactivity)	Moderate	Possibly related
716.016.27017	M	12	39 (-20)	30	Hostility (defiant)	Moderate	Related
			39 (-20)	30	Hyperkinesia (hyperactivity)	Moderate	Related
716.016.27019	M	11	48 (-45)	30	Lack of emotion (apathy)	Moderate	Related
716.020.25461	F	11	65 (-120)	50	Nervousness (irritable)	Mild	Possibly related

Source: Table 15.1.8, Section 12; Listings 13.5.1 and 13.10.1, Appendix B; Listing 15.1.1, Appendix D

* Relative to the first day of open-label study medication [relative to the first dose of paroxetine in the acute study, including acute-study taper] (relative to the last day of open-label medication, excluding taper)

** In Listing 15.1.1, AEs, patient 716.006.25420 is listed as having dose decreases for 2 episodes of insomnia. One of them has no dose at onset and no onset date, and does not appear in Table 15.1.8, Dose Decreases due to AEs (see Section 3.14.10, Data Irregularities).

† AE started on Day 0 and is not included in Table 15.1.8, Section 12 (see Section 3.14.10, Data Irregularities).

†† Dose at onset of AE was different in Listing 13.10.1, Appendix B, and Listing 15.1.4, Appendix D (see Section 13, Errata).

Table continues

Table 32 (Continued) Open-label Treatment Phase-emergent Adverse Events That Led to Dose Reductions by Acute-study treatment group (ITT Population)

Patient Number	Gender (M/F)	Age (Yrs)	Day of Onset *	Dose at Onset (mg/day)	AE Preferred Term (Verbatim)	Intensity	Relationship
Placebo (continued)							
716.027.27092	F	11	81 (-80)	40	Anxiety (increased anxiety)	Moderate	Possibly related
716.028.27683	F	11	36 (-30)	20 ††	Nausea (nausea)	Moderate	Probably unrelated
			36 (-30)	20 ††	Vomiting (vomiting)	Mild	Possibly related
716.040.27112	F	8	19 (-149)	20	Hostility (disruptive behavior)	Moderate	Unrelated
716.049.28152	M	14	48 (-126)	50	Decreased appetite (decreased appetite)	Mild	Possibly related
			164 (-10)	50	Decreased appetite (decreased appetite)	Moderate	Possibly related
			164 (-10)	50	Weight loss (weight loss)	Moderate	Possibly related
716.159.25798	F	13	106 (-69)	20	Abdominal pain (stomach aches)	Moderate	Possibly related
			106 (-69)	20	Headache (headaches)	Moderate	Possibly related
			106 (-69)	20	Insomnia (insomnia)	Mild	Possibly related
716.165.25664	M	9	109 (-18)	50	Agitation (increased agitation)	Moderate	Unrelated
716.167.25696	M	8	95 (-73)	30	Urinary incontinence (enuresis)	Mild	Possibly related
716.168.27071	M	10	53 (-11)	20	Anxiety (anxiety)	Moderate	Possibly related
			53 (-11)	20	Nervousness (irritability)	Moderate	Possibly related

Source: Table 15.1.8, Section 12; Listings 13.5.1 and 13.10.1, Appendix B; Listing 15.1.1, Appendix D

* Relative to the first day of open-label study medication [relative to the first dose of paroxetine in the acute study, including acute-study taper] (relative to the last day of open-label medication, excluding taper)

** In Listing 15.1.1, AEs, patient 716.006.25420 is listed as having dose decreases for 2 episodes of insomnia. One of them has no dose at onset and no onset date, and does not appear in Table 15.1.8, Dose Decreases due to AEs (see Section 3.14.10, Data Irregularities).

† AE started on Day 0 and is not included in Table 15.1.8, Section 12 (see Section 3.14.10, Data Irregularities).

†† Dose at onset of AE was different in Listing 13.10.1, Appendix B, and Listing 15.1.4, Appendix D (see Section 13, Errata).

Table continues

Table 32 (Continued) Open-label Treatment Phase-emergent Adverse Events That Led to Dose Reductions by Acute-study treatment group (ITT Population)

Patient Number	Gender (M/F)	Age (Yrs)	Day of Onset *	Dose at Onset (mg/day)	AE Preferred Term (Verbatim)	Intensity	Relationship
Placebo (continued)							
716.170.25634	F	10	45 (-99)	30	Tremor (hand shaking)	Moderate	Related
			45 (-99)	30	Tremor (hand tremors)	Moderate	Possibly related
716.176.27174	M	7	39 (-50)	40	Nervousness (restless)	Moderate	Possibly related
716.179.25922	M	10	24 (-144)	30	Dyspepsia (upset stomach)	Mild	Probably unrelated
			11 (-157)	20	Insomnia (insomnia)	Mild	Probably unrelated
716.192.25874	M	14	30 (-139)	40	Emotional lability (emotional crisis)	Moderate	Possibly related

Source: Table 15.1.8, Section 12; Listings 13.5.1 and 13.10.1, Appendix B; Listing 15.1.1, Appendix D

* Relative to the first day of open-label study medication [relative to the first dose of paroxetine in the acute study, including acute-study taper] (relative to the last day of open-label medication, excluding taper)

** In Listing 15.1.1, AEs, patient 716.006.25420 is listed as having dose decreases for 2 episodes of insomnia. One of them has no dose at onset and no onset date, and does not appear in Table 15.1.8, Dose Decreases due to AEs (see Section 3.14.10, Data Irregularities).

† AE started on Day 0 and is not included in Table 15.1.8, Section 12 (see Section 3.14.10, Data Irregularities).

†† Dose at onset of AE was different in Listing 13.10.1, Appendix B, and Listing 15.1.4, Appendix D (see Section 13, Errata).

The proportion of patients reporting gender-non-specific open-label Treatment Phase-emergent adverse events that required dose reduction was slightly higher in patients with a primary diagnosis of OCD (18.1%, 21/116) than in patients with a primary diagnosis of MDD (14.3%, 21/147) (Table 15.1.8, Section 12). Among patients with a primary diagnosis of MDD, 16.0% (13/81) of patients in the acute-study paroxetine group and 12.1% (8/66) of patients in the acute-study placebo group had at least one adverse event that resulted in a dose reduction. Among patients with a primary diagnosis of OCD, 13.5% (7/52) of patients in the acute-study paroxetine group and 21.9% (14/64) of patients in the acute-study placebo group had at least one adverse event that resulted in a dose reduction.

5.2.2 Taper and/or Follow-up Phase-emergent Adverse Events

During the Taper Phase, open-label study medication was reduced by 10 mg/day every week for a period of up to 4 weeks for patients who completed the open-label Treatment Phase or were prematurely withdrawn at a dose of ≥20 mg/day. Patients completing or withdrawing at 10 mg/day did not enter the Taper Phase. Patients completing or withdrawing at ≥20 mg/day commenced Taper Phase dosing at a dose of 10 mg/day below the dose of their final open-label Treatment Phase dose (see Section 3.5.3, Dosage and Administration). All patients, whether or not they completed the open-label study and whether or not they required down-titration, were scheduled to return for a Follow-up Visit 14 days (± 3 days) after the last dose of open-label study medication, including taper.

The number and percentage of patients with emergent adverse events during the combined Taper Phase and Follow-up Phase are summarized in Tables 15.1.1.5, Section 12 (by body system and preferred term), and 15.1.1.5.X, Section 12 (by preferred term occurring in 1% or more of the population in descending order). Per-patient details may be found in Listing 15.1.2, Appendix D.

Of the 263 patients in the open-label Treatment Phase, 67 (25.5%) entered the Taper Phase: 23.3% (31/133) of the acute-study paroxetine patients and 27.7% (36/130) of the acute-study placebo patients. A total of 139 patients (52.9%) entered the Follow-up Phase: 54.1% (72/133) of the acute-study paroxetine patients and 51.5% (67/130) of the acute-study placebo patients. A total of 156 patients (59.3%) entered the Taper Phase and/or the Follow-up Phase: 58.6% (78/133) of the acute-study paroxetine patients and 60.0% (78/130) of the acute-study placebo patients.

A summary of the most frequent (incidence ≥2% in the total population or in either acute-study treatment group) gender-non-specific Taper Phase or Follow-up

Phase-emergent adverse events regardless of treatment attribution by acute-study treatment group are presented in Table 33. Overall, 34.6% (54/156) of patients reported a gender-non-specific adverse event during the Taper Phase or Follow-up Phase. The proportion of patients reporting at least one gender-non-specific adverse event during the Taper Phase or Follow-up Phase was higher in the acute-study paroxetine group (41.0%, 32/78) than in the acute-study placebo group (28.2%, 22/78). The most common (≥5%) gender-non-specific adverse events for patients in the acute-study paroxetine group were headache, respiratory disorder, and abdominal pain; in the acute-study placebo group, only respiratory disorder occurred in ≥5% of patients.

No gender-specific adverse events were reported in either acute-study treatment group during the Taper Phase and/or Follow-up Phase.

Table 33 Number (%) of Patients with the Most Frequent (≥2% in the Total Population or in Either Acute-study Treatment Group) Taper or Follow-up Phase-emergent Adverse Events by Acute-study Treatment Group (ITT Population Entering the Taper or Follow-up Phase)

	Acute-study Treatment Group					
	Paroxetine (N = 78)		Placebo (N = 78)		Total (N = 156)	
AE Preferred Term	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least One AE	32	(41.0)	22	(28.2)	54	(34.6)
Headache	6	(7.7)	3	(3.8)	9	(5.8)
Respiratory disorder	5	(6.4)	4	(5.1)	9	(5.8)
Abdominal pain	4	(5.1)	0	–	4	(2.6)
Nausea	1	(1.3)	3	(3.8)	4	(2.6)
Sinusitis	3	(3.8)	0	–	3	(1.9)
Depression	2	(2.6)	1	(1.3)	3	(1.9)
Fever	2	(2.6)	1	(1.3)	3	(1.9)
Diarrhea	1	(1.3)	2	(2.6)	3	(1.9)
Infection	0	–	3	(3.8)	3	(1.9)
Neurosis	2	(2.6)	0	–	2	(1.3)
Tooth disorder	2	(2.6)	0	–	2	(1.3)

Source: Table 15.1.1.5.X, Section 12; Listing 15.1.2, Appendix D
N = number of patients entering the Taper Phase or Follow-up Phase
Sorted by decreasing frequency in the total group

5.2.2.1 Taper Phase-emergent Adverse Events

The number and percentage of patients with emergent adverse events during the Taper Phase are summarized in Tables 15.1.1.2, Section 12 (by body system and preferred term), and 15.1.1.2.X, Section 12 (by preferred term occurring in 1% or more of the population in descending order).

A summary of gender-non-specific Taper Phase-emergent adverse events regardless of treatment attribution is presented by acute-study treatment group in Table 34. Overall, 31.3% (21/67) of patients who entered the Taper Phase reported a gender-non-specific adverse event during the Taper Phase. The proportion of patients reporting at least one gender-non-specific adverse event during the Taper Phase was slightly higher in the acute-study paroxetine group (35.5%, 11/31) than the acute-study placebo group (27.8%, 10/36). The only adverse event reported by more than one patient in either acute-study treatment group was depression, reported by two patients in the acute-study paroxetine group with a primary diagnosis of MDD (716.172.25619 and 716.176.25795) and one patient in the acute-study placebo group with a primary diagnosis of MDD (716.028.27683).

No gender-specific adverse events were reported during the Taper Phase.

Three adverse events emerged during the Taper Phase that had not occurred in either treatment group during the open-label Treatment Phase (Tables 15.1.1.1, 15.1.1.1.X, 15.1.1.2 and 15.1.1.2.X, Section 12; Listing 15.1.2, Appendix D):

- Patient 716.006.25420, a 14-year-old female in the acute-study paroxetine group, had bradycardia (pulse 62 bpm) 1 day after the last dose of open-label study medication in the open-label Treatment Phase. The value was not of potential clinical concern (<55 or >110). This event, which lasted 29 days, was considered by the investigator to be moderate in intensity and possibly related to study medication. The event occurred after 166 days of open-label medication and 90 days of acute-study treatment and taper medication (i.e., after a total of 256 days paroxetine exposure).

- Patient 716.179.25922, a 10-year-old male in the acute-study placebo group, had hysteria 7 days after the last dose of open-label study medication in the open-label Treatment Phase. This event, which lasted 5 days, was considered by the investigator to be moderate in intensity and probably unrelated to study medication. The event occurred after 175 days of open-label treatment (including taper).

- Patient 716.176.27678, a 9-year-old male in the acute-study placebo group, experienced puncture site pain (verbatim: allergy testing discomfort) 10 days after the last dose of open-label study medication in the open-label Treatment Phase. This event, which lasted 1 day, was considered by the investigator to be moderate in intensity and unrelated to study medication. The event occurred after 178 days of open-label treatment (including taper).

Table 34 Number (%) of Patients with Taper Phase-emergent Adverse Events by Acute-study Treatment Group (ITT Population Entering the Taper Phase)

	Acute-study Treatment Group					
	Paroxetine (N = 31)		Placebo (N = 36)		Total (N = 67)	
AE Preferred Term	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least One AE	11	(35.5)	10	(27.8)	21	(31.3)
Depression	2	(6.5)	1	(2.8)	3	(4.5)
Headache	1	(3.2)	1	(2.8)	2	(3.0)
Weight gain	1	(3.2)	1	(2.8)	2	(3.0)
Abdominal pain	1	(3.2)	0	–	1	(1.5)
Bradycardia	1	(3.2)	0	–	1	(1.5)
Dyspepsia	1	(3.2)	0	–	1	(1.5)
Fever	1	(3.2)	0	–	1	(1.5)
Hostility	1	(3.2)	0	–	1	(1.5)
Leukopenia	1	(3.2)	0	–	1	(1.5)
Neurosis	1	(3.2)	0	–	1	(1.5)
Respiratory disorder	1	(3.2)	0	–	1	(1.5)
Sinusitis	1	(3.2)	0	–	1	(1.5)
Abnormal dreams	0	–	1	(2.8)	1	(1.5)
Hysteria	0	–	1	(2.8)	1	(1.5)
Infection	0	–	1	(2.8)	1	(1.5)
Insomnia	0	–	1	(2.8)	1	(1.5)
Myalgia	0	–	1	(2.8)	1	(1.5)
Nausea	0	–	1	(2.8)	1	(1.5)
Puncture site pain	0	–	1	(2.8)	1	(1.5)
Somnolence	0	–	1	(2.8)	1	(1.5)
Syncope	0	–	1	(2.8)	1	(1.5)
Withdrawal syndrome	0	–	1	(2.8)	1	(1.5)

Source: Table 15.1.1.2, Section 12; Listing 15.1.2, Appendix D
N = number of patients entering the Taper Phase
Sorted by decreasing frequency in the total group

The number and percentage of patients with related or possibly related Taper Phase-emergent adverse events are summarized by body system and preferred term in Table 15.1.4.2, Section 12.

A summary of gender-non-specific Taper Phase-emergent adverse events that were judged by the investigator to be related or possibly related to open-label study medication is presented in Table 35 by acute-study treatment group. Overall, 14.9% (10/67) of patients who entered the Taper Phase reported a gender-non-specific adverse event judged by the investigator to be related or possibly related to open-label study medication during the Taper Phase: 16.1% (5/31) of patients in the acute-study paroxetine group and 13.9% (5/36) of patients in the acute-study placebo group. Weight gain was the only related or possibly related adverse event reported during the taper phase by more than one patient, one in each acute-study treatment group.

Table 35 Number (%) of Patients with Related or Possibly Related Taper Phase-emergent Adverse Events by Acute-study Treatment Group (ITT Population Entering the Taper Phase)

	Acute-study Treatment Group					
	Paroxetine (N = 31)		Placebo (N = 36)		Total (N = 67)	
AE Preferred Term	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least One Related or Possibly Related AE	5	(16.1)	5	(13.9)	10	(14.9)
Weight gain	1	(3.2)	1	(2.8)	2	(3.0)
Bradycardia	1	(3.2)	0	–	1	(1.5)
Depression	1	(3.2)	0	–	1	(1.5)
Hostility	1	(3.2)	0	–	1	(1.5)
Leukopenia	1	(3.2)	0	–	1	(1.5)
Myalgia	0	–	1	(2.8)	1	(1.5)
Nausea	0	–	1	(2.8)	1	(1.5)
Somnolence	0	–	1	(2.8)	1	(1.5)
Syncope	0	–	1	(2.8)	1	(1.5)
Withdrawal syndrome	0	–	1	(2.8)	1	(1.5)

Source: Table 15.1.4.2, Section 12; Listing 15.1.2, Appendix D
N = number of patients entering the Taper Phase
Sorted by decreasing frequency in the total group

The number and percentage of patients with emergent adverse events during the Taper Phase by intensity are summarized in Tables 15.1.3.2, Section 12 (by body system and preferred term), and 15.1.3.2.X, Section 12 (by preferred term occurring in 1% or more of the population in descending order). In addition, Taper Phase-emergent adverse events are summarized by maximum intensity by body system and preferred term in Table 15.1.7.2, Section 12. Two patients in the acute-study paroxetine group and one patient in the acute-study placebo group had a Taper Phase-emergent adverse event that was considered severe by the investigator (Tables 15.1.3.2 and 15.1.3.2.X, Section 12; Listing 15.1.2, Appendix D). All were considered by the investigator to be unrelated to study medication:

- Patient 716.172.25619, a 10-year-old male in the acute-study paroxetine group, had a fever 1 day after the last dose of open-label study medication in the open-label Treatment Phase. The event lasted 1 day. The event occurred after 176 days of open-label medication (including taper) and 62 days of acute-study treatment and taper medication (i.e., after a total of 238 days paroxetine exposure).

- Patient 716.176.27164, an 11-year-old male in the acute-study paroxetine group, had neurosis (re-emergence of OCD symptoms) 4 days after the last dose of open-label study medication in the open-label Treatment Phase. The event lasted 25 days. The event occurred after 171 days of open-label medication and 97 days of acute-study treatment and taper medication (i.e., after a total of 268 days paroxetine exposure).

- Patient 716.002.25443, an 11-year-old male in the acute-study placebo group, had an infection (Strep throat) on Day 1 and Day 20 after the last dose of open-label study medication in the open-label Treatment Phase. The events occurred after 133 and 152 days, respectively, of open-label treatment (including taper) and lasted 10 and 11 days, respectively.

The number and percentage of patients with emergent adverse events during the combined open-label Treatment Phase and Taper Phase are summarized in Table 15.1.1.3, Section 12 (by body system and preferred term) and Table 15.1.1.3.X, Section 12 (by preferred term occurring in 1% or more of the population in descending order). The number and percentage of patients with related or possibly related open-label Treatment Phase or Taper Phase-emergent adverse events are summarized by body system and preferred term in Table 15.1.4.3, Section 12. The number and percentage of patients with emergent adverse events during the open-label Treatment Phase or Taper Phase by intensity are summarized in Table 15.1.3.3, Section 12, and by maximum intensity in Table 15.1.7.3, Section 12.

5.2.2.2 Follow-up Phase-emergent Adverse Events

The number and percentage of patients with emergent adverse events during the Follow-up Phase are summarized in Tables 15.1.1.4, Section 12 (by body system and preferred term), and 15.1.1.4.X, Section 12 (by preferred term occurring in 1% or more of the population in descending order).

A summary of gender-non-specific Follow-up Phase-emergent adverse events regardless of treatment attribution is presented by acute-study treatment group in Table 36. Overall, 28.8% (40/139) of patients who entered the Follow-up Phase reported a gender-non-specific adverse event during the Follow-up Phase. The proportion of patients reporting at least one gender-non-specific adverse event during the Follow-up Phase was 34.7% (25/72) of patients in the acute-study paroxetine group compared to 22.4% (15/67) of patients in the acute-study placebo group. Adverse events reported by more than one patient in the acute-study paroxetine group were headache, respiratory disorder, abdominal pain, sinusitis, and tooth disorder. Adverse events reported by more than one patient in the acute-study placebo group were respiratory disorder, headache, diarrhea, nausea, and infection.

Table 36 Number (%) of Patients with Follow-up Phase-emergent Adverse Events by Acute-study Treatment Group (ITT Population Entering the Follow-up Phase)

	Acute-study Treatment Group					
	Paroxetine (N = 72)		Placebo (N = 67)		Total (N = 139)	
AE Preferred Term	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least One AE	25	(34.7)	15	(22.4)	40	(28.8)
Respiratory disorder	4	(5.6)	4	(6.0)	8	(5.8)
Headache	5	(6.9)	2	(3.0)	7	(5.0)
Abdominal pain	3	(4.2)	0	–	3	(2.2)
Diarrhea	1	(1.4)	2	(3.0)	3	(2.2)
Nausea	1	(1.4)	2	(3.0)	3	(2.2)
Sinusitis	2	(2.8)	0	–	2	(1.4)
Tooth disorder	2	(2.8)	0	–	2	(1.4)
Concentration impaired	1	(1.4)	1	(1.5)	2	(1.4)
Cough increased	1	(1.4)	1	(1.5)	2	(1.4)
Fever	1	(1.4)	1	(1.5)	2	(1.4)
Vomiting	1	(1.4)	1	(1.5)	2	(1.4)
Infection	0	–	2	(3.0)	2	(1.4)
Albuminuria	1	(1.4)	0	–	1	(0.7)
Anxiety	1	(1.4)	0	–	1	(0.7)
Asthma	1	(1.4)	0	–	1	(0.7)
Colitis	1	(1.4)	0	–	1	(0.7)
Depression	1	(1.4)	0	–	1	(0.7)
Dizziness	1	(1.4)	0	–	1	(0.7)
Ear pain	1	(1.4)	0	–	1	(0.7)
Emotional lability	1	(1.4)	0	–	1	(0.7)
Gastrointestinal disorder	1	(1.4)	0	–	1	(0.7)
Increased appetite	1	(1.4)	0	–	1	(0.7)
Insomnia	1	(1.4)	0	–	1	(0.7)
Migraine	1	(1.4)	0	–	1	(0.7)

Source: Table 15.1.1.4, Section 12; Listing 15.1.2, Appendix D
N = number of patients entering the Follow-up Phase
Sorted by decreasing frequency in the total group
* Patient 716.028.27685 had a verbatim of elevated liver enzymes, with a preferred term of SGOT increased. Patient 716.006.25418 also had a verbatim of elevated liver enzymes, with a preferred term of Liver function tests abnormal. See Section 3.14.10, Data Irregularities.

Table continues

Table 36 (Continued) Number (%) of Patients with Follow-up Phase-emergent Adverse Events by Acute-study Treatment Group (ITT Population Entering the Follow-up Phase)

	Acute-study Treatment Group					
	Paroxetine		Placebo		Total	
	(N = 72)		(N = 67)		(N = 139)	
AE Preferred Term	n	(%)	n	(%)	n	(%)
Myalgia	1	(1.4)	0	–	1	(0.7)
Nervousness	1	(1.4)	0	–	1	(0.7)
Neurosis	1	(1.4)	0	–	1	(0.7)
Pain	1	(1.4)	0	–	1	(0.7)
Paresthesia	1	(1.4)	0	–	1	(0.7)
Pharyngitis	1	(1.4)	0	–	1	(0.7)
Withdrawal syndrome	1	(1.4)	0	–	1	(0.7)
Allergic reaction	0	–	1	(1.5)	1	(0.7)
Fecal incontinence	0	–	1	(1.5)	1	(0.7)
Fungal dermatitis	0	–	1	(1.5)	1	(0.7)
Hostility	0	–	1	(1.5)	1	(0.7)
Liver function tests abnormal *	0	–	1	(1.5)	1	(0.7)
Lymphocytosis	0	–	1	(1.5)	1	(0.7)
SGOT increased *	0	–	1	(1.5)	1	(0.7)
Urinary incontinence	0	–	1	(1.5)	1	(0.7)

Source: Table 15.1.1.4, Section 12; Listing 15.1.2, Appendix D
N = number of patients entering the Follow-up Phase
Sorted by decreasing frequency in the total group
Sorted by decreasing frequency in the total group
* Patient 716.028.27685 had a verbatim of elevated liver enzymes, with a preferred term of SGOT increased. Patient 716.006.25418 also had a verbatim of elevated liver enzymes, with a preferred term of Liver function tests abnormal. See Section 3.14.10, Data Irregularities.

No gender-specific adverse events were reported during the Follow-up Phase.

Four patients had five adverse events during the Follow-up Phase that had not occurred during the open-label Treatment Phase or Taper Phase (Tables 15.1.1.3 and 15.1.1.4, Section 12; Listing 15.1.2, Appendix D):

- Patient 716.205.00510, a 12-year-old male in the acute-study paroxetine group, had colitis (verbatim: irritable bowel syndrome) 11 days after the last dose of open-label study medication (the patient did not take taper mediation). The duration of open-label treatment was 164 days. The

patient had taken paroxetine for 43 days during the acute study, including taper (i.e., after a total of 207 days paroxetine exposure). This event, which remained ongoing, was considered by the investigator to be mild in intensity and probably unrelated to study medication.

- Patient 716.167.25696, an 8-year-old male in the acute-study placebo group, had lymphocytosis (verbatim: high lymphocytes) 14 days after the last dose of open-label study medication (the patient did not take taper mediation). The duration of open-label treatment was 168 days. This event, which lasted 6 days, was considered by the investigator to be moderate in intensity and possibly related to study medication. Absolute lymphocyte values were 13 x 10^9/L (reference range 0.85 to 4.10 x 10^9/L). This value is not reported in Listing 15.3.1, Appendix D, or Tables 15.3.1.3 or 15.3.1.4, Section 12 (see Section 13, Errata). A narrative for this patient can be located in Table 15.0, Section 12.

- Patient 716.028.27685, a 10-year-old female in the acute-study placebo group, discontinued study medication for an unspecified adverse event on Day 35 (see Section 13, Errata). The patient had fecal incontinence (verbatim: incontinence, stool, urine) 8 days after the last dose of open-label study medication (the patient did not take taper mediation). This event, which lasted 12 days, was considered by the investigator to be mild in intensity and unrelated to study medication. On the same day, the patient had increased SGOT levels (verbatim: elevated liver enzymes); SGOT (AST) was 51 IU/L (reference range 0-42 IU/L) and alkaline phosphatase was 432 IU/L (reference range 60-415 IU/L). The adverse event lasted 177 days and was considered by the investigator to be moderate in intensity and possibly related to study medication.

- Patient 716.055.28172, a 9-year-old male in the acute-study placebo group, had fungal dermatitis (verbatim: tinea capitis on neck and head) 9 days after the last dose of open-label study medication (the patient did not take taper mediation). This event, which remained ongoing, was considered by the investigator to be moderate in intensity and unrelated to study medication. The patient had withdrawn from the study after 38 days due to a protocol violation, including non-compliance.

The number and percentage of patients with related or possibly related Follow-up Phase-emergent adverse events are summarized by body system and preferred term in Table 15.1.4.4, Section 12.

A summary of gender-non-specific Follow-up Phase-emergent adverse events that were judged by the investigator to be related or possibly related to open-label study medication is presented by acute-study treatment group in Table 37. Overall, 9.4% (13/139) of patients who entered the Follow-up Phase had a gender-non-specific adverse event judged by the investigator to be related or possibly related to open-label study medication during the Follow-up Phase: 11.1% (8/72) of patients in the acute-study paroxetine group and 7.5% (5/67) of patients in the acute-study placebo group. The only related or possibly related adverse event reported during the Follow-up Phase by more than one patient in either acute-study treatment group was headache (2 patients in each group).

Table 37 Number (%) of Patients with Related or Possibly Related Follow-up Phase-emergent Adverse Events by Acute-study Treatment Group (ITT Population Entering the Follow-up Phase)

	Acute-study Treatment Group					
	Paroxetine (N = 72)		Placebo (N = 67)		Total (N = 139)	
AE Preferred Term	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Total Patients with at Least One AE	8	(11.1)	5	(7.5)	13	(9.4)
Headache	2	(2.8)	2	(3.0)	4	(2.9)
Anxiety	1	(1.4)	0	–	1	(0.7)
Concentration impaired	1	(1.4)	0	–	1	(0.7)
Dizziness	1	(1.4)	0	–	1	(0.7)
Increased appetite	1	(1.4)	0	–	1	(0.7)
Insomnia	1	(1.4)	0	–	1	(0.7)
Myalgia	1	(1.4)	0	–	1	(0.7)
Nervousness	1	(1.4)	0	–	1	(0.7)
Neurosis	1	(1.4)	0	–	1	(0.7)
Paresthesia	1	(1.4)	0	–	1	(0.7)
Respiratory disorder	1	(1.4)	0	–	1	(0.7)
Withdrawal syndrome	1	(1.4)	0	–	1	(0.7)
Liver function tests abnormal *	0	–	1	(1.5)	1	(0.7)
Lymphocytosis	0	–	1	(1.5)	1	(0.7)
SGOT increased *	0	–	1	(1.5)	1	(0.7)

Source: Table 15.1.4.4, Section 12; Listing 15.1.2, Appendix D
N = number of patients entering the Follow-up Phase
Sorted by decreasing frequency in the total group
* Patient 716.028.27685 had a verbatim of elevated liver enzymes, with a preferred term of SGOT increased. Patient 716.006.25418 also had a verbatim of elevated liver enzymes, with a preferred term of Liver function tests abnormal. See Section 3.14.10, Data Irregularities.

The number and percentage of patients with emergent adverse events during the Follow-up Phase by intensity are summarized in Tables 15.1.3.4, Section 12 (by body system and preferred term) and 15.1.3.4.X, Section 12 (by preferred term occurring in 1% or more of the population in descending order). In addition, Follow-up Phase-emergent adverse events are summarized by maximum intensity by body system and preferred term in Table 15.1.7.4, Section 12. Per-patient details may be found in Listing 15.1.2, Appendix D. In Listing 15.1.2, patient 716.026.27047 has an AE of dehydration that has a missing intensity (see Section 13, Errata).

One patient in the acute-study placebo group had a Follow-up Phase-emergent adverse event that was considered severe by the investigator. Patient 716.026.27047, a 10-year-old male, had a viral infection 1 day after the last dose of open-label study medication. This event, which lasted 7 days, was considered by the investigator to be unrelated to study medication.

5.3 Deaths

There were no deaths during the study, and no deaths have been reported since the completion of the study (Listing 15.1.5, Appendix D).

5.4 Serious Adverse Events

A serious adverse event was defined as any event that is fatal, life threatening, disabling/incapacitating or resulted in hospitalization,[3] prolonged a hospital stay or was associated with congenital abnormality, cancer or overdose (either accidental or intentional). In addition, any event that the investigator regarded as serious or that would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the study medication was documented as a serious adverse event. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug event when, based upon appropriate medical judgment, they may jeopardize the patient or patients and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Pregnancy

[3] Elective surgery or routine clinical procedures that required hospitalization but were not the result of an adverse event, and were completed without complication as planned, were not to be considered as adverse events and were to be recorded on the medical procedures page of the CRF.

was to be captured as a serious adverse event for the purpose of tracking the status of pregnancies to term; however, no pregnancies occurred during the course of the study.

The number of patients with serious adverse events emergent during the open-label Treatment Phase, Taper Phase or Follow-up Phase by body system and preferred term by primary diagnosis and acute-study treatment group is presented in Table 15.1.2.1, Section 12. Listings of patients with serious emergent adverse events during the open-label Treatment Phase, Taper Phase, Follow-up Phase or post-Follow-up Phase are provided in Listings 15.1.3.2 and 15.1.3.3, Appendix D.

The number and percentage of patients with non-fatal serious emergent adverse events during the open-label Treatment, Taper, or Follow-up Phase are presented by acute-study treatment group in Table 38. Overall, 5.7% (15/265) of patients reported at least one serious adverse event during the open-label Treatment Phase or Taper Phase or within 30 days of the last dose of open-label study medication (including taper). (Note: the total number of patients includes two patients in the acute-study paroxetine group who had no post-baseline assessments in Study 716 and thus are not included in the ITT population).

The most common serious adverse event was emotional lability, occurring in 2.3% (6/265) of patients entered into the study. Verbatim terms that coded to a preferred term of emotional lability were suicidal ideation (2 patients), attempted suicide (2 patients) and suicidal (1 patient) in the acute-study paroxetine group, and hospitalization for suicide attempt (1 patient) in the acute-study placebo group. One patient (716.013.00701) in the acute-study paroxetine group had two episodes of emotional lability; only one is counted in Table 38. No other specific SAE was experienced by more than 2 patients. Of the 18 serious adverse events reported (including both episodes of emotional lability in one patient), 14 occurred during the open-label Treatment Phase. The majority of serious adverse events were judged moderate or severe in intensity and unrelated to open-label study medication (Listings 15.1.3.2 and 15.1.3.3, Appendix D). No gender-specific serious adverse events were reported for either acute-study treatment group.

The proportion of patients reporting at least one serious adverse event was similar between the two acute-study treatment groups: 5.9% (8/135) of patients in the acute-study paroxetine group and 5.4% (7/130) of patients in the acute-study placebo group. The proportion of patients with emotional lability was higher in the acute-study paroxetine group (3.7%, 5/135) than in the acute-study placebo group (0.8%, 1/130). The number of children with serious adverse events during

the open-label Treatment, Taper, or Follow-up Phase was slightly greater (6.5%, 9/139) than adolescents (4.8%, 6/126).

Table 38 Number (%) of Patients with Non-Fatal Serious Emergent Adverse Events (Open-label Treatment Phase or Taper Phase, or within 30 Days of the Last Dose of Open-label Study Medication) by Acute-study Treatment Group (All Patients)

	Acute-study Treatment Group					
	Paroxetine		Placebo		Total	
Serious Adverse Event	(N = 135)		(N = 130)		(N = 265)	
Preferred Term	n	(%)	n	(%)	n	(%)
Total Patients with at Least One SAE *	8	(5.9)	7	(5.4)	15	(5.7)
Emotional Lability **	5	(3.7)	1	(0.8)	6	(2.3)
Depression	1	(0.7)	1	(0.8)	2	(0.8)
Hostility	1	(0.7)	1	(0.8)	2	(0.8)
Abnormal Laboratory Value	1	(0.7)	0	–	1	(0.4)
Abscess	1	(0.7)	0	–	1	(0.4)
Hallucinations	0	–	1	(0.8)	1	(0.4)
Paralysis	0	–	1	(0.8)	1	(0.4)
Psychosis	0	–	1	(0.8)	1	(0.4)
Trauma	0	–	1	(0.8)	1	(0.4)
Asthma	0	–	1	(0.8)	1	(0.4)

Source: Table 15.1.2.1, Section 12; Listings 15.1.3.2 and 15.1.3.3, Appendix D
N = total number of patients; it includes two adolescents in the acute-study paroxetine group who did not have any post-baseline assessments in Study 716
* Serious adverse events up to 30 days after the last dose of open-label medication (including taper) are included in this summary.
** Patient 716.013.00701 in the acute-study paroxetine group had two episodes of emotional lability; only one is counted in this table

Table 39 presents a listing of all patients with serious adverse events occurring during the open-label Treatment Phase or Taper Phase, or within 30 days of the last dose of open-label study medication (including taper). One patient (716.020.25458) had an SAE of psychosis that led to withdrawal from the study. The event was reported in the interim report for this study as having led to a dose reduction (see Section 13, Errata).

Twelve of the 18 serious adverse events were considered by the investigator to be severe in intensity. None was considered related or possibly related to study medication.

Serious adverse events leading to the withdrawal of patients were emotional lability (3 patients), depression, hostility, hallucinations and psychosis (1 patient each).

Complete narratives for these patients can be located in Table 15.0, Section 12. There may be minor discrepancies in the details of the serious adverse events included in the clinical narratives compared with the safety tabulations, because the data come from two different databases and have been collected at different points in time. However, it is considered that these differences, if any, are minor in nature and do not change the overall clinical significance or understanding of the serious adverse events. In the safety tabulations, serious adverse events were coded by the WHO ART dictionary and mapped by ADECS for preferred term. In the separate database used for preparing the clinical narratives, serious adverse events were coded by the WHO ART dictionary.

Table 39 Patients with Non-Fatal Serious Adverse Events (Open-label Treatment Phase or Taper Phase, or within 30 Days of the Last Dose of Open-label Study Medication) (All Patients)

Patient Number	Gender (M/F)	Age (yrs)	Dose at Onset	SAE		Intensity	Relationship	Day of Onset *	Duration (days)
				Preferred Term	Verbatim Term				
Acute-study Paroxetine Patients									
716.004.25405	F	7	20 mg	Abscess	Left retropharyngeal abscess	Severe	Unrelated	158 [236] (-23)	8
716.013.00701	F	15	–	Emotional lability **	Suicidal ideation	Severe	Probably unrelated	24 [66] (3)	6
				Emotional lability ** †	Suicidal ideation	Mild	Probably unrelated	30 [72] (9)	6
716.014.25652	F	9	30 mg	Depression ††	Increased depression	Severe	Unrelated	108 [162] (-2)	2
			30 mg	Emotional lability ††	Suicidal ideation, held knife to chest	Severe	Unrelated	108 [162] (-2)	2
716.017.00004	M	15	40 mg	Emotional lability	Attempted suicide	Severe	Unrelated	125 [165] (-26)	3
716.025.25802	M	11	30 mg	Hostility ††	Homicidal ideation	Severe	Unrelated	42 [100] (0)	6
716.044.27656	M	12	50 mg	Emotional lability ††	Suicidal	Severe	Unrelated	39 [100] (-4)	7
716.049.28149	M	14	50 mg	Abnormal laboratory value	Unintentional overdose	Mild	Unrelated	87 [174] (-89)	1
716.201.00109	F	17	40 mg	Emotional lability ††	Suicide attempt	Severe	Unrelated	104 [147] (0)	5

Source: Table 15.1.2.1, Section 12; Listing 13.5.1, Appendix B; Listing 15.1.3.2 and 15.1.3.3, Appendix D; Table DS2, Study 715

* Relative to the first day of open-label study medication [relative to the first dose of paroxetine in the acute study, including acute-study taper] (relative to the last day of open-label medication, excluding taper)

** Serious adverse event occurred during the Taper Phase or Follow-up Phase

† Not included in Table 15.1.2.1, Section 12

†† Patient was withdrawn from Study 716 because of the serious adverse event

Table continues

Table 39 (Continued) Patients with Non-Fatal Serious Adverse Events (Open-label Treatment Phase or Taper Phase, or within 30 Days of the Last Dose of Open-label Study Medication) (All Patients)

Patient Number	Gender (M/F)	Age (yrs)	Dose at Onset	SAE (Preferred Term)	SAE (Verbatim Term)	Intensity	Relationship	Day of Onset *	Duration (days)
Acute-study Placebo Patients									
716.019.25751	M	9	20 mg	Trauma	Fractured left ulna and radius (compound fracture of left arm)	Severe	Unrelated	45 (–133)	43
716.019.25752	M	11	20 mg	Paralysis	Temporary paralysis of right leg	Severe	Unrelated	31 (-37)	1
			30 mg	Hallucinations ††	Auditory hallucinations	Moderate	Probably unrelated	68 (0)	Ongoing
716.020.25458	F	11	50 mg	Psychosis ††	Psychosis NOS	Moderate	Probably Unrelated	67 (0)	Ongoing
716.028.27683	F	11	10 mg	Depression **	Acute exacerbation of MDD	Moderate	Unrelated	77 (11)	5
716.028.27685	F	11	–	Hostility **	Aggression	Moderate	Unrelated	36 (1)	6
716.151.25607	F	16	30 mg	Emotional lability	Hospitalization for suicide attempt	Severe	Unrelated	95 (0)	3
716.176.27678	M	9	40 mg	Asthma	Worsening of asthma	Severe	Unrelated	105 (-63)	3

Source: Table 15.1.2.1, Section 12; Listing 13.5.1, Appendix B; Listing 15.1.3.2 and 15.1.3.3, Appendix D; Table DS2, Study 715

* Relative to the first day of open-label study medication [relative to the first dose of paroxetine in the acute study, including acute-study taper] (relative to the last day of open-label medication, excluding taper)

** Serious adverse event occurred during the Taper Phase or Follow-up Phase

† Not included in Table 15.1.2.1, Section 12

†† Patient was withdrawn from Study 716 because of the serious adverse event

5.5 Withdrawals Due to Adverse Events

The number of patients with emergent adverse events leading to withdrawal during the open-label Treatment Phase by body system and preferred term by primary diagnosis, age group, and acute-study treatment group is presented in Table 15.1.5.1, Section 12 (by body system and preferred term) and Table 15.1.5.1.X, Section 12 (by preferred term occurring in 1% or more of the population in descending order). Listing 15.1.4, Appendix D, provides details regarding the events, including intensity, time of occurrence relative to the start of study medication, duration and investigator assessment of relationship to study medication.

Table 40 presents a summary of the number of patients who were withdrawn for an adverse event during the open-label Treatment Phase (excluding Taper). Overall, 11.8% (31/263) of patients were withdrawn from the Treatment Phase of the study because of an adverse event emergent during the Treatment Phase.

The proportion of patients withdrawn because of an adverse event was lower in the acute-study paroxetine group (7.5%, 10/133) than in the acute-study placebo group (16.2%, 21/130). The most frequently reported AE that led to withdrawal during the open-label Treatment Phase was emotional lability in the acute-study paroxetine group (3.0%, 4/133) and hostility in the acute-study placebo group (4.6%, 6/130). The number of patients with adverse events leading to withdrawal was generally similar among children (12.9%, 18/139) and adolescents (10.5%, 13/124), and between patients with a primary diagnosis of OCD (12.9%, 15/116) than patients with a primary diagnosis of MDD (10.9%, 16/147) (Table 15.1.5.1, Section 12).

Adverse events leading to withdrawal emergent during the open-label Treatment Phase occurring in more than 1% of the population were hostility (3.4%, 9/263), emotional lability (1.9%, 5/263), hyperkinesia (1.5%, 4/263) and nervousness (1.1%, 3/263). One patient in the acute-study placebo group reported a gender-specific adverse event leading to withdrawal (libido decreased).

An additional 3 patients withdrew during the Treatment Phase for an adverse event that started during the Acute Phase of the prior study: patient 716.008.25644 (somnolence) in the acute-study paroxetine group and patients 716.015.25464 (manic reaction) and 716.010.25371 (abnormal ejaculation) in the acute-study placebo group (see Section 3.14.10, Data Irregularities). These patients are not included in Table 40 but are listed in Table 41.

An additional 2 patients were reported as withdrawing during the Taper or Follow-up Phase due to an adverse event: patient 716.010.25606 (hostility) in the acute-study paroxetine group and patient 716.176.25794 (syncope) in the acute-study placebo group. These patients also are not included in Table 40 but are listed in Table 41 (see Section 13, Errata).

Patient 716.028.27685, in the acute-study placebo group, withdrew due to an adverse event according to the investigator, but the patient is not included in Table 40 because there was no corresponding adverse event with an action of study medication stopped (Section 13, Errata).

Patient 716.019.25753, in the acute-study paroxetine group, had the reason for withdrawal reported by the investigator as "other," occurring at Week 4; however, the patient had an adverse event of vomiting for which study medication was coded "stopped." Since the AE occurred on Day 3 with a duration of 4 days, and the patient had dosing records through Day 21, it appears that the patient did not withdraw due to the AE of vomiting. Patient 716.040.27112, in the acute-study placebo group, was reported by the investigator as having completed the study; however, the patient had an adverse event of infection for which study medication was coded "stopped." Since the AE occurred on Day 100 with a duration of 2 days, and the patient had dosing records through Day 168, it appears that the patient did not withdraw due to the AE of infection (Listing 13.10.1, Appendix B; Listing 15.1.1, Appendix D). These patients are included in Table 40 but are not listed in Table 41 (see Section 13, Errata).

Patient 716.183.25901, in the acute-study placebo group, had an adverse event "decreased libido inorgasmia." The decreased libido coded to "Libido decreased," a gender-non-specific adverse event. The inorgasmia coded to "Female genital disorders," a gender- specific adverse event. These events appear separately in Table 40, but the patient is counted only once. Both events are included in Table 41 (see Section 3.14.10, Data Irregularities).

Table 40 indicates that 31 patients were withdrawn from the study due to adverse events, whereas Table 10 indicates that 35 patients were withdrawn from the study due to adverse events. This difference is due to the different data sources for these tables. Table 40 is based on Data Source Table 15.1.5.1, which includes all adverse events with a drug action coded as STP (study medication stopped). Table 10 is based on Data Source Table 13.3.1b, which is derived from a checkbox in the CRF where the investigator supplies the reason for withdrawal.

Table 40 Number (%) of Patients Withdrawn Due to an Adverse Event During the Open-label Treatment Phase (Excluding Taper) by Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group					
	Paroxetine		Placebo		Total	
Adverse Event	(N = 133)		(N = 130)		(N = 263)	
Preferred Term	n	(%)	n	(%)	n	(%)
Total Patients with an AE Leading to Withdrawal *	10	(7.5)	21	(16.2)	31	(11.8)
Hostility	3	(2.3)	6	(4.6)	9	(3.4)
Emotional lability	4	(3.0)	1	(0.8)	5	(1.9)
Hyperkinesia	1	(0.8)	3	(2.3)	4	(1.5)
Nervousness	0	–	3	(2.3)	3	(1.1)
Agitation	0	–	2	(1.5)	2	(0.8)
Anxiety	0	–	2	(1.5)	2	(0.8)
Hallucinations	0	–	2	(1.5)	2	(0.8)
Concentration impaired	1	(0.8)	0	–	1	(0.4)
Convulsion	1	(0.8)	0	–	1	(0.4)
Depression	1	(0.8)	0	–	1	(0.4)
Nausea	1	(0.8)	0	–	1	(0.4)
Vomiting **	1	(0.8)	0	–	1	(0.4)
Libido decreased †	0	–	1	(0.8)	1	(0.4)
Manic reaction	0	–	1	(0.8)	1	(0.4)
Psychosis	0	–	1	(0.8)	1	(0.4)
Asthenia	0	–	1	(0.8)	1	(0.4)
Infection ††	0	–	1	(0.8)	1	(0.4)
Bundle branch block	0	–	1	(0.8)	1	(0.4)
Female genital disorders †	0	–	1	(2.0)	1	(0.9)

Source: Table 15.1.5.1, Section 12; Listing 15.1.4, Appendix D
Sorted by total number of adverse events
Patients who withdrew for an adverse event that started before the open-label Treatment Phase or who withdrew during the Taper or Follow-up Phase are not included in this summary table.
* A patient may have more than one adverse event leading to withdrawal
** Patient 716.019.25753 had an adverse event (vomiting) with an action of study medication stopped and is therefore included in Table 15.1.5.1 as withdrawing because of an adverse event. However, according to Table 13.3.1b and Listing 13.3.1b, this patient was withdrawn for "other" reason (see Section 13, Errata).
† These events occurred as one event in Patient 716.183.25901, "decreased libido inorgasmia," which coded to two separate events (see Section 3.14.10, Data Irregularities). Percent for "Female genital disorders" is based on 51 females in the acute-study placebo group, 112 females total.
†† Patient 716.040.27112 had an adverse event (infection) with an action of study medication stopped and is therefore included in Table 15.1.5.1 as withdrawing because of an adverse event. However, according to Table 13.3.1b and Listing 13.3.1b, this patient was withdrawn for "other" reason (see Section 13, Errata).

Table 41 presents a listing of patients withdrawn because of an adverse event. The majority of the adverse events leading to withdrawal were judged by the investigator to be moderate or severe in intensity.

For 4 patients in the acute-study paroxetine group and 2 patients in the acute-study placebo group, the adverse event that resulted in withdrawal was considered a serious adverse event. Narratives for these patients can be located in Table 15.0, Section 12.

Table 41 Patients Withdrawn from Study During the Open-label Treatment or Taper Phase Because of an Adverse Event (ITT Population)

Patient Number	Gender/ Age	MDD/ OCD	Dose at Onset	AE Leading to Withdrawal Preferred Term (Verbatim Term)	Intensity	Relationship	Day of Onset *	Duration (days)
Acute-study Paroxetine Patients								
716.008.25644	M/16	MDD	20 mg	Somnolence (sedation) **	Moderate	Possibly related	-40 [16] (-58)	62
716.010.25606	F/13	MDD	10 mg †	Hostility (aggression) ††	Moderate	Possibly related	150 [210] (25)	3
716.014.25652	F/9	MDD	30 mg	Depression (increased depression) ‡	Severe	Unrelated	108 [162] (-2)	2
			30 mg	Emotional lability (suicidal ideation, held knife to chest) ‡	Severe	Unrelated	108 [162] (-2)	2
716.015.25469	M/8	OCD	30 mg	Concentration impaired (exacerbation of attention deficit hyperactivity disorder)	Mild	Related	34 [104] (-29)	Ongoing
				Hostility (exacerbation of ADHD)				Ongoing
			30 mg	Hyperkinesia (exacerbation of ADHD)	Mild	Related	34 [104] (-29)	
			30 mg		Mild	Related	34 [104] (-29)	Ongoing
716.015.27043	F/16	OCD	30 mg	Emotional lability (suicidal ideation)	Moderate	Possibly related	41 [139] (-24)	2
716.025.25802	M/11	MDD	30 mg	Hostility (homicidal ideation) ‡	Severe	Unrelated	42 [100] (0)	6
716.044.27656	M/12	MDD	50 mg	Emotional lability (suicidal) ‡	Severe	Unrelated	39 [100] (-4)	7

Source: Table 15.1.5.1, Section 12; Listing 13.5.1, Appendix B; Listing 15.1.4, Appendix D

Note: Note: Patients 716.040.27112 and 716.028.27685 (both acute-study placebo group) and 716.019.25753 (acute-study paroxetine group) are not included in this table (see Section 13, Errata).

* Relative to the first day of open-label study medication [relative to the first dose of paroxetine in the acute study] (relative to the last dose of open-label study medication, excluding taper)

** AE leading to withdrawal started during the acute study and therefore is not counted in Table 40.

† Dose at onset of AE was different in Listing 13.10.1, Appendix B, and Listing 15.1.4, Appendix D (see Section 13, Errata).

†† AE leading to withdrawal started after the last dose of Treatment Phase study medication and therefore is not counted in Table 40.

‡ AE leading to withdrawal was considered to be a serious AE.

Table continues

Table 41 (Continued) Patients Withdrawn from Study During the Open-label Treatment or Taper Phase Because of an Adverse Event (ITT Population)

Patient Number	Gender/ Age	MDD/OCD	Dose at Onset	AE Leading to Withdrawal Preferred Term (Verbatim Term)	Intensity	Relationship	Day of Onset *	Duration (days)
Acute-study Paroxetine Patients (continued)								
716.164.25721	M/14	MDD	20 mg	Nausea (nausea)	Moderate	Possibly related	85 [141] (-14)	21
716.180.25776	M/7	MDD	10 mg	Convulsion (possible seizure activity)	Moderate	Possibly related	6 [65] (-15)	26
716.201.00109	F/17	MDD	40	Emotional lability (suicide attempt) ‡	Severe	Unrelated	104 [147] (0)	5
716.201.00110	M/9	MDD	10	Hostility (Increased behavior problems)	Severe	Possibly related	30 [73](-8)	Ongoing
Acute-study Placebo Patients								
716.004.25403	M/10	OCD	20 mg	Hyperkinesia (hyperactivity)	Moderate	Possibly related	16 (-5)	Ongoing
			20 mg	Manic reaction (hypomanic symptoms)	Moderate	Possibly related	16 (-5)	Ongoing
Source: Table 15.1.5.1, Section 12; Listing 13.5.1, Appendix B; Listing 15.1.4, Appendix D								
716.006.25418	M/13	OCD	30 mg	Agitation (increased agitation)	Moderate	Possibly related	30 (-7)	Ongoing
			30 mg	Emotional lability (mood swing)	Moderate	Probably unrelated	30 (-7)	Ongoing
			30 mg	Hostility (aggression/temper outburst)	Moderate	Probably unrelated	30 (-7)	Ongoing
			30 mg	Nervousness (irritability)	Moderate	Probably unrelated	30 (-7)	Ongoing
716.010.25371	M/15	OCD	–	Abnormal ejaculation (delayed ejaculation) **	Moderate	Related	-16 (-30)	32

Note: Patients 716.019.25753 (acute-study paroxetine group) and 716.040.27112 (acute-study placebo group) are not included in this table as they had an adverse event coded as leading to withdrawal but did not withdrew from the study at that time or for that reason. Patient 716.028.27685 (acute-study placebo group) is not included in this table as no AE was coded STP (withdrawal due to an adverse event). (See Section 13, Errata.)

* Relative to the first day of open-label study medication [relative to the first dose of paroxetine in the acute study] (relative to the last dose of open-label study medication, excluding taper)

** AE leading to withdrawal started during the acute study and therefore is not counted in Table 40.

‡ Dose at onset of AE was different in Listing 13.10.1, Appendix B, and Listing 15.1.4, Appendix D (see Section 13, Errata).

†† AE leading to withdrawal started after the last dose of Treatment Phase study medication and therefore is not counted in Table 40.

‡ AE leading to withdrawal was considered to be a serious AE.

Table continues

Table 41 (Continued) Patients Withdrawn from Study During the Open-label Treatment or Taper Phase Because of an Adverse Event (ITT Population)

Patient Number	Gender/ Age	MDD/OCD	Dose at Onset	AE Leading to Withdrawal Preferred Term (Verbatim Term)	Intensity	Relationship	Day of Onset *	Duration (days)
Acute-study Placebo Patients (continued)								
716.014.25651	F/17	MDD	50 mg	Hostility (aggression anger)	Moderate	Possibly related	37 (-2)	1
716.015.25464	M/7	OCD	–	Manic reaction (manic activation) **	Related	Moderate	-18 (-53)	Ongoing
716.015.25466	M/13	OCD	50 mg	Nervousness (irritability)	Moderate	Related	44 (-12)	Ongoing
716.016.25447	M/7	OCD	20 mg	Hostility (aggression)	Severe	Possibly related	47 (-2)	8
716.016.25450	F/11	OCD	20 mg	Nervousness (irritability)	Severe	Possibly related	45 (-2)	6
716.016.27017	M/12	OCD	20 mg	Hostility (oppositional behavior)	Severe	Related	52 (-7)	10
716.016.27019	M/11	OCD	20 mg †	Hyperkinesia (hyperactivity)	Moderate	Related	90 (-3)	5
716.016.27021	M/8	OCD	20 mg	Hyperkinesia (hyperactivity)	Severe	Related	27 (-3)	8
716.019.25752	M/11	MDD	30 mg	Hallucinations (auditory hallucinations) ‡	Moderate	Probably unrelated	68 (0)	Ongoing

Source: Table 15.1.5.1, Section 12; Listing 13.5.1, Appendix B; Listing 15.1.4, Appendix D

Note: Patients 716.019.25753 (acute-study paroxetine group) and 716.040.27112 (acute-study placebo group) are not included in this table as they had an adverse event coded as leading to withdrawal but did not withdrew from the study at that time or for that reason. Patient 716.028.27685 (acute-study placebo group) is not included in this table as no AE was coded STP (withdrawal due to an adverse event). (See Section 13, Errata.)

* Relative to the first day of open-label study medication [relative to the first dose of paroxetine in the acute study] (relative to the last dose of open-label study medication, excluding taper)

** AE leading to withdrawal started during the acute study and therefore is not counted in Table 40.

‡ Dose at onset of AE was different in Listing 13.10.1, Appendix B, and Listing 15.1.4, Appendix D (see Section 13, Errata).

†† AE leading to withdrawal started after the last dose of Treatment Phase study medication and therefore is not counted in Table 40.

‡ AE leading to withdrawal was considered to be a serious AE.

Table continues

Table 41 (Continued) Patients Withdrawn from Study During the Open-label Treatment or Taper Phase Because of an Adverse Event (ITT Population)

Patient Number	Gender/ Age	MDD/ OCD	Dose at Onset	AE Leading to Withdrawal Preferred Term (Verbatim Term)	Intensity	Relationship	Day of Onset *	Duration (days)
Acute-study Placebo Patients (continued)								
716.020.25458	F/11	OCD	50 mg	Psychosis (psychosis NOS) ‡	Moderate	Probably unrelated	67 (0)	Ongoing
716.025.25822	M/7	MDD	30 mg	Agitation (increased agitation)	Moderate	Possibly related	20 (0)	18
716.025.27059	M/14	OCD	20 mg	Anxiety (anxiety increased)	Moderate	Unrelated	129 (-14)	Ongoing
716.025.27060	M/8	OCD	20 mg	Hostility (oppositional defiant)	Moderate	Unrelated	127 (-14)	Ongoing
716.043.27696	M/8	MDD	10 mg	Hostility (defiant behavior)	Severe	Unrelated	27 (-11)	24
716.044.27655	F/12	MDD	20 mg	Anxiety (post traumatic syndrome)	Severe	Unrelated	24 (-5)	Ongoing
716.047.27156	F/12	OCD	10 mg	Asthenia (fatigue)	Moderate	Possibly related	1 (-7)	10
716.165.25664	M/9	MDD	50 mg	Bundle branch block (abnormal ECG)	Mild	Unrelated	127 (0)	15
716.176.25794	M/11	MDD	30 mg	Syncope (syncope) ††	Moderate	Possibly related	62 (6)	1
716.183.25901	F/17	MDD	30 mg	Female genital disorders (inorgasmia)	Mild	Related	98 (0)	15
			30 mg	Libido decreased (decreased libido)	Mild	Related	98 (0)	15
716.192.25870	M/17	MDD	40 mg	Hallucinations (auditory hallucinations)	Severe	Unrelated	127 (-11)	Ongoing
			40 mg	Hallucinations (visual hallucinations)	Severe	Unrelated	127 (-11)	Ongoing

Source: Table 15.1.5.1, Section 12; Listing 13.5.1, Appendix B; Listing 15.1.4, Appendix D

Note: Patients 716.019.25753 (acute-study paroxetine group) and 716.040.27112 (acute-study placebo group) are not included in this table as they had an adverse event coded as leading to withdrawal but did not withdrew from the study at that time or for that reason. Patient 716.028.27685 (acute-study placebo group) is not included in this table as no AE was coded STP (withdrawal due to an adverse event). (See Section 13, Errata.)

* Relative to the first day of open-label study medication [relative to the first dose of paroxetine in the acute study] (relative to the last dose of open-label study medication, excluding taper)

** AE leading to withdrawal started during the acute study and therefore is not counted in Table 40.

‡ Dose at onset of AE was different in Listing 13.10.1, Appendix B, and Listing 15.1.4, Appendix D (see Section 13, Errata).

†† AE leading to withdrawal started after the last dose of Treatment Phase study medication and therefore is not counted in Table 40.

‡ AE leading to withdrawal was considered to be a serious AE.

5.6 Medical Procedures

Elective therapeutic, diagnostic or surgical procedures that required hospitalization but were not the result of an adverse event and were completed without complication as planned, were not to be considered as adverse events and were to be recorded on the medical procedures page of the CRF. A listing of non-medication therapeutic, diagnostic or surgical procedures performed during this study may be found in Listing 15.5.1, Appendix D.

Overall, 30 acute-study paroxetine patients (20 children and 10 adolescents) and 28 acute-study placebo patients (18 children and 10 adolescents) had at least one medical procedure. The majority of medical procedures in both treatment groups were either non-routine dental work, treatment for injury, or diagnostic procedures for concurrent adverse events.

5.7 Pregnancy

None of the female patients in Study 716 had a positive serum HCG pregnancy test at baseline, and none of the patients had a positive serum HCG pregnancy test or became pregnant during the study (Listing 15.3.2, Appendix F).

5.8 Vital Signs

5.8.1 Vital Signs of Potential Clinical Concern

Vital signs data were listed by acute-study treatment group, age group and patient number. Patient listings of vital signs data are provided in Listing 15.2.1, Appendix E. All vital signs that were assessed after the last dose of open-label study medication, even if the patient was still considered by the investigator to be on therapy (e.g., the patient came in for the Week 24 or Early Withdrawal visit one or more days after the last dose of study medication), were coded as occurring during the Follow-up Phase if the patient did not enter the Taper Phase, and as occurring during the Taper Phase if the patient did enter the Taper Phase. Vital sign assessments that occurred after the last dose of taper medication were coded as occurring during the Follow-up Phase.

The number and percentage of patients with a significant increase or decrease in any vital sign from acute-study baseline that was of potential clinical concern was tabulated by parameter by acute-study treatment group. Table 4, Section 3.14.6.2,

Vital Signs, shows these pre-defined levels of potential clinical concern for vital signs.

Summaries of the number of patients with vital signs of potential clinical concern during the open-label Treatment Phase (including taper) are provided in Table 15.2.2.1, Section 12.

A summary of the number and percentage of patients with vital sign measurements meeting the pre-defined clinical concern criteria (i.e., both an absolute value of concern and a significant increase or decrease from acute-study baseline in the same direction during the open-label Treatment, Taper, or Follow-up Phase is presented in Table 42. Overall, 55 patients had a vital sign meeting the potential clinical concern criteria during the open-label Treatment, Taper or Follow-up Phase, 34 of which were weight gain. There were no important differences between the acute-study treatment groups or age groups in the number or the type of vital signs meeting this combination of clinical concern criteria (Table 15.2.2.2, Section 12).

Of the 220 patients who had a measurement for weight at acute-study baseline and at any time during the open-label Treatment, Taper or Follow-up Phase, 15.5% (34/220) had an increase in weight that met the pre-defined clinical concern criteria: 17.0% (19/112) of patients who received paroxetine in their acute study and 13.9% (15/108) of patients who received placebo in their acute study (Table 42). Seven of these patients, 4 in the acute-study paroxetine group and 3 in the acute-study placebo group, had an increase in weight that was considered clinically significant by the investigator and recorded as an adverse event; narratives for these patients can be located in Table 15.0, Section 12.

Table 42 Number (%) of Patients with Vital Sign Values Meeting Pre-defined Clinical Concern Criteria During the Open-label Treatment, Taper, or Follow-up Phase by Acute-study Treatment Group (ITT Population)

	Acute-study Treatment Group								
Vital Sign	**Paroxetine**			**Placebo**			**Total**		
Sponsor-defined Clinical Concern Criteria	**N**	**n**	**(%)**	**N**	**n**	**(%)**	**N**	**n**	**(%)**
Total patients with a vital sign of clinical concern		29 *			26 *			55 *	
Systolic Blood Pressure (mmHg)									
>145 and increase of ≥40	130	0	–	129	2	(1.6)	259	2	(0.8)
<95 and decrease of ≥30	130	3	(2.3)	129	3	(2.3)	259	6	(2.3)
Diastolic Blood Pressure (mmHg)									
>85 and increase ≥30	130	2	(1.5)	129	2	(1.6)	259	4	(1.5)
<50 and decrease ≥20	130	3	(2.3)	129	4	(3.1)	259	7	(2.7)
Heart Rate (bpm)									
Ages 7 to 12 >115, ages 13 to 17 >110, plus increase ≥30	130	3	(2.3)	129	1	(0.8)	259	4	(1.52)
Ages 7 to 12 <65, ages 13 to 17 <55, plus decrease ≥30	130	1	(0.8)	129	3	(2.3)	259	4	(1.5)
Weight (kg)									
Above reference range † and increase ≥7%	112	19	(17.0)	108	15	(13.9)	220	34	(15.5)
Below reference range † and decrease ≥7%	112	1	(0.9)	108	0	–	220	1	(0.5)

Source: Table 15.2.2.2, Section 12; Listing 15.2.1, Appendix E

N = number of patients who had a measurement for this vital sign at acute-study baseline and at any time during the open-label Treatment, Taper or Follow-up Phase; n = number of patients meeting the pre-defined clinical concern criteria

* Some patients had more than one vital sign of potential clinical concern.

† Reference ranges for weight may be found in Table 4.

A list of patients with vital sign values meeting pre-defined clinical concern criteria during the open-label Treatment, Taper or Follow-up Phase is provided in Table 43. As shown in Table 42 and Table 43, 29 patients in the acute-study paroxetine group and 26 patients in the acute-study placebo group were identified as having a change and absolute value in one or more of the vital signs that met the criteria for clinical concern. A small number of patients had more than one vital sign flagged as meeting the criteria for clinical concern (3 patients in the acute-study paroxetine group and 4 patients in the acute-study placebo group).

In addition, 4 patients (Patient 716.015.25469 from the acute-study paroxetine group and Patients 716.015.25464, 716.016.27017, and 716.026.25817 from the acute-study placebo group) had one or more vital sign values of potential clinical concern at Study 716 Baseline. An additional 2 patients (716.004.25405 and 716.025.25805), both in the acute-study paroxetine group, had values of potential clinical concern during the Treatment Phase of the study but a repeat measurement was within normal limits. One patient in the acute-study paroxetine group (716.028.25962) had a value of potential clinical concern at a visit >14 days after the last dose of study medication, including taper. These 7 patients are included in Table 43 but not in Table 42 or Data Source Table 15.2.2.2, Section 12; details about vital signs for these patients may be found in Listing 15.2.1, Appendix E.

Table 43 Patients with Vital Sign Values Meeting Pre-defined Clinical Concern Criteria at Any Time (ITT Population)

Patient Number	Gender (M/F)	Diagnosis	Age (yrs)	Vital Sign of Concern	Acute-study Baseline Value *	Value of Concern	Visit
Acute-study Paroxetine Group							
716.002.27191	M	OCD	14	Weight high/increase **	74.9 kg (BMI 25.3)	88.6 kg (BMI 29.3)	Week 12
						96.4 kg (BMI 31.8)	Week 24
716.004.25405	F	OCD	7	Diastolic BP low/decrease	71 mmHg	42 mmHg †	Week 4
716.010.25603	M	MDD	13	Weight high/increase	56.8 kg (BMI 18.5)	69.5 kg (BMI 22.6)	Week 24
716.012.25480	M	OCD	9	Weight high/increase	69.9 kg (BMI 32.8)	77.1 kg (BMI 35.4)	Week 12
						77.5 kg (BMI 34.5)	Week 24
716.013.00707	M	MDD	8	Weight high/increase	34.4 kg (BMI 17.1)	38.1 kg (BMI 18.1)	Week 24
716.014.25652	F	MDD	9	Diastolic BP low/decrease	70 mmHg	42 mmHg	Week 16
716.014.25652	F	MDD	9	Weight high/increase	48.6 kg (BMI 27.9)	54.9 kg (BMI 28.7)	Week 12
						52.7 kg (BMI 28.0)	Week 16
716.015.25469	M	OCD	8	Pulse rate high/increase	72 bpm	120 bpm	716 Baseline ††
716.016.25448	F	OCD	11	Diastolic BP high/increase	60 mmHg	90 mmHg	Week 3
716.016.27018	F	OCD	6	Weight high/increase	30.3 kg (BMI 19.4)	37.9 kg (BMI 23.5)	Post-Week 24
716.019.25943	F	MDD	7	Pulse rate low/decrease	97 bpm	60 bpm	Week 12

Source: Table 15.2.2.2, Section 12; Listings 13.1.2, 13.5.1, Appendix B; Listing 15.2.1, Appendix E.

* For height, weight and BMI, the last pre-acute-study treatment assessment is taken to be acute-study baseline.

** An adverse event was reported in association with this vital sign value.

† Value was within normal limits at repeat testing and is not included in Table 42.

†† Value of potential clinical concern occurred at Study 716 Baseline only and is not included in Table 42.

‡ Value of concern occurred >14 days after the last dose of study medication and is not included in Table 42.

Table continues

Table 43 (Continued) Patients with Vital Sign Values Meeting Pre-defined Clinical Concern Criteria at Any Time (ITT Population)

Patient Number	Gender (M/F)	Diagnosis	Age (yrs)	Vital Sign of Concern	Acute-study Baseline Value *	Value of Concern	Visit
Acute-study Paroxetine Group (continued)							
716.025.25801	M	MDD	8	Diastolic BP low/decrease	76 mmHg	45 mmHg	Week 2
						45 mmHg	Week 8
716.025.25802	M	MDD	11	Pulse rate high/increase	96 bpm	128 bpm	Week 2
						128 bpm	Week 4
716.025.25805	F	MDD	12	Diastolic BP high/increase	59 mmHg	104 mmHg †	Week 3
716.025.25849	M	MDD	14	Diastolic BP high/increase	68 mmHg	102 mmHg	Week 20
716.026.27045	F	OCD	9	Weight high/increase	40.9 kg (BMI 18.5)	45.0 kg (BMI 20.0)	Week 12
716.028.25962	M	MDD	15	Pulse rate high/increase	68 bpm	116 bpm ‡	Week 16
716.028.25962	M	MDD	15	Weight low/decrease **	40.9 kg (BMI 19.9)	36.8 kg (BMI 18.0)	Week 12
716.043.27130	F	OCD	9	Diastolic BP low/decrease	62 mmHg	42 mmHg	Week 3
716.043.27694	M	MDD	9	Weight high/increase	39.5 kg (BMI 15.1)	44.0 kg (BMI 21.5)	Week 24
716.044.27654	M	MDD	14	Weight high/increase	65.0 kg (BMI 26.2)	78.0 kg (BMI 29.7)	Week 24
716.055.28133	F	OCD	13	Systolic BP low/decrease	125 mmHg	94 mmHg	Week 8
716.055.28137	F	OCD	10	Systolic BP low/decrease	117 mmHg	87 mmHg	Week 2

Source: Table 15.2.2.2, Section 12; Listings 13.1.2, 13.5.1, Appendix B; Listing 15.2.1, Appendix E.

* For height, weight and BMI, the last pre-acute-study treatment assessment is taken to be acute-study baseline.

** An adverse event was reported in association with this vital sign value.

† Value was within normal limits at repeat testing and is not included in Table 42.

†† Value of potential clinical concern occurred at Study 716 Baseline only and is not included in Table 42.

‡ Value of concern occurred >14 days after the last dose of study medication and is not included in Table 42.

Table continues

Table 43 (Continued) Patients with Vital Sign Values Meeting Pre-defined Clinical Concern Criteria at Any Time (ITT Population)

Patient Number	Gender (M/F)	Diagnosis	Age (yrs)	Vital Sign of Concern	Acute-study Baseline Value *	Value of Concern	Visit
Acute-study Paroxetine Group (continued)							
716.159.25626	M	MDD	13	Weight high/increase	74.5 kg (BMI 27.3)	81.8 kg (BMI 30.5)	Week 12
						82.0 kg (BMI 30.1)	Week 24
716.159.25797	F	MDD	9	Pulse rate high/increase	72 bpm	120 bpm	Week 16
716.168.25809	M	MDD	12	Weight high/increase	105.0 kg (BMI 38.6)	113.0 kg (BMI 41.5)	Week 12
						113.0 kg (BMI 41.5)	Week 24
716.168.25809	M	MDD	12	Pulse rate high/increase	74 bpm	112 bpm	Week 2
716.176.25668	F	MDD	10	Systolic BP low/decrease	122 mmHg	92 mmHg	Week 24
716.176.25668	F	MDD	10	Weight high/increase **	67.0 kg (BMI 31.0)	77.5 kg (BMI 34.9)	Week 12
						81.8 kg (BMI 34.5)	Week 24
716.176.25795	F	MDD	11	Weight high/increase **	60.0 kg (BMI 27.4)	69.0 kg (BMI 29.9)	Week 12
						72.5 kg (BMI 31.0)	Week 24
716.183.25899	F	MDD	13	Weight high/increase	66.7 kg (BMI 25.2)	74.9 kg (BMI 28.4)	Week 24
716.192.25872	M	MDD	13	Weight high/increase **	68.0 kg (BMI 20.9)	79.0 kg (BMI 24.3)	Week 24
716.205.00506	M	MDD	12	Weight high/increase	58.6 kg (BMI 24.0)	66.8 kg (BMI 25.5)	Week 24
716.205.00507	M	MDD	12	Weight high/increase	69.0 kg (BMI 25.9)	74.3 kg (BMI 26.8)	Week 24

Source: Table 15.2.2.2, Section 12; Listings 13.1.2, 13.5.1, Appendix B; Listing 15.2.1, Appendix E.

* For height, weight and BMI, the last pre-acute-study treatment assessment is taken to be acute-study baseline.

** An adverse event was reported in association with this vital sign value.

† Value was within normal limits at repeat testing and is not included in Table 42.

†† Value of potential clinical concern occurred at Study 716 Baseline only and is not included in Table 42.

‡ Value of concern occurred >14 days after the last dose of study medication and is not included in Table 42.

Table continues

Table 43 (Continued) Patients with Vital Sign Values Meeting Pre-defined Clinical Concern Criteria at Any Time (ITT Population)

Patient Number	Gender (M/F)	Diagnosis	Age (yrs)	Vital Sign of Concern	Acute-study Baseline Value *	Value of Concern	Visit
Acute-study Paroxetine Group (continued)							
716.208.00811	F	OCD	12	Weight high/increase	73.6 kg (BMI 29.7)	79.4 kg (BMI 30.6)	Week 12
716.208.00825	F	MDD	16	Weight high/increase	81.8 kg (BMI 29.7)	87.7 kg (BMI 31.3)	Week 12
						88.6 kg (BMI 31.4)	Week 24
Acute-study Placebo Group							
716.002.25439	M	OCD	14	Systolic BP high/increase	126 mmHg	168 mmHg	Week 1
716.002.25439	M	OCD	14	Weight high/increase	78.1 kg (BMI 27.3)	90.0 kg (BMI 31.1)	Week 24
716.009.25505	M	OCD	10	Pulse rate low/decrease	97 bpm	58 bpm	Week 8
716.009.25505	M	OCD	10	Diastolic BP high/increase	65 mmHg	96 mmHg	Week 24
716.010.25604	M	MDD	9	Systolic BP low/decrease	110 mmHg	80 mmHg	Week 6
716.010.27025	M	OCD	15	Weight high/increase	80.9 kg (BMI 26.3)	92.3 kg (BMI 28.4)	Week 12
						95.8 kg (BMI 31.2)	Week 24
716.014.25651	F	MDD	17	Weight high/increase	96.3 kg (BMI 31.3)	105.3 kg (BMI 34.1)	Week 6
716.014.25913	F	MDD	8	Weight high/increase	62.6 kg (BMI 33.3)	68.1 kg (BMI 31.9)	Week 24
716.015.25464	M	OCD	7	Pulse rate high/increase	88 bpm	120 bpm	716 Baseline ††

Source: Table 15.2.2.2, Section 12; Listings 13.1.2, 13.5.1, Appendix B; Listing 15.2.1, Appendix E.

* For height, weight and BMI, the last pre-acute-study treatment assessment is taken to be acute-study baseline.

** An adverse event was reported in association with this vital sign value.

† Value was within normal limits at repeat testing and is not included in Table 42.

†† Value of potential clinical concern occurred at Study 716 Baseline only and is not included in Table 42.

‡ Value of concern occurred >14 days after the last dose of study medication and is not included in Table 42.

Table continues

Table 43 (Continued) Patients with Vital Sign Values Meeting Pre-defined Clinical Concern Criteria at Any Time (ITT Population)

Patient Number	Gender (M/F)	Diagnosis	Age (yrs)	Vital Sign of Concern	Acute-study Baseline Value *	Value of Concern	Visit
Acute-study Placebo Group (continued)							
716.015.25464	M	OCD	7	Diastolic BP low/decrease	70 mmHg	40 mmHg	Week 2
						48 mmHg	Week 4
716.015.25466	M	OCD	13	Pulse rate high/increase	88 bpm	120 bpm	Week 2
716.016.25447	M	OCD	7	Weight high/increase	50.0 kg (BMI 25.1)	55.0 kg (BMI 26.2)	Week 8
716.016.27017	M	OCD	12	Weight high/increase	54.2 kg (BMI 21.3)	60.5 kg (BMI 22.5)	716 Baseline ††
716.016.27021	M	OCD	8	Systolic BP low/decrease	122 mmHg	90 mmHg	Week 3
716.019.25751	M	MDD	9	Weight high/increase	52.3 kg (BMI 28.3)	57.2 kg (BMI 27.8)	Week 24
716.025.25806	M	MDD	13	Pulse rate low/decrease	88 bpm	48 bpm	Week 24
716.025.25995	M	MDD	10	Diastolic BP high/increase	65 mmHg	98 mmHg	Week 8
716.025.27059	M	OCD	14	Weight high/increase	69.5 kg (BMI 23.0)	80.8 kg (BMI 26.1)	Week 12
						77.3 kg (BMI 24.4)	Week 20
716.025.27060	M	OCD	8	Pulse rate low/decrease	96 bpm	64 bpm	Week 1
						63 bpm	Week 2
716.026.25817	M	MDD	8	Systolic BP low/decrease	118 mmHg	79 mmHg	716 Baseline ††
716.028.27079	F	OCD	10	Weight high/increase	39.0 kg (BMI 19.6)	50.0 kg (BMI 25.1)	Week 24

Source: Table 15.2.2.2, Section 12; Listings 13.1.2, 13.5.1, Appendix B; Listing 15.2.1, Appendix E.

* For height, weight and BMI, the last pre-acute-study treatment assessment is taken to be acute-study baseline.

** An adverse event was reported in association with this vital sign value.

† Value was within normal limits at repeat testing and is not included in Table 42.

†† Value of potential clinical concern occurred at Study 716 Baseline only and is not included in Table 42.

‡ Value of concern occurred >14 days after the last dose of study medication and is not included in Table 42.

Table continues

Table 43 (Continued) Patients with Vital Sign Values Meeting Pre-defined Clinical Concern Criteria at Any Time (ITT Population)

Acute-study Placebo Group (continued)							
716.028.27683	F	MDD	11	Weight high/increase	58.6 kg (BMI 25.2)	64.5 kg (BMI 26.5)	Week 8
716.040.27112	F	OCD	8	Systolic BP low/decrease	111 mmHg	75 mmHg	Week 3
716.040.27112	F	OCD	8	Diastolic BP low/decrease	66 mmHg	42 mmHg	Week 12
716.044.27138	M	OCD	12	Weight high/increase	80.0 kg (BMI 34.2)	90.0 kg (BMI 37.5)	Post-Week 24
716.055.28136	M	OCD	13	Diastolic BP low/decrease	66 mmHg	46 mmHg	Week 4
716.151.25609	M	MDD	7	Diastolic BP low/decrease	64 mmHg	40 mmHg	Week 3
						44 mmHg	Week 4
						34 mmHg	Week 20
716.159.25628	M	MDD	12	Systolic BP high/increase	100 mmHg	150 mmHg	Week 4
716.159.25628	M	MDD	14	Weight high/increase **	95.0 kg (BMI 29.2)	109.1 kg (BMI 32.2)	Week 12
						111.8 kg (BMI 33.0)	Week 24
716.159.25629	M	MDD	12	Weight high/increase	71.8 kg (BMI 26.3)	79.5 kg (BMI 26.6)	Week 24
716.167.25903	F	MDD	12	Weight high/increase **	60.4 kg (BMI 25.6)	66.4 kg (BMI 26.8)	Week 24
716.171.25673	F	MDD	10	Weight high/increase	68.2 kg (BMI 30.4)	75.2 kg (BMI 33.0)	Week 20
716.176.27171	F	OCD	10	Weight high/increase **	104.0 kg (BMI 40.1)	112.7 kg (BMI 42.4)	Week 12
						119.8 kg (BMI 44.0)	Week 24

Source: Table 15.2.2.2, Section 12; Listings 13.1.2, 13.5.1, Appendix B; Listing 15.2.1, Appendix E.

* For height, weight and BMI, the last pre-acute-study treatment assessment is taken to be acute-study baseline.

** An adverse event was reported in association with this vital sign value.

† Value was within normal limits at repeat testing and is not included in Table 42.

†† Value of potential clinical concern occurred at Study 716 Baseline only and is not included in Table 42.

‡ Value of concern occurred >14 days after the last dose of study medication and is not included in Table 42.

If any vital signs or vital sign changes were considered clinically significant by the investigator, whether or not they met the sponsor-defined potential clinical concern criteria, they were to be recorded as adverse events in the patient's CRF. A total of 13 patients in the acute-study paroxetine group had vital sign changes during any phase of Study 716 that were considered clinically significant by the investigator and were recorded as adverse events (Tables 15.1.1.0.3 and 15.1.1.6, Section 12; Listings 15.1.1 and 15.1.2, Appendix D). Ten of these patients had weight gain, and 1 each had weight loss, bradycardia, and hypertension:

- Patient 716.002.27191, a 14-year-old male, was reported as having an AE of moderate weight gain at Study 716 Baseline, judged by the investigator to be possibly related to study medication. The patient's weight measured at acute screening (74.9 kg) and at Study 716 baseline (78.5 kg) was above the reference range (35.9 kg to 74.5 kg) but was not at a pre-defined level of potential clinical concern. The patient's weight subsequently reached a level of concern (88.6 kg at Week 12 and 96.4 kg at Week 24). The patient had taken paroxetine for 98 days during the acute study, including taper. A narrative for this patient can be located in Table 15.0, Section 12.

- Patient 716.005.25409, an 8-year-old female, was reported as having an AE of moderate weight gain at Study 716 Baseline, judged by the investigator to be possibly related to study medication. The patient's weight measured at acute screening (26.4 kg) and at Study 716 baseline (26.6 kg) was within the reference range (17.3 kg to 36.8 kg). The patient had taken paroxetine for 72 days during the acute study, including taper.

- Patient 716.006.25420, a 14-year-old female, was reported as having an adverse event of moderate bradycardia, judged by the investigator to be possibly related to study medication, on Day 167, 1 day after the last dose of open-label study medication, while taking taper medication. The patient had taken paroxetine for 90 days during the acute study, including taper (i.e., after a total of 257 days paroxetine exposure). The patient's heart rate was 60 bpm measured at acute screening and at Study 716 baseline and 62 bpm at Week 24, all within the reference range (55 to 110 bpm). All other values were also within reference range.

- Patient 716.020.25456, a 16-year-old female, was reported as having an AE of moderate weight gain, judged by the investigator to be possibly related to study medication, on Day 75 of open-label treatment. The patient had taken paroxetine for 78 days during the acute study, including taper (i.e., after a total of 153 days paroxetine exposure). The patient's

weight measured at acute screening (62.7 kg), at Week 12 (64.5 kg) and at Week 24 (71.8 kg) was within the reference range (40.9 kg to 83.1 kg).

- Patient 716.025.25921, a 7-year-old female, was reported as having an AE of mild weight gain, judged by the investigator to be possibly related to study medication, on Day 93 of open-label treatment. The patient had taken paroxetine for 57 days during the acute study, including taper (i.e., after a total of 150 days paroxetine exposure). The patient's weight, measured at acute screening (24.9 kg) and Week 12 (29.9 kg) was within the reference range (17.3 kg to 36.8 kg).

- Patient 716.028.25962, a 15-year-old female, was reported as having an AE of moderate weight loss, judged by the investigator to be unrelated to study medication, on Day 14 of open-label treatment. The patient had taken paroxetine for 57 days during the acute study, including taper (i.e., after a total of 71 days paroxetine exposure). The patient's weight, measured at Week 12 (36.8 kg) was outside the reference range (38.6 kg to 79.9 kg). The patient's weight at acute screening was 40.9 kg. This patient's vital sign value met the criteria both for absolute value of clinical concern and a decrease of ≥7% from acute-study baseline. A narrative for this patient can be located in Table 15.0, Section 12.

- Patient 716.049.28149, a 13-year-old male, was reported as having an adverse event of weight gain, judged by the investigator to be mild in intensity and possibly related to study medication, on Day 144 of open-label treatment. The patient had taken paroxetine for 87 days during the acute study, including taper (i.e., after a total of 231 days paroxetine exposure). The patient's weight, measured at acute screening (57.8 kg) and at Week 24 (66.9 kg) was within the reference range (31.8 kg to 69.5 kg). However, this patient's weight at Week 24 represented an increase ≥7% from acute-study baseline.

- Patient 716.167.25691, a 10-year-old female, was reported as having an AE of mild weight gain, judged by the investigator to be possibly related to study medication, on Day 166 of open-label treatment. The patient had taken paroxetine for 59 days during the acute study, including taper (i.e., after a total of 225 days paroxetine exposure). The patient's weight measured at acute screening (28.6 kg) and Week 24 (34.1 kg) was within the reference range (21.8 kg to 49.5 kg).

- Patient 716.176.25668, a 10-year-old female, was reported as having an AE of moderate weight gain, judged by the investigator to be possibly related to study medication, on Day 1 of open-label treatment. The patient had taken paroxetine for 56 days during the acute study, including taper (i.e., after a total of 57 days paroxetine exposure). The patient's weight measured at acute screening (67.0 kg), Study 716 baseline (73.0 kg), Week 12 (77.5 kg) and Week 24 (81.8 kg) was outside the reference range (21.8 kg to 49.5 kg). This patient's vital sign value met the criteria both for absolute value of clinical concern and an increase of ≥7% from acute-study baseline. A narrative for this patient can be located in Table 15.0, Section 12.

- Patient 716.176.25795, an 11-year-old female, was reported as having an AE of moderate weight gain, judged by the investigator to be possibly related to study medication, on Day 85 of open-label treatment. The patient had taken paroxetine for 56 days during the acute study, including taper (i.e., after a total of 141 days paroxetine exposure). The patient's weight measured at acute screening (60.0 kg), at Week 12 (69.0 kg) and Week 24 (72.5 kg) was outside the reference range (25.0 kg to 56.3 kg). This patient's vital sign value met the criteria both for absolute value of clinical concern and an increase of ≥7% from acute-study baseline. A narrative for this patient can be located in Table 15.0, Section 12.

- Patient 716.176.27173, a 13-year-old male, was reported as having an AE of moderate hypertension, judged by the investigator to be possibly related to study medication, 77 days before the start of open-label treatment, after 21 days of paroxetine in the acute study. The hypertension was continuing at Study 716 Baseline. The patient's blood pressure measured at acute screening was 120/80 and at Study 716 baseline was 130/90, with the diastolic pressure above the reference range (50 to 85 mmHg) but was not an increase from baseline of potential clinical concern (≥30 mmHg). All subsequent values were within reference range except at Week 20, when diastolic blood pressure was 88 mmHg.

- Patient 716.183.25902, a 15-year-old female, was reported as having an increase in weight, judged by the investigator to be moderate in intensity and possibly related to study medication, on Day 84 of open-label treatment. The patient had taken paroxetine for 56 days during the acute study, including taper (i.e., after a total of 140 days paroxetine exposure). The patient's weight, measured at acute screening (64.5 kg) and at Week 24 (73.6 kg) was within the reference range (38.6 kg to 79.9 kg).

However, this patient's weight at Week 24 represented an increase ≥7% from acute-study baseline.

- Patient 716.192.25872, a 13-year-old male, was reported as having an increase in weight, judged mild in intensity and possibly study related by the investigator, on Day 169 of open-label treatment. The patient had taken paroxetine for 61 days during the acute study, including taper (i.e., after a total of 230 days paroxetine exposure). The patient's weight, measured at acute screening (68.0 kg) and at Week 24 (79.0 kg) was outside the reference range (31.3 kg to 67.2 kg). This patient's vital sign value met the criteria both for absolute value of clinical concern and an increase ≥7% from acute-study baseline. A narrative for this patient can be located in Table 15.0, Section 12.

A total of 12 patients in the acute-study placebo group recorded vital sign changes during Study 716 that were considered clinically significant by the investigator and recorded as an adverse event. Ten of these patients had weight gain and 1 each had weight loss and tachycardia/palpitations:

- Patient 716.002.25443, an 11-year-old male, was reported as having an AE of moderate weight gain, judged by the investigator to be possibly related to study medication, on Day 84 and 133 of open-label treatment. The patient's weight measured at acute screening (34.9 kg), at Week 12 (39.9 kg), and at Week 24 (44.5 kg) was within the reference range (24.5 kg to 53.6 kg). The patient's paroxetine dose on Day 84 was 50 mg/day. The dose of paroxetine was reduced as a result of this adverse event.

- Patient 716.009.25505, a 10-year-old male, was reported as having an AE of mild weight gain, judged by the investigator to be possibly related to study medication, on Day 98 of open-label treatment. The patient's weight measured at acute screening (38.1 kg), at Week 12 (43.1 kg), and at Week 24 (44.0 kg) was within the reference range (21.8 kg to 47.2 kg). The patient's paroxetine dose on Day 98 was 40 mg/day. The dose of paroxetine was reduced on Day 98 as a result of this adverse event.

- Patient 716.049.28152, a 14-year-old male, was reported as having an AE of moderate weight loss, judged by the investigator to be possibly related to study medication, on Day 24, 44, and 164 of open-label treatment. The patient's weight measured at acute screening (69.1 kg) and at Week 16

(52.2 kg) was within the reference range (35.9 kg to 74.5 kg). The dose of paroxetine was reduced on Day 164 as a result of this adverse event.

- Patient 716.159.25628, a 14-year-old male, was reported as having an AE of mild weight gain, judged by the investigator to be possibly related to study medication, at the Study 716 baseline. The patient's weight measured at acute screening (95.0 kg), at Study 716 baseline (102.3 kg), and at Week 12 (109.1 kg) was outside the reference range (35.9 kg to 74.5 kg). At Week 24, the patient's weight had increased to 111.8 kg. This vital sign value met the criteria both for absolute value of clinical concern and an increase ≥7% from acute-study baseline. A narrative for this patient can be located in Table 15.0, Section 12.

- Patient 716.165.25664, a 9-year-old male, was reported as having an AE of mild weight gain, judged by the investigator to be probably unrelated to study medication, on Day 127 of open-label treatment. The patient's weight measured at acute screening (32.7 kg) and at Week 20 (38.2 kg) was within the reference range (20.0 kg to 41.8 kg).

- Patient 716.167.25903, a 12-year-old female, was reported as having an AE of mild weight gain, judged by the investigator to be possibly related to study medication, on Day 111 of open-label treatment. The patient's weight measured at acute screening (60.4 kg) was within the reference range, but at Week 12 (63.6 kg) and at Week 24 (66.4 kg) was outside the reference range (28.1 kg to 63.1 kg). This vital sign value met the criteria both for absolute value of clinical concern and an increase ≥7% from acute-study baseline at Week 24. A narrative for this patient can be located in Table 15.0, Section 12.

- Patient 716.176.25672, a 12-year-old male, was reported as having an AE of mild weight gain, judged by the investigator to be possibly related to study medication, on Day 7 of open-label treatment. The patient's weight measured at acute screening (40.0 kg) and at Week 8 (40.5 kg) was within the reference range (27.2 kg to 60.4 kg).

- Patient 716.176.27171, a 10-year-old female, was reported as having an AE of severe weight gain, judged by the investigator to be possibly related to study medication, on Day 30 of open-label treatment. The patient's weight measured at acute screening (104.0 kg), at Study 716 baseline (110.0 kg), Week 12 (112.7 kg), and Week 24 (119.8 kg) was above the reference range (21.8 kg to 49.5 kg). This patient's vital sign value met the

criteria both for absolute value of clinical concern and an increase of ≥7% from acute-study baseline. A narrative for this patient can be located in Table 15.0, Section 12.

- Patient 716.179.25922, a 10-year-old male, was reported as having an AE of moderate weight gain, judged by the investigator to be possibly related to study medication, on Day 45 of open-label treatment. The patient's weight measured at acute screening (38.5 kg), at Week 12 (39.9 kg), and at Week 20 (42.5 kg) was within the reference range (21.8 kg to 47.2 kg).

- Patient 716.180.25969, a 10-year-old male, was reported as having AEs of mild palpitations and tachycardia, judged by the investigator to be possibly related to study medication, 10 days before the start of open-label treatment. The events were continuing at Study 716 Baseline. The patient's heart rate was 72 bpm measured at acute screening and at Study 716 baseline, within the reference range (65 to 115 bpm). All subsequent values were also within reference range.

- Patient 716.183.27647, an 11-year-old female, was reported as having an AE of mild weight gain, judged by the investigator to be possibly related to study medication, on Day 84 of open-label treatment. The patient's weight measured at acute screening was 39.0 kg; at Week 12 (42.9 kg) and at Week 24 (45.5 kg), the weight increase was significant (≥7%) but was within the reference range (25.0 kg to 56.3 kg).

- Patient 716.192.25870, a 17-year-old male, was reported as having an AE of mild weight gain, judged by the investigator to be possibly related to study medication, on Day 95 of open-label treatment. The patient's weight, measured at acute screening (67.2 kg) and at Week 12 (71.0 kg) was within the reference range (49.0 kg to 93.5 kg). At week 24, the weight was 75.0 kg, a significant increase (≥7%) but was within the reference range.

Detailed patient narratives have been prepared for patients with any vital sign value that met the pre-defined criteria both for absolute value of clinical concern and an increase or decrease from acute-study baseline (in the same direction as the absolute value), and that was reported as an adverse event by the investigator. Eight patients (4 with weight gain and 1 with weight loss in the acute-study paroxetine group, and 3 with weight gain in the acute-study placebo group) met this combination of criteria. Narratives for these patients can be located in Table 15.0, Section 12.

5.8.2 Changes in Vital Signs

Summary statistics for acute-study baseline and change from acute-study baseline for vital signs at each visit by acute-study treatment group (pre-open-label Treatment Phase and open-label Treatment Phase) are presented in Table 15.2.1.1, Section 12. Table 44 presents a summary of blood pressure, pulse rate, height, weight and BMI at acute-study baseline and change from acute-study baseline at Week 24. Data are included in the summary for those patients who had a value both at acute-study baseline and at Week 24.

Overall, all changes in vital sign parameters were small. Baseline values were comparable between acute-study treatment groups, and mean changes in all vital sign parameters were small except for weight, and generally comparable between acute-study treatment groups. The mean increase in weight in both acute-study treatment groups based on 89 patients (51 in the acute-study paroxetine group and 38 in the acute-study placebo group) was slightly under 10% from acute-study baseline to Week 24 of Study 716.

Summary statistics for acute-study baseline and change from acute-study baseline for vital signs at each visit by acute-study treatment group (pre-open-label Treatment Phase, Taper Phase and Follow-up Phase) are presented in Table 15.2.1.2, Section 12.

Table 44 Summary Statistics for Acute-study Baseline and Change from Acute-study Baseline to Week 24 in Vital Signs by Acute-study Treatment Group (Pre-Open-label Treatment Phase and Open-label Treatment Phase) (ITT Population)

	Acute-study Treatment Group											
	Paroxetine				Placebo				Total			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Systolic Blood Pressure (mmHg)												
Acute-study baseline	133	108.7	(11.68)	83 to 140	130	107.3	(11.49)	74 to 142	263	108.0	(11.59)	74 to 142
Change at Week 24	54	3.3	(11.37)	-30 to 30	42	4.6	(13.04)	-22 to 34	96	3.9	(12.08)	-30 to 34
Diastolic Blood Pressure (mmHg)												
Acute-study baseline	133	66.2	(8.60)	40 to 86	130	67.5	(9.33)	40 to 86	263	66.9	(8.97)	40 to 86
Change at Week 24	54	2.2	(9.70)	-22 to 22	42	-0.2	(9.16)	-30 to 13	96	1.1	(9.49)	-30 to 22
Heart Rate (bpm)												
Acute-study baseline	133	80.6	(10.77)	50 to 104	130	78.3	(11.02)	52 to 110	263	79.5	(10.93)	50 to 110
Change at Week 24	54	-1.3	(12.29)	-36 to 37	42	0.3	(14.18)	-40 to 26	96	-0.6	(13.10)	-40 to 37
Weight (kg)												
Acute-study baseline	133	55.8	(23.38)	20.4 to 143.8	129	51.5	(22.21)	20.5 to 131.4	262	53.7	(22.87)	20.4 to 143.8
Change at Week 24	51	5.1	(5.24)	-19.6 to 21.5	38	4.6	(6.26)	-19.1 to 16.8	89	4.9	(5.67)	-19.6 to 21.5
Height (cm)												
Acute-study baseline	133	153.37	(16.65)	114.5 to 188.0	129	150.85	(16.45)	115.6 to 180.3	262	152.13	(16.56)	114.5 to 188.0
Change at Week 24	51	2.86	(6.52)	-19.0 to 39.5	38	2.96	(2.92)	-3.0 to 8.9	89	2.90	(5.27)	-19.0 to 39.5
BMI (kg/m^2)												
Acute-study baseline	133	22.9	(6.50)	13.8 to 45.9	129	21.8	(6.18)	13.6 to 45.4	262	22.3	(6.35)	13.6 to 45.9
Change at Week 24	51	1.4	(2.44)	-9.0 to 6.5	38	1.0	(2.10)	-6.6 to 5.4	89	1.2	(2.29)	-9.0 to 6.5

Source: Table 15.2.1.1, Section 12; Listing 15.2.1, Appendix E

For height, weight, and BMI the last pre-acute-study treatment assessment is taken to be acute-study baseline

5.9 Laboratory Data

5.9.1 Laboratory Values of Potential Clinical Concern

The number and percentage of patients with a significant increase or decrease in any laboratory parameter from acute-study baseline that was of potential clinical concern was tabulated. Table 5, Section 3.14.6.4, Laboratory Values, shows these pre-defined levels of potential clinical concern for laboratory parameters.

All laboratory parameters that were assessed after the last dose of open-label study medication, even if the patient was still considered by the investigator to be on therapy (e.g., the patient came in for the Week 24 or Early Withdrawal visit one or more days after the last dose of study medication), were coded as occurring during the Follow-up Phase if the patient did not enter the Taper Phase, and as occurring during the Taper Phase if the patient did enter the Taper Phase. Laboratory assessments that occurred after the last dose of taper medication were coded as occurring during the Follow-up Phase. All laboratory parameters that were assessed more than 14 days after the last dose of study medication (including taper) were listed but not tabulated (see Section 3.14.10, Data Irregularities).

Summaries of the number and percentage of patients with laboratory values flagged as of potential clinical concern by acute-study treatment group may be found in Table 15.3.1.1 (acute-study baseline), Table 15.3.1.2 (open-label Treatment Phase including Taper Phase), Table 15.3.1.3 (Follow-up Phase), and Table 15.3.1.4 (open-label Treatment Phase, Taper Phase or Follow-up Phase), Section 12. Individual values of potential clinical concern are provided in Listing 15.3.3, Appendix F.

In the interim report for this study, 15 laboratory values that should have been flagged as being of clinical concern were not flagged in the Study 716 interim RAP output. The clinical concern values were corrected in the output for this final report (see Section 13, Errata).

Table 45 presents a summary of the number and percentage of patients with open-label treatment (including taper) laboratory values meeting sponsor-defined criteria for potential clinical concern during Study 716. During the open-label Treatment Phase (including taper), 36 patients in the acute-study paroxetine group and 35 patients in the acute-study placebo group were identified as having an absolute value in one or more of the laboratory parameters that met the criteria for clinical concern. Seventeen patients had more than one laboratory parameter flagged as

meeting the criteria for clinical concern (5 patients in the acute-study paroxetine group and 12 patients in the acute-study placebo group, including 1 patient in the acute-study placebo group with three flagged parameters).

Low hematocrit was the laboratory finding most frequently associated with values of potential clinical concern: 18.7% (23/123) of patients in the acute-study paroxetine group and 19.1% (22/115) of patients in the acute-study placebo group had low hematocrit values of potential clinical concern during the open-label Treatment, Taper or Follow-up Phase. Low hematocrit values of potential clinical concern were comparable between age groups: 19.2% (24/125) of children and 18.6% (21/113) of adolescents during the open-label Treatment, Taper or Follow-up Phase. A total of 3.8% (9/238) of patients had hemoglobin values that were low and of potential clinical concern, all but one of whom also had low hematocrit of concern. They included 2 patients in the acute-study paroxetine group and 7 patients in the acute-study placebo group (1.6% [2/123] of children and 6.1% [7/115] of adolescents) (Table 15.3.1.4, Section 12, Listing 15.3.3, Appendix F).

One patient in each acute-study treatment group (716.168.27077 paroxetine and 716.004.27003 placebo) had low hematocrit of potential clinical concern at a visit more than 14 days after the last dose of study medication (including taper) (Listing 15.3.3, Appendix F). These patients do not appear in Table 45 or Data Source Table 15.3.1.4, Section 12.

High lymphocyte values of potential clinical concern were reported in more patients in the acute-study paroxetine group (4.1%, 5/123) than in the acute-study placebo group (0.9%, 1/115). Similarly, more children (4.0%, 5/125) reported high lymphocyte values of potential clinical concern than adolescents (0.9%, 1/113). However, these numbers are too small to draw any meaningful conclusions. Two of these children, both in the acute-study paroxetine group, had high lymphocyte values at acute-study screening. Other laboratory values of potential clinical concern occurred with comparable frequency in the both acute-study treatment groups and age groups.

Laboratory values by patient and parameter may be found in Listing 15.3.1 and Listing 15.3.2, Appendix F, respectively. Laboratory values during the Follow-up Phase may be found in Table 15.3.1.3, Section 12. Laboratory values during the combined Treatment and Taper Phases may be found in Table 15.3.1.2, Section 12.

Table 45 Number (%) of Patients with Laboratory Values Meeting Pre-defined Clinical Concern Criteria During the Open-label Treatment, Taper or Follow-up Phase by Acute-study Treatment Group (ITT Population)

		Acute-study Treatment Group								
		Paroxetine			Placebo			Total		
Laboratory Parameter	**High/Low**	**N**	**n**	**(%)**	**N**	**n**	**(%)**	**N**	**n**	**(%)**
Total Patients with a Laboratory Parameter of Clinical Concern *			36			35			71	
Hematocrit	Low	123	23	(18.7)	115	22	(19.1)	238	45	(18.9)
Hemoglobin	Low	123	2	(1.6)	115	7	(6.1)	238	9	(3.8)
Neutrophils, absolute	Low	123	4	(3.3)	115	5	(4.3)	238	9	(3.8)
Neutrophils, absolute	High	123	3	(2.4)	115	2	(1.7)	238	5	(2.1)
Eosinophils, absolute	High	123	2	(1.6)	115	5	(4.3)	238	7	(2.9)
Lymphocytes, absolute	High	123	5	(4.1)	115	1	(0.9)	238	6	(2.5)
White blood cell count	Low	123	0	–	115	2	(1.7)	238	2	(0.8)
Potassium	High	124	2	(1.6)	117	0	–	241	2	(0.8)
SGPT (ALT)	High	124	0	–	117	2	(1.7)	241	2	(0.8)
Monocytes, absolute	High	123	0	–	115	1	(0.9)	238	1	(0.4)
Platelets	Low	123	0	–	115	1	(0.9)	238	1	(0.4)

Source: Table 15.3.1.4, Section 12; Listing 15.3.3, Appendix F

Note: Pre-defined laboratory values of potential clinical concern may be found in Table 5.

N = the number of patients who had a measurement for this laboratory parameter at any time during the open-label Treatment, Taper or Follow-up Phase

n = number of patients meeting the pre-defined clinical concern criteria

* Some patients had more than one laboratory value of potential clinical concern.

If any laboratory parameters or laboratory parameter changes were considered clinically significant by the investigator, whether or not they met the sponsor-defined potential clinical concern criteria, they were to be recorded as adverse events in the patient's CRF (Listings 15.1.1 and 15.1.2, Appendix D). Five patients in the acute-study paroxetine group had laboratory values at some time during Study 716, including Taper and Follow-up, that were considered clinically significant by the investigator and recorded as an adverse event (ages given are age at Study 716 baseline):

- Patient 716.176.25671, a 13-year-old male, had mild leukopenia (verbatim: leukopenia and neutropenia), which was considered possibly related to open-label study medication, during the Taper Phase, 1 day after the last dose of open-label Treatment Phase medication, after 168 days of open-label paroxetine. The patient had taken paroxetine for 56 days during the acute study, including taper (i.e., after a total of 224 days paroxetine exposure). Laboratory tests on blood drawn on the last day of study medication showed neutrophil value of 1.73 x 10^9/L (reference range 1.8–8.0 x 10^9/L).

- Patient 716.176.27164, an 11-year-old male, had mild anemia (verbatim: low hematocrit and low hemoglobin), which was considered unrelated to open-label study medication, on Day 84 of open-label treatment. The patient had taken paroxetine for 97 days during the acute study, including taper (i.e., after a total of 181 days paroxetine exposure). This patient's hematocrit value met the criteria for clinical concern at acute-study screening (33.7%, reference range low is 35.0%), Week 4 (33.9%), Week 12 (33.2%) and Week 24 (31.8%). The patient's hematocrit value was within the reference range at the final assessment in the acute study and it was not necessary to do a repeat assessment at Study 716 baseline. The patient's hemoglobin was low and of clinical concern at Week 12 (112 g/L, reference range low is 115 g/L) and Week 24 (109 g/L). A narrative for this patient can be located in Table 15.0, Section 12.

- Patient 716.192.25868, a 16-year-old male, had mild leukopenia (verbatim: low absolute neutrophils and low white blood cell count), which was considered possibly related to open-label study medication, on Day 70 of open-label treatment. The patient had taken paroxetine for 55 days during the acute study, including taper (i.e., after a total of 125 days paroxetine exposure). The patient's neutrophil count decreased from normal at acute-study screening (2.1 x 10^9/L) to below the reference range at Week 8 (1.0

x 10^9/L, reference range low is 1.8 x 10^9/L) and Week 12 (1.15 x 10^9/L). The patient's neutrophil value at Week 8 and Week 12 met the criteria for clinical concern. In addition, the patient's white blood cell count decreased from normal at acute-study screening (5.1 x 10^9/L) to below the reference range at Week 8 (3.0 x 10^9/L, reference range low is 4.5 x 10^9/L). All laboratory values at Day 111, 14 days after the last dose of study medication, were within reference range. A narrative for this patient can be located in Table 15.0, Section 12.

- Patient 716.192.25946, a 12-year-old female, had mild leukopenia (verbatim: abnormal monocyte count), which was considered possibly related to open-label study medication, on Day 29 of open-label treatment. The patient had taken paroxetine for 52 days during the acute study, including taper (i.e., after a total of 81 days paroxetine exposure). The patient's monocyte count decreased from normal at acute-study screening (0.4 x 10^9/L) to below the reference range at Week 4 (0.1 x 10^9/L, reference range low is 0.2 x 10^9/L), Week 8 (0.06 x 10^9/L), and Week 16 (0.16 x 10^9/L). At Week 24, monocytes were within reference range. No concern criterion for low monocytes was pre-defined by the sponsor.

- Patient 716.049.28149, a 14-year-old male, had an adverse event of abnormal laboratory values on Day 87. The patient had taken paroxetine for 87 days during the acute study, including taper (i.e., after a total of 174 days paroxetine exposure). However, the AE was coded from a verbatim of unintentional overdose and did not reflect a clinically significant laboratory value.

Seven patients in the acute-study placebo group had laboratory values during Study 716 Treatment, Taper, or Follow-up Phase that were considered clinically significant by the investigator and recorded as an adverse event:

- Patient 716.006.25418, a 13-year-old male, had abnormal liver function tests (verbatim: elevated liver enzymes), which was mild in intensity and considered possibly related to open-label study medication 6 days after the last dose of study medication. The patient's liver enzyme levels increased from normal at acute-study screening (SGOT, 27 IU/L; SGPT, 18 IU/L) to above the reference range at Week 6 (SGOT, 104 IU/L, reference range high is 42 IU/L; SGPT, 169 IU/L, reference range high is 48 IU/L). SGPT was above the pre-determined level of potential clinical concern (>165 IU/L). The patient had stopped open-label study medication 6 days before

the onset of this adverse event. A narrative for this patient can be located in Table 15.0, Section 12.

- Patient 716.028.27685, an 11-year-old female, had increased SGOT (AST) (verbatim: elevated liver enzymes), which was moderate in intensity and considered possibly related to open-label study medication, 8 days after the last dose of open-label treatment. The patient's SGOT levels increased from acute-study baseline (47 IU/L) to above the reference range 7 days after the last dose of open-label medication (82 IU/L, reference range high 42 IU/L), but did not reach a level of potential clinical concern (>150 IU/L). The value of SGPT (ALT) was 64 IU/L, above the reference range (0 to 45 IU/L) but not at the level of potential clinical concern (>156 IU/L). Other liver values at that visit were within reference range. Alkaline phosphatase had been above the reference range at acute screening. SGOT was 48 IU/L and SGPT was 20 IU/L on day 219, 184 days after the last dose of study medication.

- Patient 716.031.25533, a 16-year-old male, had mild leukocytosis (verbatim: increased white cell count), which was considered unrelated to open-label study medication on Day 165 of open-label treatment. Laboratory results at Week 24 show the patient's white blood cell count to be below the reference range (4.3×10^9/L, reference range low is 4.5×10^9/L) but not at a level of potential clinical concern ($<2.8 \times 10^9$/L). WBC at acute baseline was 4.1×10^9/L.

- Patient 716.165.25664, a 10-year-old male, had abnormal liver function test (verbatim: increase in liver enzymes), which was considered to be mild in intensity and unrelated to open-label study medication, on Day 85 of open-label treatment. The patient's SGOT levels increased from normal at acute-study screening (42 IU/L) to above the reference range at Week 12 (54 IU/L, reference range high is 42 IU/L). In addition, the patient's SGPT levels were above the reference range (normal high is 45 IU/L) at acute-study screening (46 IU/L) and Week 12 (84 IU/L). At Follow-up, 14 days after the last dose of study medication, SGPT was 179 IU/L, above the pre-determined level of potential clinical concern (>165 IU/L). A narrative for this patient can be located in Table 15.0, Section 12.

- Patient 716.167.25696, an 8-year-old male, had leukopenia (verbatim: low eosinophils absolute, low neutrophils absolute, and low white cell count) on Day 168 (Week 24) of open-label treatment, which was considered to

be moderate in intensity and possibly related to study medication. The patient's white blood cell count decreased from 6.3 x 10^9/L at acute-study screening to below the reference range (reference range low 4.5 x 10^9/L) at Week 24 (3.0 x 10^9/L) and the Follow-up Visit (2.0 x 10^9/L), which was below the pre-determined level of potential clinical concern (<2.8 x 10^9/L). The patient's absolute eosinophil count decreased from 0.1 x 10^9/L at screening to 0.0 x 10^9/L at Week 24 (reference range low 0.0 x 10^9/L) and 0.02 x 10^9/L at the Follow-up Visit. The patient's absolute neutrophil count decreased from normal (4.06 x 10^9/L) at screening to below the reference range (reference range low 1.80 x 10^9/L) at Week 24 (1.44 x 10^9/L) and the Follow-up Visit (0.90 x 10^9/L), which was below the pre-determined level of potential clinical concern (<1.58 x 10^9/L). On Day 182, 14 days after the last dose of study medication, an adverse event of moderately severe lymphocytosis (verbatim: high lymphocytes) was reported, judged by the investigator to be possibly related to study medication. Absolute lymphocyte values were 13 x 10^9/L (reference range 0.85 to 4.10 x 10^9/L). This value is not reported in Listing 15.3.1, Appendix D, or Tables 15.3.1.3 or 15.3.1.4, Section 12 (see Section 13, Errata). A narrative for this patient can be located in Table 15.0, Section 12.

- Patient 716.169.25781, a 10-year-old female, had anemia and leukopenia (verbatim: abnormal laboratory results), which were considered to be mild in intensity and unrelated to open-label study medication, on Day 85 of open-label treatment. This patient's hematocrit value met the criteria for clinical concern at acute-study screening (33.1%, reference range low is 35.0%), Week 4 (34.6%), Week 12 (32.7%) and Week 24 (34.8%). In addition, the patient's hemoglobin level and white blood cell count were low, but not of clinical concern, at Week 12 (hemoglobin, 108 g/L, reference range low is 115 g/L, clinical concern low is 95 g/L; white blood cell count 4.1 x 10^9/L, reference range low is 4.5 x 10^9/L, clinical concern low is 2.8 x 10^9/L). At Week 12, red blood cells were 3.7 x 1012/L (baseline value 3.7 x 10^{12}/L), both below reference range (4.0 to 5.2 x 10^9/L). At Week 12, monocytes were decreased from normal at baseline (0.27 x 10^9/L) to below reference range (0.06 x 10^9/L, reference range 0.20 to 1.10). A narrative for this patient can be located in Table 15.0, Section 12.

- Patient 716.176.27172, a 16-year-old male, had eosinophilia (verbatim: elevated eosinophils) and monocytosis (elevated monocytes), which were moderate in intensity and considered unrelated to open-label study medication, on Day 12 of open-label treatment. The patient's monocyte and eosinophil levels increased from acute-study baseline (eosinophils, 0.40 x 10^9/L; monocytes, 0.56 x 10^9/L) to above the reference range at Week 2 (eosinophils, 1.12 x 10^9/L, reference range high is 0.55 x 10^9/L; monocytes, 1.6 x 10^9/L, reference range high is 1.1 x 10^9/L). The patient's eosinophil (1.12 x 10^9/L) and monocyte (1.61 x 10^9/L) levels at Week 2 met the criteria for clinical concern (>0.79 x 10^9/L for eosinophils and >1.38 x 10^9/L for monocytes). A narrative for this patient can be located in Table 15.0, Section 12.

Detailed patient narratives have been prepared for patients with any laboratory value meeting the potential clinical concern criteria, and that was reported as an adverse event by the investigator. Seven patients (2 in the acute-study paroxetine group and 5 in the acute-study placebo group) met this combination of criteria. Narratives for these patients can be located in Table 15.0, Section 12.

5.9.2 Changes in Laboratory Values

Summary statistics for acute-study baseline and change from acute-study baseline to endpoint for laboratory parameters by acute-study treatment group are presented in Table 46. Summary statistics for thyroid tests are not presented here because they were not required to be performed at endpoint (Table 15.3.6, Section 12, includes acute-study baseline values). Overall, changes in laboratory parameters from acute-study baseline to Week 24 or endpoint were small. The acute-study treatment groups were comparable at acute-study baseline with respect to laboratory parameters, and there were no substantial differences between the acute-study paroxetine and acute-study placebo groups at Week 24, at endpoint, or in change from acute-study baseline to Week 24 or endpoint.

Table 46 Summary Statistics for Acute-study Baseline and Change from Acute-study Baseline to Week 24 and Endpoint for Laboratory Parameters by Acute-study Treatment Group (ITT Population)

Laboratory Test	Acute-study Treatment Group											
	Paroxetine				Placebo				Total			
(units)	N	Mean	(SD)	Range	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Hemoglobin g/L												
Acute-study baseline	132	133.4	10.74	106 to 164	130	132.3	11.38	104 to 163	262	132.8	11.05	104 to 164
Change to Week 24	58	-1.0	6.80	-16 to 14	41	-2.6	9.67	-22 to 20	99	-1.7	8.10	-22 to 20
Change to Endpoint	119	-2.2	6.91	-19 to 16	109	-1.5	7.61	-22 to 20	228	-1.9	7.24	-22 to 20
Hematocrit (%)												
Acute-study baseline	132	39.47	3.285	32.5 to 52.5	130	39.27	3.416	31.8 to 48.8	262	39.37	3.346	31.8 to 52.5
Change to Week 24	58	-0.47	2.337	-5.0 to 6.1	41	-1.01	2.741	-7.8 to 4.7	99	-0.69	2.513	-7.8 to 6.1
Change to Endpoint	119	-0.68	2.396	-8.1 to 6.1	109	-0.52	2.498	-7.8 to 6.2	228	-0.60	2.441	-8.1 to 6.2
RBC Count (10^{12}/L)												
Acute-study baseline	132	4.62	0.338	3.8 to 5.6	130	4.58	0.376	3.7 to 5.4	262	4.60	0.358	3.7 to 5.6
Change to Week 24	58	-0.03	0.245	-0.5 to 0.7	41	-0.11	0.322	-1.0 to 0.5	99	-0.06	0.281	-1.0 to 0.7
Change to Endpoint	119	-0.07	0.253	-0.8 to 0.7	109	-0.05	0.267	-1.0 to 0.5	228	-0.06	0.260	-1.0 to 0.7
WBC Count (10^{9}/L)												
Acute-study baseline	132	6.93	2.079	3.0 to 14.9	130	6.80	1.771	3.5 to 13.2	262	6.87	1.930	3.0 to 14.9
Change to Week 24	58	-0.26	1.842	-4.3 to 5.2	41	-0.11	1.983	-4.1 to 4.2	99	-0.20	1.893	-4.3 to 5.2
Change to Endpoint	119	-0.24	2.004	-6.5 to 5.2	109	0.12	1.825	-4.1 to 5.8	228	-0.06	1.925	-6.5 to 5.8

Source: Table 15.3.6, Section 12; Listings 15.3.1 and 15.3.2, Appendix F

For laboratory assessments the last pre-acute study medication assessment was taken to be acute-study baseline.

Endpoint was the last open-label treatment assessment (including taper).

Week 24 includes only assessments that occurred on treatment (including taper).

Table continues

Table 46 (Continued) Summary Statistics for Acute-study Baseline and Change from Acute-study Baseline to Week 24 and Endpoint for Laboratory Parameters by Acute-study Treatment Group (ITT Population)

Laboratory Test (units)	Acute-study Treatment Group: Paroxetine N	Paroxetine Mean	Paroxetine (SD)	Paroxetine Range	Placebo N	Placebo Mean	Placebo (SD)	Placebo Range	Total N	Total Mean	Total (SD)	Total Range
Platelets (10^9/L)												
Acute-study baseline	132	287.1	61.38	154 to 469	130	293.7	63.31	115 to 468	262	290.4	62.32	115 to 469
Change to Week 24	58	-6.2	47.91	-142 to 171	41	5.9	43.92	-92 to 130	99	-1.2	46.46	-142 to 171
Change to Endpoint	119	-11.1	45.36	-145 to 171	109	-3.9	46.89	-154 to 130	228	-7.7	46.14	-154 to 171
Basophils (10^9/L)												
Acute-study baseline	132	0.021	0.0146	0.00 to 0.11	130	0.020	0.0127	0.00 to 0.07	262	0.0205	0.0137	0.00 to 0.11
Change to Week 24	58	-0.003	0.0207	-0.09 to 0.03	41	-0.002	0.0151	-0.03 to 0.03	99	-0.003	0.0185	-0.09 to 0.03
Change to Endpoint	119	-0.004	0.0175	-0.09 to 0.03	109	0.000	0.0264	-0.06 to 0.17	228	-0.002	0.0223	-0.09 to 0.17
Eosinophils (10^9/L)												
Acute-study baseline	132	0.267	0.1985	0.00 to 0.96	130	0.246	0.2012	0.00 to 1.33	262	0.257	0.1997	0.00 to 1.33
Change to Week 24	58	-0.045	0.2006	-0.62 to 0.28	41	-0.019	0.1785	-0.54 to 0.46	99	-0.034	0.1913	-0.62 to 0.46
Change to Endpoint	119	-0.027	0.1926	-0.60 to 0.43	109	0.014	0.2045	-0.54 to 0.82	228	-0.007	0.1990	-0.60 to 0.82
Lymphocytes (10^9/L)												
Acute-study baseline	132	2.469	0.7848	1.02 to 5.80	130	2.374	0.6692	0.80 to 4.87	262	2.422	0.7299	0.80 to 5.80
Change to Week 24	58	-0.076	0.6623	-1.35 to 1.61	41	-0.011	0.4415	-1.03 to 1.05	99	-0.049	0.5794	-1.35 to 1.61
Change to Endpoint	119	-0.081	0.6903	-2.44 to 1.73	109	-0.070	0.5396	-2.46 to 1.33	228	-0.076	0.6215	-2.46 to 1.73

Source: Table 15.3.6, Section 12; Listings 15.3.1 and 15.3.2, Appendix F

For laboratory assessments the last pre-acute study medication assessment was taken to be acute-study baseline.

Endpoint was the last open-label treatment assessment (including taper).

Week 24 includes only assessments that occurred on treatment (including taper).

Table continues

Table 46 (Continued) Summary Statistics for Acute-study Baseline and Change from Acute-study Baseline to Week 24 and Endpoint for Laboratory Parameters by Acute-study Treatment Group (ITT Population)

Laboratory Test (units)	Acute-study Treatment Group: Paroxetine N	Paroxetine Mean	Paroxetine (SD)	Paroxetine Range	Placebo N	Placebo Mean	Placebo (SD)	Placebo Range	Total N	Total Mean	Total (SD)	Total Range
Monocytes (10^9/L)												
Acute-study baseline	132	0.413	0.1910	0.06 to 0.92	130	0.353	0.1886	0.0 to 1.4	262	0.383	0.1917	0.0 to 1.4
Change to Week 24	58	-0.038	0.1908	-0.73 to 0.43	41	0.018	0.1724	-0.41 to 0.52	99	-0.015	0.1846	-0.73 to 0.52
Change to Endpoint	119	-0.055	0.1886	-0.73 to 0.44	109	-0.002	0.1953	-0.97 to 0.54	228	-0.029	0.1933	-0.97 to 0.54
Neutrophils (10^9/L)												
Acute-study baseline	132	3.769	1.5545	0.74 to 9.00	130	3.804	1.3964	1.46 to 8.65	262	3.786	1.4755	0.74 to 9.00
Change to Week 24	58	-0.108	1.5353	-3.84 to 3.89	41	-0.096	1.6973	-3.75 to 3.51	99	-0.103	1.5959	-3.84 to 3.89
Change to Endpoint	119	-0.076	1.6360	-4.53 to 5.54	109	0.180	1.5961	-3.75 to 4.80	228	0.047	1.6186	-4.53 to 5.54
Sodium (mmol/L)												
Acute-study baseline	133	141.7	2.09	137 to 149	130	141.8	2.20	137 to 149	263	141.7	2.14	137 to 149
Change to Week 24	59	-0.7	2.89	-7 to 8	40	-0.8	3.13	-8 to 5	99	-0.8	2.97	-8 to 8
Change to Endpoint	121	-0.3	2.87	-7 to 9	110	-0.6	2.93	-8 to 5	231	-0.5	2.89	-8 to 9
Potassium (mmol/L)												
Acute-study baseline	133	4.30	0.337	3.6 to 5.6	130	4.40	0.379	3.3 to 6.1	263	4.35	0.361	3.3 to 6.1
Change to Week 24	58	0.02	0.441	-1.8 to 1.2	40	-0.07	0.355	-0.9 to 0.8	98	-0.02	0.408	-1.8 to 1.2
Change to Endpoint	121	0.00	0.00	-1.8 to 1.4	110	-0.06	0.415	-1.6 to 1.4	231	-0.03	0.427	-1.8 to 1.4

Source: Table 15.3.6, Section 12; Listings 15.3.1 and 15.3.2, Appendix F

For laboratory assessments the last pre-acute study medication assessment was taken to be acute-study baseline.

Endpoint was the last open-label treatment assessment (including taper).

Week 24 includes only assessments that occurred on treatment (including taper).

Table continues

Table 46 (Continued) Summary Statistics for Acute-study Baseline and Change from Acute-study Baseline to Week 24 and Endpoint for Laboratory Parameters by Acute-study Treatment Group (ITT Population)

Laboratory Test	Acute-study Treatment Group											
	Paroxetine				Placebo				Total			
(units)	N	Mean	(SD)	Range	N	Mean	(SD)	Range	N	Mean	(SD)	Range
BUN (mmol/L)												
Acute-study baseline	133	4.6061	1.13649	2.856 to 7.854	130	4.3829	1.29294	1.428 to 8.925	263	4.4958	1.21915	1.428 to 8.925
Change to Week 24	59	0.0061	1.28802	-3.570 to 2.499	40	0.3392	1.14317	-2.856 to 2.499	99	0.1406	1.23649	-3.570 to 2.499
Change to Endpoint	121	0.0089	1.26594	-3.570 to 2.856	110	0.3213	1.26561	-2.856 to 4.284	231	0.1576	1.27267	-3.570 to 4.284
Creatinine (umol/L)												
Acute-study baseline	133	51.977	14.1053	26.52 to 88.40	130	51.952	14.6032	26.52 to 132.60	263	51.964	14.3261	26.52 to 132.60
Change to Week 24	59	2.098	11.0532	-26.52 to 35.36	40	4.641	8.7231	-17.68 to 26.52	99	3.125	10.2060	-26.52 to 35.36
Change to Endpoint	121	2.119	10.5232	-26.52 to 35.36	110	1.125	11.6779	-79.56 to 26.52	231	1.646	11.0749	-79.56 to 35.36
Alkaline Phosphatase (IU/L)												
Acute-study baseline	133	220.0	89.55	51 to 452	130	236.6	93.39	49 to 512	263	228.2	91.67	49 to 512
Change to Week 24	59	-15.3	36.50	-158 to 72	40	-19.9	36.72	-112 to 64	99	-17.2	36.47	-158 to 72
Change to Endpoint	121	-16.9	38.64	-158 to 80	110	-19.3	42.07	-170 to 106	231	-18.0	40.24	-170 to 106

Source: Table 15.3.6, Section 12; Listings 15.3.1 and 15.3.2, Appendix F

For laboratory assessments the last pre-acute study medication assessment was taken to be acute-study baseline.

Endpoint was the last open-label treatment assessment (including taper).

Week 24 includes only assessments that occurred on treatment (including taper).

Table continues

Table 46 (Continued) Summary Statistics for Acute-study Baseline and Change from Acute-study Baseline to Week 24 and Endpoint for Laboratory Parameters by Acute-study Treatment Group (ITT Population)

Laboratory Test	Acute-study Treatment Group											
	Paroxetine				Placebo				Total			
(units)	N	Mean	(SD)	Range	N	Mean	(SD)	Range	N	Mean	(SD)	Range
AST (SGOT) (IU/L)	133	22.7	5.76	12 to 38	130	24.4	6.50	12 to 47	263	23.5	6.18	12 to 47
Acute-study baseline	59	1.3	8.53	-10 to 49	40	1.6	6.64	-16 to 28	99	1.4	7.79	-16 to 49
Change to Week 24	121	1.5	6.89	-10 to 49	110	2.0	6.03	-16 to 28	231	1.7	6.49	-16 to 49
Change to Endpoint												
ALT (SGPT) (IU/L)												
Acute-study baseline	133	16.0	6.61	6 to 47	130	16.8	8.27	7 to 59	263	16.4	7.47	6 to 59
Change to Week 24	59	2.8	11.28	-23 to 69	40	2.6	6.82	-12 to 27	99	2.7	9.68	-23 to 69
Change to Endpoint	121	2.2	10.77	-23 to 69	110	2.1	7.37	-20 to 33	231	2.1	9.28	-23 to 69
Total Bilirubin (umol/L)												
Acute-study baseline	133	7.779	3.8667	0.00 to 22.23	130	7.327	3.9904	3.42 to 34.20	263	7.555	3.9273	0.00 to 34.20
Change to Week 24	58	-0.855	3.4684	-11.97 to 6.84	40	-0.043	3.3867	-15.39 to 5.13	98	-0.523	3.4412	-15.39 to 6.84
Change to Endpoint	121	-0.579	3.1185	-11.97 to 6.84	110	-0.218	3.4051	-18.81 to 5.13	231	-0.407	3.2560	-18.81 to 6.84

Source: Table 15.3.6, Section 12; Listings 15.3.1 and 15.3.2, Appendix F

For laboratory assessments the last pre-acute study medication assessment was taken to be acute-study baseline.

Endpoint was the last open-label treatment assessment (including taper).

Week 24 includes only assessments that occurred on treatment (including taper).

Acute-study baseline values, endpoint values (including taper), and Follow-up values were categorized as high and of clinical concern, above reference range, within range, below reference range, and low and of clinical concern. Table 15.3.4, Section 12, presents the number and percentage of patients with transitions in laboratory values per parameter (that is, whose laboratory value changed categories) from acute-study baseline to endpoint and/or follow-up.

Transitions were generally comparable between the acute-study treatment groups. The number of transitions was small except for hemoglobin and hematocrit. In the acute-study paroxetine group, 4 patients had low hemoglobin values of potential clinical concern and 6 patients had a value below the reference range at endpoint (including taper) compared to 2 patients with low values and 1 with a value of potential clinical concern at Study 716 baseline. At follow-up, only 1 patient had a low value. In the acute-study placebo group, 2 patients had low hemoglobin values of potential clinical concern and 7 patients had a value below the reference range at endpoint (including taper) compared to 2 patients with low values at Study 716 baseline. At follow-up, only 1 patient had a low value.

For hematocrit, in the acute-study paroxetine group, 17 patients had low hematocrit values of potential clinical concern at endpoint (including taper) compared to 2 patients with values of potential clinical concern at Study 716 baseline. At follow-up, only 2 patients had values of potential clinical concern. In the acute-study placebo group, 12 patients had low hematocrit values of potential clinical concern at endpoint (including taper) compared to 2 patients with values of potential clinical concern at Study 716 baseline. At follow-up, only 2 patients had values of potential clinical concern.

For monocytes, RBC, and WBC, there were also more values below the reference range at endpoint (including taper) than at Study 716 baseline, but few of potential clinical concern.

5.9.3 Urinalysis Results

The number and percentage of patients with abnormal urine results during the open-label Treatment Phase (including Taper Phase) may be found in Table 15.3.5.2, Section 12. The number and percentage of patients with abnormal urine test results during the Follow-up Phase are provided in Table 15.3.5.3, Section 12. Urinalysis results for each patient are provided by patient and by parameter in Listing 15.3.1 and Listing 15.3.2, respectively, Appendix F.

Ten patients in the acute-study paroxetine group had urine abnormalities associated with an adverse event during Study 716 (Listings 15.5.1 and 15.1.2, Appendix D) (age given is age at Study 716 baseline):

- Patient 716.006.25420, a 15-year-old female, had mild albuminuria (verbatim: proteinuria), judged by the investigator to be probably unrelated to open-label medication, on Day 44 of open-label treatment, and mild hematuria (verbatim: hematuria), judged unrelated to open-label medication by the investigator, on Day 85 of open-label treatment. The patient had taken paroxetine for 90 days during the acute study, including taper (i.e., after a total of 134 days paroxetine exposure).

- Patient 716.006.27177, a 10-year-old female, had an AE of mild albuminuria (verbatim: urine trace protein), judged by the investigator to be probably unrelated to open-label medication, on Day 182 of open-label treatment. The patient had taken paroxetine for 91 days during the acute study, including taper (i.e., after a total of 273 days paroxetine exposure).

- Patient 716.017.00003, a 17-year-old female, had an AE of mild albuminuria (verbatim: urine dipstick positive for trace of protein) judged by the investigator to be unrelated to open-label medication, on Day 27 of open-label treatment. The patient had taken paroxetine for 43 days during the acute study, including taper (i.e., after a total of 70 days paroxetine exposure).

- Patient 716.017.00004, a 16-year-old male, had an AE of mild albuminuria (verbatim: trace protein on urine dipstick test) judged by the investigator to be unrelated to open-label medication, on Day 86 of open-label treatment. The patient had taken paroxetine for 40 days during the acute study, including taper (i.e., after a total of 126 days paroxetine exposure).

- Patient 716.028.25962, a 15-year-old female, had mild albuminuria (verbatim: trace protein urine dipstick), judged by the investigator to be unrelated to open-label medication, on Day 29 of open-label treatment. Positive urinalysis results on Day 29 of open-label treatment were amorphous sediment, bacteria, generic dipstick and white blood cells. At Day 83, positive urinalysis were white blood cells, bacteria, protein +1, calcium oxalate crystals, amorphous sediment, generic dipstick, mucus threads, and squamous epithelial cells. The patient had taken paroxetine for 27 days during the acute study, including taper (i.e., after a total of 96 days paroxetine exposure).

- Patient 716.049.28148, a 13-year-old female, had recorded mild albuminuria (verbatim: urinalysis Wk 4 positive dipstick protein) judged probably unrelated to open-label medication by the investigator, on Day 36 of open-label treatment. A repeat test was positive for albuminuria on Day 38 of open-label study medication and an AE of albuminuria (verbatim: protein in urine). Other positive urinalysis results on Day 36 of open-label treatment were amorphous sediment, blood dipstick, red blood cells, generic dipstick and squamous epithelial cells. The patient had taken paroxetine for 77 days during the acute study, including taper (i.e., after a total of 113 days paroxetine exposure).

- Patient 716.201.00102, an 8-year-old male, had an AE of mild pyuria (verbatim: urine positive for trace bacteria) judged by the investigator to be unrelated to open-label medication, on Day 27 of open-label treatment. The patient had taken paroxetine for 41 days during the acute study, including taper (i.e., after a total of 68 days paroxetine exposure).

- Patient 716.201.00108, a 12-year-old female, had an AE of mild albuminuria (verbatim: urine dipstick positive for protein) judged by the investigator to be unrelated to open-label medication, on Day 82 of open-label treatment. Other positive urinalysis results were white blood cells, amorphous sediment, generic dipstick and squamous epithelial cells. The patient also had an AE of mild glycosuria (verbatim: urine dipstick positive for glucose) judged by the investigator to be unrelated to open-label medication, on the same day. No urine glucose results are available after baseline, which was negative. The patient had taken paroxetine for 43 days during the acute study, including taper (i.e., after a total of 125 days paroxetine exposure)s.

- Patient 716.205.00506, a 12-year-old male, had an AE of mild albuminuria (verbatim: +1 protein level) on Day 90 of open-label treatment, judged by the investigator to be probably unrelated to open-label medication. The patient had taken paroxetine for 40 days during the acute study, including taper (i.e., after a total of 130 days paroxetine exposure).

- Patient 716.208.00809, a 17-year-old male, had an AE of mild albuminuria (verbatim: trace protein in urine) 1 day after the last dose of open-label study medication, judged by the investigator to be unrelated to open-label medication. Only generic dipstick was positive at that visit. The patient had taken paroxetine for 42 days during the acute study, including taper,

and 168 days during the open-label Treatment Phase (i.e., after a total of 210 days paroxetine exposure).

Five patients in the acute-study placebo group had urine abnormalities associated with an adverse event during Study 716:

- Patient 716.028.25964, a 10-year-old male, had mild hematuria (verbatim: trace blood urine dipstick), judged unrelated to open-label medication by the investigator, at the Study 716 Baseline Visit. At the Study 716 Baseline Visit the generic urine dipstick results were positive. On Day 7 he had an AE of mild albuminuria, which lasted 37 days, also judged unrelated to open-label study medication.

- Patient 716.031.25534, a 10-year-old male, had mild hematuria (verbatim: occult urine), judged unrelated to open-label medication by the investigator, at the Study 716 Baseline Visit. At the Study 716 Baseline Visit the generic urine dipstick results were positive.

- Patient 716.167.25696, an 8-year-old male, had mild albuminuria (verbatim: urine dipstick positive for protein), judged unrelated to study medication by the investigator, on Day 26 of open-label treatment. Other positive urinalysis results on Day 26 of open-label treatment were amorphous sediment, red blood cells, white blood cells, generic dipstick, protein dipstick, and squamous epithelial cells.

- Patient 716.170.25634, a 10-year-old female, had mild hematuria (verbatim: blood in urine), judged unrelated to open-label medication by the investigator, on Day 91 of open-label treatment. Urine was negative for RBCs. Positive urinalysis results on Day 91 were white blood cells, bacteria, amorphous sediment, generic dipstick, mucous threads, and squamous epithelial cells.

- Patient 716.192.25874, a 15-year-old male, had mild albuminuria (verbatim: urine dipstick positive protein) and mild hematuria (verbatim: urine dipstick positive for blood), both judged by the investigator to be probably unrelated to open-label medication, on Day 169 of open-label treatment. Urine was negative for RBCs. Positive urinalysis results on Day 169 of open-label treatment were white blood cells, generic dipstick, mucous threads, and squamous epithelial cells.

5.10 Electrocardiographic Data

A 12-lead ECG was conducted at the open-label Study 716 Baseline Visit (the last assessment from Study 701, 704 or 715 was acceptable if taken within 3 weeks of the open-label baseline assessment and not clinically significant). An additional ECG was performed at the Week 24 or Early Withdrawal visit; a repeat ECG was performed at the Taper End visit and Follow-up visit if clinically significant abnormalities were found at the previous visit. Table 15.4.1, Section 12, presents summary data for all patients with ECG assessments during the study. Per-patient information is provided in Listing 15.4.1, Appendix E.

According to Table 15.4.1, Section 12, no patients in the study had abnormal ECG assessments at the Study 716 Baseline Visit, Week 24, or Taper End. One acute-study paroxetine patient (716.006.25420) had an abnormal ECG assessment at the Taper End visit (Listing 15.4.1, Appendix E); this patient does not appear in Table 15.4.1, Section 12, as the repeat ECG was normal.

Patients 716.172.25619 and 716.014.25353 had an on-treatment ECG reported on a Baseline page of the CRF, which cannot be assigned to a visit window. The ECG for patient 716.172.25619 was listed as missing; the ECG for patient 716.014.25353 was slotted to Taper End. Patient 716.010.28172 had an on-treatment ECG reported on a Follow-up page of the CRF; the ECG was slotted to Follow-up. These ECGs are not included in the summary tables (see Section 13, Errata). Results for all were normal.

Two patients, one in each acute-study treatment group, had an abnormal ECG during the study that was reported as an adverse event:

- Patient 716.025.25805, a 12-year-old female in the acute-study paroxetine group, had an adverse event of mild electrocardiogram abnormal (verbatim: abnormal ECG), judged by the investigator to be unrelated to study medication, 18 days after the last dose of study medication (study Day 59) (Listing 15.1.2, Appendix D). This adverse event does not appear in Table 15.1.1.6 because the event occurred more than 14 days after the last dose of study medication. The patient had taken paroxetine for 58 days during the acute study, including taper, and 41 days during the open-label Treatment Phase (i.e., after a total of 99 days paroxetine exposure).

- Patient 716.165.25664, a 9-year-old male in the acute-study placebo group, had an adverse event of mild bundle branch block (verbatim: abnormal ECG), judged unrelated to open-label study medication by the

investigator, on Day 127 of open-label study medication (Listing 15.1.1, Appendix D). Study medication was stopped due to this event. A narrative for this patient can be located in Table 15.0, Section 12.

6 Efficacy Results

6.1 Efficacy Evaluations

This section presents summaries for all of the efficacy variables. Efficacy variables were summarized descriptively for the ITT and PPX populations (see Section 3.14.3, Population/Datasets To Be Evaluated), except for the CGI–Global Improvement item, which was summarized for the ITT population only, since it was based on acute-study baseline. The ITT population comprised 133 patients in the acute-study paroxetine group and 130 patients in the acute-study placebo group. The PPX population comprised 96 patients, 50 with a primary diagnosis of MDD and 46 with a primary diagnosis of OCD.

Data are presented in the form of data listings and tables of counts, means and standard deviations. Listings and tables were obtained using the SAS statistical package, version 6.12.

6.1.1 Datasets Analyzed

Two datasets were used to summarize the efficacy results: an OC dataset and a Week 24 LOCF dataset. For both the ITT and PPX populations, descriptive summaries are provided based on the OC dataset at each visit and the LOCF dataset, with primary inferences based on the protocol-defined Week 24 endpoint.

In the OC dataset, efficacy data were assessed at the timepoint at which they were collected; no data were carried forward to estimate missing data.

In the LOCF datasets for change in CY–BOCS total score and change in CDRS–R total score, the last known non-missing post-baseline score for each patient was carried forward to estimate missing data points. In the LOCF datasets for change in CGI–Severity of Illness and proportion of responders based on the CGI–Global Improvement item, the last non-zero post-baseline score for each patient was carried forward to estimate missing data points. The LOCF dataset contains all data from the Week 24 visit, plus the last on-treatment assessment for patients who withdrew before Week 24.

6.2 Primary Efficacy Variable

There was no primary measure of efficacy in this study.

6.3 Secondary Efficacy Variables

6.3.1 Change from Baseline in Children's Depression Rating Scale–Revised (CDRS–R)

The pre-defined endpoint was the change from baseline in CDRS–R total score at the Week 24 visit (OC and LOCF). As this efficacy variable was specific to MDD, only those patients entering from Study 701, and from Study 715 with a primary diagnosis of MDD, were included in these summaries. Individual and total CDRS–R scores are listed by patient, by acute-study treatment group, and by age group in Listing 14.1.1, Appendix C.

The Week 24 OC dataset based on the ITT population for the change from acute-study baseline in CDRS–R total score contained 41 patients from the acute-study paroxetine group and 23 patients from the acute-study placebo group. The Week 24 LOCF dataset based on the ITT population for change from baseline in CDRS–R total score contained 54 patients from the acute-study paroxetine group and 47 patients from the acute-study placebo group.

Table 47 presents summary statistics for the change from acute-study baseline in CDRS–R total score for the Week 24 OC and Week 24 LOCF datasets by acute-study treatment group for both age groups separately and combined (ITT population). The mean CDRS–R total score decreased from acute-study baseline to the Week 24 OC and Week 24 LOCF endpoints for both acute-study treatment groups. The overall mean change from acute-study baseline was a decrease of 33.8 points (SD 12.22) for Week 24 OC and a decrease of 27.7 points (SD 15.55) for Week 24 LOCF.

At the Week 24 LOCF endpoint, patients who had received paroxetine in their acute study had slightly greater decreases from acute-study in mean CDRS–R total score than did patients who had received placebo in their acute study. Children in both acute-study treatment groups improved slightly more than adolescents at both the Week 24 LOCF and OC endpoints.

Table 47 Summary Statistics for Acute-study Baseline and Change from Acute-study Baseline in CDRS–R Total Score by Age Group and Acute-study Treatment Group (ITT Population with Primary Diagnosis of MDD)

	Acute-study Treatment Group											
	Paroxetine				Placebo				Total			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Age Group: Total												
Acute-study baseline	81	60.4	(8.95)	45 to 84	66	60.4	(7.97)	45 to 87	147	60.4	(8.49)	45 to 87
Change from Acute-study baseline to:												
Week 24 OC	41	-33.4	(13.01)	-54 to 2	23	-34.5	(10.90)	-60 to -8	64	-33.8	(12.22)	-60 to 2
Week 24 LOCF	54	-29.3	(15.25)	-54 to 13	47	-25.9	(15.85)	-60 to 3	101	-27.7	(15.55)	-60 to 13
Age Group: Children												
Acute-study baseline	39	57.5	(6.54)	46 to 78	36	59.7	(8.04)	45 to 82	75	58.6	(7.33)	45 to 82
Change from Acute-study baseline to:												
Week 24 OC	17	-34.0	(9.51)	-52 to -14	10	-35.9	(12.39)	-60 to -22	27	-34.7	(10.47)	-60 to -14
Week 24 LOCF	23	-30.6	(11.53)	-52 to -5	27	-27.3	(15.78)	-60 to 1	50	-28.8	(13.95)	-60 to 1
Age Group: Adolescents												
Acute-study baseline	42	63.1	(10.06)	45 to 84	30	61.3	(7.92)	46 to 87	72	62.4	(9.21)	45 to 87
Change from Acute-study baseline to:												
Week 24 OC	24	-33.0	(15.20)	-54 to 2	13	-33.5	(10.01)	-46 to -8	37	-33.2	(13.46)	-54 to 2
Week 24 LOCF	31	-28.4	(17.63)	-54 to 13	20	-24.2	(16.18)	-46 to 3	51	-26.7	(17.04)	-54 to 13

Source: Table 14.1.1b, Section 11; Listing 14.1.1, Appendix C

Note: Study 715 data were collected at Screening rather than Baseline.

The PPX population for the Week 24 OC and Week 24 LOCF datasets for the change from acute-study Treatment Phase endpoint in CDRS–R total score contained 28 and 37 patients, respectively. All patients in the PPX population received paroxetine in their acute study and had a CDRS–R assessment scheduled at the final visit of the acute-study Treatment Phase (i.e., excludes Study 715 patients). Table 48 presents summary statistics for the change from acute-study Treatment Phase endpoint in CDRS–R total score for the Week 24 OC and Week 24 LOCF datasets for both age groups separately and combined (PPX population). The mean decrease in CDRS–R total score observed in the acute study was maintained during this open-label extension phase. Furthermore, the mean CDRS–R total score decreased from acute-study Treatment Phase endpoint to the Week 24 OC endpoint and Week 24 LOCF endpoint. Children had a greater decrease in CDRS–R total score from acute-study Treatment Phase endpoint to the Week 24 OC and Week 24 LOCF endpoints than adolescents, for whom the Week 24 LOCF scores were essentially the same as at acute-study treatment phase endpoint.

Table 48 Summary Statistics for Acute-study Treatment Phase Endpoint and Change from Acute-study Treatment Phase Endpoint in CDRS–R Total Score by Age Group (PPX Population with Primary Diagnosis of MDD)

	Acute-study paroxetine Group			
	N	**Mean**	**(SD)**	**Range**
Age Group: Total				
Acute-study Treatment Phase Endpoint	50	33.9	(12.23)	18 to 71
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	28	-6.7	(14.35)	-37 to 30
Week 24 LOCF	37	-3.1	(16.44)	-37 to 33
Age Group: Children				
Acute-study Treatment Phase Endpoint	25	33.2	(11.95)	18 to 63
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	13	-8.2	(13.87)	-37 to 3
Week 24 LOCF	15	-8.3	(12.89)	-37 to 3
Age Group: Adolescents				
Acute-study Treatment Phase Endpoint	25	34.5	(12.72)	19 to 71
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	15	-5.4	(15.11)	-30 to 30
Week 24 LOCF	22	0.5	(17.87)	-30 to 33

Source: Table 14.1.1d, Section 11; Listing 14.1.1; Appendix C

For patients in the acute-study placebo group (ITT population), summary statistics for change from acute-study Treatment Phase endpoint in CDRS–R total score for the Week 24 OC and Week 24 LOCF datasets for both age groups separately and combined are presented in Table 49. CDRS–R total scores decreased at Week 24 OC similar to the decreases seen in the PPX population. Changes at Week 24 LOCF in both age groups were very small.

Table 49 Summary Statistics for Acute-study Treatment Phase Endpoint and Change from Acute-study Treatment Phase Endpoint in CDRS–R Total Score by Age Group (ITT Population with Primary Diagnosis of MDD and Acute-study Treatment Group of Placebo)

	Acute-study placebo Group			
	N	**Mean**	**(SD)**	**Range**
Age Group: Total				
Acute-study Treatment Phase Endpoint	65	34.4	(11.65)	18 to 65
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	23	-6.6	(12.96)	-31 to 29
Week 24 LOCF	46	0.3	(16.25)	-31 to 45
Age Group: Children				
Acute-study Treatment Phase Endpoint	36	32.7	(10.47)	18 to 51
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	10	-8.3	(10.30)	-25 to 3
Week 24 LOCF	27	-0.3	(15.05)	-25 to 38
Age Group: Adolescents				
Acute-study Treatment Phase Endpoint	29	36.6	(12.83)	18 to 65
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	13	-5.2	(14.97)	-31 to 29
Week 24 LOCF	19	1.1	(18.23)	-30 to 45

Source: Table 14.1.1e, Section 11; Listing 14.1.1; Appendix C

6.3.2 Change from Baseline in Children's Yale-Brown Obsessive Compulsive Scale (CY–BOCS)

The pre-defined endpoint was the change from baseline in CY–BOCS total score at the Week 24 visit (OC and LOCF). As this efficacy variable was specific to OCD, only those patients entering from Study 704, or from Study 715 with a primary diagnosis of OCD, were included in these summaries. Individual and total CY–BOCS scores are listed by patient, by acute-study treatment group, and age group in Listing 14.2.1, Appendix C.

The Week 24 OC dataset based on the ITT population for the change from acute-study baseline in CY–BOCS total score contained 24 patients from the acute-study paroxetine group and 21 patients from the acute-study placebo group. The Week 24 LOCF dataset based on the ITT population for change from baseline in CY–BOCS total score contained 32 patients from the acute-study paroxetine group and 38 patients from the acute-study placebo group.

Table 50 presents summary statistics for change from acute-study baseline in CY–BOCS total score for the Week 24 OC and Week 24 LOCF datasets by acute-study treatment group for both age groups separately and combined (ITT population). The overall mean change from acute-study baseline was a decrease of 16.2 points (SD 7.31) for Week 24 OC and a decrease of 12.9 points (SD 9.25) for Week 24 LOCF. The overall mean change in CY–BOCS total score from acute-study baseline was similar in the two acute-study treatment groups at the Week 24 OC endpoint, but at the Week 24 LOCF endpoint the decrease was greater among patients who had received paroxetine in their acute study. The overall mean change in CY–BOCS total score from acute-study baseline was similar in children and adolescents.

Table 50 Summary Statistics for Acute-study Baseline and Change from Acute-study Baseline in CY–BOCS Total Score by Age Group and Acute-study Treatment Group (ITT Population with Primary Diagnosis of OCD)

	Acute-study Treatment Group											
	Paroxetine				Placebo				Total			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Age Group: Total												
Acute-study baseline	52	24.8	(4.73)	18 to 36	64	24.8	(4.81)	16 to 37	116	24.8	(4.75)	16 to 37
Change from Acute-study baseline to:												
Week 24 OC	24	-16.2	(7.02)	-29 to -7	21	-16.2	(7.80)	-33 to -6	45	-16.2	(7.31)	-33 to -6
Week 24 LOCF	32	-15.8	(8.74)	-29 to 12	38	-10.6	(9.10)	-33 to 3	70	-12.9	(9.25)	-33 to 12
Age Group: Children												
Acute-study baseline	28	23.6	(4.36)	18 to 34	36	25.0	(5.11)	16 to 37	64	24.4	(4.81)	16 to 37
Change from Acute-study baseline to:												
Week 24 OC	13	-15.2	(6.20)	-25 to -7	11	-16.9	(8.93)	-33 to -6	24	-16.0	(7.45)	-33 to -6
Week 24 LOCF	17	-14.9	(9.34)	-27 to 12	21	-10.5	(9.93)	-33 to 2	38	-12.4	(9.80)	-33 to 12
Age Group: Adolescents												
Acute-study baseline	24	26.0	(4.89)	19 to 36	28	24.5	(4.46)	16 to 37	52	25.2	(4.69)	16 to 37
Change from Acute-study baseline to:												
Week 24 OC	11	-17.5	(7.99)	-29 to -7	10	-15.5	(6.75)	-23 to -6	21	-16.5	(7.31)	-29 to -6
Week 24 LOCF	15	-16.8	(8.20)	-29 to -2	17	-10.6	(8.25)	-23 to 3	32	-13.5	(8.68)	-29 to 3

Source: Table 14.2.1b, Section 11; Listing 14.2.1, Appendix C

Note: Study 715 data were collected at Screening rather than Baseline.

The PPX population for the Week 24 OC and Week 24 LOCF datasets for change from acute-study Treatment Phase endpoint in CY–BOCS total score contained 22 and 30 patients, respectively. All patients in the PPX population received paroxetine in their acute study and had a CY-BOCS assessment scheduled at the final visit of the acute-study Treatment Phase (i.e., excludes Study 715 patients). Table 51 presents summary statistics for change from acute-study Treatment Phase endpoint in CY–BOCS total score for the Week 24 OC and Week 24 LOCF datasets for both age groups separately and combined (PPX population). The mean decrease in CY–BOCS total score observed in the acute study was maintained during this open-label extension phase. The mean CY–BOCS total score decreased slightly from acute-study Treatment Phase endpoint to the Week 24 OC and Week 24 LOCF endpoints. Adolescents had a greater decrease in CY–BOCS total score from acute-study Treatment Phase endpoint to the Week 24 OC and Week 24 LOCF endpoints than children.

Table 51 Summary Statistics for Acute-study Treatment Phase Endpoint and Change from Acute-study Treatment Phase Endpoint in CY–BOCS Total Score by Age Group (PPX Population with Primary Diagnosis of OCD)

	Acute-study paroxetine Group			
	N	**Mean**	**(SD)**	**Range**
Age Group: Total				
Acute-study Treatment Phase Endpoint	46	14.2	(8.30)	0 to 34
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	22	-3.8	(4.87)	-13 to 4
Week 24 LOCF	30	-3.8	(6.54)	-20 to 15
Age Group: Children				
Acute-study Treatment Phase Endpoint	25	12.1	(8.39)	0 to 34
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	12	-1.9	(5.02)	-13 to 4
Week 24 LOCF	16	-1.8	(7.73)	-20 to 15
Age Group: Adolescents	21	16.6	(7.68)	3 to 34
Acute-study Treatment Phase Endpoint				
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	10	-6.0	(3.80)	-10 to 2
Week 24 LOCF	14	-6.1	(3.92)	-12 to 2

Source: Table 14.2.1d, Section 11; Listing 14.2.1; Appendix C

For patients in the acute-study placebo group, summary statistics for change from acute-study Treatment Phase endpoint in CY–BOCS total score for the Week 24

OC and Week 24 LOCF datasets for both age groups separately and combined are presented in Table 52. CY–BOCS total score decreases at Week 24 OC and LOCF were similar to the decreases seen in the PPX population.

Table 52 Summary Statistics for Acute-study Treatment Phase Endpoint and Change from Acute-study Treatment Phase Endpoint in CY–BOCS Total Score by Age Group (ITT Population with Primary Diagnosis of OCD and Acute-study Treatment Group of Placebo)

	Acute-study placebo Group			
	N	**Mean**	**(SD)**	**Range**
Age Group: Total				
Acute-study Treatment Phase Endpoint	63	17.3	(7.64)	0 to 36
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	20	-4.9	(7.38)	-18 to 10
Week 24 LOCF	37	-2.6	(6.57)	-18 to 10
Age Group: Children				
Acute-study Treatment Phase Endpoint	35	16.7	(7.99)	0 to 33
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	10	-4.4	(8.50)	-16 to 10
Week 24 LOCF	20	-2.0	(7.06)	-16 to 10
Age Group: Adolescents	28	18.0	(7.27)	0 to 36
Acute-study Treatment Phase Endpoint				
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	10	-5.4	(6.48)	-18 to 3
Week 24 LOCF	17	-3.4	(6.07)	-18 to 6

Source: Table 14.2.1e, Section 11; Listing 14.2.1; Appendix C

6.3.3 Proportion of Responders Based on the Clinical Global Impression (CGI)–Global Improvement Item

CGI–Global Improvement item scores are listed by patient by acute-study treatment group and age group in Listing 14.3.1, Appendix C.

6.3.3.1 CGI–Global Improvement in Patients with a Primary Diagnosis of MDD

The number of patients in each category of the CGI–Global Improvement item for patients in the ITT population with a primary diagnosis of MDD is presented in Table 53. Results are presented for Week 24 OC and Week 24 LOCF datasets by acute-study treatment group for both age groups separately and combined. A

responder was defined as a patient who scored 1 (very much improved) or 2 (much improved) at endpoint compared to acute-study baseline. The majority of patients had a score of 1 or 2 at both the Week 24 OC (90.8%, 59/65) and Week 24 LOCF (70.4%, 100/142) endpoints.

In the Week 24 OC dataset for the combined age groups, 90.5% (38/42) of patients in the acute-study paroxetine group and 91.3% (21/23) of patients in the acute-study placebo group had a score of 1 (very much improved) or 2 (much improved). In the Week 24 LOCF dataset for the combined age groups, 74.4% (58/78) of patients in the acute-study paroxetine group and 65.6% (42/64) patients in the acute-study placebo group had a score of 1 (very much improved) or 2 (much improved).

Table 54 shows the number and percentage of responders based on the CGI–Global Improvement item for patients in the ITT population with a primary diagnosis of MDD by visit week. Results are presented for each visit by acute-study treatment group for both age groups separately and combined. Generally, there was a slightly higher proportion of responders in the acute-study paroxetine group than in the acute-study placebo group. In addition, slightly higher percentages of children were generally rated 1 (very much improved) or 2 (much improved) than adolescents.

Table 53 Number (%) of Patients in Each Category of CGI–Global Improvement Item by Age Group and Acute-study Treatment Group (ITT Population with Primary Diagnosis of MDD)

	Week 24 OC						Week 24 LOCF					
	Paroxetine		Placebo		Total		Paroxetine		Placebo		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Total	**(N = 81)**		**(N = 66)**		**(N = 147)**		**(N = 81)**		**(N = 66)**		**(N = 147)**	
Very much improved	23	(54.8)	9	(39.1)	32	(49.2)	33	(42.3)	15	(23.4)	48	(33.8)
Much improved	15	(35.7)	12	(52.2)	27	(41.5)	25	(32.1)	27	(42.2)	52	(36.6)
Minimally improved	1	(2.4)	1	(4.3)	2	(3.1)	11	(14.1)	9	(14.1)	20	(14.1)
No change	1	(2.4)	1	(4.3)	2	(3.1)	6	(7.7)	8	(12.5)	14	(9.9)
Minimally worse	0	–	0	–	0	–	0	–	3	(4.7)	3	(2.1)
Much worse	0	–	0	–	0	–	2	(2.6)	2	(3.1)	4	(2.8)
Very much worse	0	–	0	–	0	–	1	(1.3)	0	–	1	(0.7)
Not assessed	2	(4.8)	0	–	2	(3.1)	0	–	0	–	0	–
Total	42	(100.0)	23	(100.0)	65	(100.0)	78	(100.0)	64	(100.0)	142	(100.0)
Age Group: Children	**(N = 39)**		**(N = 36)**		**(N = 75)**		**(N = 39)**		**(N = 36)**		**(N = 75)**	
Very much improved	11	(64.7)	3	(30.0)	14	(51.9)	16	(43.2)	9	(25.7)	25	(34.7)
Much improved	5	(29.4)	6	(60.0)	11	(40.7)	13	(35.1)	16	(45.7)	29	(40.3)
Minimally improved	0	–	1	(10.0)	1	(3.7)	4	(10.8)	5	(14.3)	9	(12.5)
No change	0	–	0	–	0	–	3	(8.1)	4	(11.4)	7	(9.7)
Minimally worse	0	–	0	–	0	–	0	–	1	(2.9)	1	(1.4)
Much worse	0	–	0	–	0	–	1	(2.7)	0	–	1	(1.4)
Very much worse	0	–	0	–	0	–	0	–	0	–	0	–
Not assessed	1	(5.9)	0	–	1	(3.7)	0	–	0	–	0	–
Total	17	(100.0)	10	(100.0)	27	(100.0)	37	(100.0)	35	(100.0)	72	(100.0)

Source: Table 14.3.1, Section 11; Listing 14.3.1, Appendix C
Total row = number of patients with a Week 24 OC or LOCF assessment

Table continues

Table 53 (Continued) Number (%) of Patients in Each Category of CGI–Global Improvement Item by Age Group and Acute-study Treatment Group (ITT Population with Primary Diagnosis of MDD)

	Week 24 OC						Week 24 LOCF					
	Paroxetine		Placebo		Total		Paroxetine		Placebo		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group:	(N = 42)		(N = 30)		(N = 72)		(N = 42)		(N = 30)		(N = 72)	
Adolescents												
Very much improved	12	(48.0)	6	(46.2)	18	(47.4)	17	(41.5)	6	(20.7)	23	(32.9)
Much improved	10	(40.0)	6	(46.2)	16	(42.1)	12	(29.3)	11	(37.9)	23	(32.9)
Minimally improved	1	(4.0)	0	–	1	(2.6)	7	(17.1)	4	(13.8)	11	(15.7)
No change	1	(4.0)	1	(7.7)	2	(5.3)	3	(7.3)	4	(13.8)	7	(10.0)
Minimally worse	0	–	0	–	0	–	0	–	2	(6.9)	2	(2.9)
Much worse	0	–	0	–	0	–	1	(2.4)	2	(6.9)	3	(4.3)
Very much worse	0	–	0	–	0	–	1	(2.4)	0	–	1	(1.4)
Not assessed	1	(4.0)	0	–	1	(2.6)	0	–	0	–	0	–
Total	25	(100.0)	13	(100.0)	38	(100.0)	41	(100.0)	29	(100.0)	70	(100.0)

Source: Table 14.3.1, Section 11; Listing 14.3.1, Appendix C

Total row = number of patients with a Week 24 OC or LOCF assessment

Table 54 Proportion of Responders Based on CGI–Global Improvement Item by Age Group and Acute-study Treatment Group (ITT Population with Primary Diagnosis of MDD)

	Acute-study Treatment Group								
	Paroxetine			Placebo			Total		
Visit	N*	n**	%	N*	n**	(%)	N*	n**	(%)
Age Group: Total									
Week 1	68	35	(51.5)	59	28	(47.5)	127	63	(49.6)
Week 2	69	38	(55.1)	57	35	(61.4)	126	73	(57.9)
Week 3	68	48	(70.6)	53	37	(69.8)	121	85	(70.2)
Week 4	71	55	(77.5)	55	36	(65.5)	126	91	(72.2)
Week 8	60	48	(80.0)	47	37	(78.7)	107	85	(79.4)
Week 12	56	49	(87.5)	41	33	(80.5)	97	82	(84.5)
Week 16	48	40	(83.3)	37	30	(81.1)	85	70	(82.4)
Week 20	43	41	(95.3)	30	25	(83.3)	73	66	(90.4)
Week 24 OC	40	38	(95.0)	23	21	(91.3)	63	59	(93.7)
Wk 24 LOCF	78	58	(74.4)	64	42	(65.6)	142	100	(70.4)
Age Group: Children									
Week 1	33	20	(60.6)	33	19	(57.6)	66	39	(59.1)
Week 2	33	18	(54.5)	32	20	(62.5)	65	38	(58.5)
Week 3	33	26	(78.8)	31	23	(74.2)	64	49	(76.6)
Week 4	36	27	(75.0)	31	21	(67.7)	67	48	(71.6)
Week 8	29	21	(72.4)	27	22	(81.5)	56	43	(76.8)
Week 12	24	20	(83.3)	22	17	(77.3)	46	37	(80.4)
Week 16	18	16	(88.9)	21	18	(85.7)	39	34	(87.2)
Week 20	18	18	(100.0)	17	14	(82.4)	35	32	(91.4)
Week 24 OC	16	16	(100.0)	10	9	(90.0)	26	25	(96.2)
Wk 24 LOCF	37	29	(78.4)	35	25	(71.4)	72	54	(75.0)
Age Group: Adolescents									
Week 1	35	15	(42.9)	26	9	(34.6)	61	24	(39.3)
Week 2	36	20	(55.6)	25	15	(60.0)	61	35	(57.4)
Week 3	35	22	(62.9)	22	14	(63.6)	57	36	(63.2)
Week 4	35	28	(80.0)	24	15	(62.5)	59	43	(72.9)
Week 8	31	27	(87.1)	20	15	(75.0)	51	42	(82.4)
Week 12	32	29	(90.6)	19	16	(84.2)	51	45	(88.2)
Week 16	30	24	(80.0)	16	12	(75.0)	46	36	(78.3)
Week 20	25	23	(92.0)	13	11	(84.6)	38	34	(89.5)
Week 24 OC	24	22	(91.7)	13	12	(92.3)	37	34	(91.9)
Wk 24 LOCF	41	29	(70.7)	29	17	(58.6)	70	46	(65.7)

Source: Table 14.3.2, Section 11; Listing 14.3.1, Appendix C

* N = total number of patients at the visit

** Responders (n) are defined as patients with a score of 1 (very much improved) or 2 (much improved) on the scale at the visit or endpoint

6.3.3.2 CGI–Global Improvement in Patients with a Primary Diagnosis of OCD

The number of patients in each category of the CGI–Global Improvement item for patients in the ITT population with a primary diagnosis of OCD is presented in Table 55. Results are presented for Week 24 OC and Week 24 LOCF datasets by acute-study treatment group for both age groups separately and combined. The majority of patients had a score of 1 (very much improved) or 2 (much improved) at the Week 24 OC (87.8%, 43/49) and Week 24 LOCF (67.5%, 77/114) endpoints.

In the Week 24 OC dataset for the combined age groups, 84.6% (22/26) of patients in the acute-study paroxetine group and 91.3% (21/23) of patients in the acute-study placebo group had a score of 1 (very much improved) or 2 (much improved). In the Week 24 LOCF dataset for the combined age groups, 72.5% (37/51) of patients in the acute-study paroxetine group and 63.5% (40/63) patients in the acute-study placebo group had a score of 1 (very much improved) or 2 (much improved).

Table 56 shows the number and percentage of responders based on the CGI–Global Improvement item for patients in the ITT population with a primary diagnosis of OCD. Results are presented for each visit by acute-study treatment group for both age groups separately and combined. There were no notable differences between acute-study treatment groups or age groups with respect to the number and percentage of responders based on the CGI–Global Improvement item.

Table 55 Number (%) of Patients in Each Category of CGI–Global Improvement Item by Age Group and Acute-study Treatment Group (ITT Population with Primary Diagnosis of OCD)

	Week 24 OC						Week 24 LOCF					
	Paroxetine		Placebo		Total		Paroxetine		Placebo		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Total	**(N = 52)**		**(N = 64)**		**(N = 116)**		**(N = 52)**		**(N = 64)**		**(N = 116)**	
Very much improved	14	(53.8)	13	(56.5)	27	(55.1)	22	(43.1)	18	(28.6)	40	(35.1)
Much improved	8	(30.8)	8	(34.8)	16	(32.7)	15	(29.4)	22	(34.9)	37	(32.5)
Minimally improved	3	(11.5)	1	(4.3)	4	(8.2)	10	(19.6)	11	(17.5)	21	(18.4)
No change	1	(3.8)	1	(4.3)	2	(4.1)	2	(3.9)	9	(14.3)	11	(9.6)
Minimally worse	0	–	0	–	0	–	2	(3.9)	1	(1.6)	3	(2.6)
Much worse	0	–	0	–	0	–	0	–	2	(3.2)	2	(1.8)
Very much worse	0	–	0	–	0	–	0	–	0	–	0	–
Not assessed	0	–	0	–	0	–	0	–	0	–	0	–
Total	26	(100.0)	23	(100.0)	49	(100.0)	51	(100.0)	63	(100.0)	114	(100.0)
Age Group: Children	**(N = 28)**		**(N = 36)**		**(N = 64)**		**(N = 28)**		**(N = 36)**		**(N = 64)**	
Very much improved	8	(53.3)	8	(66.7)	16	(59.3)	11	(39.3)	11	(31.4)	22	(34.9)
Much improved	5	(33.3)	3	(25.0)	8	(29.6)	9	(32.1)	10	(28.6)	19	(30.2)
Minimally improved	2	(13.3)	1	(8.3)	3	(11.1)	5	(17.9)	8	(22.9)	13	(20.6)
No change	0	–	0	–	0	–	1	(3.6)	5	(14.3)	6	(9.5)
Minimally worse	0	–	0	–	0	–	2	(7.1)	1	(2.9)	3	(4.8)
Much worse	0	–	0	–	0	–	0	–	0	–	0	–
Very much worse	0	–	0	–	0	–	0	–	0	–	0	–
Not assessed	0	–	0	–	0	–	0	–	0	–	0	–
Total	15	(100.0)	12	(100.0)	27	(100.0)	28	(100.0)	35	(100.0)	63	(100.0)

Source: Table 14.3.1, Section 11; Listing 14.3.1, Appendix C

Total row = number of patients with a Week 24 OC or LOCF assessment

Table continues

Table 55 (Continued) Number (%) of Patients in Each Category of CGI–Global Improvement Item by Age Group and Acute-study Treatment Group (ITT Population with Primary Diagnosis of OCD)

	Week 24 OC						Week 24 LOCF					
	Paroxetine		Placebo		Total		Paroxetine		Placebo		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Adolescents	(N = 24)		(N = 28)		(N = 52)		(N = 24)		(N = 28)		(N = 52)	
Very much improved	6	(54.5)	5	(45.5)	11	(50.0)	11	(47.8)	7	(25.0)	18	(35.3)
Much improved	3	(27.3)	5	(45.5)	8	(36.4)	6	(26.1)	12	(42.9)	18	(35.3)
Minimally improved	1	(9.1)	0	.	1	(4.5)	5	(21.7)	3	(10.7)	8	(15.7)
No change	1	(9.1)	1	(9.1)	2	(9.1)	1	(4.3)	4	(14.3)	5	(9.8)
Minimally worse	0	–	0	–	0	–	0	–	0	–	0	–
Much worse	0	–	0	–	0	–	0	–	2	(7.1)	2	(3.9)
Very much worse	0	–	0	–	0	–	0	–	0	–	0	–
Not assessed	0	–	0	–	0	–	0	–	0	–	0	–
Total	11	(100.0)	11	(100.0)	22	(100.0)	23	(100.0)	28	(100.0)	51	(100.0)

Source: Table 14.3.1, Section 11; Listing 14.3.1, Appendix C

Total row = number of patients with a Week 24 OC or LOCF assessment

Table 56 Proportion of Responders Based on CGI–Global Improvement Item by Age Group and Acute-study Treatment Group (ITT Population with Primary Diagnosis of OCD)

	Acute-study Treatment Group								
	Paroxetine			Placebo			Total		
Visit	N*	n**	(%)	N*	n**	(%)	N*	n**	(%)
Age Group: Total									
Week 1	45	21	(46.7)	54	12	(22.2)	99	33	(33.3)
Week 2	40	22	(55.0)	55	21	(38.2)	95	43	(45.3)
Week 3	40	24	(60.0)	57	31	(54.4)	97	55	(56.7)
Week 4	49	33	(67.3)	55	33	(60.0)	104	66	(63.5)
Week 8	44	31	(70.5)	39	25	(64.1)	83	56	(67.5)
Week 12	33	27	(81.8)	35	26	(74.3)	68	53	(77.9)
Week 16	30	23	(76.7)	30	25	(83.3)	60	48	(80.0)
Week 20	23	18	(78.3)	25	22	(88.0)	48	40	(83.3)
Week 24 OC	26	22	(84.6)	23	21	(91.3)	49	43	(87.8)
Wk 24 LOCF	51	37	(72.5)	63	40	(63.5)	114	77	(67.5)
Age Group: Children									
Week 1	22	11	(50.0)	30	11	(36.7)	52	22	(42.3)
Week 2	20	11	(55.0)	31	14	(45.2)	51	25	(49.0)
Week 3	22	14	(63.6)	34	18	(52.9)	56	32	(57.1)
Week 4	26	18	(69.2)	30	18	(60.0)	56	36	(64.3)
Week 8	23	16	(69.6)	22	15	(68.2)	45	31	(68.9)
Week 12	17	14	(82.4)	21	14	(66.7)	38	28	(73.7)
Week 16	15	12	(80.0)	14	10	(71.4)	29	22	(75.9)
Week 20	12	11	(91.7)	13	12	(92.3)	25	23	(92.0)
Week 24 OC	15	13	(86.7)	12	11	(91.7)	27	24	(88.9)
Wk 24 LOCF	28	20	(71.4)	35	21	(60.0)	63	41	(65.1)
Age Group: Adolescents									
Week 1	23	10	(43.5)	24	1	(4.2)	47	11	(23.4)
Week 2	20	11	(55.0)	24	7	(29.2)	44	18	(40.9)
Week 3	18	10	(55.6)	23	13	(56.5)	41	23	(56.1)
Week 4	23	15	(65.2)	25	15	(60.0)	48	30	(62.5)
Week 8	21	15	(71.4)	17	10	(58.8)	38	25	(65.8)
Week 12	16	13	(81.3)	14	12	(85.7)	30	25	(83.3)
Week 16	15	11	(73.3)	16	15	(93.8)	31	26	(83.9)
Week 20	11	7	(63.6)	12	10	(83.3)	23	17	(73.9)
Week 24 OC	11	9	(81.8)	11	10	(90.9)	22	19	(86.4)
Wk 24 LOCF	23	17	(73.9)	28	19	(67.9)	51	36	(70.6)

Source: Table 14.3.2, Section 11; Listing 14.3.1, Appendix C

* N = total number of patients at the visit

** Responders (n) are defined as patients with a score of 1 (very much improved) or 2 (much improved) on the scale at the visit or endpoint

6.3.4 Change from Baseline in the Clinical Global Impression (CGI)-Severity of Illness Score

CGI–Severity of Illness item scores are listed by patient by acute-study treatment group and age group in Listing 14.4.1, Appendix C. The number and percentage of patients in each category of the CGI–Severity of Illness score at each visit by age group and acute-study treatment group are presented for the ITT population for patients with a primary diagnosis of MDD and OCD separately in Section 6.3.4.1 and Section 6.3.4.2, respectively.

The number and percentage of patients in each category of the CGI–Severity of Illness score at each visit by age group is presented for the PPX population in Table 14.4.1d, Section 11, and for the ITT population acute-study placebo patients only in Table 14.4.1e, Section 11.

The number and percentage of patients by change in CGI–Severity of Illness from acute-study baseline is presented for the ITT population in Table 14.4.2b, Section 11. The number and percentage of patients by change in CGI–Severity of Illness from acute-study Treatment Phase endpoint is presented for the PPX population in Table 14.4.2d, Section 11, and for the ITT population acute-study placebo patients only in Table 14.4.2e, Section 11.

6.3.4.1 CGI–Severity of Illness in Patients with a Primary Diagnosis of MDD

The number and percentage of patients in each category of the CGI–Severity of Illness item for patients in the ITT population with a primary diagnosis of MDD are presented in Table 57. Results are presented for acute-study baseline, Week 24 OC and Week 24 LOCF by acute-study treatment group for both age groups separately and combined.

Overall, 76.6% (49/64) of patients in the Week 24 OC dataset and 58.0% (83/143) of patients in the Week 24 LOCF dataset were rated as normal or borderline mentally ill, compared to no patients at acute-study baseline. In the Week 24 OC dataset for the combined age groups, 81.0% (34/42) of patients in the acute-study paroxetine group and 65.2% (15/23) of patients in the acute-study placebo group were rated as normal or borderline mentally ill. At acute-study baseline, 3.4% (5/147) of patients were rated as severely ill compared to no patients at the Week 24 OC endpoint. Similarly, in the Week 24 LOCF dataset for the combined age groups, 64.6% (51/79) of patients in the acute-study paroxetine group and 50.0% (32/64) of patients in the acute-study placebo group were rated as normal

or borderline mentally ill. At Week 24 LOCF one patient in the acute-study paroxetine group was rated as severely ill.

Overall, 61.1% (44/72) of children and 54.9% (39/71) of adolescents were rated normal or borderline mentally ill at Week 24 LOCF. Among children, at the Week 24 LOCF endpoint, 67.6% (25/37) of acute-study paroxetine patients were rated normal or borderline mentally ill compared to 54.3% (19/35) of acute-study placebo patients. Among adolescents, at Week 24 LOCF endpoint, 61.9% (26/42) of acute-study paroxetine patients were rated normal or borderline mentally ill compared to 44.8% (13/29) of acute-study placebo patients. Among children, at the Week 24 OC endpoint, 94.1% (16/17) of acute-study paroxetine patients were rated normal or borderline mentally ill compared to 60.0% (6/10) of acute-study placebo patients. Among adolescents, at the Week 24 OC endpoint, 75.0% (18/24) of acute-study paroxetine patients were rated normal or borderline mentally ill compared to 69.3% (9/13) of acute-study placebo patients.

Summary statistics for change from acute-study baseline in CGI–Severity of Illness score for Week 24 OC and Week 24 LOCF datasets by acute-study treatment group for both age groups separately and combined are presented for patients with a primary diagnosis of MDD (ITT population) in Table 58. The median CGI–Severity of Illness score decreased from acute-study baseline to the Week 24 OC and Week 24 LOCF endpoints for the overall population and for both acute-study treatment groups. There were no notable differences between acute-study treatment groups or age groups in the median change from acute-study baseline in CGI–Severity of Illness for the Week 24 OC and Week 24 LOCF datasets.

Table 57 Number (%) of Patients in Each Category of CGI–Severity of Illness Item by Age Group and Acute-study Treatment Group (ITT Population with Primary Diagnosis of MDD)

	Acute-study baseline						Week 24 OC						Week 24 LOCF					
	Paroxetine		Placebo		Total		Paroxetine		Placebo		Total		Paroxetine		Placebo		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Total	**(N = 81)**		**(N = 66)**		**(N = 147)**		**(N = 81)**		**(N = 66)**		**(N = 147)**		**(N = 81)**		**(N = 66)**		**(N = 147)**	
Normal, not at all ill	0	–	0	–	0	–	17	41.5	7	30.4	24	37.5	25	31.6	12	18.8	37	25.9
Borderline mentally ill	0	–	0	–	0	–	17	41.5	8	34.8	25	39.1	26	32.9	20	31.3	46	32.2
Mildly ill	1	1.2	2	3.0	3	2.0	5	12.2	5	21.7	10	15.6	14	17.7	11	17.2	25	17.5
Moderately ill	61	75.3	48	72.7	109	74.1	1	2.4	2	8.7	3	4.7	10	12.7	17	26.6	27	18.9
Markedly ill	15	18.5	15	22.7	30	20.4	1	2.4	1	4.3	2	3.1	3	3.8	4	6.3	7	4.9
Severely ill	4	4.9	1	1.5	5	3.4	0	–	0	–	0	–	1	1.3	0	–	1	0.7
Among most extremely ill	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–
Not assessed	0	–	0	–	0	–	1	–	0	–	1	–	0	–	0	–	0	–
Total	81	100.0	66	100.0	147	100.0	41	100.0	23	100.0	64	100.0	79	100.0	64	100.0	143	100.0
Age Group: Children	**(N = 39)**		**(N = 36)**		**(N = 75)**		**(N = 39)**		**(N = 36)**		**(N = 75)**		**(N = 39)**		**(N = 36)**		**(N = 75)**	
Normal, not at all ill	0	–	0	–	0	–	8	47.1	2	20.0	10	37.0	10	27.0	6	17.1	16	22.2
Borderline mentally ill	0	–	0	–	0	–	8	47.1	4	40.0	12	44.4	15	40.5	13	37.1	28	38.9
Mildly ill	0	–	2	5.6	2	2.7	1	5.9	2	20.0	3	11.1	8	21.6	6	17.1	14	19.4
Moderately ill	31	79.5	26	72.2	57	76.0	0	–	2	20.0	2	7.4	3	8.1	9	25.7	12	16.7
Markedly ill	7	17.9	7	19.4	14	18.7	0	–	0	–	0	–	1	2.7	1	2.9	2	2.8
Severely ill	1	2.6	1	2.8	2	2.7	0	–	0	–	0	–	0	–	0	–	0	–
Among most extremely ill	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–
Not assessed	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–
Total	39	100.0	36	100.0	75	100.0	17	100.0	10	100.0	27	100.0	37	100.0	35	100.0	72	100.0

Source: Table 14.4.1b, Section 11; Listing 14.4.1, Appendix C

Total row = number of patients with an acute-study baseline, Week 24 OC or LOCF assessment

Note: Study 715 data were collected at Screening rather than Baseline.

Table continues

Table 57 (Continued) Number (%) of Patients in Each Category of CGI–Severity of Illness Item by Age Group and Acute-study Treatment Group (ITT Population with Primary Diagnosis of MDD)

	Acute-study baseline						Week 24 OC						Week 24 LOCF					
	Paroxetine		Placebo		Total		Paroxetine		Placebo		Total		Paroxetine		Placebo		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group:	(N = 42)		(N = 30)		(N = 72)		(N = 42)		(N = 30)		(N = 72)		(N = 42)		(N = 30)		(N = 72)	
Adolescents																		
Normal, not at all ill	0	–	0	–	0	–	9	37.5	5	38.5	14	37.8	15	35.7	6	20.7	21	29.6
Borderline mentally ill	0	–	0	–	0	–	9	37.5	4	30.8	13	35.1	11	26.2	7	24.1	18	25.4
Mildly ill	1	2.4	0	–	1	1.4	4	16.7	3	23.1	7	18.9	6	14.3	5	17.2	11	15.5
Moderately ill	30	71.4	22	73.3	52	72.2	1	4.2	0	–	1	2.7	7	16.7	8	27.6	15	21.1
Markedly ill	8	19.0	8	26.7	16	22.2	1	4.2	1	7.7	2	5.4	2	4.8	3	10.3	5	7.0
Severely ill	3	7.1	0	–	3	4.2	0	–	0	–	0	–	1	2.4	0	–	1	1.4
Among most extremely ill	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–
Not assessed	0	–	0	–	0	–	1	–	0	–	1	–	0	–	0	–	0	–
Total	42	100.0	30	100.0	72	100.0	24	100.0	13	100.0	37	100.0	42	100.0	29	100.0	71	100.0

Source: Table 14.4.1b, Section 11; Listing 14.4.1, Appendix C
Total row = number of patients with an acute-study baseline, Week 24 OC or LOCF assessment
Note: Study 715 data were collected at Screening rather than Baseline.

Table 58 Summary Statistics for Acute-study Baseline and Change from Acute-study Baseline in CGI–Severity of Illness Score by Age Group and Acute-study Treatment Group (ITT Population with Primary Diagnosis of MDD)

	Acute-study Treatment Group											
	Paroxetine				Placebo				Total			
	N	Mean	Median	Range	N	Mean	Median	Range	N	Mean	Median	Range
Age Group: Total												
Acute-study baseline	81	4.3	4.0	3 to 6	66	4.2	4.0	3-6	147	4.3	4.0	3 to 6
Change from Acute-study baseline to:												
Week 24 OC	41	-2.5	-3.0	-5 to 1	23	-2.0	-2.0	-4 to 0	64	-2.3	-2.0	-5 to 1
Week 24 LOCF	79	-2.0	-2.0	-5 to 2	64	-1.5	-2.0	-4 to 1	143	-1.8	-2.0	-5 to 2
Age Group: Children												
Acute-study baseline	39	4.2	4.0	4 to 6	36	4.2	4.0	3 to 6	75	4.2	4.0	3 to 6
Change from Acute-study baseline to:												
Week 24 OC	17	-2.7	-3.0	-5 to -1	10	-1.8	-2.0	-4 to 0	27	-2.4	-2.0	-5 to 0
Week 24 LOCF	37	-2.0	-2.0	-5 to 0	35	-1.6	-2.0	-4 to 0	72	-1.8	-2.0	-5 to 0
Age Group: Adolescents												
Acute-study baseline	42	4.3	4.0	3 to 6	30	4.3	4.0	4 to 5	72	4.3	4.0	3 to 6
Change from Acute-study baseline to:												
Week 24 OC	24	-2.3	-2.5	-5 to 1	13	-2.2	-2.0	-4 to 0	37	-2.3	-2.0	-5 to 1
Week 24 LOCF	42	-2.0	-2.0	-5 to 2	29	-1.4	-1.0	-4 to 1	71	-1.7	-2.0	-5 to 2

Source: Table 14.4.3b, Section 11; Listing 14.4.1, Appendix C

Note: Study 715 data were collected at Screening rather than Baseline.

Summary statistics for change from acute-study Treatment Phase endpoint in CGI–Severity of Illness score for the Week 24 OC and Week 24 LOCF datasets for both age groups separately and combined are presented for patients with a primary diagnosis of MDD (PPX population) in Table 59. The median change from acute-study Treatment Phase endpoint to the Week 24 OC and Week 24 LOCF endpoints was 0.0, indicating no further change in CGI–Severity of Illness score during the open-label Treatment Phase of Study 716.

Table 59 Summary Statistics for Acute-study Treatment Phase Endpoint and Change from Acute-study Treatment Phase Endpoint in CGI–Severity of Illness Score by Age Group (PPX Population with Primary Diagnosis of MDD)

	Acute-study paroxetine Group			
	N	**Mean**	**Median**	**Range**
Age Group: Total				
Acute-study Treatment Phase Endpoint	50	2.6	2.0	1 to 5
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	28	-0.6	0.0	-4 to 1
Week 24 LOCF	49	-0.1	0.0	-4 to 3
Age Group: Children				
Acute-study Treatment Phase Endpoint	25	2.5	2.0	1 to 5
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	13	-0.5	0.0	-4 to 1
Week 24 LOCF	24	-0.2	0.0	-4 to 2
Age Group: Adolescents				
Acute-study Treatment Phase Endpoint	25	2.6	3.0	1 to 5
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	15	-0.7	-1.0	-3 to 1
Week 24 LOCF	25	0.0	0.0	-3 to 3

Source: Table 14.4.3d, Section 11; Listing 14.4.1; Appendix C

Summary statistics for change from acute-study Treatment Phase endpoint in CGI–Severity of Illness score for the Week 24 OC and Week 24 LOCF datasets for both age groups separately and combined for patients in the acute-study placebo group with a primary diagnosis of MDD are provided in Table 60. CGI–Severity of Illness score decreases at Week 24 OC and LOCF were similar to the negligible decreases seen in the PPX population.

Table 60 Summary Statistics for Acute-study Treatment Phase Endpoint and Change from Acute-study Treatment Phase Endpoint in CGI–Severity of Illness Score by Age Group (ITT Population with Primary Diagnosis of MDD and Acute-study Treatment of Placebo)

	Acute-study placebo Group			
	N	**Mean**	**Median**	**Range**
Age Group: Total				
Acute-study Treatment Phase Endpoint	65	2.9	3.0	1 to 5
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	23	-0.5	0.0	-4 to 3
Week 24 LOCF	63	-0.2	0.0	-4 to 3
Age Group: Children				
Acute-study Treatment Phase Endpoint	36	3.0	3.0	1 to 5
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	10	-1.0	-0.5	-4 to 0
Week 24 LOCF	35	-0.4	0.0	-4 to 3
Age Group: Adolescents				
Acute-study Treatment Phase Endpoint	29	2.8	3.0	1 to 4
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	13	-0.2	0.0	-2 to 3
Week 24 LOCF	28	0.0	0.0	-2 to 3

Source: Table 14.4.3e, Section 11; Listing 14.4.1; Appendix C

6.3.4.2 CGI–Severity of Illness in Patients with a Primary Diagnosis of OCD

The number and percentage of patients in each category of the CGI–Severity of Illness item for patients in the ITT population with a primary diagnosis of OCD are presented in Table 61. Results are presented for acute-study baseline, Week 24 OC and Week 24 LOCF by acute-study treatment group for both age groups separately and combined.

Overall, 53.1% (26/49) of patients in the Week 24 OC dataset and 33.3% (38/114) of patients in the Week 24 LOCF dataset with a primary diagnosis of OCD were rated as normal or borderline mentally ill, compared to no patients at acute-study baseline. In the Week 24 OC dataset for the combined age groups, 57.7% (15/26) of patients in the acute-study paroxetine group and 47.8% (11/23) of patients in the acute-study placebo group were rated as normal or borderline mentally ill. Similarly, in the Week 24 LOCF dataset for the combined age groups, 45.1% (23/51) of patients in the acute-study paroxetine group and 23.8% (15/63)

of patients in the acute-study placebo group were rated as normal or borderline mentally ill.

At acute-study baseline, 50.9% (59/116) of patients were rated as markedly ill or severely ill, compared to no patients at the Week 24 OC endpoint. At the Week 24 LOCF endpoint, 7 patients were rated markedly ill and 1 patient was rated severely ill.

Overall, 30.2% (19/63) of children and 37.3% (19/51) of adolescents were rated normal or borderline mentally ill at Week 24 LOCF. Among children, at the Week 24 LOCF endpoint, 39.3% (11/28) of acute-study paroxetine patients were rated normal or borderline mentally ill compared to 22.9% (8/35) of acute-study placebo patients. Among adolescents, at the Week 24 LOCF endpoint, 52.2% (12/23) of acute-study paroxetine patients were rated normal or borderline mentally ill compared to 25.0% (7/28) of acute-study placebo patients. Among children, at the Week 24 OC endpoint, 53.3% (8/15) of acute-study paroxetine patients were rated normal or borderline mentally ill compared to 58.3% (7/12) of acute-study placebo patients. Among adolescents, at the Week 24 OC endpoint, 63.6% (7/11) of acute-study paroxetine patients were rated normal or borderline mentally ill compared to 36.4% (4/11) of acute-study placebo patients.

Summary statistics for change from acute-study baseline in CGI–Severity of Illness score for Week 24 OC and Week 24 LOCF datasets by acute-study treatment group for both age groups separately and combined are presented for patients with a primary diagnosis of OCD (ITT population) in Table 62. The median CGI–Severity of Illness score decreased 2.0 points from acute-study baseline to the Week 24 OC and Week 24 LOCF endpoints for the overall population and for both acute-study treatment groups. There were no notable differences between acute-study treatment groups or age groups in the median change from acute-study baseline in CGI–Severity of Illness for the Week 24 OC and Week 24 LOCF datasets.

Table 61 Number (%) of Patients in Each Category of CGI–Severity of Illness Item by Age Group and Acute-study Treatment Group (ITT Population with Primary Diagnosis of OCD)

	Acute-study Baseline						Week 24 OC						Week 24 LOCF					
	Paroxetine		Placebo		Total		Paroxetine		Placebo		Total		Paroxetine		Placebo		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group: Total	**(N = 52)**		**(N = 64)**		**(N = 116)**		**(N = 52)**		**(N = 64)**		**(N = 116)**		**(N = 52)**		**(N = 64)**		**(N = 116)**	
Normal, not at all ill	0	–	0	–	0	–	8	(30.8)	6	(26.1)	14	(28.6)	14	(27.5)	8	(12.7)	22	(19.3)
Borderline mentally ill	0	–	0	–	0	–	7	(26.9)	5	(21.7)	12	(24.5)	9	(17.6)	7	(11.1)	16	(14.0)
Mildly ill	0	–	2	(3.1)	2	(1.7)	10	(38.5)	10	(43.5)	20	(40.8)	16	(31.4)	25	(39.7)	41	(36.0)
Moderately ill	29	(55.8)	26	(40.6)	55	(47.4)	1	(3.8)	2	(8.7)	3	(6.1)	9	(17.6)	18	(28.6)	27	(23.7)
Markedly ill	20	(38.5)	26	(40.6)	46	(39.7)	0	–	0	–	0	–	3	(5.9)	4	(6.3)	7	(6.1)
Severely ill	3	(5.8)	10	(15.6)	13	(11.2)	0	–	0	–	0	–	0	–	1	(1.6)	1	(0.9)
Among most extremely ill	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–
Total	52	100.0	64	100.0	116	100.0	26	100.0	23	100.0	49	100.0	51	100.0	63	100.0	114	100.0
Age Group: Children	**(N = 28)**		**(N = 36)**		**(N = 64)**		**(N = 28)**		**(N = 36)**		**(N = 64)**		**(N = 28)**		**(N = 36)**		**(N = 64)**	
Normal, not at all ill	0	–	0	–	0	–	5	(33.3)	4	(33.3)	9	(33.3)	7	(25.0)	5	(14.3)	12	(19.0)
Borderline mentally ill	0	–	0	–	0	–	3	(20.0)	3	(25.0)	6	(22.2)	4	(14.3)	3	(8.6)	7	(11.1)
Mildly ill	0	–	1	(2.8)	1	(1.6)	7	(46.7)	5	(41.7)	12	(44.4)	10	(35.7)	15	(42.9)	25	(39.7)
Moderately ill	18	(64.3)	17	(47.2)	35	(54.7)	0	–	0	–	0	–	6	(21.4)	10	(28.6)	16	(25.4)
Markedly ill	9	(32.1)	11	(30.6)	20	(31.3)	0	–	0	–	0	–	1	(3.6)	2	(5.7)	3	(4.8)
Severely ill	1	(3.6)	7	(19.4)	8	(12.5)	0	–	0	–	0	–	0	–	0	–	0	–
Among most extremely ill	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–
Total	28	100.0	36	100.0	64	100.0	15	100.0	12	100.0	27	100.0	23	100.0	35	100.0	63	100.0

Source: Table 14.4.1b, Section 11; Listing 14.4.1, Appendix C

N = number of patients with an acute-study baseline, Week 24 OC or LOCF assessment.

Note: Study 715 data were collected at Screening rather than Baseline.

Table continues

Table 61 (Continued) Number (%) of Patients in Each Category of CGI–Severity of Illness Item by Age Group and Acute-study Treatment Group (ITT Population with Primary Diagnosis of OCD)

	Acute-study baseline						Week 24 OC						Week 24 LOCF					
	Paroxetine		Placebo		Total		Paroxetine		Placebo		Total		Paroxetine		Placebo		Total	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Age Group:	(N = 24)		(N = 28)		(N = 52)		(N = 24)		(N = 28)		(N = 52)		(N = 24)		(N = 28)		(N = 52)	
Adolescents																		
Normal, not at all ill	0	–	0	–	0	–	3	(27.3)	2	(18.2)	5	(22.7)	7	(30.4)	3	(10.7)	10	(19.6)
Borderline mentally ill	0	–	0	–	0	–	4	(36.4)	2	(18.2)	6	(27.3)	5	(21.7)	4	(14.3)	9	(17.6)
Mildly ill	0	–	1	(3.6)	1	(1.9)	3	(27.3)	5	(45.5)	8	(36.4)	6	(26.1)	10	(35.7)	16	(31.4)
Moderately ill	11	(45.8)	9	(32.1)	20	(38.5)	1	(9.1)	2	(18.2)	3	(13.6)	3	(13.0)	8	(28.6)	11	(21.6)
Markedly ill	11	(45.8)	15	(53.6)	26	(50.0)	0	–	0	–	0	–	2	(8.7)	2	(7.1)	4	(7.8)
Severely ill	2	(8.3)	3	(10.7)	5	(9.6)	0	–	0	–	0	–	0	–	1	(3.6)	1	(2.0)
Among most extremely ill	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–	0	–
Total	24	100.0	28	100.0	52	100.0	11	100.0	11	100.0	22	100.0	23	100.0	28	100.0	51	100.0

Source: Table 14.4.1b, Section 11; Listing 14.4.1, Appendix C

N = number of patients with an acute-study baseline, Week 24 OC or LOCF assessment.

Note: Study 715 data were collected at Screening rather than Baseline.

Table 62 Summary Statistics for Acute-study Baseline and Change from Acute-study Baseline in CGI–Severity of Illness Score by Age Group and Acute-study Treatment Group (ITT Population with Primary Diagnosis of OCD)

	Acute-study Treatment Group											
	Paroxetine				Placebo				Total			
	N	Mean	Median	Range	N	Mean	Median	Range	N	Mean	Median	Range
Age Group: Total	52	4.5	4.0	4 to 6	64	4.7	5.0	3 to 6	116	4.6	5.0	3 to 6
Acute-study baseline												
Change from Acute-study baseline to:												
Week 24 OC	26	-2.2	-2.0	-4 to -1	23	-2.3	-2.0	-5 to 0	49	-2.2	-2.0	-5 to 0
Week 24 LOCF	51	-1.9	-2.0	-5 to 1	63	-1.6	-2.0	-5 to 2	114	-1.7	-2.0	-5 to 2
Age Group: Children												
Acute-study baseline	28	4.4	4.0	4 to 6	36	4.7	4.5	3 to 6	64	4.5	4.0	3 to 6
Change from Acute-study baseline to:												
Week 24 OC	15	-2.1	-2.0	-3 to -1	12	-2.5	-2.0	-5 to -1	27	-2.3	-2.0	-5 to -1
Week 24 LOCF	28	-1.8	-2.0	-4 to 1	35	-1.7	-2.0	-5 to 2	63	-1.7	-2.0	-5 to 2
Age Group: Adolescents												
Acute-study baseline	24	4.6	5.0	4 to 6	28	4.7	5.0	3 to 6	52	4.7	5.0	3 to 6
Change from Acute-study baseline to:												
Week 24 OC	11	-2.3	-2.0	-4 to -1	11	-2.0	-2.0	-4 to 0	22	-2.1	-2.0	-4 to 0
Week 24 LOCF	23	-2.1	-2.0	-5 to 0	28	-1.5	-2.0	-5 to 0	51	-1.8	-2.0	-5 to 0

Source: Table 14.4.3b, Section 11; Listing 14.4.1, Appendix C

Note: Study 715 data were collected at Screening rather than Baseline.

Summary statistics for change from acute-study Treatment Phase endpoint in CGI–Severity of Illness score for the Week 24 OC and Week 24 LOCF datasets for both age groups separately and combined are presented for patients with a primary diagnosis of OCD (PPX population) in Table 63. The median decrease from acute-study Treatment Phase endpoint to the Week 24 OC endpoint was 1.0 and for the Week 24 LOCF endpoint was 0.0, indicating no real further change in the CGI–Severity of Illness score during the open-label Treatment Phase of Study 716. The median decrease in children to both timepoints was 0.0 and for adolescents was 1.0.

Table 63 Summary Statistics for Acute-Study Treatment Phase Endpoint and Change from Acute-Study Treatment Phase Endpoint in CGI–Severity of Illness Score by Age Group (PPX Population with Primary Diagnosis of OCD)

	Acute-study paroxetine Group			
	N	**Mean**	**Median**	**Range**
Age Group: Total				
Acute-study Treatment Phase Endpoint	46	3.2	3.0	1 to 5
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	23	-0.7	-1.0	-2 to 1
Week 24 LOCF	45	-0.5	0.0	-3 to 2
Age Group: Children				
Acute-study Treatment Phase Endpoint	25	2.8	3.0	1 to 5
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	13	-0.5	0.0	-2 to 1
Week 24 LOCF	25	-0.2	0.0	-2 to 2
Age Group: Adolescents				
Acute-study Treatment Phase Endpoint	21	3.6	4.0	2 to 5
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	10	-1.1	-1.0	-2 to 0
Week 24 LOCF	20	-1.0	-1.0	-3 to 0

Source: Table 14.4.3d, Section 11; Listing 14.4.1; Appendix C

Summary statistics for change from acute-study Treatment Phase endpoint in CGI–Severity of Illness score for the Week 24 OC and Week 24 LOCF datasets for both age groups separately and combined for patients in the acute-study placebo group with a primary diagnosis of OCD are provided in Table 64. CGI–Severity of Illness score decreases at Week 24 OC and Week 24 LOCF were similar to the negligible decreases seen in the PPX population.

Table 64 Summary Statistics for Acute-Study Treatment Phase Endpoint and Change from Acute-Study Treatment Phase Endpoint in CGI–Severity of Illness Score by Age Group (ITT Population with Primary Diagnosis of OCD and Acute-study Treatment of Placebo)

	Acute-study placebo Group			
	N	**Mean**	**Median**	**Range**
Age Group: Total				
Acute-study Treatment Phase Endpoint	63	3.6	4.0	1 to 6
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	22	-0.8	-1.0	-2 to 1
Week 24 LOCF	62	-0.5	0.0	-3 to 3
Age Group: Children				
Acute-study Treatment Phase Endpoint	35	3.4	4.0	1 to 5
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	11	-0.6	0.0	-2 to 1
Week 24 LOCF	34	-0.3	0.0	-3 to 3
Age Group: Adolescents				
Acute-study Treatment Phase Endpoint	28	3.8	4.0	1 to 6
Change from Acute-study Treatment Phase Endpoint to:				
Week 24 OC	11	-0.9	-1.0	-2 to 0
Week 24 LOCF	28	-0.6	-0.5	-2 to 1

Source: Table 14.4.3e, Section 11; Listing 14.4.1; Appendix C

6.3.5 Change in CDRS–R Total Score from Acute-study Treatment Phase Endpoint to Study 716 Baseline

Table 65 presents summary statistics for the change in CDRS–R total score from acute-study Treatment Phase endpoint (pre-Taper Phase) to Study 716 baseline, by dose level at the end of the acute-study Treatment Phase and by acute-study treatment group and age group, for the ITT population. As the CDRS–R was specific to MDD and as it was not administered at Study 715 Treatment Phase endpoint, only those patients entering from acute Study 701 are included in this summary.

The mean CDRS–R total score increased from acute-study Treatment Phase endpoint to Study 716 baseline for each ending dose level in both acute-study treatment groups and both age groups except for slight decreases among adolescents in the acute-study paroxetine group at 30-mg and 50-mg doses. There was no clear relationship between the dose level at the end of the acute-study Treatment Phase, the acute-study treatment group or age group in the change in

CDRS–R total score from acute-study Treatment Phase endpoint to Study 716 baseline. However, as the numbers involved are small it is difficult to draw any meaningful conclusions.

6.3.6 Change in CY–BOCS Total Score from Acute-study Treatment Phase Endpoint to Study 716 Baseline

Table 66 presents summary statistics for the change in CY–BOCS total score from acute-study Treatment Phase endpoint (pre-Taper Phase) to Study 716 baseline, by dose level at the end of the acute-study Treatment Phase and by acute-study treatment group and age group, for the ITT population. As the CY–BOCS was specific to OCD and as it was not administered at Study 715 Treatment Phase endpoint, only those patients entering from acute Study 704 are included in this summary.

For the combined age groups, the mean CY–BOCS total score increased from acute-study Treatment Phase endpoint to Study 716 baseline for both acute-study treatment groups for each ending dose level. There was no clear relationship between the dose level at the end of the acute-study Treatment Phase, the acute-study treatment group or age group in the change in CY–BOCS total score from acute-study Treatment Phase endpoint to Study 716 baseline, with the exception that children generally worsened more than adolescents. However, as the numbers involved are small it is difficult to draw any meaningful conclusions.

Table 65 Summary Statistics for Change in CDRS–R Total Score from Acute-study Treatment Phase Endpoint to Study 716 Baseline by Dose Level, Acute-study Treatment Group and Age Group (ITT Population with Primary Diagnosis of MDD)

		Acute-study Treatment Group											
		Paroxetine				Placebo				Total			
Dose *	**Age Group**	**N**	**Mean**	**(SD)**	**Range**	**N**	**Mean**	**(SD)**	**Range**	**N**	**Mean**	**(SD)**	**Range**
2 (20 mg)	Total	15	4.9	9.28	-4 to 30	15	2.4	12.19	-9 to 44	30	3.7	10.72	-9 to 44
	Children	8	7.1	12.09	-4 to 30	8	4.4	16.69	-9 to 44	16	5.8	14.15	-9 to 44
	Adolescents	7	2.4	4.08	-2 to 8	7	0.1	3.24	-3 to 6	14	1.3	3.73	-3 to 8
3 (30 mg)	Total	15	0.0	11.61	-24 to 24	22	1.6	6.69	-10 to 18	37	1.0	8.90	-24 to 24
	Children	5	3.4	11.37	-14 to 15	10	1.5	7.59	-10 to 18	15	2.1	8.65	-14 to 18
	Adolescents	10	-1.7	11.94	-24 to 24	12	1.8	6.20	-7 to 14	22	0.2	9.18	-24 to 24
4 (40 mg)	Total	10	2.8	8.02	-13 to 16	5	9.0	9.59	-4 to 18	15	4.9	8.77	-13 to 18
	Children	5	0.0	9.30	-13 to 12	2	10.5	10.61	3 to 18	7	3.0	10.13	-13 to 18
	Adolescents	5	5.6	6.23	0 to 16	3	8.0	11.14	-4 to 18	8	6.5	7.69	-4 to 18
5 (50 mg)	Total	3	8.0	15.62	-2 to 26	11	7.0	11.25	-5 to 28	14	7.2	11.62	-5 to 28
	Children	1	26.0	–	26 to 26	6	3.8	8.93	-3 to 21	7	7.0	11.69	-3 to 26
	Adolescents	2	-1.0	1.41	-2 to 0	5	10.8	13.55	-5 to 28	7	7.4	12.49	-5 to 28

Source: Table 14.5.1, Section 11; Listing 14.1.1, Appendix C

Note: Patients who complete Paroxetine Study 701 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their Study 716 baseline assessment.

Note: Study 715 patients do not have a treatment phase endpoint CDRS-R assessment and therefore are not included in this table.

* Dose level at acute-study Treatment Phase endpoint

Table 66 Summary Statistics for Change in CY–BOCS Total Score from Acute-study Treatment Phase Endpoint to Study 716 Baseline by Dose Level, Acute-study Treatment Group and Age Group (ITT Population with Primary Diagnosis of OCD)

		Acute-study Treatment Group											
		Paroxetine				Placebo				Total			
Dose *	Age Group	N	Mean	(SD)	Range	N	Mean	(SD)	Range	N	Mean	(SD)	Range
2 (20 mg)	Total	12	0.9	(5.18)	-7 to 11	7	2.4	(6.02)	-4 to 15	19	1.5	(5.39)	-7 to 15
	Children	10	1.5	(5.19)	-7 to 11	5	4.2	(6.22)	0 to 15	15	2.4	(5.49)	-7 to 15
	Adolescents	2	-2.0	(5.66)	-6 to 2	2	-2.0	(2.83)	-4 to 0	4	-2.0	(3.65)	-6 to 2
3 (30 mg)	Total	6	2.3	(5.68)	-3 to 13	7	3.7	(8.69)	-2 to 23	13	3.1	(7.19)	-3 to 23
	Children	5	2.8	(6.22)	-3 to 13	3	-0.3	(1.53)	-2 to 1	8	1.6	(5.04)	-3 to 13
	Adolescents	1	0.0	–	0 to 0	4	6.8	(11.00)	0 to 23	5	5.4	(9.99)	0 to 23
4 (40 mg)	Total	8	1.0	(5.42)	-6 to 13	14	1.9	(3.76)	-3 to 10	22	1.5	(4.33)	-6 to 13
	Children	2	6.5	(9.19)	0 to 13	10	1.4	(3.44)	-3 to 9	12	2.3	(4.61)	-3 to 13
	Adolescents	6	-0.8	(2.86)	-6 to 2	4	3.0	(4.83)	-1 to 10	10	0.7	(4.03)	-6 to 10
5 (50 mg)	Total	14	3.2	(5.48)	-1 to 15	32	2.7	(5.53)	-9 to 15	46	2.8	(5.46)	-9 to 15
	Children	5	3.6	(6.54)	-1 to 15	14	2.3	(7.13)	-9 to 15	19	2.6	(6.82)	-9 to 15
	Adolescents	9	3.0	(5.22)	-1 to 14	18	2.9	(4.09)	-4 to 10	27	3.0	(4.40)	-4 to 14

Source: Table 14.5.2, Section 11; Listing 14.2.1, Appendix C

Note: Patients who complete Paroxetine Study 704 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their Study 716 baseline assessment.

Note: Study 715 patients do not have a treatment phase endpoint CY-BOCS assessment and therefore are not included in this table.

* Dose level at acute-study Treatment Phase endpoint

7 Discussion

The primary objective of this multicenter, open-label, 6-month extension study was to assess the long-term (24 weeks) safety and tolerability of paroxetine in pediatric patients with MDD or OCD. The long-term efficacy of paroxetine in these patient populations was evaluated informally as a secondary objective. Children and adolescents who completed Study 701, 704, or 715 and who chose to enter this study were considered eligible if they met all the inclusion criteria and none of the exclusion criteria.

This safety database includes a substantial amount of paroxetine exposure data in pediatric patients. It includes data from 263 ITT patients (147 MDD patients and 116 OCD patients). The mean number of days of exposure to open-label Treatment Phase study medication (i.e., excluding acute-study dosing and Taper Phase dosing) alone was nearly 4 months (116.2 days, range 2 to 204 days). For the 96 patients in Studies 701 and 704 who had received paroxetine in their acute study (PPX population), the overall mean number of days of exposure to paroxetine (including taper medication in both studies) was 210.3 days (range 65 to 304; 202.5 days in children and 218.7 days in adolescents). Both children (ages 7 to 11, N = 50) and adolescents (ages 12 to 17, N = 46) are well represented. The overall mean dose of paroxetine to which patients were exposed in the open-label study (excluding taper) was 22.9 mg/day, which is representative of that which occurs in clinical practice.

There were some differences in exposure to open-label study medication among subgroups. For patients with a primary diagnosis of MDD, the overall mean dose of paroxetine was 21.7 mg/day, with 8.2% (12/147) of patients reaching a maximum dose of 50 mg/day. Patients with a primary diagnosis of OCD had greater exposure: the overall mean dose of paroxetine was 24.3 mg/day, with 23.3% (27/116) of patients reaching a maximum dose of 50 mg/day. For children, the overall mean dose of paroxetine was 20.9 mg/day, with 9.4% (13/139) of patients reaching a maximum dose of 50 mg/day. Adolescents had greater exposure: the overall mean dose of paroxetine was 25.0 mg/day, with 21.0% (26/124) of patients reaching a maximum dose of 50 mg/day. Mean duration of exposure to open-label study medication (excluding taper medication) was also greater among adolescents than among children (122.4 days for adolescents, 110.7 days for children), reflecting the higher withdrawal rate among children.

Mean duration of exposure to open-label study medication only (excluding taper medication) was 125.1 days for patients who had received paroxetine in their acute

study and 107.2 days for patients who had received placebo in their acute study, reflecting the higher withdrawal rate among patients from the acute-study placebo group.

The withdrawal rate over the 6 months of the study was high: 49.6% among patients who had received paroxetine in their acute study and 64.6% among patients who had received placebo in their acute study. The withdrawal rate was slightly higher for children than adolescents, but was independent of primary diagnosis.

Safety

The safety profile of paroxetine observed in pediatric patients with MDD or OCD following longer-term administration in this study was similar to that observed in the acute and PK studies [2] [4] [5] [7] [8] [9]. The results of this study indicate that paroxetine is safe and generally well tolerated when used in children and adolescents over a period of up to 24 weeks over the dose range of 10–50 mg/day. Although fewer patients were exposed to paroxetine for periods exceeding 6 months, the safety data generated from patients with exposure exceeding 6 months appear to be consistent with those data generated from patients exposed to paroxetine for shorter durations. There were no deaths or any unexpected safety findings.

Overall, 75.7% (199/263) of patients reported a gender-non-specific emergent adverse event during the open-label Treatment Phase**:** 79.7% (106/133) of patients who had received paroxetine in the acute study and 71.5% (93/130) of patients who had received placebo in the acute study. Overall, the most common (≥10%) gender-non-specific adverse events were headache (25.1%, 66/263), respiratory disorder (18.3%, 48/263), trauma (13.7%, 36/263), infection (12.5%, 33/263), pharyngitis (10.6%, 28/263), and abdominal pain (10.3%, 27/263), and for the most part this held true irrespective of whether the patient had received paroxetine or placebo in the acute study. Five adverse events occurred with an incidence of ≥5% in the acute-study paroxetine group and with an incidence of at least twice that in the acute-study placebo group: vomiting (9.8% [13/133] compared to 3.1% (4/130)], sinusitis (8.3% [11/133] compared to 1.5% [2/130]), emotional lability (7.5% [10/133] compared to 3.1% (4/130)], diarrhea (6.8% [9/133] compared to 2.3% [3/130]), and albuminuria (6.0% [8/133] compared to 1.5% [2/130]). No adverse event occurred with an incidence of ≥5% in the acute-study placebo group and with an incidence of at least twice that in the acute-study paroxetine group.

The majority of adverse events were mild to moderate in intensity, with 11.8% (31/263) of the patients experiencing an adverse event considered by the investigator to be severe in nature. The proportion of patients reporting a gender-non-specific severe emergent adverse event during the open-label Treatment Phase was slightly less among patients who had received paroxetine in the acute study (9.8%) than among patients who had received placebo in the acute study (13.8%).

Overall, 5.7% (15/265) of all patients enrolled experienced at least one serious adverse event during Study 716 (or within 30 days of the last dose of open-label study medication, including taper). The proportion of patients reporting at least one serious adverse event did not differ based on acute-study treatment assignment: 5.9% (8/135) of patients who had received paroxetine in the acute study and 5.4% (7/130) of patients who had received placebo in the acute study. Of the 18 serious adverse events reported, 14 were reported during the open-label Treatment Phase. The proportion of patients reporting serious adverse events was slightly greater in children (6.5%, 9/139) than adolescents (4.8%, 6/126). Serious adverse events leading to the withdrawal of patients were emotional lability (3 patients; verbatims: suicidal ideation, suicidal, suicide attempt), depression (patient also had emotional lability), hostility, hallucinations and psychosis (1 patient each).

Approximately half (49.4%, 130/263) of the patients with open-label Treatment Phase emergent adverse events had at least one AE considered by the investigator to be related or possibly related to the study treatment, and there was no difference between patients coming from the two acute-study treatment groups in this regard.

Although the early withdrawal rate in this study was quite high (56.7%, 149/263), this did not appear to be due to safety/tolerability issues but instead appears to be due to a higher than expected drop-out rate due to miscellaneous reasons: i.e., 31.2% (82/263) of patients withdrew due to “lost to follow-up,” “protocol deviation” or “other” reasons.

Overall, 11.8% (31/263) of patients were withdrawn from the study during the open-label Treatment Phase because of an adverse event, which is not substantially different from the withdrawal due to adverse event rates observed in the paroxetine groups in acute Studies 701 (9.9%) and 704 (10.2%). However, the proportion of patients withdrawn because of an adverse event was higher in patients who had received placebo in the acute study (16.2%, 21/130) than in patients who had received paroxetine in the acute study (7.5%, 10/133). Not unexpectedly for antidepressants with a predominant action on serotonin uptake, adverse events that resulted in withdrawal were primarily associated with the

nervous system (32/39 adverse events that resulted in withdrawal from the study were associated with the nervous system). Of those adverse events leading to the withdrawal of two or more patients in this open-label extension study, only the adverse event hallucinations (which led to the withdrawal of two patients in this study) was unique to the extension study (i.e., was not reported in Study 701, 704, or 715).

There were no unexpected safety findings during the Taper or Follow-up Phase. Approximately one-third (34.6%, 54/156) of the patients with open-label Taper Phase/Follow-up Phase data available experienced an emergent adverse event during the Taper and/or Follow-up Phases. However, the proportion of patients reporting at least one gender-non-specific adverse event during the Taper Phase or Follow-up Phase was higher in patients who had received paroxetine in the acute study than in patients who had received placebo in the acute study (41.0% [32/78] compared to 28.2% [22/78]), which may suggest that discontinuation events may be somewhat more likely to occur following longer-term exposure.

However, these data do not suggest that the nature or severity of the adverse events occurring following cessation of longer-term exposure are qualitatively different from those that occur following cessation of dosing after shorter-term exposure. The most common (≥5%) gender-non-specific open-label Taper Phase or Follow-up Phase emergent adverse events for patients who had received paroxetine in the acute study were headache, respiratory disorder, and abdominal pain. The only adverse event that occurred during the open-label Taper Phase or Follow-up Phase in patients who had received placebo in the acute study at a frequency of ≥5% was respiratory disorder (5.1%). One patient who had received paroxetine in the acute study experienced a serious adverse event (emotional lability; verbatim: suicidal ideation) during the Follow-up Phase (3 days after discontinuing from a 30-mg dose for protocol violation, including non-compliance). Among patients who had received placebo in the acute study, one patient experienced a serious adverse event (depression) during the Study 716 Taper Phase and one patient experienced a serious adverse event (hostility) during the Follow-up Phase (one day after stopping open-label treatment).

The data from this study do not suggest that the overall likelihood of experiencing an adverse event upon longer-term paroxetine exposure differs substantially between children and adolescents. The overall frequency of gender-non-specific adverse events was only slightly higher among children (78.4% [109/139]) than adolescents (72.6% [90/124]). However, although the nature of the adverse events was generally similar between children and adolescents, there were some differences in the rates of occurrence of individual AEs. Adverse events that

occurred in children with an incidence of ≥5% and with an incidence of at least twice that in adolescents were pharyngitis, hyperkinesia, vomiting, otitis media, cough increased, and pain. Adverse events that occurred in adolescents with an incidence of ≥5% and with an incidence of at least twice that in children were allergic reaction, emotional lability, asthenia, somnolence, asthma, and albuminuria.

The number of patients with adverse events leading to withdrawal was similar among children (12.9%, 18/139) and adolescents (10.5%, 13/124). The primary reasons for withdrawal among children were lost to follow-up and "other" (each 13.4%, 9/67) in the acute-study paroxetine group, and adverse event and "other" (each 19.4%, 14/72) in the acute-study placebo group. The primary reason for withdrawal among adolescents was "other" in the acute-study paroxetine group (13.6%, 9/66 patients) and adverse event in the acute-study placebo group (17.2%, 10/58 patients).

The number of patients with adverse events leading to withdrawal was similar between patients with a primary diagnosis of OCD (12.9%, 15/116) than patients with a primary diagnosis of MDD (10.9%, 16/147). As expected, there was a small number of gender-specific adverse events reported; these occurred only in the adolescent population.

Data from this study suggest that longer-term tolerability for paroxetine is similar in patients with a primary diagnosis of MDD and patients with a primary diagnosis of OCD. The overall frequency of gender-non-specific adverse events in patients with a primary diagnosis of MDD was 74.8% (110/147) during the open-label Treatment Phase (81.5% [66/81] of patients from the acute-study paroxetine group and 66.7% [44/66] of patients from the acute-study placebo group). The overall frequency of gender-non-specific adverse events in patients with a primary diagnosis of OCD was 76.7% (89/116) during the open-label Treatment Phase (76.9% [40/52] of patients from the acute-study paroxetine group and 76.6% [49/64] of patients from the acute-study placebo group). Adverse events that occurred in patients with a primary diagnosis of MDD with an incidence of ≥5% and with an incidence of at least twice that in patients with a primary diagnosis of OCD were vomiting and emotional lability. Adverse events that occurred in patients with a primary diagnosis of OCD with an incidence of ≥5% and with an incidence of at least twice that in patients with a primary diagnosis of MDD were hyperkinesia and anxiety. The clinical relevance of these findings is unclear. However, hyperkinesia occurred in Study 704 (OCD) in 12.2% (12/98) of paroxetine patients and 5.7% (6/105) of placebo patients, compared to 3.0% (3/101) of paroxetine patients and 1.0% (1/102) of placebo

patients in Study 701 (MDD), suggesting the possibility of a relationship to the underlying illness.

Mean changes from baseline in all laboratory parameters were small in the overall Study 716 population and generally comparable between patients coming from the two different acute-study treatment groups. No clinically relevant patterns of change resulting from longer-term exposure were clearly apparent. Similarly, clinical laboratory abnormalities meeting pre-defined potential concern criteria were clinically unremarkable (i.e., comparable to that observed following acute exposure) and similar in patients coming from the two different acute-study treatment groups. Hematocrit (low) was the laboratory parameter most frequently meeting the potential clinical concern criteria.

Mean changes in vital signs parameters were also generally small in the overall Study 716 population except for weight, and comparable between patients coming from the two acute-study treatment groups. Vital sign changes meeting pre-defined criteria for potential clinical concern upon longer-term exposure were infrequent, were similar between patients coming from the two acute-study treatment groups, and were comparable to that observed following acute exposure with the exception of body weight gain (≥7% increase and outside normal range).

The mean increase in body weight from acute-study baseline to Week 24 of the open-label study was 4.9 kg (data from 89 patients) (5.1 kg in patients receiving paroxetine in the acute study [data from 51 patients] versus 4.6 kg in patients receiving placebo in the acute study [data from 38 patients]). The mean increase in BMI (kg/m^2) was 1.2 in the overall Study 716 population (1.4 in patients who had received paroxetine in the acute study and 1.0 in patients who had received placebo in the acute study). Overall, 15.5% (34/220) of patients had an increase in weight that met the pre-defined clinical concern criteria during the open-label Treatment, Taper or Follow-up Phase: 17.0% (19/112) of patients who received paroxetine in their acute study and 13.9% (15/108) of patients who received placebo in their acute study. However, for only seven of these patients was the increase in weight considered clinically significant by the investigator and recorded as an adverse event. The clinical relevance, if any, of this magnitude of increase in mean body weight over a period of 7-9 months in an actively growing and maturing population such as this is not clear.

Efficacy

This was primarily a safety study; there was no primary efficacy endpoint defined, although summaries were provided for several secondary endpoints.

At Study 716 baseline, the mean CDRS–R total score, which was specific to MDD, was 35.5 (SD 13.14) among patients who had received paroxetine in their acute study and 37.4 (SD 13.93) among patients who had received placebo in their acute study, indicative of relatively mild depressive symptomatology following treatment in Studies 701 and 715. The overall mean change from acute-study baseline was a decrease of 33.8 points (SD 12.22) for Week 24 OC and a decrease of 27.7 points (SD 15.55) for Week 24 LOCF. At the Week 24 LOCF endpoint, patients who had received paroxetine in their acute study had slightly greater decreases from acute-study baseline in mean CDRS–R total score than did patients who had received placebo in their acute study. Children in both acute-study treatment groups improved slightly more than adolescents at both the Week 24 LOCF and OC endpoints.

The results for the PPX population, which evaluated the change in CDRS–R total score from acute-study Treatment Phase endpoint to extension phase Week 24, showed small but further reductions in CDRS–R total scores in both the OC and LOCF datasets in the population of patients who had received paroxetine in the acute study, indicating that the improvements in MDD symptoms experienced in the acute study were maintained during longer-term paroxetine exposure.

At Study 716 baseline, the mean CY–BOCS total score, which was specific to OCD, was 16.2 (SD 8.78) for acute-study paroxetine patients, indicative of mild obsessive-compulsive symptomatology, and 20.0 (SD 7.51) for acute-study placebo patients, indicative of mild to moderate obsessive-compulsive symptomatology, following treatment in Studies 704 and 715. The overall mean change from acute-study baseline was a decrease of 16.2 points (SD 7.31) for Week 24 OC and a decrease of 12.9 (SD 9.25) points for Week 24 LOCF. In the LOCF datasets, the reduction in CY–BOCS total score was greater in patients who had received paroxetine in their acute study than it was in patients who had received placebo in the acute study, both in the combined age group (total) population (-15.8 versus -10.6), as well as among children (-14.9 versus -10.5) and among adolescents (-16.8 versus -10.6).

The results for the PPX population, which evaluated the change in CY–BOCS total score from acute-study Treatment Phase endpoint to extension phase Week 24, suggest that adolescents who had received paroxetine in the acute study continued to demonstrate further reductions in CY–BOCS Total score during the extension phase. This did not appear to be the case among children, although the symptom reduction achieved in the acute study was maintained.

A CGI responder was defined as a patient who scored 1 (very much improved) or 2 (much improved) at endpoint compared to acute-study baseline. The majority of patients continued to meet the CGI responder criteria at the extension phase Week 24 OC and Week 24 LOCF endpoints.

For patients with MDD, 93.7% (59/63) of patients met the response criteria at Week 24 OC and 70.4%, 100/142, at Week 24 LOCF. At Week 24 LOCF, the percentage of responders was slightly higher in patients who had received paroxetine in the acute study (74.4%, 58/78) than in those patients who had received placebo in the acute study (65.6%, 42/64). The percentage of responders at Week 24 LOCF was slightly higher in children than in adolescents (75.0% versus 65.7%, respectively).

For patients with OCD, 87.8% (43/49) of patients met the response criteria at Week 24 OC and 67.5%, 77/114 at Week 24 LOCF. The responder rate in children with OCD was comparable to that in adolescents with OCD.

Although not formally designed to evaluate efficacy, the data do suggest that patients who responded in the acute study in general continued to respond to paroxetine with continued administration in this follow-up extension study.

8 Conclusions

Data from this study demonstrate that paroxetine (10–50 mg/day) is safe and generally well tolerated when used to treat children and adolescents with MDD or OCD for a period of up to 24 weeks. The adverse event profile with longer-term dosing was comparable to that observed during acute (short-term) dosing in earlier studies. As was the case in the prior acute studies, the long-term safety data suggest that the common adverse event profile may differ somewhat between children and adolescents.

Although this study was designed primarily to assess safety, the efficacy results suggest that patients who responded in the acute study are likely to continue to respond to paroxetine during long-term administration.

9 References

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10 Source Tables: Study Population

Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Children
Primary Diagnosis : MDD

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=39)		Placebo (N=36)		Total (N=75)	
716 Baseline Only	0		0		0	
Number Entered	39	(100.0%)	36	(100.0%)	75	(100.0%)
Completed	17	(43.6%)	11	(30.6%)	28	(37.3%)
Early Withdrawal	22	(56.4%)	25	(69.4%)	47	(62.7%)
Intention-to-Treat Population	39	(100.0%)	36	(100.0%)	75	(100.0%)
Pure Paroxetine Population	25	(64.1%)	N/A		25	(33.3%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

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Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Children
Primary Diagnosis: OCD

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=28)		Placebo (N=36)		Total (N=64)	
716 Baseline Only	0		0		0	
Number Entered	28	(100.0%)	36	(100.0%)	64	(100.0%)
Completed	14	(50.0%)	11	(30.6%)	25	(39.1%)
Early Withdrawal	14	(50.0%)	25	(69.4%)	39	(60.9%)
Intention-to-Treat Population	28	(100.0%)	36	(100.0%)	64	(100.0%)
Pure Paroxetine Population	25	(89.3%)	N/A		25	(39.1%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

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Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Children
Primary Diagnosis: Total

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=67)		Placebo (N=72)		Total (N=139)	
716 Baseline Only	0		0		0	
Number Entered	67	(100.0%)	72	(100.0%)	139	(100.0%)
Completed	31	(46.3%)	22	(30.6%)	53	(38.1%)
Early Withdrawal	36	(53.7%)	50	(69.4%)	86	(61.9%)
Intention-to-Treat Population	67	(100.0%)	72	(100.0%)	139	(100.0%)
Pure Paroxetine Population	50	(74.6%)	N/A		50	(36.0%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
and 1 patient took their last dose of non-taper study medication after relative day 196
and hence had their visit re-categorised as post week 24

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Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Adolescents
Primary Diagnosis: MDD

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=43)		Placebo (N=30)		Total (N=73)	
716 Baseline Only	0		0		0	
Number Entered	43	(100.0%)	30	(100.0%)	73	(100.0%)
Completed	25	(58.1%)	13	(43.3%)	38	(52.1%)
Early Withdrawal	18	(41.9%)	17	(56.7%)	35	(47.9%)
Intention-to-Treat Population	42	(97.7%)	30	(100.0%)	72	(98.6%)
Pure Paroxetine Population	25	(58.1%)	N/A		25	(34.2%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

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Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Adolescents
Primary Diagnosis: OCD

Study Stage/Population	Paroxetine (N=25)		Placebo (N=28)		Total (N=53)	
716 Baseline Only	0		0		0	
Number Entered	25	(100.0%)	28	(100.0%)	53	(100.0%)
Completed	12	(48.0%)	11	(39.3%)	23	(43.4%)
Early Withdrawal	13	(52.0%)	17	(60.7%)	30	(56.6%)
Intention-to-Treat Population	24	(96.0%)	28	(100.0%)	52	(98.1%)
Pure Paroxetine Population	21	(84.0%)	N/A		21	(39.6%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

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Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Adolescents
Primary Diagnosis: Total

Study Stage/Population	Paroxetine (N=68)		Placebo (N=58)		Total (N=126)	
716 Baseline Only	0		0		0	
Number Entered	68	(100.0%)	58	(100.0%)	126	(100.0%)
Completed	37	(54.4%)	24	(41.4%)	61	(48.4%)
Early Withdrawal	31	(45.6%)	34	(58.6%)	65	(51.6%)
Intention-to-Treat Population	66	(97.1%)	58	(100.0%)	124	(98.4%)
Pure Paroxetine Population	46	(67.6%)	N/A		46	(36.5%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

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Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Total
Primary Diagnosis: MDD

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=82)		Placebo (N=66)		Total (N=148)	
716 Baseline Only	0		0		0	
Number Entered	82	(100.0%)	66	(100.0%)	148	(100.0%)
Completed	42	(51.2%)	24	(36.4%)	66	(44.6%)
Early Withdrawal	40	(48.8%)	42	(63.6%)	82	(55.4%)
Intention-to-Treat Population	81	(98.8%)	66	(100.0%)	147	(99.3%)
Pure Paroxetine Population	50	(61.0%)	N/A		50	(33.8%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

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Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Total
Primary Diagnosis: OCD

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=53)		Placebo (N=64)		Total (N=117)	
716 Baseline Only	0		0		0	
Number Entered	53	(100.0%)	64	(100.0%)	117	(100.0%)
Completed	26	(49.1%)	22	(34.4%)	48	(41.0%)
Early Withdrawal	27	(50.9%)	42	(65.6%)	69	(59.0%)
Intention-to-Treat Population	52	(98.1%)	64	(100.0%)	116	(99.1%)
Pure Paroxetine Population	46	(86.8%)	N/A		46	(39.3%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
and 1 patient took their last dose of non-taper study medication after relative day 196
and hence had their visit re-categorised as post week 24

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Table 13.1.1

Number (%) of Patients by Population and Acute Study Treatment Group
All Patients

Age Group : Total
Primary Diagnosis: Total

Study Stage/Population	Paroxetine (N=135)		Placebo (N=130)		Total (N=265)	
	Acute Study Treatment Group					
716 Baseline Only	0		0		0	
Number Entered	135	(100.0%)	130	(100.0%)	265	(100.0%)
Completed	68	(50.4%)	46	(35.4%)	114	(43.0%)
Early Withdrawal	67	(49.6%)	84	(64.6%)	151	(57.0%)
Intention-to-Treat Population	133	(98.5%)	130	(100.0%)	263	(99.2%)
Pure Paroxetine Population	96	(71.1%)	N/A		96	(36.2%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

Table 13.1.2

Number (%) of Patients by Country, Population and Acute Study Treatment Group
All Patients

Country : Canada (2 Centres)
Age Group : Children

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=1)	Placebo (N=3)	Total (N=4)
716 Baseline Only	0	0	0
Number Entered	1 (100.0%)	3 (100.0%)	4 (100.0%)
Completed	1 (100.0%)	1 (33.3%)	2 (50.0%)
Early Withdrawal	0	2 (66.7%)	2 (50.0%)
Intention-to-Treat Population	1 (100.0%)	3 (100.0%)	4 (100.0%)
Pure Paroxetine Population	1 (100.0%)	N/A	1 (25.0%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

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Table 13.1.2

Number (%) of Patients by Country, Population and Acute Study Treatment Group
All Patients

Country : Canada (2 Centres)
Age Group : Adolescents

Study Stage / Population	Acute Study Treatment Group: Paroxetine (N=2)		Placebo (N=4)		Total (N=6)	
716 Baseline Only	0		0		0	
Number Entered	2	(100.0%)	4	(100.0%)	6	(100.0%)
Completed	1	(50.0%)	2	(50.0%)	3	(50.0%)
Early Withdrawal	1	(50.0%)	2	(50.0%)	3	(50.0%)
Intention-to-Treat Population	2	(100.0%)	4	(100.0%)	6	(100.0%)
Pure Paroxetine Population	2	(100.0%)	N/A		2	(33.3%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
and 1 patient took their last dose of non-taper study medication after relative day 196
and hence had their visit re-categorised as post week 24

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Table 13.1.2

Number (%) of Patients by Country, Population and Acute Study Treatment Group
All Patients

Country : Canada (2 Centres)
Age Group : Total

Study Stage / Population	Paroxetine (N=3)		Placebo (N=7)		Total (N=10)	
	Acute Study Treatment Group					
716 Baseline Only	0		0		0	
Number Entered	3	(100.0%)	7	(100.0%)	10	(100.0%)
Completed	2	(66.7%)	3	(42.9%)	5	(50.0%)
Early Withdrawal	1	(33.3%)	4	(57.1%)	5	(50.0%)
Intention-to-Treat Population	3	(100.0%)	7	(100.0%)	10	(100.0%)
Pure Paroxetine Population	3	(100.0%)	N/A		3	(30.0%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
and 1 patient took their last dose of non-taper study medication after relative day 196
and hence had their visit re-categorised as post week 24

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Table 13.1.2

Number (%) of Patients by Country, Population and Acute Study Treatment Group
All Patients

Country : United States of America (49 Centres)
Age Group : Children

Study Stage/Population	Acute Study Treatment Group: Paroxetine (N=66)		Placebo (N=69)		Total (N=135)	
716 Baseline Only	0		0		0	
Number Entered	66	(100.0%)	69	(100.0%)	135	(100.0%)
Completed	30	(45.5%)	21	(30.4%)	51	(37.8%)
Early Withdrawal	36	(54.5%)	48	(69.6%)	84	(62.2%)
Intention-to-Treat Population	66	(100.0%)	69	(100.0%)	135	(100.0%)
Pure Paroxetine Population	49	(74.2%)	N/A		49	(36.3%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

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Table 13.1.2

Number (%) of Patients by Country, Population and Acute Study Treatment Group
All Patients

Country : United States of America (49 Centres)
Age Group : Adolescents

Study Stage / Population	Paroxetine (N=66)		Placebo (N=54)		Total (N=120)	
	Acute Study Treatment Group					
716 Baseline Only	0		0		0	
Number Entered	66	(100.0%)	54	(100.0%)	120	(100.0%)
Completed	36	(54.5%)	22	(40.7%)	58	(48.3%)
Early Withdrawal	30	(45.5%)	32	(59.3%)	62	(51.7%)
Intention-to-Treat Population	64	(97.0%)	54	(100.0%)	118	(98.3%)
Pure Paroxetine Population	44	(66.7%)	N/A		44	(36.7%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
and 1 patient took their last dose of non-taper study medication after relative day 196
and hence had their visit re-categorised as post week 24

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Table 13.1.2

Number (%) of Patients by Country, Population and Acute Study Treatment Group
All Patients

Country : United States of America (49 Centres)
Age Group : Total

Study Stage / Population	Paroxetine (N=132)		Placebo (N=123)		Total (N=255)	
	Acute Study Treatment Group					
716 Baseline Only	0		0		0	
Number Entered	132	(100.0%)	123	(100.0%)	255	(100.0%)
Completed	66	(50.0%)	43	(35.0%)	109	(42.7%)
Early Withdrawal	66	(50.0%)	80	(65.0%)	146	(57.3%)
Intention-to-Treat Population	130	(98.5%)	123	(100.0%)	253	(99.2%)
Pure Paroxetine Population	93	(70.5%)	N/A		93	(36.5%)

Note: Total (N) includes '716 Baseline Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
and 1 patient took their last dose of non-taper study medication after relative day 196
and hence had their visit re-categorised as post week 24

Table 13.3.1a

Number (%) of Patients who were Withdrawn Pre-Open-Label Treatment by the Reason for Withdrawal
716 Baseline Only

NO DATA AVAILABLE FOR THIS REPORT

Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Children
Primary Diagnosis: MDD

	Acute Study Treatment Group					
	Paroxetine (N=39)		Placebo (N=36)		Total (N=75)	
Reason For Study Conclusion						
Completed Study*	17	(43.6%)	11	(30.6%)	28	(37.3%)
Adverse Experience	4	(10.3%)	6	(16.7%)	10	(13.3%)
Lack of Efficacy	6	(15.4%)	5	(13.9%)	11	(14.7%)
Protocol deviation (including non-compliance)	3	(7.7%)	1	(2.8%)	4	(5.3%)
Lost to Follow-up	6	(15.4%)	3	(8.3%)	9	(12.0%)
Other+	3	(7.7%)	10	(27.8%)	13	(17.3%)
Total withdrawn	22	(56.4%)	25	(69.4%)	47	(62.7%)

* Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20.
and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24
+ Includes unknown and non-study-related personal reasons

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Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Children
Primary Diagnosis: OCD

	Acute Study Treatment Group					
	Paroxetine (N=28)		Placebo (N=36)		Total (N=64)	
Reason For Study Conclusion						
Completed Study*	14	(50.0%)	11	(30.6%)	25	(39.1%)
Adverse Experience	1	(3.6%)	8	(22.2%)	9	(14.1%)
Lack of Efficacy	2	(7.1%)	5	(13.9%)	7	(10.9%)
Protocol deviation (including non-compliance)	2	(7.1%)	3	(8.3%)	5	(7.8%)
Lost to Follow-up	3	(10.7%)	5	(13.9%)	8	(12.5%)
Other+	6	(21.4%)	4	(11.1%)	10	(15.6%)
Total withdrawn	14	(50.0%)	25	(69.4%)	39	(60.9%)

* Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24
+ Includes unknown and non-study-related personal reasons

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Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Children
Primary Diagnosis: Total

Reason For Study Conclusion	Paroxetine (N=67)		Placebo (N=72)		Total (N=139)	
	Acute Study Treatment Group					
Completed Study*	31	(46.3%)	22	(30.6%)	53	(38.1%)
Adverse Experience	5	(7.5%)	14	(19.4%)	19	(13.7%)
Lack of Efficacy	8	(11.9%)	10	(13.9%)	18	(12.9%)
Protocol deviation (including non-compliance)	5	(7.5%)	4	(5.6%)	9	(6.5%)
Lost to Follow-up	9	(13.4%)	8	(11.1%)	17	(12.2%)
Other+	9	(13.4%)	14	(19.4%)	23	(16.5%)
Total withdrawn	36	(53.7%)	50	(69.4%)	86	(61.9%)

* Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24
+ Includes unknown and non-study-related personal reasons

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Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis: MDD

	Acute Study Treatment Group					
	Paroxetine (N=42)		Placebo (N=30)		Total (N=72)	
Reason For Study Conclusion						
Completed Study*	25	(59.5%)	13	(43.3%)	38	(52.8%)
Adverse Experience	5	(11.9%)	4	(13.3%)	9	(12.5%)
Lack of Efficacy	3	(7.1%)	6	(20.0%)	9	(12.5%)
Protocol deviation (including non-compliance)	4	(9.5%)	2	(6.7%)	6	(8.3%)
Lost to Follow-up	3	(7.1%)	4	(13.3%)	7	(9.7%)
Other+	2	(4.8%)	1	(3.3%)	3	(4.2%)
Total withdrawn	17	(40.5%)	17	(56.7%)	34	(47.2%)

* Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24
+ Includes unknown and non-study-related personal reasons

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Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis: OCD

	Acute Study Treatment Group					
	Paroxetine (N=24)		Placebo (N=28)		Total (N=52)	
Reason For Study Conclusion						
Completed Study*	12	(50.0%)	11	(39.3%)	23	(44.2%)
Adverse Experience	1	(4.2%)	6	(21.4%)	7	(13.5%)
Lack of Efficacy	2	(8.3%)	3	(10.7%)	5	(9.6%)
Protocol deviation (including non-compliance)	0		3	(10.7%)	3	(5.8%)
Lost to Follow-up	2	(8.3%)	2	(7.1%)	4	(7.7%)
Other+	7	(29.2%)	3	(10.7%)	10	(19.2%)
Total withdrawn	12	(50.0%)	17	(60.7%)	29	(55.8%)

* Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24
+ Includes unknown and non-study-related personal reasons

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Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis: Total

Reason For Study Conclusion	Paroxetine (N=66)		Placebo (N=58)		Total (N=124)	
Completed Study*	37	(56.1%)	24	(41.4%)	61	(49.2%)
Adverse Experience	6	(9.1%)	10	(17.2%)	16	(12.9%)
Lack of Efficacy	5	(7.6%)	9	(15.5%)	14	(11.3%)
Protocol deviation (including non-compliance)	4	(6.1%)	5	(8.6%)	9	(7.3%)
Lost to Follow-up	5	(7.6%)	6	(10.3%)	11	(8.9%)
Other+	9	(13.6%)	4	(6.9%)	13	(10.5%)
Total withdrawn	29	(43.9%)	34	(58.6%)	63	(50.8%)

* Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24
+ Includes unknown and non-study-related personal reasons

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Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Total
Primary Diagnosis: MDD

Reason For Study Conclusion	Paroxetine (N=81)		Placebo (N=66)		Total (N=147)	
	Acute Study Treatment Group					
Completed Study*	42	(51.9%)	24	(36.4%)	66	(44.9%)
Adverse Experience	9	(11.1%)	10	(15.2%)	19	(12.9%)
Lack of Efficacy	9	(11.1%)	11	(16.7%)	20	(13.6%)
Protocol deviation (including non-compliance)	7	(8.6%)	3	(4.5%)	10	(6.8%)
Lost to Follow-up	9	(11.1%)	7	(10.6%)	16	(10.9%)
Other+	5	(6.2%)	11	(16.7%)	16	(10.9%)
Total withdrawn	39	(48.1%)	42	(63.6%)	81	(55.1%)

* Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24
+ Includes unknown and non-study-related personal reasons

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Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Total
Primary Diagnosis: OCD

Reason For Study Conclusion	Paroxetine (N=52)		Placebo (N=64)		Total (N=116)	
	Acute Study Treatment Group					
Completed Study*	26	(50.0%)	22	(34.4%)	48	(41.4%)
Adverse Experience	2	(3.8%)	14	(21.9%)	16	(13.8%)
Lack of Efficacy	4	(7.7%)	8	(12.5%)	12	(10.3%)
Protocol deviation (including non-compliance)	2	(3.8%)	6	(9.4%)	8	(6.9%)
Lost to Follow-up	5	(9.6%)	7	(10.9%)	12	(10.3%)
Other+	13	(25.0%)	7	(10.9%)	20	(17.2%)
Total withdrawn	26	(50.0%)	42	(65.6%)	68	(58.6%)

* Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24
+ Includes unknown and non-study-related personal reasons

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Table 13.3.1b

Number (%) of Patients Who Completed the Study or Were Withdrawn by
Reason for Withdrawal and Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Total
Primary Diagnosis: Total

Reason For Study Conclusion	Paroxetine (N=133)		Placebo (N=130)		Total (N=263)	
	Acute Study Treatment Group					
Completed Study*	68	(51.1%)	46	(35.4%)	114	(43.3%)
Adverse Experience	11	(8.3%)	24	(18.5%)	35	(13.3%)
Lack of Efficacy	13	(9.8%)	19	(14.6%)	32	(12.2%)
Protocol deviation (including non-compliance)	9	(6.8%)	9	(6.9%)	18	(6.8%)
Lost to Follow-up	14	(10.5%)	14	(10.8%)	28	(10.6%)
Other+	18	(13.5%)	18	(13.8%)	36	(13.7%)
Total withdrawn	65	(48.9%)	84	(64.6%)	149	(56.7%)

* Completed = Patients who completed a week 24 visit CRF, note 2 patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24
+ Includes unknown and non-study-related personal reasons

Table 13.3.1d

Number (%) of Patients Who Completed the Study or Were Withdrawn by Reason for Withdrawal

Pure Paroxetine Population
Age Group: Children
Primary Diagnosis: MDD

Reason For Study Conclusion	Paroxetine (N=25)	
Completed Study*	13	(52.0%)
Adverse Experience	3	(12.0%)
Lack of Efficacy	2	(8.0%)
Protocol deviation (including non-compliance)	1	(4.0%)
Lost to Follow-up	3	(12.0%)
Other+	3	(12.0%)
Total withdrawn	12	(48.0%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient in the Pure Paroxetine Population took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24
+ Includes unknown and non-study-related personal reasons

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Table 13.3.1d

Number (%) of Patients Who Completed the Study or Were Withdrawn by Reason for Withdrawal

Pure Paroxetine Population
Age Group: Children
Primary Diagnosis: OCD

Reason For Study Conclusion	Paroxetine (N=25)	
Completed Study*	12	(48.0%)
Adverse Experience	1	(4.0%)
Lack of Efficacy	2	(8.0%)
Protocol deviation (including non-compliance)	2	(8.0%)
Lost to Follow-up	2	(8.0%)
Other+	6	(24.0%)
Total withdrawn	13	(52.0%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient in the Pure Paroxetine Population took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

+ Includes unknown and non-study-related personal reasons

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Table 13.3.1d

Number (%) of Patients Who Completed the Study or Were Withdrawn by Reason for Withdrawal

Pure Paroxetine Population
Age Group: Children
Primary Diagnosis: Total

Reason For Study Conclusion	Paroxetine (N=50)	
Completed Study*	25	(50.0%)
Adverse Experience	4	(8.0%)
Lack of Efficacy	4	(8.0%)
Protocol deviation (including non-compliance)	3	(6.0%)
Lost to Follow-up	5	(10.0%)
Other+	9	(18.0%)
Total withdrawn	25	(50.0%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient in the Pure Paroxetine Population took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

+ Includes unknown and non-study-related personal reasons

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Table 13.3.1d

Number (%) of Patients Who Completed the Study or Were Withdrawn by Reason for Withdrawal

Pure Paroxetine Population
Age Group: Adolescents
Primary Diagnosis: MDD

Reason For Study Conclusion	Paroxetine (N=25)	
Completed Study*	14	(56.0%)
Adverse Experience	4	(16.0%)
Lack of Efficacy	3	(12.0%)
Protocol deviation (including non-compliance)	3	(12.0%)
Lost to Follow-up	1	(4.0%)
Other+	0	
Total withdrawn	11	(44.0%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient in the Pure Paroxetine Population took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

+ Includes unknown and non-study-related personal reasons

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Table 13.3.1d

Number (%) of Patients Who Completed the Study or Were Withdrawn by Reason for Withdrawal

Pure Paroxetine Population
Age Group: Adolescents
Primary Diagnosis: OCD

Reason For Study Conclusion	Paroxetine (N=21)	
Completed Study*	11	(52.4%)
Adverse Experience	1	(4.8%)
Lack of Efficacy	1	(4.8%)
Protocol deviation (including non-compliance)	0	
Lost to Follow-up	2	(9.5%)
Other+	6	(28.6%)
Total withdrawn	10	(47.6%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient in the Pure Paroxetine Population took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

+ Includes unknown and non-study-related personal reasons

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Table 13.3.1d

Number (%) of Patients Who Completed the Study or Were Withdrawn by Reason for Withdrawal

Pure Paroxetine Population
Age Group: Adolescents
Primary Diagnosis: Total

Reason For Study Conclusion	Paroxetine (N=46)	
Completed Study*	25	(54.3%)
Adverse Experience	5	(10.9%)
Lack of Efficacy	4	(8.7%)
Protocol deviation (including non-compliance)	3	(6.5%)
Lost to Follow-up	3	(6.5%)
Other+	6	(13.0%)
Total withdrawn	21	(45.7%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient in the Pure Paroxetine Population took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

+ Includes unknown and non-study-related personal reasons

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Table 13.3.1d

Number (%) of Patients Who Completed the Study or Were Withdrawn by Reason for Withdrawal

Pure Paroxetine Population
Age Group: Total
Primary Diagnosis: MDD

Reason For Study Conclusion	Paroxetine (N=50)	
Completed Study*	27	(54.0%)
Adverse Experience	7	(14.0%)
Lack of Efficacy	5	(10.0%)
Protocol deviation (including non-compliance)	4	(8.0%)
Lost to Follow-up	4	(8.0%)
Other+	3	(6.0%)
Total withdrawn	23	(46.0%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient in the Pure Paroxetine Population took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

+ Includes unknown and non-study-related personal reasons

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Table 13.3.1d

Number (%) of Patients Who Completed the Study or Were Withdrawn by Reason for Withdrawal

Pure Paroxetine Population
Age Group: Total
Primary Diagnosis: OCD

Reason For Study Conclusion	Paroxetine (N=46)	
Completed Study*	23	(50.0%)
Adverse Experience	2	(4.3%)
Lack of Efficacy	3	(6.5%)
Protocol deviation (including non-compliance)	2	(4.3%)
Lost to Follow-up	4	(8.7%)
Other+	12	(26.1%)
Total withdrawn	23	(50.0%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient in the Pure Paroxetine Population took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

+ Includes unknown and non-study-related personal reasons

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Table 13.3.1d

Number (%) of Patients Who Completed the Study or Were Withdrawn by Reason for Withdrawal

Pure Paroxetine Population
Age Group: Total
Primary Diagnosis: Total

Reason For Study Conclusion	Paroxetine (N=96)	
Completed Study*	50	(52.1%)
Adverse Experience	9	(9.4%)
Lack of Efficacy	8	(8.3%)
Protocol deviation (including non-compliance)	6	(6.3%)
Lost to Follow-up	8	(8.3%)
Other+	15	(15.6%)
Total withdrawn	46	(47.9%)

* Completed = Patients who completed a week 24 visit CRF, note 1 patient in the Pure Paroxetine Population took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

+ Includes unknown and non-study-related personal reasons

Table 13.3.2

Number (%) of Patients Remaining/withdrawing from the Study at Each Visit by Acute Study Treatment Group

Intention-To-Treat Population

Visit	Status	Paroxetine (N=133)		Placebo (N=130)		Total (N=263)	
716 Baseline	Entered	133	(100.0%)	130	(100.0%)	263	(100.0%)
Week 1	Still in Study	128	(96.2%)	125	(96.2%)	253	(96.2%)
	Withdrawn	5	(3.8%)	5	(3.8%)	10	(3.8%)
Week 2	Still in Study	127	(95.5%)	122	(93.8%)	249	(94.7%)
	Withdrawn	1	(0.8%)	3	(2.4%)	4	(1.6%)
Week 3	Still in Study	124	(93.2%)	117	(90.0%)	241	(91.6%)
	Withdrawn	3	(2.4%)	5	(4.1%)	8	(3.2%)
Week 4	Still in Study	117	(88.0%)	108	(83.1%)	225	(85.6%)
	Withdrawn	7	(5.6%)	9	(7.7%)	16	(6.6%)
Week 6	Still in Study	112	(84.2%)	93	(71.5%)	205	(77.9%)
	Withdrawn	5	(4.3%)	15	(13.9%)	20	(8.9%)
Week 8	Still in Study	100	(75.2%)	81	(62.3%)	181	(68.8%)
	Withdrawn	12	(10.7%)	12	(12.9%)	24	(11.7%)
Week 12	Still in Study	88	(66.2%)	70	(53.8%)	158	(60.1%)
	Withdrawn	12	(12.0%)	11	(13.6%)	23	(12.7%)
Week 16	Still in Study	77	(57.9%)	59	(45.4%)	136	(51.7%)
	Withdrawn	11	(12.5%)	11	(15.7%)	22	(13.9%)
Week 20	Still in Study	70	(52.6%)	47	(36.2%)	117	(44.5%)
	Withdrawn	6	(7.8%)	11	(18.6%)	17	(12.5%)
	Completed	1	(0.8%)	1	(0.8%)	2	(0.8%)
Week 24	Still in Study	0		2	(1.5%)	2	(0.8%)
	Withdrawn	3	(4.3%)	1	(2.1%)	4	(3.4%)
	Completed	67	(50.4%)	44	(33.8%)	111	(42.2%)
Post Week 24	Withdrawn	0		1	(50.0%)	1	(50.0%)

Completed = Patients who completed a week 24 visit CRF, note 2 Patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24
Date of withdrawal = date of last dose of study medication (excluding Taper), Efficacy assessments up to 7 days after this date are considered evaluable.

Note: Percentages for patients still in the study, or completed at each visit are based on the total no. of patients at study 716 baseline, whilst percentages for patients withdrawing at each visit are based on the total no. of patients at each visit.

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Table 13.3.2

Number (%) of Patients Remaining/withdrawing from the Study at Each Visit by Acute Study Treatment Group

Intention-To-Treat Population

Visit	Status	Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Post Week 24	Completed	0	1 (0.8%)	1 (0.4%)

Completed = Patients who completed a week 24 visit CRF, note 2 Patients took their last dose of non-taper study medication before relative day 155 and hence had their visit re-categorised as Week 20. and 1 patient took their last dose of non-taper study medication after relative day 196 and hence had their visit re-categorised as post week 24

Date of withdrawal = date of last dose of study medication (excluding Taper), Efficacy assessments up to 7 days after this date are considered evaluable.

Note: Percentages for patients still in the study, or completed at each visit are based on the total no. of patients at study 716 baseline, whilst percentages for patients withdrawing at each visit are based on the total no. of patients at each visit.

Table 13.3.3

Cumulative Number (%) of All Patients Withdrawn During the Study by Reason for Withdrawal and Acute Study Treatment Group

Intention-To-Treat Population
Age Group : Children

	Acute Study Treatment Group															
	Paroxetine (N = 67)				Placebo (N = 72)				Total (N = 139)			
	AE	LE	Other	Total	AE	LE	Other	Total	AE	LE	Other	Total
	n | %	n | %	n | %	n | %	n | %	n | %	n | %	n | %	n | %	n | %	n | %	n | %
Visit												
Week 1	0 | 0.0	1 | 1.5	3 | 4.5	4 | 6.0	0 | 0.0	0 | 0.0	2 | 2.8	2 | 2.8	0 | 0.0	1 | 0.7	5 | 3.6	6 | 4.3
Week 2	0 | 0.0	1 | 1.5	3 | 4.5	4 | 6.0	0 | 0.0	0 | 0.0	3 | 4.2	3 | 4.2	0 | 0.0	1 | 0.7	6 | 4.3	7 | 5.0
Week 3	1 | 1.5	1 | 1.5	3 | 4.5	5 | 7.5	2 | 2.8	0 | 0.0	5 | 6.9	7 | 9.7	3 | 2.2	1 | 0.7	8 | 5.8	12 | 8.6
Week 4	1 | 1.5	2 | 3.0	6 | 9.0	9 |13.4	5 | 6.9	0 | 0.0	8 |11.1	13 |18.1	6 | 4.3	2 | 1.4	14 |10.1	22 |15.8
Week 6	3 | 4.5	2 | 3.0	7 |10.4	12 |17.9	8 |11.1	1 | 1.4	12 |16.7	21 |29.2	11 | 7.9	3 | 2.2	19 |13.7	33 |23.7
Week 8	4 | 6.0	4 | 6.0	14 |20.9	22 |32.8	11 |15.3	3 | 4.2	13 |18.1	27 |37.5	15 |10.8	7 | 5.0	27 |19.4	49 |35.3
Week 12	4 | 6.0	7 |10.4	19 |28.4	30 |44.8	12 |16.7	8 |11.1	16 |22.2	36 |50.0	16 |11.5	15 |10.8	35 |25.2	66 |47.5
Week 16	5 | 7.5	7 |10.4	19 |28.4	31 |46.3	12 |16.7	9 |12.5	20 |27.8	41 |56.9	17 |12.2	16 |11.5	39 |28.1	72 |51.8
Week 20	5 | 7.5	8 |11.9	21 |31.3	34 |50.7	14 |19.4	10 |13.9	24 |33.3	48 |66.7	19 |13.7	18 |12.9	45 |32.4	82 |59.0
Week 24	5 | 7.5	8 |11.9	23 |34.3	36 |53.7	14 |19.4	10 |13.9	25 |34.7	49 |68.1	19 |13.7	18 |12.9	48 |34.5	85 |61.2
Post Week 24	5 | 7.5	8 |11.9	23 |34.3	36 |53.7	14 |19.4	10 |13.9	26 |36.1	50 |69.4	19 |13.7	18 |12.9	49 |35.3	86 |61.9

AE = adverse experience LE = lack of efficacy
Other = Protocol Deviation (including non-compliance), Lost to follow-up, Unknown and non-study related personal reasons

Table 13.3.3

Cumulative Number (%) of All Patients Withdrawn During the Study by Reason for Withdrawal and Acute Study Treatment Group

Intention-To-Treat Population
Age Group : Adolescents

	Acute Study Treatment Group															
	Paroxetine (N = 66)				Placebo (N = 58)				Total (N = 124)			
	AE		LE		Other		Total		AE		LE		Other		Total	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																								
Week 1	0	0.0	0	0.0	1	1.5	1	1.5	1	1.7	1	1.7	1	1.7	3	5.2	1	0.8	1	0.8	2	1.6	4	3.2
Week 2	0	0.0	0	0.0	2	3.0	2	3.0	2	3.4	2	3.4	1	1.7	5	8.6	2	1.6	2	1.6	3	2.4	7	5.6
Week 3	1	1.5	0	0.0	3	4.5	4	6.1	2	3.4	2	3.4	2	3.4	6	10.3	3	2.4	2	1.6	5	4.0	10	8.1
Week 4	1	1.5	0	0.0	6	9.1	7	10.6	3	5.2	2	3.4	4	6.9	9	15.5	4	3.2	2	1.6	10	8.1	16	12.9
Week 6	2	3.0	1	1.5	6	9.1	9	13.6	5	8.6	3	5.2	8	13.8	16	27.6	7	5.6	4	3.2	14	11.3	25	20.2
Week 8	3	4.5	2	3.0	6	9.1	11	16.7	7	12.1	5	8.6	10	17.2	22	37.9	10	8.1	7	5.6	16	12.9	33	26.6
Week 12	3	4.5	3	4.5	9	13.6	15	22.7	8	13.8	6	10.3	10	17.2	24	41.4	11	8.9	9	7.3	19	15.3	39	31.5
Week 16	6	9.1	5	7.6	14	21.2	25	37.9	8	13.8	8	13.8	14	24.1	30	51.7	14	11.3	13	10.5	28	22.6	55	44.4
Week 20	6	9.1	5	7.6	17	25.8	28	42.4	10	17.2	9	15.5	15	25.9	34	58.6	16	12.9	14	11.3	32	25.8	62	50.0
Week 24	6	9.1	5	7.6	18	27.3	29	43.9	10	17.2	9	15.5	15	25.9	34	58.6	16	12.9	14	11.3	33	26.6	63	50.8
Post Week 24	6	9.1	5	7.6	18	27.3	29	43.9	10	17.2	9	15.5	15	25.9	34	58.6	16	12.9	14	11.3	33	26.6	63	50.8

AE = adverse experience LE = lack of efficacy
Other = Protocol Deviation (including non-compliance), Lost to follow-up, Unknown and non-study related personal reasons

Table 13.3.3

Cumulative Number (%) of All Patients Withdrawn During the Study by Reason for Withdrawal and Acute Study Treatment Group

Intention-To-Treat Population
Age Group : Total

	Acute Study Treatment Group															
	Paroxetine (N = 133)				Placebo (N = 130)				Total (N = 263)			
	AE		LE		Other		Total		AE		LE		Other		Total	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																								
Week 1	0	0.0	1	0.8	4	3.0	5	3.8	1	0.8	1	0.8	3	2.3	5	3.8	1	0.4	2	0.8	7	2.7	10	3.8
Week 2	0	0.0	1	0.8	5	3.8	6	4.5	2	1.5	2	1.5	4	3.1	8	6.2	2	0.8	3	1.1	9	3.4	14	5.3
Week 3	2	1.5	1	0.8	6	4.5	9	6.8	4	3.1	2	1.5	7	5.4	13	10.0	6	2.3	3	1.1	13	4.9	22	8.4
Week 4	2	1.5	2	1.5	12	9.0	16	12.0	8	6.2	2	1.5	12	9.2	22	16.9	10	3.8	4	1.5	24	9.1	38	14.4
Week 6	5	3.8	3	2.3	13	9.8	21	15.8	13	10.0	4	3.1	20	15.4	37	28.5	18	6.8	7	2.7	33	12.5	58	22.1
Week 8	7	5.3	6	4.5	20	15.0	33	24.8	18	13.8	8	6.2	23	17.7	49	37.7	25	9.5	14	5.3	43	16.3	82	31.2
Week 12	7	5.3	10	7.5	28	21.1	45	33.8	20	15.4	14	10.8	26	20.0	60	46.2	27	10.3	24	9.1	54	20.5	105	39.9
Week 16	11	8.3	12	9.0	33	24.8	56	42.1	20	15.4	17	13.1	34	26.2	71	54.6	31	11.8	29	11.0	67	25.5	127	48.3
Week 20	11	8.3	13	9.8	38	28.6	62	46.6	24	18.5	19	14.6	39	30.0	82	63.1	35	13.3	32	12.2	77	29.3	144	54.8
Week 24	11	8.3	13	9.8	41	30.8	65	48.9	24	18.5	19	14.6	40	30.8	83	63.8	35	13.3	32	12.2	81	30.8	148	56.3
Post Week 24	11	8.3	13	9.8	41	30.8	65	48.9	24	18.5	19	14.6	41	31.5	84	64.6	35	13.3	32	12.2	82	31.2	149	56.7

AE = adverse experience LE = lack of efficacy
Other = Protocol Deviation (including non-compliance), Lost to follow-up, Unknown and non-study related personal reasons

Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : MDD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
004	xxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.3%)
010	xxxxxxxxxxxx	Entered	2 (5.1%)	2 (5.6%)	4 (5.3%)
		Completed	1 (2.6%)	0	1 (1.3%)
013	xxxxxxxxxxxxxxxxxxxx	Entered	5 (12.8%)	0	5 (6.7%)
		Completed	2 (5.1%)	0	2 (2.7%)
014	xxxxxxxxxxxxxxx	Entered	1 (2.6%)	2 (5.6%)	3 (4.0%)
		Completed	0	1 (2.8%)	1 (1.3%)
017	xxxxxxxxxxxxxxxxxxxxxxxx	Entered	1 (2.6%)	0	1 (1.3%)
019	xxxxxxxxxxxxxxxx	Entered	3 (7.7%)	2 (5.6%)	5 (6.7%)
		Completed	0	1 (2.8%)	1 (1.3%)
025	xxxxxxxxxxxxxxxx	Entered	3 (7.7%)	3 (8.3%)	6 (8.0%)
		Completed	2 (5.1%)	1 (2.8%)	3 (4.0%)
026	xxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.3%)
028	xxxxxxxxxxxxx	Entered	1 (2.6%)	4 (11.1%)	5 (6.7%)
		Completed	1 (2.6%)	0	1 (1.3%)
043	xxxxxxxxxxxxxxxxxxx	Entered	2 (5.1%)	1 (2.8%)	3 (4.0%)
		Completed	1 (2.6%)	0	1 (1.3%)
044	xxxxxxxxxxxx	Entered	0	2 (5.6%)	2 (2.7%)
		Completed	0	1 (2.8%)	1 (1.3%)
148	xxxxxxxxxxxxxxxx	Entered	1 (2.6%)	0	1 (1.3%)
151	xxxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.3%)
		Completed	0	1 (2.8%)	1 (1.3%)
159	xxxxxxxxxxxxxxxx	Entered	2 (5.1%)	0	2 (2.7%)
		Completed	1 (2.6%)	0	1 (1.3%)
164	xxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.3%)
165	xxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.3%)
167	xxxxxxxxxxxxxxxx	Entered	1 (2.6%)	1 (2.8%)	2 (2.7%)
		Completed	1 (2.6%)	1 (2.8%)	2 (2.7%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : MDD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
169	xxxxxxxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.3%)
		Completed	0	1 (2.8%)	1 (1.3%)
170	xxxxxxxxxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.3%)
171	xxxxxxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.3%)
172	xxxxxxxxxxxxxxxx	Entered	1 (2.6%)	0	1 (1.3%)
		Completed	1 (2.6%)	0	1 (1.3%)
173	xxxxxxxxxxxx	Entered	1 (2.6%)	0	1 (1.3%)
		Completed	1 (2.6%)	0	1 (1.3%)
176	xxxxxxxxxxxxxxxxx	Entered	2 (5.1%)	2 (5.6%)	4 (5.3%)
		Completed	2 (5.1%)	1 (2.8%)	3 (4.0%)
179	xxxxxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.3%)
		Completed	0	1 (2.8%)	1 (1.3%)
180	xxxxxxxxxxxxxxx	Entered	1 (2.6%)	1 (2.8%)	2 (2.7%)
183	xxxxxxxxxxxxxx	Entered	1 (2.6%)	4 (11.1%)	5 (6.7%)
		Completed	0	1 (2.8%)	1 (1.3%)
186	xxxxxxxxxxxxxx	Entered	2 (5.1%)	2 (5.6%)	4 (5.3%)
		Completed	1 (2.6%)	1 (2.8%)	2 (2.7%)
192	xxxxxxxxxxxxxxxx	Entered	1 (2.6%)	1 (2.8%)	2 (2.7%)
		Completed	1 (2.6%)	0	1 (1.3%)
201	xxxxxxxxxxxxxxx	Entered	6 (15.4%)	0	6 (8.0%)
208	xxxxxxxxxxxxxxx	Entered	2 (5.1%)	0	2 (2.7%)
		Completed	2 (5.1%)	0	2 (2.7%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : OCD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
002	xxxxxxxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)
004	xxxxxxxxxxxxxx	Entered	3 (10.7%)	1 (2.8%)	4 (6.3%)
		Completed	2 (7.1%)	0	2 (3.1%)
005	xxxxxxxxxxxxxxxxx	Entered	3 (10.7%)	2 (5.6%)	5 (7.8%)
		Completed	1 (3.6%)	1 (2.8%)	2 (3.1%)
006	xxxxxxxxxx	Entered	1 (3.6%)	0	1 (1.6%)
		Completed	1 (3.6%)	0	1 (1.6%)
008	xxxxxxxxxxxx	Entered	1 (3.6%)	0	1 (1.6%)
009	xxxxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)
		Completed	0	1 (2.8%)	1 (1.6%)
012	xxxxxxxxxxxxxx	Entered	1 (3.6%)	0	1 (1.6%)
		Completed	1 (3.6%)	0	1 (1.6%)
014	xxxxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)
		Completed	0	1 (2.8%)	1 (1.6%)
015	xxxxxxxxxxxxxxxxxx	Entered	2 (7.1%)	2 (5.6%)	4 (6.3%)
		Completed	1 (3.6%)	0	1 (1.6%)
016	xxxxxxxxxxxxxxxx	Entered	2 (7.1%)	4 (11.1%)	6 (9.4%)
		Completed	2 (7.1%)	0	2 (3.1%)
019	xxxxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)
020	xxxxxxxxxxxxx	Entered	1 (3.6%)	4 (11.1%)	5 (7.8%)
		Completed	1 (3.6%)	1 (2.8%)	2 (3.1%)
025	xxxxxxxxxxxxxxxx	Entered	1 (3.6%)	3 (8.3%)	4 (6.3%)
		Completed	1 (3.6%)	0	1 (1.6%)
026	xxxxxxxxxxxxxx	Entered	1 (3.6%)	1 (2.8%)	2 (3.1%)
027	xxxxxxxxxxxxxx	Entered	1 (3.6%)	2 (5.6%)	3 (4.7%)
		Completed	0	2 (5.6%)	2 (3.1%)
028	xxxxxxxxxxxxx	Entered	1 (3.6%)	1 (2.8%)	2 (3.1%)
		Completed	0	1 (2.8%)	1 (1.6%)

Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : OCD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
031	xxxxxxxxxxxxx	Entered	0	2 (5.6%)	2 (3.1%)
		Completed	0	1 (2.8%)	1 (1.6%)
040	xxxxxxxxxxxxxx	Entered	1 (3.6%)	1 (2.8%)	2 (3.1%)
		Completed	0	1 (2.8%)	1 (1.6%)
043	xxxxxxxxxxxxxxxxxxxx	Entered	1 (3.6%)	0	1 (1.6%)
		Completed	1 (3.6%)	0	1 (1.6%)
044	xxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)
		Completed	0	1 (2.8%)	1 (1.6%)
052	xxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)
055	xxxxxxxxxxxxxxxxxx	Entered	2 (7.1%)	3 (8.3%)	5 (7.8%)
159	xxxxxxxxxxxxxxx	Entered	0	1 (2.8%)	1 (1.6%)
168	xxxxxxxxxxxxxxxxx	Entered	1 (3.6%)	1 (2.8%)	2 (3.1%)
170	xxxxxxxxxxxxxxxxxxxxx	Entered	1 (3.6%)	0	1 (1.6%)
176	xxxxxxxxxxxxxxxxx	Entered	2 (7.1%)	2 (5.6%)	4 (6.3%)
		Completed	1 (3.6%)	1 (2.8%)	2 (3.1%)
201	xxxxxxxxxxxxxxx	Entered	1 (3.6%)	0	1 (1.6%)
		Completed	1 (3.6%)	0	1 (1.6%)
202	xxxxxxxxxxxxxxx	Entered	1 (3.6%)	0	1 (1.6%)
		Completed	1 (3.6%)	0	1 (1.6%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
002	xxxxxxxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.7%)
004	xxxxxxxxxxxxxx	Entered	3 (4.5%)	2 (2.8%)	5 (3.6%)
		Completed	2 (3.0%)	0	2 (1.4%)
005	xxxxxxxxxxxxxxxxx	Entered	3 (4.5%)	2 (2.8%)	5 (3.6%)
		Completed	1 (1.5%)	1 (1.4%)	2 (1.4%)
006	xxxxxxxxxx	Entered	1 (1.5%)	0	1 (0.7%)
		Completed	1 (1.5%)	0	1 (0.7%)
008	xxxxxxxxxxxx	Entered	1 (1.5%)	0	1 (0.7%)
009	xxxxxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.7%)
		Completed	0	1 (1.4%)	1 (0.7%)
010	xxxxxxxxxxxx	Entered	2 (3.0%)	2 (2.8%)	4 (2.9%)
		Completed	1 (1.5%)	0	1 (0.7%)
012	xxxxxxxxxxxxxx	Entered	1 (1.5%)	0	1 (0.7%)
		Completed	1 (1.5%)	0	1 (0.7%)
013	xxxxxxxxxxxxxxxxxxxxx	Entered	5 (7.5%)	0	5 (3.6%)
		Completed	2 (3.0%)	0	2 (1.4%)
014	xxxxxxxxxxxxxxxx	Entered	1 (1.5%)	3 (4.2%)	4 (2.9%)
		Completed	0	2 (2.8%)	2 (1.4%)
015	xxxxxxxxxxxxxxxxxx	Entered	2 (3.0%)	2 (2.8%)	4 (2.9%)
		Completed	1 (1.5%)	0	1 (0.7%)
016	xxxxxxxxxxxxxxxx	Entered	2 (3.0%)	4 (5.6%)	6 (4.3%)
		Completed	2 (3.0%)	0	2 (1.4%)
017	xxxxxxxxxxxxxxxx	Entered	1 (1.5%)	0	1 (0.7%)
019	xxxxxxxxxxxxxxxx	Entered	3 (4.5%)	3 (4.2%)	6 (4.3%)
		Completed	0	1 (1.4%)	1 (0.7%)
020	xxxxxxxxxxxxx	Entered	1 (1.5%)	4 (5.6%)	5 (3.6%)
		Completed	1 (1.5%)	1 (1.4%)	2 (1.4%)
025	xxxxxxxxxxxxxxxx	Entered	4 (6.0%)	6 (8.3%)	10 (7.2%)
		Completed	3 (4.5%)	1 (1.4%)	4 (2.9%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
026	xxxxxxxxxxxxxx	Entered	1 (1.5%)	2 (2.8%)	3 (2.2%)
027	xxxxxxxxxxxxxx	Entered	1 (1.5%)	2 (2.8%)	3 (2.2%)
		Completed	0	2 (2.8%)	2 (1.4%)
028	xxxxxxxxxxxxx	Entered	2 (3.0%)	5 (6.9%)	7 (5.0%)
		Completed	1 (1.5%)	1 (1.4%)	2 (1.4%)
031	xxxxxxxxxxxx	Entered	0	2 (2.8%)	2 (1.4%)
		Completed	0	1 (1.4%)	1 (0.7%)
040	xxxxxxxxxxxxxx	Entered	1 (1.5%)	1 (1.4%)	2 (1.4%)
		Completed	0	1 (1.4%)	1 (0.7%)
043	xxxxxxxxxxxxxxxxxxxx	Entered	3 (4.5%)	1 (1.4%)	4 (2.9%)
		Completed	2 (3.0%)	0	2 (1.4%)
044	xxxxxxxxxxxx	Entered	0	3 (4.2%)	3 (2.2%)
		Completed	0	2 (2.8%)	2 (1.4%)
052	xxxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.7%)
055	xxxxxxxxxxxxxxxxx	Entered	2 (3.0%)	3 (4.2%)	5 (3.6%)
148	xxxxxxxxxxxxxxxx	Entered	1 (1.5%)	0	1 (0.7%)
151	xxxxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.7%)
		Completed	0	1 (1.4%)	1 (0.7%)
159	xxxxxxxxxxxxxxx	Entered	2 (3.0%)	1 (1.4%)	3 (2.2%)
		Completed	1 (1.5%)	0	1 (0.7%)
164	xxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.7%)
165	xxxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.7%)
167	xxxxxxxxxxxxxxxx	Entered	1 (1.5%)	1 (1.4%)	2 (1.4%)
		Completed	1 (1.5%)	1 (1.4%)	2 (1.4%)
168	xxxxxxxxxxxxxxxxx	Entered	1 (1.5%)	1 (1.4%)	2 (1.4%)
169	xxxxxxxxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.7%)
		Completed	0	1 (1.4%)	1 (0.7%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
170	xxxxxxxxxxxxxxxxxxxxx	Entered	1 (1.5%)	1 (1.4%)	2 (1.4%)
171	xxxxxxxxxxxxxxxxxx	Entered	0	1 (1.4%)	1 (0.7%)
172	xxxxxxxxxxxxxxxx	Entered	1 (1.5%)	0	1 (0.7%)
		Completed	1 (1.5%)	0	1 (0.7%)
173	xxxxxxxxxxxx	Entered	1 (1.5%)	0	1 (0.7%)
		Completed	1 (1.5%)	0	1 (0.7%)
176	xxxxxxxxxxxxxxxxx	Entered	4 (6.0%)	4 (5.6%)	8 (5.8%)
		Completed	3 (4.5%)	2 (2.8%)	5 (3.6%)
179	xxxxxxxxxxxxxcxxx	Entered	0	1 (1.4%)	1 (0.7%)
		Completed	0	1 (1.4%)	1 (0.7%)
180	xxxxxxxxxxxxxx	Entered	1 (1.5%)	1 (1.4%)	2 (1.4%)
183	xxxxxxxxxxxxxx	Entered	1 (1.5%)	4 (5.6%)	5 (3.6%)
		Completed	0	1 (1.4%)	1 (0.7%)
186	xxxxxxxxxxxxxx	Entered	2 (3.0%)	2 (2.8%)	4 (2.9%)
		Completed	1 (1.5%)	1 (1.4%)	2 (1.4%)
192	xxxxxxxxxxxxxxxx	Entered	1 (1.5%)	1 (1.4%)	2 (1.4%)
		Completed	1 (1.5%)	0	1 (0.7%)
201	xxxxxxxxxxxxxxx	Entered	7 (10.4%)	0	7 (5.0%)
		Completed	1 (1.5%)	0	1 (0.7%)
202	xxxxxxxxxxxxxxx	Entered	1 (1.5%)	0	1 (0.7%)
		Completed	1 (1.5%)	0	1 (0.7%)
208	xxxxxxxxxxxxxxx	Entered	2 (3.0%)	0	2 (1.4%)
		Completed	2 (3.0%)	0	2 (1.4%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : MDD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
005	xxxxxxxxxxxxxxxxx	Entered	0	1 (3.3%)	1 (1.4%)
008	xxxxxxxxxxxx	Entered	1 (2.4%)	0	1 (1.4%)
010	xxxxxxxxxxxx	Entered	4 (9.5%)	2 (6.7%)	6 (8.3%)
		Completed	3 (7.1%)	2 (6.7%)	5 (6.9%)
013	xxxxxxxxxxxxxxxxxxxxx	Entered	2 (4.8%)	0	2 (2.8%)
		Completed	1 (2.4%)	0	1 (1.4%)
014	xxxxxxxxxxxxxxxx	Entered	0	2 (6.7%)	2 (2.8%)
017	xxxxxxxxxxxxxxx.	Entered	2 (4.8%)	0	2 (2.8%)
		Completed	1 (2.4%)	0	1 (1.4%)
019	xxxxxxxxxxxxxxxxx	Entered	1 (2.4%)	2 (6.7%)	3 (4.2%)
		Completed	1 (2.4%)	0	1 (1.4%)
025	xxxxxxxxxxxxxxxx	Entered	3 (7.1%)	3 (10.0%)	6 (8.3%)
		Completed	2 (4.8%)	2 (6.7%)	4 (5.6%)
028	xxxxxxxxxxxx	Entered	1 (2.4%)	0	1 (1.4%)
044	xxxxxxxxxxxx	Entered	2 (4.8%)	1 (3.3%)	3 (4.2%)
		Completed	1 (2.4%)	0	1 (1.4%)
151	xxxxxxxxxxxxxxx	Entered	0	1 (3.3%)	1 (1.4%)
154	xxxxxxxxxxxx	Entered	1 (2.4%)	0	1 (1.4%)
159	xxxxxxxxxxxxxxx	Entered	1 (2.4%)	4 (13.3%)	5 (6.9%)
		Completed	0	3 (10.0%)	3 (4.2%)
164	xxxxxxxxxxxx	Entered	1 (2.4%)	0	1 (1.4%)
165	xxxxxxxxxxxxxx	Entered	0	1 (3.3%)	1 (1.4%)
167	xxxxxxxxxxxxxxxx	Entered	0	1 (3.3%)	1 (1.4%)
		Completed	0	1 (3.3%)	1 (1.4%)
168	xxxxxxxxxxxxxxxxx	Entered	2 (4.8%)	1 (3.3%)	3 (4.2%)
		Completed	1 (2.4%)	1 (3.3%)	2 (2.8%)
170	xxxxxxxxxxxxxxxxxxxx	Entered	0	1 (3.3%)	1 (1.4%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : MDD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
170	xxxxxxxxxxxxxxxxxxxxx	Completed	0	1 (3.3%)	1 (1.4%)
176	xxxxxxxxxxxxxxxxxx	Entered	1 (2.4%)	2 (6.7%)	3 (4.2%)
		Completed	1 (2.4%)	1 (3.3%)	2 (2.8%)
180	xxxxxxxxxxxxxx	Entered	1 (2.4%)	0	1 (1.4%)
183	xxxxxxxxxxxxxxx	Entered	3 (7.1%)	4 (13.3%)	7 (9.7%)
		Completed	3 (7.1%)	1 (3.3%)	4 (5.6%)
186	xxxxxxxxxxxxxx	Entered	1 (2.4%)	1 (3.3%)	2 (2.8%)
		Completed	1 (2.4%)	0	1 (1.4%)
192	xxxxxxxxxxxxxxxx	Entered	2 (4.8%)	3 (10.0%)	5 (6.9%)
		Completed	1 (2.4%)	1 (3.3%)	2 (2.8%)
201	xxxxxxxxxxxxxxx	Entered	2 (4.8%)	0	2 (2.8%)
		Completed	1 (2.4%)	0	1 (1.4%)
205	xxxxxxxxxxxxx	Entered	4 (9.5%)	0	4 (5.6%)
		Completed	3 (7.1%)	0	3 (4.2%)
206	xxxxxxxxxxxxxxx	Entered	2 (4.8%)	0	2 (2.8%)
		Completed	1 (2.4%)	0	1 (1.4%)
208	xxxxxxxxxxxxxxx	Entered	5 (11.9%)	0	5 (6.9%)
		Completed	4 (9.5%)	0	4 (5.6%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : OCD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
002	xxxxxxxxxxxxxxxxxx	Entered	1 (4.2%)	1 (3.6%)	2 (3.8%)
		Completed	1 (4.2%)	1 (3.6%)	2 (3.8%)
004	xxxxxxxxxxxxxx	Entered	0	1 (3.6%)	1 (1.9%)
005	xxxxxxxxxxxxxxxxx	Entered	1 (4.2%)	1 (3.6%)	2 (3.8%)
		Completed	0	1 (3.6%)	1 (1.9%)
006	xxxxxxxxxx	Entered	2 (8.3%)	1 (3.6%)	3 (5.8%)
		Completed	2 (8.3%)	0	2 (3.8%)
008	xxxxxxxxxxxx	Entered	1 (4.2%)	1 (3.6%)	2 (3.8%)
009	xxxxxxxxxxxxxxxx	Entered	1 (4.2%)	0	1 (1.9%)
		Completed	1 (4.2%)	0	1 (1.9%)
010	xxxxxxxxxxxx	Entered	0	3 (10.7%)	3 (5.8%)
		Completed	0	1 (3.6%)	1 (1.9%)
014	xxxxxxxxxxxxxxxx	Entered	2 (8.3%)	1 (3.6%)	3 (5.8%)
		Completed	1 (4.2%)	0	1 (1.9%)
015	xxxxxxxxxxxxxxxxxx	Entered	1 (4.2%)	1 (3.6%)	2 (3.8%)
016	xxxxxxxxxxxxxxxx	Entered	2 (8.3%)	1 (3.6%)	3 (5.8%)
		Completed	2 (8.3%)	0	2 (3.8%)
017	xxxxxxxxxxxxxxxx	Entered	2 (8.3%)	0	2 (3.8%)
		Completed	2 (8.3%)	0	2 (3.8%)
020	xxxxxxxxxxxxx	Entered	3 (12.5%)	2 (7.1%)	5 (9.6%)
		Completed	2 (8.3%)	1 (3.6%)	3 (5.8%)
025	xxxxxxxxxxxxxxxx	Entered	0	2 (7.1%)	2 (3.8%)
		Completed	0	1 (3.6%)	1 (1.9%)
028	xxxxxxxxxxxxx	Entered	0	1 (3.6%)	1 (1.9%)
		Completed	0	1 (3.6%)	1 (1.9%)
031	xxxxxxxxxxxxx	Entered	0	1 (3.6%)	1 (1.9%)
		Completed	0	1 (3.6%)	1 (1.9%)
044	xxxxxxxxxxxx	Entered	0	1 (3.6%)	1 (1.9%)
		Completed	0	1 (3.6%)	1 (1.9%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : OCD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
047	xxxxxxxxxxx	Entered	1 (4.2%)	2 (7.1%)	3 (5.8%)
049	xxxxxxxxxxxxxx	Entered	2 (8.3%)	3 (10.7%)	5 (9.6%)
		Completed	1 (4.2%)	2 (7.1%)	3 (5.8%)
055	xxxxxxxxxxxxxxxxx	Entered	2 (8.3%)	2 (7.1%)	4 (7.7%)
168	xxxxxxxxxxxxxxxxx	Entered	1 (4.2%)	1 (3.6%)	2 (3.8%)
176	xxxxxxxxxxxxxxxxx	Entered	1 (4.2%)	2 (7.1%)	3 (5.8%)
		Completed	0	1 (3.6%)	1 (1.9%)
208	xxxxxxxxxxxxxxx	Entered	1 (4.2%)	0	1 (1.9%)

Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
002	xxxxxxxxxxxxxxxxxx	Entered	1 (1.5%)	1 (1.7%)	2 (1.6%)
		Completed	1 (1.5%)	1 (1.7%)	2 (1.6%)
004	xxxxxxxxxxxxx	Entered	0	1 (1.7%)	1 (0.8%)
005	xxxxxxxxxxxxxxxxx	Entered	1 (1.5%)	2 (3.4%)	3 (2.4%)
		Completed	0	1 (1.7%)	1 (0.8%)
006	xxxxxxxxxx	Entered	2 (3.0%)	1 (1.7%)	3 (2.4%)
		Completed	2 (3.0%)	0	2 (1.6%)
008	xxxxxxxxxxx	Entered	2 (3.0%)	1 (1.7%)	3 (2.4%)
009	xxxxxxxxxxxxxxxx	Entered	1 (1.5%)	0	1 (0.8%)
		Completed	1 (1.5%)	0	1 (0.8%)
010	xxxxxxxxxxxx	Entered	4 (6.1%)	5 (8.6%)	9 (7.3%)
		Completed	3 (4.5%)	3 (5.2%)	6 (4.8%)
013	xxxxxxxxxxxxxxxxxxxx	Entered	2 (3.0%)	0	2 (1.6%)
		Completed	1 (1.5%)	0	1 (0.8%)
014	xxxxxxxxxxxxxxxx	Entered	2 (3.0%)	3 (5.2%)	5 (4.0%)
		Completed	1 (1.5%)	0	1 (0.8%)
015	xxxxxxxxxxxxxxxxx	Entered	1 (1.5%)	1 (1.7%)	2 (1.6%)
016	xxxxxxxxxxxxxxxx	Entered	2 (3.0%)	1 (1.7%)	3 (2.4%)
		Completed	2 (3.0%)	0	2 (1.6%)
017	xxxxxxxxxxxxxxxx	Entered	4 (6.1%)	0	4 (3.2%)
		Completed	3 (4.5%)	0	3 (2.4%)
019	xxxxxxxxxxxxxxxx	Entered	1 (1.5%)	2 (3.4%)	3 (2.4%)
		Completed	1 (1.5%)	0	1 (0.8%)
020	xxxxxxxxxxxxx	Entered	3 (4.5%)	2 (3.4%)	5 (4.0%)
		Completed	2 (3.0%)	1 (1.7%)	3 (2.4%)
025	xxxxxxxxxxxxxxxx	Entered	3 (4.5%)	5 (8.6%)	8 (6.5%)
		Completed	2 (3.0%)	3 (5.2%)	5 (4.0%)
028	xxxxxxxxxxxxx	Entered	1 (1.5%)	1 (1.7%)	2 (1.6%)
		Completed	0	1 (1.7%)	1 (0.8%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
031	xxxxxxxxxxxxx	Entered	0	1 (1.7%)	1 (0.8%)
		Completed	0	1 (1.7%)	1 (0.8%)
044	xxxxxxxxxxxx	Entered	2 (3.0%)	2 (3.4%)	4 (3.2%)
		Completed	1 (1.5%)	1 (1.7%)	2 (1.6%)
047	xxxxxxxxxxx	Entered	1 (1.5%)	2 (3.4%)	3 (2.4%)
049	xxxxxxxxxxxxxx	Entered	2 (3.0%)	3 (5.2%)	5 (4.0%)
		Completed	1 (1.5%)	2 (3.4%)	3 (2.4%)
055	xxxxxxxxxxxxxxxxx	Entered	2 (3.0%)	2 (3.4%)	4 (3.2%)
151	xxxxxxxxxxxxxxx	Entered	0	1 (1.7%)	1 (0.8%)
154	xxxxxxxxxxxxx	Entered	1 (1.5%)	0	1 (0.8%)
159	xxxxxxxxxxxxxxx	Entered	1 (1.5%)	4 (6.9%)	5 (4.0%)
		Completed	0	3 (5.2%)	3 (2.4%)
164	xxxxxxxxxxxxx	Entered	1 (1.5%)	0	1 (0.8%)
165	xxxxxxxxxxxxxx	Entered	0	1 (1.7%)	1 (0.8%)
167	xxxxxxxxxxxxxxxx	Entered	0	1 (1.7%)	1 (0.8%)
		Completed	0	1 (1.7%)	1 (0.8%)
168	xxxxxxxxxxxxxxxxx	Entered	3 (4.5%)	2 (3.4%)	5 (4.0%)
		Completed	1 (1.5%)	1 (1.7%)	2 (1.6%)
170	xxxxxxxxxxxxxxxxxxxxx	Entered	0	1 (1.7%)	1 (0.8%)
		Completed	0	1 (1.7%)	1 (0.8%)
176	xxxxxxxxxxxxxxxxx	Entered	2 (3.0%)	4 (6.9%)	6 (4.8%)
		Completed	1 (1.5%)	2 (3.4%)	3 (2.4%)
180	xxxxxxxxxxxxxx	Entered	1 (1.5%)	0	1 (0.8%)
183	xxxxxxxxxxxxxx	Entered	3 (4.5%)	4 (6.9%)	7 (5.6%)
		Completed	3 (4.5%)	1 (1.7%)	4 (3.2%)
186	xxxxxxxxxxxxxx	Entered	1 (1.5%)	1 (1.7%)	2 (1.6%)
		Completed	1 (1.5%)	0	1 (0.8%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
192	xxxxxxxxxxxxxxxx	Entered	2 (3.0%)	3 (5.2%)	5 (4.0%)
		Completed	1 (1.5%)	1 (1.7%)	2 (1.6%)
201	xxxxxxxxxxxxxxx	Entered	2 (3.0%)	0	2 (1.6%)
		Completed	1 (1.5%)	0	1 (0.8%)
205	xxxxxxxxxxxxx	Entered	4 (6.1%)	0	4 (3.2%)
		Completed	3 (4.5%)	0	3 (2.4%)
206	xxxxxxxxxxxxxxx	Entered	2 (3.0%)	0	2 (1.6%)
		Completed	1 (1.5%)	0	1 (0.8%)
208	xxxxxxxxxxxxxxx	Entered	6 (9.1%)	0	6 (4.8%)
		Completed	4 (6.1%)	0	4 (3.2%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : MDD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
004	xxxxxxxxxxxxxx	Entered	0	1 (1.5%)	1 (0.7%)
005	xxxxxxxxxxxxxxxxx	Entered	0	1 (1.5%)	1 (0.7%)
008	xxxxxxxxxxxx	Entered	1 (1.2%)	0	1 (0.7%)
010	xxxxxxxxxxxx	Entered	6 (7.4%)	4 (6.1%)	10 (6.8%)
		Completed	4 (4.9%)	2 (3.0%)	6 (4.1%)
013	xxxxxxxxxxxxxxxxxxxxx	Entered	7 (8.6%)	0	7 (4.8%)
		Completed	3 (3.7%)	0	3 (2.0%)
014	xxxxxxxxxxxxxxxx	Entered	1 (1.2%)	4 (6.1%)	5 (3.4%)
		Completed	0	1 (1.5%)	1 (0.7%)
017	xxxxxxxxxxxxxxxx	Entered	3 (3.7%)	0	3 (2.0%)
		Completed	1 (1.2%)	0	1 (0.7%)
019	xxxxxxxxxxxxxxxx	Entered	4 (4.9%)	4 (6.1%)	8 (5.4%)
		Completed	1 (1.2%)	1 (1.5%)	2 (1.4%)
025	xxxxxxxxxxxxxxxx	Entered	6 (7.4%)	6 (9.1%)	12 (8.2%)
		Completed	4 (4.9%)	3 (4.5%)	7 (4.8%)
026	xxxxxxxxxxxxxx	Entered	0	1 (1.5%)	1 (0.7%)
028	xxxxxxxxxxxxx	Entered	2 (2.5%)	4 (6.1%)	6 (4.1%)
		Completed	1 (1.2%)	0	1 (0.7%)
043	xxxxxxxxxxxxxxxxxxx	Entered	2 (2.5%)	1 (1.5%)	3 (2.0%)
		Completed	1 (1.2%)	0	1 (0.7%)
044	xxxxxxxxxxxx	Entered	2 (2.5%)	3 (4.5%)	5 (3.4%)
		Completed	1 (1.2%)	1 (1.5%)	2 (1.4%)
148	xxxxxxxxxxxxxxxx	Entered	1 (1.2%)	0	1 (0.7%)
151	xxxxxxxxxxxxxxx	Entered	0	2 (3.0%)	2 (1.4%)
		Completed	0	1 (1.5%)	1 (0.7%)
154	xxxxxxxxxxxxx	Entered	1 (1.2%)	0	1 (0.7%)
159	xxxxxxxxxxxxxxx	Entered	3 (3.7%)	4 (6.1%)	7 (4.8%)
		Completed	1 (1.2%)	3 (4.5%)	4 (2.7%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : MDD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
164	xxxxxxxxxxxxx	Entered	1 (1.2%)	1 (1.5%)	2 (1.4%)
165	xxxxxxxxxxxxxx	Entered	0	2 (3.0%)	2 (1.4%)
167	xxxxxxxxxxxxxxxx	Entered	1 (1.2%)	2 (3.0%)	3 (2.0%)
		Completed	1 (1.2%)	2 (3.0%)	3 (2.0%)
168	xxxxxxxxxxxxxxxxx	Entered	2 (2.5%)	1 (1.5%)	3 (2.0%)
		Completed	1 (1.2%)	1 (1.5%)	2 (1.4%)
169	xxxxxxxxxxxxxxxxxxx	Entered	0	1 (1.5%)	1 (0.7%)
		Completed	0	1 (1.5%)	1 (0.7%)
170	xxxxxxxxxxxxxxxxxxxxx	Entered	0	2 (3.0%)	2 (1.4%)
		Completed	0	1 (1.5%)	1 (0.7%)
171	xxxxxxxxxxxxxxxxx	Entered	0	1 (1.5%)	1 (0.7%)
172	xxxxxxxxxxxxxxxx	Entered	1 (1.2%)	0	1 (0.7%)
		Completed	1 (1.2%)	0	1 (0.7%)
173	xxxxxxxxxxxx	Entered	1 (1.2%)	0	1 (0.7%)
		Completed	1 (1.2%)	0	1 (0.7%)
176	xxxxxxxxxxxxxxxxx	Entered	3 (3.7%)	4 (6.1%)	7 (4.8%)
		Completed	3 (3.7%)	2 (3.0%)	5 (3.4%)
179	xxxxxxxxxxxxxxxxx	Entered	0	1 (1.5%)	1 (0.7%)
		Completed	0	1 (1.5%)	1 (0.7%)
180	xxxxxxxxxxxxxxx	Entered	2 (2.5%)	1 (1.5%)	3 (2.0%)
183	xxxxxxxxxxxxxx	Entered	4 (4.9%)	8 (12.1%)	12 (8.2%)
		Completed	3 (3.7%)	2 (3.0%)	5 (3.4%)
186	xxxxxxxxxxxxxx	Entered	3 (3.7%)	3 (4.5%)	6 (4.1%)
		Completed	2 (2.5%)	1 (1.5%)	3 (2.0%)
192	xxxxxxxxxxxxxxxx	Entered	3 (3.7%)	4 (6.1%)	7 (4.8%)
		Completed	2 (2.5%)	1 (1.5%)	3 (2.0%)
201	xxxxxxxxxxxxxxx	Entered	8 (9.9%)	0	8 (5.4%)
		Completed	1 (1.2%)	0	1 (0.7%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : MDD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
205	xxxxxxxxxxxxx	Entered	4 (4.9%)	0	4 (2.7%)
		Completed	3 (3.7%)	0	3 (2.0%)
206	xxxxxxxxxxxxxxx	Entered	2 (2.5%)	0	2 (1.4%)
		Completed	1 (1.2%)	0	1 (0.7%)
208	xxxxxxxxxxxxxxx	Entered	7 (8.6%)	0	7 (4.8%)
		Completed	6 (7.4%)	0	6 (4.1%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : OCD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
002	xxxxxxxxxxxxxxxxxx	Entered	1 (1.9%)	2 (3.1%)	3 (2.6%)
		Completed	1 (1.9%)	1 (1.6%)	2 (1.7%)
004	xxxxxxxxxxxxxx	Entered	3 (5.8%)	2 (3.1%)	5 (4.3%)
		Completed	2 (3.8%)	0	2 (1.7%)
005	xxxxxxxxxxxxxxxxx	Entered	4 (7.7%)	3 (4.7%)	7 (6.0%)
		Completed	1 (1.9%)	2 (3.1%)	3 (2.6%)
006	xxxxxxxxxx	Entered	3 (5.8%)	1 (1.6%)	4 (3.4%)
		Completed	3 (5.8%)	0	3 (2.6%)
008	xxxxxxxxxxx	Entered	2 (3.8%)	1 (1.6%)	3 (2.6%)
009	xxxxxxxxxxxxxxx	Entered	1 (1.9%)	1 (1.6%)	2 (1.7%)
		Completed	1 (1.9%)	1 (1.6%)	2 (1.7%)
010	xxxxxxxxxxx	Entered	0	3 (4.7%)	3 (2.6%)
		Completed	0	1 (1.6%)	1 (0.9%)
012	xxxxxxxxxxxxx	Entered	1 (1.9%)	0	1 (0.9%)
		Completed	1 (1.9%)	0	1 (0.9%)
014	xxxxxxxxxxxxxxx	Entered	2 (3.8%)	2 (3.1%)	4 (3.4%)
		Completed	1 (1.9%)	1 (1.6%)	2 (1.7%)
015	xxxxxxxxxxxxxxxxx	Entered	3 (5.8%)	3 (4.7%)	6 (5.2%)
		Completed	1 (1.9%)	0	1 (0.9%)
016	xxxxxxxxxxxxxxx	Entered	4 (7.7%)	5 (7.8%)	9 (7.8%)
		Completed	4 (7.7%)	0	4 (3.4%)
017	xxxxxxxxxxxxxxx	Entered	2 (3.8%)	0	2 (1.7%)
		Completed	2 (3.8%)	0	2 (1.7%)
019	xxxxxxxxxxxxxxx	Entered	0	1 (1.6%)	1 (0.9%)
020	xxxxxxxxxxxxx	Entered	4 (7.7%)	6 (9.4%)	10 (8.6%)
		Completed	3 (5.8%)	2 (3.1%)	5 (4.3%)
025	xxxxxxxxxxxxxxx	Entered	1 (1.9%)	5 (7.8%)	6 (5.2%)
		Completed	1 (1.9%)	1 (1.6%)	2 (1.7%)
026	xxxxxxxxxxxxxx	Entered	1 (1.9%)	1 (1.6%)	2 (1.7%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : OCD

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
027	xxxxxxxxxxxxxx	Entered	1 (1.9%)	2 (3.1%)	3 (2.6%)
		Completed	0	2 (3.1%)	2 (1.7%)
028	xxxxxxxxxxxx	Entered	1 (1.9%)	2 (3.1%)	3 (2.6%)
		Completed	0	2 (3.1%)	2 (1.7%)
031	xxxxxxxxxxxxx	Entered	0	3 (4.7%)	3 (2.6%)
		Completed	0	2 (3.1%)	2 (1.7%)
040	xxxxxxxxxxxxxx	Entered	1 (1.9%)	1 (1.6%)	2 (1.7%)
		Completed	0	1 (1.6%)	1 (0.9%)
043	xxxxxxxxxxxxxxxxxxxx	Entered	1 (1.9%)	0	1 (0.9%)
		Completed	1 (1.9%)	0	1 (0.9%)
044	xxxxxxxxxxxx	Entered	0	2 (3.1%)	2 (1.7%)
		Completed	0	2 (3.1%)	2 (1.7%)
047	xxxxxxxxxxx	Entered	1 (1.9%)	2 (3.1%)	3 (2.6%)
049	xxxxxxxxxxxxxx	Entered	2 (3.8%)	3 (4.7%)	5 (4.3%)
		Completed	1 (1.9%)	2 (3.1%)	3 (2.6%)
052	xxxxxxxxxxxxxx	Entered	0	1 (1.6%)	1 (0.9%)
055	xxxxxxxxxxxxxxxxx	Entered	4 (7.7%)	5 (7.8%)	9 (7.8%)
159	xxxxxxxxxxxxxxx	Entered	0	1 (1.6%)	1 (0.9%)
168	xxxxxxxxxxxxxxxxx	Entered	2 (3.8%)	2 (3.1%)	4 (3.4%)
170	xxxxxxxxxxxxxxxxxxxx	Entered	1 (1.9%)	0	1 (0.9%)
176	xxxxxxxxxxxxxxxxx	Entered	3 (5.8%)	4 (6.3%)	7 (6.0%)
		Completed	1 (1.9%)	2 (3.1%)	3 (2.6%)
201	xxxxxxxxxxxxxxx	Entered	1 (1.9%)	0	1 (0.9%)
		Completed	1 (1.9%)	0	1 (0.9%)
202	xxxxxxxxxxxxxxx	Entered	1 (1.9%)	0	1 (0.9%)
		Completed	1 (1.9%)	0	1 (0.9%)
208	Wxxxxxxxxxxxxxx	Entered	1 (1.9%)	0	1 (0.9%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
002	xxxxxxxxxxxxxxxxxx	Entered	1 (0.8%)	2 (1.5%)	3 (1.1%)
		Completed	1 (0.8%)	1 (0.8%)	2 (0.8%)
004	xxxxxxxxxxxxxx	Entered	3 (2.3%)	3 (2.3%)	6 (2.3%)
		Completed	2 (1.5%)	0	2 (0.8%)
005	xxxxxxxxxxxxxxxxx	Entered	4 (3.0%)	4 (3.1%)	8 (3.0%)
		Completed	1 (0.8%)	2 (1.5%)	3 (1.1%)
006	xxxxxxxxxx	Entered	3 (2.3%)	1 (0.8%)	4 (1.5%)
		Completed	3 (2.3%)	0	3 (1.1%)
008	xxxxxxxxxxxx	Entered	3 (2.3%)	1 (0.8%)	4 (1.5%)
009	xxxxxxxxxxxxxxxx	Entered	1 (0.8%)	1 (0.8%)	2 (0.8%)
		Completed	1 (0.8%)	1 (0.8%)	2 (0.8%)
010	xxxxxxxxxxxx	Entered	6 (4.5%)	7 (5.4%)	13 (4.9%)
		Completed	4 (3.0%)	3 (2.3%)	7 (2.7%)
012	xxxxxxxxxxxxx	Entered	1 (0.8%)	0	1 (0.4%)
		Completed	1 (0.8%)	0	1 (0.4%)
013	xxxxxxxxxxxxxxxxxxxx	Entered	7 (5.3%)	0	7 (2.7%)
		Completed	3 (2.3%)	0	3 (1.1%)
014	xxxxxxxxxxxxxxx	Entered	3 (2.3%)	6 (4.6%)	9 (3.4%)
		Completed	1 (0.8%)	2 (1.5%)	3 (1.1%)
015	xxxxxxxxxxxxxxxxx	Entered	3 (2.3%)	3 (2.3%)	6 (2.3%)
		Completed	1 (0.8%)	0	1 (0.4%)
016	xxxxxxxxxxxxxxx	Entered	4 (3.0%)	5 (3.8%)	9 (3.4%)
		Completed	4 (3.0%)	0	4 (1.5%)
017	xxxxxxxxxxxxxxx	Entered	5 (3.8%)	0	5 (1.9%)
		Completed	3 (2.3%)	0	3 (1.1%)
019	xxxxxxxxxxxxxxx	Entered	4 (3.0%)	5 (3.8%)	9 (3.4%)
		Completed	1 (0.8%)	1 (0.8%)	2 (0.8%)
020	xxxxxxxxxxxxx	Entered	4 (3.0%)	6 (4.6%)	10 (3.8%)
		Completed	3 (2.3%)	2 (1.5%)	5 (1.9%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
025	xxxxxxxxxxxxxxxx	Entered	7 (5.3%)	11 (8.5%)	18 (6.8%)
		Completed	5 (3.8%)	4 (3.1%)	9 (3.4%)
026	xxxxxxxxxxxxxx	Entered	1 (0.8%)	2 (1.5%)	3 (1.1%)
027	xxxxxxxxxxxxxx	Entered	1 (0.8%)	2 (1.5%)	3 (1.1%)
		Completed	0	2 (1.5%)	2 (0.8%)
028	xxxxxxxxxxxxx	Entered	3 (2.3%)	6 (4.6%)	9 (3.4%)
		Completed	1 (0.8%)	2 (1.5%)	3 (1.1%)
031	xxxxxxxxxxxxx	Entered	0	3 (2.3%)	3 (1.1%)
		Completed	0	2 (1.5%)	2 (0.8%)
040	xxxxxxxxxxxxxx	Entered	1 (0.8%)	1 (0.8%)	2 (0.8%)
		Completed	0	1 (0.8%)	1 (0.4%)
043	xxxxxxxxxxxxxxxxxxxx	Entered	3 (2.3%)	1 (0.8%)	4 (1.5%)
		Completed	2 (1.5%)	0	2 (0.8%)
044	xxxxxxxxxxxx	Entered	2 (1.5%)	5 (3.8%)	7 (2.7%)
		Completed	1 (0.8%)	3 (2.3%)	4 (1.5%)
047	xxxxxxxxxxx	Entered	1 (0.8%)	2 (1.5%)	3 (1.1%)
049	xxxxxxxxxxxxxx	Entered	2 (1.5%)	3 (2.3%)	5 (1.9%)
		Completed	1 (0.8%)	2 (1.5%)	3 (1.1%)
052	xxxxxxxxxxxxxx	Entered	0	1 (0.8%)	1 (0.4%)
055	xxxxxxxxxxxxxxxxx	Entered	4 (3.0%)	5 (3.8%)	9 (3.4%)
148	xxxxxxxxxxxxxxxx	Entered	1 (0.8%)	0	1 (0.4%)
151	xxxxxxxxxxxxxxx	Entered	0	2 (1.5%)	2 (0.8%)
		Completed	0	1 (0.8%)	1 (0.4%)
154	xxxxxxxxxxxxx	Entered	1 (0.8%)	0	1 (0.4%)
159	xxxxxxxxxxxxxxx	Entered	3 (2.3%)	5 (3.8%)	8 (3.0%)
		Completed	1 (0.8%)	3 (2.3%)	4 (1.5%)
164	xxxxxxxxxxxxx	Entered	1 (0.8%)	1 (0.8%)	2 (0.8%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
165	xxxxxxxxxxxxxx	Entered	0	2 (1.5%)	2 (0.8%)
167	xxxxxxxxxxxxxxxx	Entered	1 (0.8%)	2 (1.5%)	3 (1.1%)
		Completed	1 (0.8%)	2 (1.5%)	3 (1.1%)
168	xxxxxxxxxxxxxxxxx	Entered	4 (3.0%)	3 (2.3%)	7 (2.7%)
		Completed	1 (0.8%)	1 (0.8%)	2 (0.8%)
169	xxxxxxxxxxxxxxxxxxx	Entered	0	1 (0.8%)	1 (0.4%)
		Completed	0	1 (0.8%)	1 (0.4%)
170	xxxxxxxxxxxxxxxxxxxxx	Entered	1 (0.8%)	2 (1.5%)	3 (1.1%)
		Completed	0	1 (0.8%)	1 (0.4%)
171	xxxxxxxxxxxxxxxxx	Entered	0	1 (0.8%)	1 (0.4%)
172	xxxxxxxxxxxxxxxx	Entered	1 (0.8%)	0	1 (0.4%)
		Completed	1 (0.8%)	0	1 (0.4%)
173	xxxxxxxxxxxx	Entered	1 (0.8%)	0	1 (0.4%)
		Completed	1 (0.8%)	0	1 (0.4%)
176	xxxxxxxxxxxxxxxxx	Entered	6 (4.5%)	8 (6.2%)	14 (5.3%)
		Completed	4 (3.0%)	4 (3.1%)	8 (3.0%)
179	xxxxxxxxxxxxxxxxx	Entered	0	1 (0.8%)	1 (0.4%)
		Completed	0	1 (0.8%)	1 (0.4%)
180	xxxxxxxxxxxxxx	Entered	2 (1.5%)	1 (0.8%)	3 (1.1%)
183	xxxxxxxxxxxxxx	Entered	4 (3.0%)	8 (6.2%)	12 (4.6%)
		Completed	3 (2.3%)	2 (1.5%)	5 (1.9%)
186	xxxxxxxxxxxxxx	Entered	3 (2.3%)	3 (2.3%)	6 (2.3%)
		Completed	2 (1.5%)	1 (0.8%)	3 (1.1%)
192	xxxxxxxxxxxxxxxx	Entered	3 (2.3%)	4 (3.1%)	7 (2.7%)
		Completed	2 (1.5%)	1 (0.8%)	3 (1.1%)
201	xxxxxxxxxxxxxxx	Entered	9 (6.8%)	0	9 (3.4%)
		Completed	2 (1.5%)	0	2 (0.8%)
202	xxxxxxxxxxxxxxx	Entered	1 (0.8%)	0	1 (0.4%)
		Completed	1 (0.8%)	0	1 (0.4%)

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Table 13.4.1

Number (%) of Patients who Entered and Completed by Centre and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : Total

Centre Number	Investigator name	Status	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
205	xxxxxxxxxxxxx	Entered	4 (3.0%)	0	4 (1.5%)
		Completed	3 (2.3%)	0	3 (1.1%)
206	xxxxxxxxxxxxxxx	Entered	2 (1.5%)	0	2 (0.8%)
		Completed	1 (0.8%)	0	1 (0.4%)
208	xxxxxxxxxxxxxxx	Entered	8 (6.0%)	0	8 (3.0%)
		Completed	6 (4.5%)	0	6 (2.3%)

Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : MDD

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Gender	Female	19 (48.7%)	14 (38.9%)	33 (44.0%)
	Male	20 (51.3%)	22 (61.1%)	42 (56.0%)
Race	White	31 (79.5%)	30 (83.3%)	61 (81.3%)
	Black	3 (7.7%)	4 (11.1%)	7 (9.3%)
	Oriental	0	0	0
	Other	5 (12.8%)	2 (5.6%)	7 (9.3%)

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : OCD

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Gender	Female	16 (57.1%)	13 (36.1%)	29 (45.3%)
	Male	12 (42.9%)	23 (63.9%)	35 (54.7%)
Race	White	25 (89.3%)	33 (91.7%)	58 (90.6%)
	Black	2 (7.1%)	3 (8.3%)	5 (7.8%)
	Oriental	0	0	0
	Other	1 (3.6%)	0	1 (1.6%)

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : Total

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Gender	Female	35 (52.2%)	27 (37.5%)	62 (44.6%)
	Male	32 (47.8%)	45 (62.5%)	77 (55.4%)
Race	White	56 (83.6%)	63 (87.5%)	119 (85.6%)
	Black	5 (7.5%)	7 (9.7%)	12 (8.6%)
	Oriental	0	0	0
	Other	6 (9.0%)	2 (2.8%)	8 (5.8%)

Note: All demographic data were obtained from the patient’s acute study

Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : MDD

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Gender	Female	14 (33.3%)	15 (50.0%)	29 (40.3%)
	Male	28 (66.7%)	15 (50.0%)	43 (59.7%)
Race	White	34 (81.0%)	24 (80.0%)	58 (80.6%)
	Black	4 (9.5%)	3 (10.0%)	7 (9.7%)
	Oriental	0	0	0
	Other	4 (9.5%)	3 (10.0%)	7 (9.7%)

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : OCD

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Gender	Female	12 (50.0%)	9 (32.1%)	21 (40.4%)
	Male	12 (50.0%)	19 (67.9%)	31 (59.6%)
Race	White	21 (87.5%)	25 (89.3%)	46 (88.5%)
	Black	1 (4.2%)	1 (3.6%)	2 (3.8%)
	Oriental	0	0	0
	Other	2 (8.3%)	2 (7.1%)	4 (7.7%)

Note: All demographic data were obtained from the patient’s acute study

Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : Total

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Gender	Female	26 (39.4%)	24 (41.4%)	50 (40.3%)
	Male	40 (60.6%)	34 (58.6%)	74 (59.7%)
Race	White	55 (83.3%)	49 (84.5%)	104 (83.9%)
	Black	5 (7.6%)	4 (6.9%)	9 (7.3%)
	Oriental	0	0	0
	Other	6 (9.1%)	5 (8.6%)	11 (8.9%)

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : MDD

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Gender	Female	33 (40.7%)	29 (43.9%)	62 (42.2%)
	Male	48 (59.3%)	37 (56.1%)	85 (57.8%)
Race	White	65 (80.2%)	54 (81.8%)	119 (81.0%)
	Black	7 (8.6%)	7 (10.6%)	14 (9.5%)
	Oriental	0	0	0
	Other	9 (11.1%)	5 (7.6%)	14 (9.5%)

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : OCD

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Gender	Female	28 (53.8%)	22 (34.4%)	50 (43.1%)
	Male	24 (46.2%)	42 (65.6%)	66 (56.9%)
Race	White	46 (88.5%)	58 (90.6%)	104 (89.7%)
	Black	3 (5.8%)	4 (6.3%)	7 (6.0%)
	Oriental	0	0	0
	Other	3 (5.8%)	2 (3.1%)	5 (4.3%)

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.1b

Number (%) of Patients by Gender, Race and Acute Study Treatment Group

Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : Total

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Gender	Female	61 (45.9%)	51 (39.2%)	112 (42.6%)
	Male	72 (54.1%)	79 (60.8%)	151 (57.4%)
Race	White	111 (83.5%)	112 (86.2%)	223 (84.8%)
	Black	10 (7.5%)	11 (8.5%)	21 (8.0%)
	Oriental	0	0	0
	Other	12 (9.0%)	7 (5.4%)	19 (7.2%)

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.1d

Number (%) of Patients by Gender and Race

Pure Paroxetine Population
Age Group: Children
Primary Diagnosis : MDD

		Paroxetine (N=25)
Gender	Female	14 (56.0%)
	Male	11 (44.0%)
Race	White	19 (76.0%)
	Black	2 (8.0%)
	Oriental	0
	Other	4 (16.0%)

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.1d

Number (%) of Patients by Gender and Race

Pure Paroxetine Population
Age Group: Children
Primary Diagnosis : OCD

		Paroxetine (N=25)
Gender	Female	14 (56.0%)
	Male	11 (44.0%)
Race	White	22 (88.0%)
	Black	2 (8.0%)
	Oriental	0
	Other	1 (4.0%)

Note: All demographic data were obtained from the patient's acute study

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Table 13.5.1d

Number (%) of Patients by Gender and Race

Pure Paroxetine Population
Age Group: Children
Primary Diagnosis : Total

		Paroxetine (N=50)
Gender	Female	28 (56.0%)
	Male	22 (44.0%)
Race	White	41 (82.0%)
	Black	4 (8.0%)
	Oriental	0
	Other	5 (10.0%)

Note: All demographic data were obtained from the patient's acute study

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Table 13.5.1d

Number (%) of Patients by Gender and Race

Pure Paroxetine Population
Age Group: Adolescents
Primary Diagnosis : MDD

		Paroxetine (N=25)
Gender	Female	9 (36.0%)
	Male	16 (64.0%)
Race	White	20 (80.0%)
	Black	2 (8.0%)
	Oriental	0
	Other	3 (12.0%)

Note: All demographic data were obtained from the patient's acute study

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Table 13.5.1d

Number (%) of Patients by Gender and Race

Pure Paroxetine Population
Age Group: Adolescents
Primary Diagnosis : OCD

		Paroxetine (N=21)
Gender	Female	9 (42.9%)
	Male	12 (57.1%)
Race	White	18 (85.7%)
	Black	1 (4.8%)
	Oriental	0
	Other	2 (9.5%)

Note: All demographic data were obtained from the patient's acute study

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Table 13.5.1d

Number (%) of Patients by Gender and Race

Pure Paroxetine Population
Age Group: Adolescents
Primary Diagnosis : Total

		Paroxetine (N=46)
Gender	Female	18 (39.1%)
	Male	28 (60.9%)
Race	White	38 (82.6%)
	Black	3 (6.5%)
	Oriental	0
	Other	5 (10.9%)

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.1d

Number (%) of Patients by Gender and Race

Pure Paroxetine Population
Age Group: Total
Primary Diagnosis : MDD

		Paroxetine (N=50)
Gender	Female	23 (46.0%)
	Male	27 (54.0%)
Race	White	39 (78.0%)
	Black	4 (8.0%)
	Oriental	0
	Other	7 (14.0%)

Note: All demographic data were obtained from the patient's acute study

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Table 13.5.1d

Number (%) of Patients by Gender and Race

Pure Paroxetine Population
Age Group: Total
Primary Diagnosis : OCD

		Paroxetine (N=46)
Gender	Female	23 (50.0%)
	Male	23 (50.0%)
Race	White	40 (87.0%)
	Black	3 (6.5%)
	Oriental	0
	Other	3 (6.5%)

Note: All demographic data were obtained from the patient's acute study

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Table 13.5.1d

Number (%) of Patients by Gender and Race

Pure Paroxetine Population
Age Group: Total
Primary Diagnosis : Total

		Paroxetine (N=96)
Gender	Female	46 (47.9%)
	Male	50 (52.1%)
Race	White	79 (82.3%)
	Black	7 (7.3%)
	Oriental	0
	Other	10 (10.4%)

Note: All demographic data were obtained from the patient’s acute study

Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : MDD

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Age (years)	N	39	36	75
	MEAN	9.3	9.4	9.3
	MEDIAN	9.0	10.0	10.0
	STDDEV	1.28	1.29	1.28
	MINIMUM	7	7	7
	MAXIMUM	11	11	11
	MISSING	0	0	0
Height (cm)	N	39	36	75
	MEAN	140.92	138.00	139.52
	MEDIAN	138.40	137.20	137.20
	STDDEV	11.340	10.359	10.906
	MINIMUM	120.0	119.4	119.4
	MAXIMUM	165.0	160.0	165.0
	MISSING	0	0	0
Weight (kg)	N	39	36	75
	MEAN	42.90	40.20	41.60
	MEDIAN	39.50	35.20	38.50
	STDDEV	14.348	14.807	14.534
	MINIMUM	24.9	21.8	21.8
	MAXIMUM	74.0	89.0	89.0
	MISSING	0	0	0
BMI (kg/m2)	N	39	36	75
	MEAN	21.20	20.68	20.95
	MEDIAN	19.90	18.50	19.20
	STDDEV	5.155	5.616	5.351
	MINIMUM	15.0	13.6	13.6
	MAXIMUM	31.0	34.8	34.8
	MISSING	0	0	0

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : OCD

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Age (years)	N	28	36	64
	MEAN	9.0	9.5	9.3
	MEDIAN	9.0	10.0	10.0
	STDDEV	1.48	1.36	1.42
	MINIMUM	6	7	6
	MAXIMUM	11	11	11
	MISSING	0	0	0
Height (cm)	N	28	36	64
	MEAN	140.74	139.79	140.20
	MEDIAN	144.45	140.95	141.00
	STDDEV	13.035	10.099	11.389
	MINIMUM	114.5	115.6	114.5
	MAXIMUM	161.3	161.0	161.3
	MISSING	0	0	0
Weight (kg)	N	28	36	64
	MEAN	40.58	37.33	38.75
	MEDIAN	35.65	33.95	34.30
	STDDEV	17.206	14.081	15.481
	MINIMUM	20.4	20.5	20.4
	MAXIMUM	79.5	104.0	104.0
	MISSING	0	0	0
BMI (kg/m2)	N	28	36	64
	MEAN	19.69	18.72	19.14
	MEDIAN	17.35	17.25	17.25
	STDDEV	5.451	4.659	5.003
	MINIMUM	13.9	13.7	13.7
	MAXIMUM	32.8	40.1	40.1
	MISSING	0	0	0

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Children
Primary Diagnosis : Total

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Age (years)	N	67	72	139
	MEAN	9.2	9.4	9.3
	MEDIAN	9.0	10.0	10.0
	STDDEV	1.36	1.32	1.34
	MINIMUM	6	7	6
	MAXIMUM	11	11	11
	MISSING	0	0	0
Height (cm)	N	67	72	139
	MEAN	140.84	138.89	139.83
	MEDIAN	138.50	140.00	139.70
	STDDEV	11.981	10.198	11.096
	MINIMUM	114.5	115.6	114.5
	MAXIMUM	165.0	161.0	165.0
	MISSING	0	0	0
Weight (kg)	N	67	72	139
	MEAN	41.93	38.77	40.29
	MEDIAN	38.10	34.50	35.50
	STDDEV	15.523	14.419	14.991
	MINIMUM	20.4	20.5	20.4
	MAXIMUM	79.5	104.0	104.0
	MISSING	0	0	0
BMI (kg/m2)	N	67	72	139
	MEAN	20.57	19.70	20.12
	MEDIAN	18.50	18.15	18.20
	STDDEV	5.293	5.217	5.253
	MINIMUM	13.9	13.6	13.6
	MAXIMUM	32.8	40.1	40.1
	MISSING	0	0	0

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : MDD

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Age (years)	N	42	30	72
	MEAN	14.2	14.3	14.3
	MEDIAN	14.0	14.0	14.0
	STDDEV	1.55	1.86	1.68
	MINIMUM	12	12	12
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	42	30	72
	MEAN	165.72	164.73	165.31
	MEDIAN	165.35	165.10	165.10
	STDDEV	8.219	8.209	8.172
	MINIMUM	143.5	149.9	143.5
	MAXIMUM	181.6	180.3	181.6
	MISSING	0	0	0
Weight (kg)	N	42	30	72
	MEAN	71.08	68.15	69.86
	MEDIAN	64.75	61.50	61.90
	STDDEV	23.121	23.143	23.012
	MINIMUM	40.9	40.0	40.0
	MAXIMUM	141.0	131.4	141.0
	MISSING	0	0	0
BMI (kg/m2)	N	42	30	72
	MEAN	25.65	24.83	25.31
	MEDIAN	22.90	22.30	22.75
	STDDEV	7.232	7.118	7.146
	MINIMUM	16.8	16.9	16.8
	MAXIMUM	45.9	45.4	45.9
	MISSING	0	0	0

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : OCD

		Acute Study Treatment Group		
		Paroxetine	Placebo	Total
	Statistic	(N=24)	(N=28)	(N=52)
Age (years)	N	24	28	52
	MEAN	14.4	14.1	14.2
	MEDIAN	14.0	14.0	14.0
	STDDEV	1.56	1.57	1.55
	MINIMUM	12	12	12
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	24	27	51
	MEAN	165.68	167.32	166.55
	MEDIAN	165.80	168.30	167.60
	STDDEV	12.575	8.492	10.532
	MINIMUM	139.5	151.3	139.5
	MAXIMUM	188.0	180.3	188.0
	MISSING	0	1	1
Weight (kg)	N	24	27	51
	MEAN	67.21	67.16	67.18
	MEDIAN	67.35	65.10	65.80
	STDDEV	18.304	15.494	16.702
	MINIMUM	30.1	38.2	30.1
	MAXIMUM	110.9	100.9	110.9
	MISSING	0	1	1
BMI (kg/m2)	N	24	27	51
	MEAN	24.38	23.98	24.17
	MEDIAN	23.35	23.00	23.30
	STDDEV	6.250	5.399	5.759
	MINIMUM	13.9	16.4	13.9
	MAXIMUM	41.9	37.7	41.9
	MISSING	0	1	1

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Adolescents
Primary Diagnosis : Total

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Age (years)	N	66	58	124
	MEAN	14.3	14.2	14.2
	MEDIAN	14.0	14.0	14.0
	STDDEV	1.54	1.72	1.62
	MINIMUM	12	12	12
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	66	57	123
	MEAN	165.70	165.96	165.82
	MEDIAN	165.35	167.60	166.40
	STDDEV	9.928	8.372	9.203
	MINIMUM	139.5	149.9	139.5
	MAXIMUM	188.0	180.3	188.0
	MISSING	0	1	1
Weight (kg)	N	66	57	123
	MEAN	69.67	67.68	68.75
	MEDIAN	65.00	62.60	63.20
	STDDEV	21.430	19.725	20.598
	MINIMUM	30.1	38.2	30.1
	MAXIMUM	141.0	131.4	141.0
	MISSING	0	1	1
BMI (kg/m2)	N	66	57	123
	MEAN	25.19	24.43	24.83
	MEDIAN	23.20	22.80	23.00
	STDDEV	6.869	6.321	6.605
	MINIMUM	13.9	16.4	13.9
	MAXIMUM	45.9	45.4	45.9
	MISSING	0	1	1

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : MDD

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Age (years)	N	81	66	147
	MEAN	11.8	11.6	11.7
	MEDIAN	12.0	11.0	11.0
	STDDEV	2.85	2.94	2.88
	MINIMUM	7	7	7
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	81	66	147
	MEAN	153.78	150.15	152.15
	MEDIAN	156.50	150.55	154.00
	STDDEV	15.849	16.364	16.128
	MINIMUM	120.0	119.4	119.4
	MAXIMUM	181.6	180.3	181.6
	MISSING	0	0	0
Weight (kg)	N	81	66	147
	MEAN	57.51	52.91	55.44
	MEDIAN	56.00	50.20	52.30
	STDDEV	23.926	23.530	23.779
	MINIMUM	24.9	21.8	21.8
	MAXIMUM	141.0	131.4	141.0
	MISSING	0	0	0
BMI (kg/m2)	N	81	66	147
	MEAN	23.51	22.56	23.08
	MEDIAN	21.40	20.85	21.00
	STDDEV	6.666	6.628	6.643
	MINIMUM	15.0	13.6	13.6
	MAXIMUM	45.9	45.4	45.9
	MISSING	0	0	0

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : OCD

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Age (years)	N	52	64	116
	MEAN	11.5	11.5	11.5
	MEDIAN	11.0	11.0	11.0
	STDDEV	3.08	2.71	2.87
	MINIMUM	6	7	6
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	52	63	115
	MEAN	152.25	151.59	151.89
	MEDIAN	152.70	151.30	152.40
	STDDEV	17.856	16.629	17.121
	MINIMUM	114.5	115.6	114.5
	MAXIMUM	188.0	180.3	188.0
	MISSING	0	1	1
Weight (kg)	N	52	63	115
	MEAN	52.87	50.11	51.36
	MEDIAN	53.75	43.60	48.80
	STDDEV	22.082	20.834	21.357
	MINIMUM	20.4	20.5	20.4
	MAXIMUM	110.9	104.0	110.9
	MISSING	0	1	1
BMI (kg/m2)	N	52	63	115
	MEAN	21.85	20.97	21.37
	MEDIAN	20.70	19.70	20.00
	STDDEV	6.238	5.600	5.887
	MINIMUM	13.9	13.7	13.7
	MAXIMUM	41.9	40.1	41.9
	MISSING	0	1	1

Note: All demographic data were obtained from the patient’s acute study

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Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group: Total
Primary Diagnosis : Total

		Acute Study Treatment Group		
	Statistic	Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Age (years)	N	133	130	263
	MEAN	11.7	11.6	11.6
	MEDIAN	11.0	11.0	11.0
	STDDEV	2.93	2.82	2.87
	MINIMUM	6	7	6
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	133	129	262
	MEAN	153.18	150.85	152.03
	MEDIAN	155.00	151.10	152.75
	STDDEV	16.612	16.445	16.540
	MINIMUM	114.5	115.6	114.5
	MAXIMUM	188.0	180.3	188.0
	MISSING	0	1	1
Weight (kg)	N	133	129	262
	MEAN	55.69	51.54	53.65
	MEDIAN	55.30	46.40	51.85
	STDDEV	23.249	22.212	22.796
	MINIMUM	20.4	20.5	20.4
	MAXIMUM	141.0	131.4	141.0
	MISSING	0	1	1
BMI (kg/m2)	N	133	129	262
	MEAN	22.86	21.79	22.33
	MEDIAN	21.10	20.10	20.80
	STDDEV	6.529	6.175	6.368
	MINIMUM	13.9	13.6	13.6
	MAXIMUM	45.9	45.4	45.9
	MISSING	0	1	1

Note: All demographic data were obtained from the patient’s acute study

Table 13.5.2d

Summary Statistics for Age, Height, Weight and Body Mass Index

Pure Paroxetine Population
Age Group: Children
Primary Diagnosis : MDD

	Statistic	Paroxetine (N=25)
Age (years)	N	25
	MEAN	9.2
	MEDIAN	9.0
	STDDEV	1.34
	MINIMUM	7
	MAXIMUM	11
	MISSING	0
Height (cm)	N	25
	MEAN	140.35
	MEDIAN	137.20
	STDDEV	12.594
	MINIMUM	120.0
	MAXIMUM	165.0
	MISSING	0
Weight (kg)	N	25
	MEAN	44.41
	MEDIAN	41.90
	STDDEV	15.064
	MINIMUM	24.9
	MAXIMUM	74.0
	MISSING	0
BMI (kg/m2)	N	25
	MEAN	22.13
	MEDIAN	21.00
	STDDEV	5.484
	MINIMUM	15.1
	MAXIMUM	31.0
	MISSING	0

Note: All demographic data were obtained from the patient's acute study

Table 13.5.2d

Summary Statistics for Age, Height, Weight and Body Mass Index

Pure Paroxetine Population
Age Group: Children
Primary Diagnosis : OCD

	Statistic	Paroxetine (N=25)
Age (years)	N	25
	MEAN	8.9
	MEDIAN	9.0
	STDDEV	1.48
	MINIMUM	6
	MAXIMUM	11
	MISSING	0
Height (cm)	N	25
	MEAN	139.44
	MEDIAN	138.50
	STDDEV	13.170
	MINIMUM	114.5
	MAXIMUM	161.3
	MISSING	0
Weight (kg)	N	25
	MEAN	38.86
	MEDIAN	30.30
	STDDEV	17.237
	MINIMUM	20.4
	MAXIMUM	79.5
	MISSING	0
BMI (kg/m2)	N	25
	MEAN	19.19
	MEDIAN	16.80
	STDDEV	5.489
	MINIMUM	13.9
	MAXIMUM	32.8
	MISSING	0

Note: All demographic data were obtained from the patient's acute study

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Table 13.5.2d

Summary Statistics for Age, Height, Weight and Body Mass Index

Pure Paroxetine Population
Age Group: Children
Primary Diagnosis : Total

	Statistic	Paroxetine (N=50)
Age (years)	N	50
	MEAN	9.0
	MEDIAN	9.0
	STDDEV	1.41
	MINIMUM	6
	MAXIMUM	11
	MISSING	0
Height (cm)	N	50
	MEAN	139.89
	MEDIAN	137.90
	STDDEV	12.762
	MINIMUM	114.5
	MAXIMUM	165.0
	MISSING	0
Weight (kg)	N	50
	MEAN	41.63
	MEDIAN	37.80
	STDDEV	16.265
	MINIMUM	20.4
	MAXIMUM	79.5
	MISSING	0
BMI (kg/m2)	N	50
	MEAN	20.66
	MEDIAN	18.45
	STDDEV	5.630
	MINIMUM	13.9
	MAXIMUM	32.8
	MISSING	0

Note: All demographic data were obtained from the patient's acute study

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Table 13.5.2d

Summary Statistics for Age, Height, Weight and Body Mass Index

Pure Paroxetine Population
Age Group: Adolescents
Primary Diagnosis : MDD

	Statistic	Paroxetine (N=25)
Age (years)	N	25
	MEAN	14.0
	MEDIAN	14.0
	STDDEV	1.50
	MINIMUM	12
	MAXIMUM	17
	MISSING	0
Height (cm)	N	25
	MEAN	165.51
	MEDIAN	165.60
	STDDEV	7.532
	MINIMUM	143.5
	MAXIMUM	180.3
	MISSING	0
Weight (kg)	N	25
	MEAN	70.86
	MEDIAN	65.00
	STDDEV	21.751
	MINIMUM	40.9
	MAXIMUM	132.6
	MISSING	0
BMI (kg/m2)	N	25
	MEAN	25.66
	MEDIAN	23.10
	STDDEV	6.965
	MINIMUM	17.4
	MAXIMUM	45.9
	MISSING	0

Note: All demographic data were obtained from the patient's acute study

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Table 13.5.2d

Summary Statistics for Age, Height, Weight and Body Mass Index

Pure Paroxetine Population
Age Group: Adolescents
Primary Diagnosis : OCD

	Statistic	Paroxetine (N=21)
Age (years)	N	21
	MEAN	14.5
	MEDIAN	14.0
	STDDEV	1.44
	MINIMUM	12
	MAXIMUM	17
	MISSING	0
Height (cm)	N	21
	MEAN	167.20
	MEDIAN	167.60
	STDDEV	12.507
	MINIMUM	139.5
	MAXIMUM	188.0
	MISSING	0
Weight (kg)	N	21
	MEAN	68.75
	MEDIAN	67.00
	STDDEV	17.692
	MINIMUM	32.5
	MAXIMUM	110.9
	MISSING	0
BMI (kg/m2)	N	21
	MEAN	24.57
	MEDIAN	23.30
	STDDEV	6.153
	MINIMUM	16.5
	MAXIMUM	41.9
	MISSING	0

Note: All demographic data were obtained from the patient's acute study

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Table 13.5.2d

Summary Statistics for Age, Height, Weight and Body Mass Index

Pure Paroxetine Population
Age Group: Adolescents
Primary Diagnosis : Total

	Statistic	Paroxetine (N=46)
Age (years)	N	46
	MEAN	14.2
	MEDIAN	14.0
	STDDEV	1.48
	MINIMUM	12
	MAXIMUM	17
	MISSING	0
Height (cm)	N	46
	MEAN	166.28
	MEDIAN	166.20
	STDDEV	10.025
	MINIMUM	139.5
	MAXIMUM	188.0
	MISSING	0
Weight (kg)	N	46
	MEAN	69.90
	MEDIAN	65.00
	STDDEV	19.813
	MINIMUM	32.5
	MAXIMUM	132.6
	MISSING	0
BMI (kg/m2)	N	46
	MEAN	25.16
	MEDIAN	23.20
	STDDEV	6.558
	MINIMUM	16.5
	MAXIMUM	45.9
	MISSING	0

Note: All demographic data were obtained from the patient's acute study

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Table 13.5.2d

Summary Statistics for Age, Height, Weight and Body Mass Index

Pure Paroxetine Population
Age Group: Total
Primary Diagnosis : MDD

	Statistic	Paroxetine (N=50)
Age (years)	N	50
	MEAN	11.6
	MEDIAN	11.5
	STDDEV	2.82
	MINIMUM	7
	MAXIMUM	17
	MISSING	0
Height (cm)	N	50
	MEAN	152.93
	MEDIAN	156.85
	STDDEV	16.339
	MINIMUM	120.0
	MAXIMUM	180.3
	MISSING	0
Weight (kg)	N	50
	MEAN	57.63
	MEDIAN	56.35
	STDDEV	22.831
	MINIMUM	24.9
	MAXIMUM	132.6
	MISSING	0
BMI (kg/m2)	N	50
	MEAN	23.90
	MEDIAN	22.90
	STDDEV	6.455
	MINIMUM	15.1
	MAXIMUM	45.9
	MISSING	0

Note: All demographic data were obtained from the patient's acute study

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Table 13.5.2d

Summary Statistics for Age, Height, Weight and Body Mass Index

Pure Paroxetine Population
Age Group: Total
Primary Diagnosis : OCD

	Statistic	Paroxetine (N=46)
Age (years)	N	46
	MEAN	11.5
	MEDIAN	11.0
	STDDEV	3.19
	MINIMUM	6
	MAXIMUM	17
	MISSING	0
Height (cm)	N	46
	MEAN	152.11
	MEDIAN	152.70
	STDDEV	18.907
	MINIMUM	114.5
	MAXIMUM	188.0
	MISSING	0
Weight (kg)	N	46
	MEAN	52.50
	MEDIAN	53.75
	STDDEV	22.897
	MINIMUM	20.4
	MAXIMUM	110.9
	MISSING	0
BMI (kg/m2)	N	46
	MEAN	21.65
	MEDIAN	19.80
	STDDEV	6.342
	MINIMUM	13.9
	MAXIMUM	41.9
	MISSING	0

Note: All demographic data were obtained from the patient's acute study

Table 13.5.2d

Summary Statistics for Age, Height, Weight and Body Mass Index

Pure Paroxetine Population
Age Group: Total
Primary Diagnosis : Total

	Statistic	Paroxetine (N=96)
Age (years)	N	96
	MEAN	11.5
	MEDIAN	11.0
	STDDEV	2.99
	MINIMUM	6
	MAXIMUM	17
	MISSING	0
Height (cm)	N	96
	MEAN	152.54
	MEDIAN	154.95
	STDDEV	17.527
	MINIMUM	114.5
	MAXIMUM	188.0
	MISSING	0
Weight (kg)	N	96
	MEAN	55.18
	MEDIAN	55.25
	STDDEV	22.888
	MINIMUM	20.4
	MAXIMUM	132.6
	MISSING	0
BMI (kg/m2)	N	96
	MEAN	22.82
	MEDIAN	21.50
	STDDEV	6.467
	MINIMUM	13.9
	MAXIMUM	45.9
	MISSING	0

Note: All demographic data were obtained from the patient's acute study

Table 13.6.1b

Summary Statistics for CDRS-R Total Score at the Study 716 Baseline by Acute Study Treatment Group

Intention-To-Treat Population with Primary Diagnosis of MDD

Age Group : Children

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
716 Baseline	N	35	36	71
	MEAN	33.9	35.3	34.6
	MEDIAN	28.0	34.0	33.0
	STDDEV	14.02	12.92	13.39
	MINIMUM	18	17	17
	MAXIMUM	75	68	75
	MISSING	4	0	4

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

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Table 13.6.1b

Summary Statistics for CDRS-R Total Score at the Study 716 Baseline by Acute Study Treatment Group

Intention-To-Treat Population with Primary Diagnosis of MDD

Age Group : Adolescents

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
716 Baseline	N	41	29	70
	MEAN	36.9	39.9	38.1
	MEDIAN	34.0	35.0	34.5
	STDDEV	12.36	14.92	13.46
	MINIMUM	20	19	19
	MAXIMUM	72	73	73
	MISSING	1	1	2

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

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Table 13.6.1b

Summary Statistics for CDRS-R Total Score at the Study 716 Baseline by Acute Study Treatment Group

Intention-To-Treat Population with Primary Diagnosis of MDD

Age Group : Total

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
716 Baseline	N	76	65	141
	MEAN	35.5	37.4	36.4
	MEDIAN	31.5	35.0	33.0
	STDDEV	13.14	13.93	13.50
	MINIMUM	18	17	17
	MAXIMUM	75	73	75
	MISSING	5	1	6

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

Table 13.6.1d

Summary Statistics for CDRS-R Total Score at the Study 716 Baseline

Pure Paroxetine Population with Primary Diagnosis of MDD

Age Group : Children

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=25)
716 Baseline	N	22
	MEAN	37.8
	MEDIAN	34.5
	STDDEV	15.12
	MINIMUM	18
	MAXIMUM	75
	MISSING	3

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

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Table 13.6.1d

Summary Statistics for CDRS-R Total Score at the Study 716 Baseline

Pure Paroxetine Population with Primary Diagnosis of MDD

Age Group : Adolescents

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=25)
716 Baseline	N	24
	MEAN	35.8
	MEDIAN	33.0
	STDDEV	11.55
	MINIMUM	20
	MAXIMUM	58
	MISSING	1

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

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Table 13.6.1d

Summary Statistics for CDRS-R Total Score at the Study 716 Baseline

Pure Paroxetine Population with Primary Diagnosis of MDD

Age Group : Total

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=50)
716 Baseline	N	46
	MEAN	36.7
	MEDIAN	34.0
	STDDEV	13.26
	MINIMUM	18
	MAXIMUM	75
	MISSING	4

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

Table 13.7.1b

Summary Statistics for CY-BOCS Total Score at the Study 716 Baseline by Acute Study Treatment Group

Intention-To-Treat Population with Primary Diagnosis of OCD

Age Group : Children

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
716 Baseline	N	27	35	62
	MEAN	14.7	19.0	17.1
	MEDIAN	16.0	21.0	19.5
	STDDEV	9.21	8.20	8.84
	MINIMUM	0	0	0
	MAXIMUM	35	34	35
	MISSING	1	1	2

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

Table 13.7.1b

Summary Statistics for CY-BOCS Total Score at the Study 716 Baseline by Acute Study Treatment Group

Intention-To-Treat Population with Primary Diagnosis of OCD

Age Group : Adolescents

		Acute Study Treatment Group		
		Paroxetine	Placebo	Total
Visit	Statistic	(N=24)	(N=28)	(N=52)
716 Baseline	N	22	28	50
	MEAN	17.9	21.1	19.7
	MEDIAN	17.5	22.0	21.0
	STDDEV	8.10	6.48	7.34
	MINIMUM	1	0	0
	MAXIMUM	34	35	35
	MISSING	2	0	2

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

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Table 13.7.1b

Summary Statistics for CY-BOCS Total Score at the Study 716 Baseline by Acute Study Treatment Group

Intention-To-Treat Population with Primary Diagnosis of OCD

Age Group : Total

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
716 Baseline	N	49	63	112
	MEAN	16.2	20.0	18.3
	MEDIAN	16.0	21.0	20.0
	STDDEV	8.78	7.51	8.27
	MINIMUM	0	0	0
	MAXIMUM	35	35	35
	MISSING	3	1	4

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

Table 13.7.1d

Summary Statistics for CY-BOCS Total Score at the Study 716 Baseline

Pure Paroxetine Population with Primary Diagnosis of OCD

Age Group : Children

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=25)
716 Baseline	N	24
	MEAN	14.6
	MEDIAN	15.0
	STDDEV	9.61
	MINIMUM	0
	MAXIMUM	35
	MISSING	1

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

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Table 13.7.1d

Summary Statistics for CY-BOCS Total Score at the Study 716 Baseline

Pure Paroxetine Population with Primary Diagnosis of OCD

Age Group : Adolescents

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=21)
716 Baseline	N	19
	MEAN	18.4
	MEDIAN	16.0
	STDDEV	7.65
	MINIMUM	8
	MAXIMUM	34
	MISSING	2

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

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Table 13.7.1d

Summary Statistics for CY-BOCS Total Score at the Study 716 Baseline

Pure Paroxetine Population with Primary Diagnosis of OCD

Age Group : Total

Visit	Statistic	Acute Study Treatment Group Paroxetine (N=46)
716 Baseline	N	43
	MEAN	16.3
	MEDIAN	16.0
	STDDEV	8.90
	MINIMUM	0
	MAXIMUM	35
	MISSING	3

Note: 'MISSING' row indicates number of patients with either missing data at study 716 baseline or insufficient data to calculate total.

Table 13.8.1b

Number (%) of Patients With Each CGI Severity of Illness Score at the Study 716 Baseline
by Primary Diagnosis and Acute Study Treatment Group
Intention-To-Treat Population

Age Group : Children

	Major Depressive Disorder			Obsessive-Compulsive Disorder		
	Paroxetine (N=39)	Placebo (N=36)	Total (N=75)	Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Not assessed (0)	0	0	0	0	0	0
Normal, not at all ill (1)	10 (26.3%)	5 (13.9%)	15 (20.3%)	3 (10.7%)	2 (5.7%)	5 (7.9%)
Borderline mentally ill (2)	6 (15.8%)	7 (19.4%)	13 (17.6%)	7 (25.0%)	1 (2.9%)	8 (12.7%)
Mildly ill (3)	12 (31.6%)	5 (13.9%)	17 (23.0%)	3 (10.7%)	7 (20.0%)	10 (15.9%)
Moderately ill (4)	7 (18.4%)	17 (47.2%)	24 (32.4%)	11 (39.3%)	15 (42.9%)	26 (41.3%)
Markedly ill (5)	2 (5.3%)	2 (5.6%)	4 (5.4%)	4 (14.3%)	7 (20.0%)	11 (17.5%)
Severely ill (6)	1 (2.6%)	0	1 (1.4%)	0	3 (8.6%)	3 (4.8%)
Among the most extremely ill patients (7)	0	0	0	0	0	0
Total	38 (100.0%)	36 (100.0%)	74 (100.0%)	28 (100.0%)	35 (100.0%)	63 (100.0%)

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Table 13.8.1b

Number (%) of Patients With Each CGI Severity of Illness Score at the Study 716 Baseline
by Primary Diagnosis and Acute Study Treatment Group
Intention-To-Treat Population

Age Group : Adolescent

	Major Depressive Disorder			Obsessive-Compulsive Disorder		
	Paroxetine (N=42)	Placebo (N=30)	Total (N=72)	Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Not assessed (0)	0	0	0	0	0	0
Normal, not at all ill (1)	7 (16.7%)	5 (16.7%)	12 (16.7%)	1 (4.2%)	1 (3.6%)	2 (3.8%)
Borderline mentally ill (2)	5 (11.9%)	7 (23.3%)	12 (16.7%)	2 (8.3%)	0	2 (3.8%)
Mildly ill (3)	18 (42.9%)	6 (20.0%)	24 (33.3%)	7 (29.2%)	3 (10.7%)	10 (19.2%)
Moderately ill (4)	10 (23.8%)	11 (36.7%)	21 (29.2%)	10 (41.7%)	16 (57.1%)	26 (50.0%)
Markedly ill (5)	2 (4.8%)	1 (3.3%)	3 (4.2%)	4 (16.7%)	7 (25.0%)	11 (21.2%)
Severely ill (6)	0	0	0	0	1 (3.6%)	1 (1.9%)
Among the most extremely ill patients (7)	0	0	0	0	0	0
Total	42 (100.0%)	30 (100.0%)	72 (100.0%)	24 (100.0%)	28 (100.0%)	52 (100.0%)

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Table 13.8.1b

Number (%) of Patients With Each CGI Severity of Illness Score at the Study 716 Baseline
by Primary Diagnosis and Acute Study Treatment Group
Intention-To-Treat Population

Age Group : Total

	Major Depressive Disorder			Obsessive-Compulsive Disorder		
	Paroxetine (N=81)	Placebo (N=66)	Total (N=147)	Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Not assessed (0)	0	0	0	0	0	0
Normal, not at all ill (1)	17 (21.3%)	10 (15.2%)	27 (18.5%)	4 (7.7%)	3 (4.8%)	7 (6.1%)
Borderline mentally ill (2)	11 (13.8%)	14 (21.2%)	25 (17.1%)	9 (17.3%)	1 (1.6%)	10 (8.7%)
Mildly ill (3)	30 (37.5%)	11 (16.7%)	41 (28.1%)	10 (19.2%)	10 (15.9%)	20 (17.4%)
Moderately ill (4)	17 (21.3%)	28 (42.4%)	45 (30.8%)	21 (40.4%)	31 (49.2%)	52 (45.2%)
Markedly ill (5)	4 (5.0%)	3 (4.5%)	7 (4.8%)	8 (15.4%)	14 (22.2%)	22 (19.1%)
Severely ill (6)	1 (1.3%)	0	1 (0.7%)	0	4 (6.3%)	4 (3.5%)
Among the most extremely ill patients (7)	0	0	0	0	0	0
Total	80 (100.0%)	66 (100.0%)	146 (100.0%)	52 (100.0%)	63 (100.0%)	115 (100.0%)

Table 13.9.1

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term (excluding Taper Phase)

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Total number of patients with at least one concomitant medication	Total	92 (69.2%)	81 (62.3%)	173 (65.8%)
ALIMENTARY TRACT/METAB	Total	29 (21.8%)	30 (23.1%)	59 (22.4%)
	ACETYLSALICYLIC ACID	4 (3.0%)	4 (3.1%)	8 (3.0%)
	ALOES	2 (1.5%)	0	2 (0.8%)
	ALUMINIUM HYDROXIDE	1 (0.8%)	5 (3.8%)	6 (2.3%)
	ANTACID NOS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	ASCORBIC ACID	3 (2.3%)	0	3 (1.1%)
	ATROPINE SULFATE	1 (0.8%)	0	1 (0.4%)
	BISMUTH SUBSALICYLATE	5 (3.8%)	5 (3.8%)	10 (3.8%)
	CALCIUM	1 (0.8%)	0	1 (0.4%)
	CALCIUM CARBONATE	3 (2.3%)	3 (2.3%)	6 (2.3%)
	DIMETICONE, ACTIVATED	1 (0.8%)	2 (1.5%)	3 (1.1%)
	DIPHENOXYLATE HYDROCHLORIDE	1 (0.8%)	0	1 (0.4%)
	FAMOTIDINE	1 (0.8%)	3 (2.3%)	4 (1.5%)
	FERROUS FUMARATE	1 (0.8%)	0	1 (0.4%)
	FLUORIDE NOS	0	1 (0.8%)	1 (0.4%)
	KAOLIN	0	1 (0.8%)	1 (0.4%)
	LOPERAMIDE HYDROCHLORIDE	3 (2.3%)	1 (0.8%)	4 (1.5%)
	MAGNESIUM HYDROXIDE	1 (0.8%)	6 (4.6%)	7 (2.7%)
	METOCLOPRAMIDE	1 (0.8%)	0	1 (0.4%)
	METOCLOPRAMIDE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
	MINERALS NOS	1 (0.8%)	0	1 (0.4%)
	NEOMYCIN	1 (0.8%)	0	1 (0.4%)
	NIZATIDINE	0	1 (0.8%)	1 (0.4%)
	OMEPRAZOLE	1 (0.8%)	1 (0.8%)	2 (0.8%)
	ONDANSETRON HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
	OXYBUTYNIN	1 (0.8%)	0	1 (0.4%)
	PECTIN	0	1 (0.8%)	1 (0.4%)
	PROMETHAZINE HYDROCHLORIDE	0	2 (1.5%)	2 (0.8%)
	RANITIDINE	0	1 (0.8%)	1 (0.4%)
	SENNA	1 (0.8%)	0	1 (0.4%)
	SENNA FRUIT	0	1 (0.8%)	1 (0.4%)
	SODIUM CHLORIDE	1 (0.8%)	1 (0.8%)	2 (0.8%)
	TRIAMCINOLONE	0	1 (0.8%)	1 (0.4%)
	TRIAMCINOLONE ACETONIDE	0	3 (2.3%)	3 (1.1%)
	TRIMETHOBENZAMIDE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
	VITAMINS NOS	10 (7.5%)	6 (4.6%)	16 (6.1%)
	YELLOW PHENOLPHTHALEIN	1 (0.8%)	0	1 (0.4%)
	ZINC GLUCONATE	0	1 (0.8%)	1 (0.4%)
ANTIINFECTIVES,SYSTEMIC	Total	37 (27.8%)	30 (23.1%)	67 (25.5%)
	AMOXICILLIN	6 (4.5%)	3 (2.3%)	9 (3.4%)
	AMOXICILLIN TRIHYDRATE	7 (5.3%)	3 (2.3%)	10 (3.8%)

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Table 13.9.1

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term (excluding Taper Phase)

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
ANTIINFECTIVES,SYSTEMIC	AMPICILLIN	1 (0.8%)	0	1 (0.4%)
	ANTIBIOTIC NOS	1 (0.8%)	0	1 (0.4%)
	AZITHROMYCIN	5 (3.8%)	8 (6.2%)	13 (4.9%)
	BENZATHINE BENZYLPENICILLIN	0	1 (0.8%)	1 (0.4%)
	CEFALEXIN	4 (3.0%)	1 (0.8%)	5 (1.9%)
	CEFALEXIN MONOHYDRATE	2 (1.5%)	1 (0.8%)	3 (1.1%)
	CEFAZOLIN	0	1 (0.8%)	1 (0.4%)
	CEFIXIME	1 (0.8%)	0	1 (0.4%)
	CEFPROZIL MONOHYDRATE	3 (2.3%)	1 (0.8%)	4 (1.5%)
	CEFTRIAXONE SODIUM	1 (0.8%)	1 (0.8%)	2 (0.8%)
	CEFUROXIME AXETIL	1 (0.8%)	3 (2.3%)	4 (1.5%)
	CEFUROXIME SODIUM	1 (0.8%)	0	1 (0.4%)
	CLARITHROMYCIN	2 (1.5%)	1 (0.8%)	3 (1.1%)
	CLAVULANIC ACID	6 (4.5%)	1 (0.8%)	7 (2.7%)
	CLINDAMYCIN	2 (1.5%)	0	2 (0.8%)
	CLINDAMYCIN HYDROCHLORIDE	2 (1.5%)	0	2 (0.8%)
	DIRITHROMYCIN	1 (0.8%)	0	1 (0.4%)
	DOXYCYCLINE	2 (1.5%)	0	2 (0.8%)
	ERYTHROMYCIN	2 (1.5%)	2 (1.5%)	4 (1.5%)
	FLUCONAZOLE	2 (1.5%)	1 (0.8%)	3 (1.1%)
	HEPATITIS B VACCINE	0	1 (0.8%)	1 (0.4%)
	INFLUENZA VIRUS VACCINE POLYVALENT	0	1 (0.8%)	1 (0.4%)
	MINOCYCLINE	1 (0.8%)	1 (0.8%)	2 (0.8%)
	MINOCYCLINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
	MUPIROCIN	0	1 (0.8%)	1 (0.4%)
	NEOMYCIN	1 (0.8%)	0	1 (0.4%)
	OFLOXACIN	0	1 (0.8%)	1 (0.4%)
	OXYTETRACYCLINE	1 (0.8%)	0	1 (0.4%)
	PENICILLIN NOS	0	2 (1.5%)	2 (0.8%)
	SULFAMETHOXAZOLE	1 (0.8%)	0	1 (0.4%)
	TETANUS TOXOID	0	1 (0.8%)	1 (0.4%)
	TETRACYCLINE	1 (0.8%)	1 (0.8%)	2 (0.8%)
	TRIMETHOPRIM	1 (0.8%)	0	1 (0.4%)
ANTINEOPLASTIC & IMMUNOSUP	Total	2 (1.5%)	0	2 (0.8%)
	MEDROXYPROGESTERONE ACETATE	2 (1.5%)	0	2 (0.8%)
BLOOD/BLOOD FORM ORGANS	Total	5 (3.8%)	5 (3.8%)	10 (3.8%)
	ACETYLSALICYLIC ACID	3 (2.3%)	4 (3.1%)	7 (2.7%)
	FERROUS SULFATE	1 (0.8%)	0	1 (0.4%)
	SODIUM CHLORIDE	1 (0.8%)	1 (0.8%)	2 (0.8%)
CARDIOVASCULAR	Total	3 (2.3%)	7 (5.4%)	10 (3.8%)
	BENZOCAINE	0	2 (1.5%)	2 (0.8%)
	BETAMETHASONE	1 (0.8%)	0	1 (0.4%)

Table 13.9.1

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term (excluding Taper Phase)

Intention-To-Treat Population

		Acute Study Treatment Group		
ATC Code Level 1	Generic Term(s)	Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
CARDIOVASCULAR	CLONIDINE	1 (0.8%)	2 (1.5%)	3 (1.1%)
	GUANFACINE	1 (0.8%)	0	1 (0.4%)
	LIDOCAINE	0	1 (0.8%)	1 (0.4%)
	PREDNISOLONE SODIUM PHOSPHATE	0	2 (1.5%)	2 (0.8%)
CENTRAL NERVOUS SYSTEM	Total	64 (48.1%)	55 (42.3%)	119 (45.2%)
	ACETYLSALICYLIC ACID	12 (9.0%)	5 (3.8%)	17 (6.5%)
	ALPRAZOLAM	0	1 (0.8%)	1 (0.4%)
	ALUMINIUM HYDROXIDE	1 (0.8%)	0	1 (0.4%)
	AMPHETAMINE ASPARTATE	0	1 (0.8%)	1 (0.4%)
	AMPHETAMINE SULFATE	0	1 (0.8%)	1 (0.4%)
	BUTALBITAL	0	1 (0.8%)	1 (0.4%)
	CAFFEINE	9 (6.8%)	2 (1.5%)	11 (4.2%)
	CHLORPHENAMINE MALEATE	3 (2.3%)	3 (2.3%)	6 (2.3%)
	CINNAMEDRINE HYDROCHLORIDE	4 (3.0%)	1 (0.8%)	5 (1.9%)
	CITALOPRAM	2 (1.5%)	1 (0.8%)	3 (1.1%)
	CLONIDINE	1 (0.8%)	2 (1.5%)	3 (1.1%)
	CODEINE	1 (0.8%)	0	1 (0.4%)
	CODEINE PHOSPHATE	2 (1.5%)	3 (2.3%)	5 (1.9%)
	DEXTROAMPHETAMINE SACCHARATE	0	1 (0.8%)	1 (0.4%)
	DEXTROAMPHETAMINE SULFATE	0	1 (0.8%)	1 (0.4%)
	DEXTROMETHORPHAN	1 (0.8%)	0	1 (0.4%)
	DEXTROMETHORPHAN HYDROBROMIDE	6 (4.5%)	2 (1.5%)	8 (3.0%)
	DEXTROPROPOXYPHENE	0	1 (0.8%)	1 (0.4%)
	DICHLORALPHENAZONE	0	1 (0.8%)	1 (0.4%)
	DIPHENHYDRAMINE HYDROCHLORIDE	1 (0.8%)	3 (2.3%)	4 (1.5%)
	DOXYLAMINE	1 (0.8%)	0	1 (0.4%)
	DOXYLAMINE SUCCINATE	5 (3.8%)	1 (0.8%)	6 (2.3%)
	FENTANYL	1 (0.8%)	2 (1.5%)	3 (1.1%)
	HYDROCODONE BITARTRATE	2 (1.5%)	0	2 (0.8%)
	HYDROXYZINE	0	1 (0.8%)	1 (0.4%)
	HYDROXYZINE HYDROCHLORIDE	1 (0.8%)	2 (1.5%)	3 (1.1%)
	IBUPROFEN	31 (23.3%)	27 (20.8%)	58 (22.1%)
	ISOMETHEPTENE	0	1 (0.8%)	1 (0.4%)
	LIDOCAINE	0	1 (0.8%)	1 (0.4%)
	MAGNESIUM HYDROXIDE	1 (0.8%)	0	1 (0.4%)
	METHYLPHENIDATE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
	MIDAZOLAM HYDROCHLORIDE	1 (0.8%)	2 (1.5%)	3 (1.1%)
	MIRTAZAPINE	0	1 (0.8%)	1 (0.4%)
	MORPHINE	0	1 (0.8%)	1 (0.4%)
	MORPHINE SULFATE	1 (0.8%)	0	1 (0.4%)
	NITROUS OXIDE	0	2 (1.5%)	2 (0.8%)
	PARACETAMOL	51 (38.3%)	25 (19.2%)	76 (28.9%)
	PAROXETINE	3 (2.3%)	2 (1.5%)	5 (1.9%)
	PETHIDINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
	PHENIRAMINE MALEATE	0	1 (0.8%)	1 (0.4%)

Table 13.9.1

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term (excluding Taper Phase)

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
CENTRAL NERVOUS SYSTEM	PHENYLEPHRINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
	PROCAINE HYDROCHLORIDE	1 (0.8%)	1 (0.8%)	2 (0.8%)
	PROCHLORPERAZINE	1 (0.8%)	0	1 (0.4%)
	PROMETHAZINE HYDROCHLORIDE	0	3 (2.3%)	3 (1.1%)
	PROPOFOL	1 (0.8%)	2 (1.5%)	3 (1.1%)
	PSEUDOEPHEDRINE	1 (0.8%)	0	1 (0.4%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	8 (6.0%)	5 (3.8%)	13 (4.9%)
	QUETIAPINE	0	1 (0.8%)	1 (0.4%)
	RISPERIDONE	1 (0.8%)	3 (2.3%)	4 (1.5%)
	SUMATRIPTAN	1 (0.8%)	0	1 (0.4%)
	VENLAFAXINE	0	1 (0.8%)	1 (0.4%)
DERMATOLOGICALS	Total	26 (19.5%)	34 (26.2%)	60 (22.8%)
	ALOES	2 (1.5%)	0	2 (0.8%)
	BACITRACIN	3 (2.3%)	1 (0.8%)	4 (1.5%)
	BENTONITE	0	1 (0.8%)	1 (0.4%)
	BENZOCAINE	0	2 (1.5%)	2 (0.8%)
	BENZOYL PEROXIDE	1 (0.8%)	0	1 (0.4%)
	BETAMETHASONE	1 (0.8%)	0	1 (0.4%)
	BETAMETHASONE DIPROPIONATE	0	1 (0.8%)	1 (0.4%)
	BUDESONIDE	1 (0.8%)	6 (4.6%)	7 (2.7%)
	CALAMINE	0	1 (0.8%)	1 (0.4%)
	CHLOROXYLENOL	0	1 (0.8%)	1 (0.4%)
	CLOTRIMAZOLE	0	1 (0.8%)	1 (0.4%)
	DIPHENHYDRAMINE	2 (1.5%)	1 (0.8%)	3 (1.1%)
	DIPHENHYDRAMINE HYDROCHLORIDE	9 (6.8%)	11 (8.5%)	20 (7.6%)
	ECONAZOLE NITRATE	0	1 (0.8%)	1 (0.4%)
	ERYTHROMYCIN	2 (1.5%)	2 (1.5%)	4 (1.5%)
	FLUTICASONE PROPIONATE	3 (2.3%)	4 (3.1%)	7 (2.7%)
	GLYCEROL	0	1 (0.8%)	1 (0.4%)
	HYDROCORTISONE	1 (0.8%)	3 (2.3%)	4 (1.5%)
	ISOTRETINOIN	1 (0.8%)	0	1 (0.4%)
	LIDOCAINE	0	1 (0.8%)	1 (0.4%)
	METHYLPREDNISOLONE SODIUM SUCCINATE	0	1 (0.8%)	1 (0.4%)
	MINERAL WAX	0	1 (0.8%)	1 (0.4%)
	MOMETASONE FUROATE	2 (1.5%)	3 (2.3%)	5 (1.9%)
	MUPIROCIN	0	1 (0.8%)	1 (0.4%)
	NEOMYCIN	1 (0.8%)	0	1 (0.4%)
	NEOMYCIN SULFATE	1 (0.8%)	0	1 (0.4%)
	OXYTETRACYCLINE	1 (0.8%)	0	1 (0.4%)
	PARAFFIN, LIQUID	0	1 (0.8%)	1 (0.4%)
	PARAFFIN, SOFT	0	1 (0.8%)	1 (0.4%)
	PERMETHRIN	1 (0.8%)	0	1 (0.4%)
	PHENOL	1 (0.8%)	0	1 (0.4%)
	PHENOL, LIQUEFIED	0	1 (0.8%)	1 (0.4%)

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Table 13.9.1

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term (excluding Taper Phase)

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
DERMATOLOGICALS	POLYMYXIN B SULFATE	2 (1.5%)	0	2 (0.8%)
	PREDNISOLONE SODIUM PHOSPHATE	0	2 (1.5%)	2 (0.8%)
	PROMETHAZINE HYDROCHLORIDE	0	2 (1.5%)	2 (0.8%)
	SALICYLIC ACID	1 (0.8%)	0	1 (0.4%)
	SODIUM CITRATE	0	1 (0.8%)	1 (0.4%)
	SULFADIAZINE SILVER	1 (0.8%)	0	1 (0.4%)
	TETRACYCLINE	1 (0.8%)	1 (0.8%)	2 (0.8%)
	TRIAMCINOLONE	0	1 (0.8%)	1 (0.4%)
	TRIAMCINOLONE ACETONIDE	0	3 (2.3%)	3 (1.1%)
	WOOL WAX ALCOHOL	0	1 (0.8%)	1 (0.4%)
	ZINC GLUCONATE	0	1 (0.8%)	1 (0.4%)
	ZINC OXIDE	0	1 (0.8%)	1 (0.4%)
GU SYSTEM/SEX HORMONES	Total	10 (7.5%)	6 (4.6%)	16 (6.1%)
	ANTIBIOTIC NOS	1 (0.8%)	0	1 (0.4%)
	BACITRACIN	1 (0.8%)	1 (0.8%)	2 (0.8%)
	CICLOPIROX OLAMINE	2 (1.5%)	0	2 (0.8%)
	CLOTRIMAZOLE	0	1 (0.8%)	1 (0.4%)
	ECONAZOLE NITRATE	0	1 (0.8%)	1 (0.4%)
	ETHINYLESTRADIOL	1 (0.8%)	1 (0.8%)	2 (0.8%)
	LEVONORGESTREL	1 (0.8%)	0	1 (0.4%)
	MEDROXYPROGESTERONE ACETATE	2 (1.5%)	0	2 (0.8%)
	NITROFURANTOIN	2 (1.5%)	1 (0.8%)	3 (1.1%)
	NORGESTIMATE	1 (0.8%)	1 (0.8%)	2 (0.8%)
	OFLOXACIN	0	1 (0.8%)	1 (0.4%)
	OXYBUTYNIN	1 (0.8%)	0	1 (0.4%)
	OXYTETRACYCLINE	1 (0.8%)	0	1 (0.4%)
	TOLTERODINE TARTRATE	1 (0.8%)	0	1 (0.4%)
MUSCULO-SKELETAL	Total	36 (27.1%)	29 (22.3%)	65 (24.7%)
	CARISOPRODOL	1 (0.8%)	0	1 (0.4%)
	IBUPROFEN	31 (23.3%)	27 (20.8%)	58 (22.1%)
	MENTHOL	0	1 (0.8%)	1 (0.4%)
	METHOCARBAMOL	1 (0.8%)	0	1 (0.4%)
	MUSCLE RELAXANT, NOS	1 (0.8%)	0	1 (0.4%)
	NAPROXEN	1 (0.8%)	0	1 (0.4%)
	NAPROXEN SODIUM	6 (4.5%)	1 (0.8%)	7 (2.7%)
	ROFECOXIB	1 (0.8%)	0	1 (0.4%)
	SALICYLIC ACID	1 (0.8%)	0	1 (0.4%)
PARASITOLOGY	Total	1 (0.8%)	1 (0.8%)	2 (0.8%)
	ECTOPARASITICIDES, NOS INCLUDING SCABICIDES	0	1 (0.8%)	1 (0.4%)
	PERMETHRIN	1 (0.8%)	0	1 (0.4%)
RESPIRATORY	Total	51 (38.3%)	57 (43.8%)	108 (41.1%)

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Table 13.9.1

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term (excluding Taper Phase)

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
RESPIRATORY	AMINOACETIC ACID	0	1 (0.8%)	1 (0.4%)
	ANTIHISTAMINE, NOS	1 (0.8%)	0	1 (0.4%)
	BENZALKONIUM CHLORIDE	0	1 (0.8%)	1 (0.4%)
	BENZOCAINE	0	2 (1.5%)	2 (0.8%)
	BENZONATATE	0	1 (0.8%)	1 (0.4%)
	BROMPHENIRAMINE	0	1 (0.8%)	1 (0.4%)
	BROMPHENIRAMINE MALEATE	3 (2.3%)	2 (1.5%)	5 (1.9%)
	BUDESONIDE	1 (0.8%)	6 (4.6%)	7 (2.7%)
	CAMPHOR	1 (0.8%)	2 (1.5%)	3 (1.1%)
	CETIRIZINE HYDROCHLORIDE	3 (2.3%)	6 (4.6%)	9 (3.4%)
	CHLORPHENAMINE MALEATE	7 (5.3%)	4 (3.1%)	11 (4.2%)
	CHLORPHENAMINE TANNATE	0	1 (0.8%)	1 (0.4%)
	CLEMASTINE FUMARATE	1 (0.8%)	0	1 (0.4%)
	CODEINE	2 (1.5%)	0	2 (0.8%)
	COUGH COLD PREPARATIONS NOS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	COUGH SYRUP/MED	1 (0.8%)	2 (1.5%)	3 (1.1%)
	DEXTROMETHORPHAN	1 (0.8%)	2 (1.5%)	3 (1.1%)
	DEXTROMETHORPHAN HYDROBROMIDE	12 (9.0%)	5 (3.8%)	17 (6.5%)
	DEXTROMETHORPHAN POLISTIREX	1 (0.8%)	0	1 (0.4%)
	DIMENHYDRINATE	1 (0.8%)	3 (2.3%)	4 (1.5%)
	DIPHENHYDRAMINE	2 (1.5%)	1 (0.8%)	3 (1.1%)
	DIPHENHYDRAMINE HYDROCHLORIDE	10 (7.5%)	13 (10.0%)	23 (8.7%)
	DOXYLAMINE	1 (0.8%)	0	1 (0.4%)
	DOXYLAMINE SUCCINATE	5 (3.8%)	2 (1.5%)	7 (2.7%)
	ETHANOL	0	1 (0.8%)	1 (0.4%)
	EUCALYPTUS OIL	1 (0.8%)	2 (1.5%)	3 (1.1%)
	FEXOFENADINE HYDROCHLORIDE	5 (3.8%)	2 (1.5%)	7 (2.7%)
	FLUTICASONE PROPIONATE	3 (2.3%)	4 (3.1%)	7 (2.7%)
	GUAIFENESIN	4 (3.0%)	6 (4.6%)	10 (3.8%)
	HYDROCODONE BITARTRATE	2 (1.5%)	0	2 (0.8%)
	LIDOCAINE	0	1 (0.8%)	1 (0.4%)
	LORATADINE	12 (9.0%)	10 (7.7%)	22 (8.4%)
	MENTHOL	1 (0.8%)	3 (2.3%)	4 (1.5%)
	MEPYRAMINE MALEATE	3 (2.3%)	0	3 (1.1%)
	MEPYRAMINE TANNATE	0	1 (0.8%)	1 (0.4%)
	MOMETASONE FUROATE	2 (1.5%)	3 (2.3%)	5 (1.9%)
	MONTELUKAST SODIUM	2 (1.5%)	3 (2.3%)	5 (1.9%)
	NASAL SPRAY	1 (0.8%)	0	1 (0.4%)
	OXYMETAZOLINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
	PARACETAMOL	14 (10.5%)	9 (6.9%)	23 (8.7%)
	PHENIRAMINE MALEATE	3 (2.3%)	1 (0.8%)	4 (1.5%)
	PHENYLEPHRINE HYDROCHLORIDE	2 (1.5%)	3 (2.3%)	5 (1.9%)
	PHENYLEPHRINE TANNATE	0	1 (0.8%)	1 (0.4%)
	PHENYLMERCURIC ACETATE	0	1 (0.8%)	1 (0.4%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	7 (5.3%)	2 (1.5%)	9 (3.4%)

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Table 13.9.1

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term (excluding Taper Phase)

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
RESPIRATORY	PIRBUTEROL ACETATE	0	1 (0.8%)	1 (0.4%)
	PREDNISONE	2 (1.5%)	2 (1.5%)	4 (1.5%)
	PROMETHAZINE HYDROCHLORIDE	1 (0.8%)	2 (1.5%)	3 (1.1%)
	PSEUDOEPHEDRINE	1 (0.8%)	2 (1.5%)	3 (1.1%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	19 (14.3%)	12 (9.2%)	31 (11.8%)
	PSEUDOEPHEDRINE SULFATE	2 (1.5%)	0	2 (0.8%)
	SALBUTAMOL	7 (5.3%)	7 (5.4%)	14 (5.3%)
	SALMETEROL HYDROXYNAPHTHOATE	1 (0.8%)	2 (1.5%)	3 (1.1%)
	SODIUM CHLORIDE	1 (0.8%)	1 (0.8%)	2 (0.8%)
	SORBITOL	0	1 (0.8%)	1 (0.4%)
	TERBUTALINE SULFATE	0	1 (0.8%)	1 (0.4%)
	TRIAMCINOLONE ACETONIDE	0	3 (2.3%)	3 (1.1%)
	TRIPROLIDINE HYDROCHLORIDE	1 (0.8%)	0	1 (0.4%)
	TURPENTINE OIL	1 (0.8%)	1 (0.8%)	2 (0.8%)
SENSORY ORGANS	Total	15 (11.3%)	15 (11.5%)	30 (11.4%)
	ANTAZOLINE PHOSPHATE	0	1 (0.8%)	1 (0.4%)
	BACITRACIN	2 (1.5%)	1 (0.8%)	3 (1.1%)
	BETAMETHASONE	1 (0.8%)	0	1 (0.4%)
	BROMPHENIRAMINE MALEATE	1 (0.8%)	0	1 (0.4%)
	DEXAMETHASONE	1 (0.8%)	0	1 (0.4%)
	DEXTRAN	1 (0.8%)	0	1 (0.4%)
	EAR MEDICATION, NOS	0	1 (0.8%)	1 (0.4%)
	ERYTHROMYCIN	2 (1.5%)	2 (1.5%)	4 (1.5%)
	HYDROCORTISONE	3 (2.3%)	4 (3.1%)	7 (2.7%)
	HYPROMELLOSE	1 (0.8%)	0	1 (0.4%)
	LIDOCAINE	0	1 (0.8%)	1 (0.4%)
	METHYLPREDNISOLONE SODIUM SUCCINATE	0	1 (0.8%)	1 (0.4%)
	NAPHAZOLINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
	NEOMYCIN	1 (0.8%)	0	1 (0.4%)
	NEOMYCIN SULFATE	2 (1.5%)	1 (0.8%)	3 (1.1%)
	OFLOXACIN	0	1 (0.8%)	1 (0.4%)
	OXYTETRACYCLINE	1 (0.8%)	0	1 (0.4%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	1 (0.8%)	0	1 (0.4%)
	POLYMYXIN B SULFATE	3 (2.3%)	1 (0.8%)	4 (1.5%)
	PREDNISOLONE SODIUM PHOSPHATE	0	2 (1.5%)	2 (0.8%)
	SODIUM CHLORIDE	1 (0.8%)	1 (0.8%)	2 (0.8%)
	TETRACYCLINE	1 (0.8%)	1 (0.8%)	2 (0.8%)
	TRIAMCINOLONE	0	1 (0.8%)	1 (0.4%)
	TRIAMCINOLONE ACETONIDE	0	3 (2.3%)	3 (1.1%)
SYSTEMIC HORMONAL	Total	6 (4.5%)	10 (7.7%)	16 (6.1%)
	BETAMETHASONE	1 (0.8%)	0	1 (0.4%)
	DESMOPRESSIN	0	2 (1.5%)	2 (0.8%)

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Table 13.9.1

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term (excluding Taper Phase)

Intention-To-Treat Population

		Acute Study Treatment Group		
ATC Code Level 1	Generic Term(s)	Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
SYSTEMIC HORMONAL	DEXAMETHASONE	1 (0.8%)	0	1 (0.4%)
	HYDROCORTISONE	1 (0.8%)	3 (2.3%)	4 (1.5%)
	LEVOTHYROXINE SODIUM	1 (0.8%)	0	1 (0.4%)
	METHYLPREDNISOLONE SODIUM SUCCINATE	0	1 (0.8%)	1 (0.4%)
	PREDNISOLONE SODIUM PHOSPHATE	0	2 (1.5%)	2 (0.8%)
	PREDNISONE	2 (1.5%)	2 (1.5%)	4 (1.5%)
	TRIAMCINOLONE	0	1 (0.8%)	1 (0.4%)
	TRIAMCINOLONE ACETONIDE	0	3 (2.3%)	3 (1.1%)
UNCLASSIFIABLE	Total	0	1 (0.8%)	1 (0.4%)
	UNKNOWN MEDICATION	0	1 (0.8%)	1 (0.4%)
VARIOUS	Total	1 (0.8%)	0	1 (0.4%)
	PROTEINS NOS	1 (0.8%)	0	1 (0.4%)

Table 13.9.2

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
(excluding Taper Phase)
Intention-To-Treat Population

Generic Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Total number of patients with at least one concomitant medication	92 (69.2%)	81 (62.3%)	173 (65.8%)
PARACETAMOL	52 (39.1%)	25 (19.2%)	77 (29.3%)
IBUPROFEN	31 (23.3%)	27 (20.8%)	58 (22.1%)
PSEUDOEPHEDRINE HYDROCHLORIDE	19 (14.3%)	12 (9.2%)	31 (11.8%)
LORATADINE	12 (9.0%)	10 (7.7%)	22 (8.4%)
ACETYLSALICYLIC ACID	12 (9.0%)	5 (3.8%)	17 (6.5%)
DEXTROMETHORPHAN HYDROBROMIDE	12 (9.0%)	5 (3.8%)	17 (6.5%)
DIPHENHYDRAMINE HYDROCHLORIDE	10 (7.5%)	13 (10.0%)	23 (8.7%)
VITAMINS NOS	10 (7.5%)	6 (4.6%)	16 (6.1%)
CAFFEINE	9 (6.8%)	2 (1.5%)	11 (4.2%)
SALBUTAMOL	7 (5.3%)	7 (5.4%)	14 (5.3%)
CHLORPHENAMINE MALEATE	7 (5.3%)	4 (3.1%)	11 (4.2%)
AMOXICILLIN TRIHYDRATE	7 (5.3%)	3 (2.3%)	10 (3.8%)
PHENYLPROPANOLAMINE HYDROCHLORIDE	7 (5.3%)	2 (1.5%)	9 (3.4%)
AMOXICILLIN	6 (4.5%)	3 (2.3%)	9 (3.4%)
CLAVULANIC ACID	6 (4.5%)	1 (0.8%)	7 (2.7%)
NAPROXEN SODIUM	6 (4.5%)	1 (0.8%)	7 (2.7%)
AZITHROMYCIN	5 (3.8%)	8 (6.2%)	13 (4.9%)
BISMUTH SUBSALICYLATE	5 (3.8%)	5 (3.8%)	10 (3.8%)
DOXYLAMINE SUCCINATE	5 (3.8%)	2 (1.5%)	7 (2.7%)
FEXOFENADINE HYDROCHLORIDE	5 (3.8%)	2 (1.5%)	7 (2.7%)
GUAIFENESIN	4 (3.0%)	6 (4.6%)	10 (3.8%)
CEFALEXIN	4 (3.0%)	1 (0.8%)	5 (1.9%)
CINNAMEDRINE HYDROCHLORIDE	4 (3.0%)	1 (0.8%)	5 (1.9%)
POLYMYXIN B SULFATE	4 (3.0%)	1 (0.8%)	5 (1.9%)
CETIRIZINE HYDROCHLORIDE	3 (2.3%)	6 (4.6%)	9 (3.4%)
FLUTICASONE PROPIONATE	3 (2.3%)	4 (3.1%)	7 (2.7%)
HYDROCORTISONE	3 (2.3%)	4 (3.1%)	7 (2.7%)
CALCIUM CARBONATE	3 (2.3%)	3 (2.3%)	6 (2.3%)
BROMPHENIRAMINE MALEATE	3 (2.3%)	2 (1.5%)	5 (1.9%)
PAROXETINE	3 (2.3%)	2 (1.5%)	5 (1.9%)
BACITRACIN	3 (2.3%)	1 (0.8%)	4 (1.5%)
CEFPROZIL MONOHYDRATE	3 (2.3%)	1 (0.8%)	4 (1.5%)
LOPERAMIDE HYDROCHLORIDE	3 (2.3%)	1 (0.8%)	4 (1.5%)
NEOMYCIN SULFATE	3 (2.3%)	1 (0.8%)	4 (1.5%)
PHENIRAMINE MALEATE	3 (2.3%)	1 (0.8%)	4 (1.5%)
ASCORBIC ACID	3 (2.3%)	0	3 (1.1%)
CODEINE	3 (2.3%)	0	3 (1.1%)
MEPYRAMINE MALEATE	3 (2.3%)	0	3 (1.1%)
CODEINE PHOSPHATE	2 (1.5%)	3 (2.3%)	5 (1.9%)
MOMETASONE FUROATE	2 (1.5%)	3 (2.3%)	5 (1.9%)
MONTELUKAST SODIUM	2 (1.5%)	3 (2.3%)	5 (1.9%)
PHENYLEPHRINE HYDROCHLORIDE	2 (1.5%)	3 (2.3%)	5 (1.9%)
ERYTHROMYCIN	2 (1.5%)	2 (1.5%)	4 (1.5%)

Table 13.9.2

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
(excluding Taper Phase)
Intention-To-Treat Population

Generic Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
PREDNISONE	2 (1.5%)	2 (1.5%)	4 (1.5%)
CEFALEXIN MONOHYDRATE	2 (1.5%)	1 (0.8%)	3 (1.1%)
CITALOPRAM	2 (1.5%)	1 (0.8%)	3 (1.1%)
CLARITHROMYCIN	2 (1.5%)	1 (0.8%)	3 (1.1%)
DIPHENHYDRAMINE	2 (1.5%)	1 (0.8%)	3 (1.1%)
FLUCONAZOLE	2 (1.5%)	1 (0.8%)	3 (1.1%)
NITROFURANTOIN	2 (1.5%)	1 (0.8%)	3 (1.1%)
ALOES	2 (1.5%)	0	2 (0.8%)
CICLOPIROX OLAMINE	2 (1.5%)	0	2 (0.8%)
CLINDAMYCIN	2 (1.5%)	0	2 (0.8%)
CLINDAMYCIN HYDROCHLORIDE	2 (1.5%)	0	2 (0.8%)
DOXYCYCLINE	2 (1.5%)	0	2 (0.8%)
HYDROCODONE BITARTRATE	2 (1.5%)	0	2 (0.8%)
MEDROXYPROGESTERONE ACETATE	2 (1.5%)	0	2 (0.8%)
PSEUDOEPHEDRINE SULFATE	2 (1.5%)	0	2 (0.8%)
BUDESONIDE	1 (0.8%)	6 (4.6%)	7 (2.7%)
MAGNESIUM HYDROXIDE	1 (0.8%)	6 (4.6%)	7 (2.7%)
ALUMINIUM HYDROXIDE	1 (0.8%)	5 (3.8%)	6 (2.3%)
CEFUROXIME AXETIL	1 (0.8%)	3 (2.3%)	4 (1.5%)
DIMENHYDRINATE	1 (0.8%)	3 (2.3%)	4 (1.5%)
FAMOTIDINE	1 (0.8%)	3 (2.3%)	4 (1.5%)
MENTHOL	1 (0.8%)	3 (2.3%)	4 (1.5%)
PROMETHAZINE HYDROCHLORIDE	1 (0.8%)	3 (2.3%)	4 (1.5%)
RISPERIDONE	1 (0.8%)	3 (2.3%)	4 (1.5%)
CAMPHOR	1 (0.8%)	2 (1.5%)	3 (1.1%)
CLONIDINE	1 (0.8%)	2 (1.5%)	3 (1.1%)
COUGH SYRUP/MED	1 (0.8%)	2 (1.5%)	3 (1.1%)
DEXTROMETHORPHAN	1 (0.8%)	2 (1.5%)	3 (1.1%)
DIMETICONE, ACTIVATED	1 (0.8%)	2 (1.5%)	3 (1.1%)
EUCALYPTUS OIL	1 (0.8%)	2 (1.5%)	3 (1.1%)
FENTANYL	1 (0.8%)	2 (1.5%)	3 (1.1%)
HYDROXYZINE HYDROCHLORIDE	1 (0.8%)	2 (1.5%)	3 (1.1%)
MIDAZOLAM HYDROCHLORIDE	1 (0.8%)	2 (1.5%)	3 (1.1%)
PROPOFOL	1 (0.8%)	2 (1.5%)	3 (1.1%)
PSEUDOEPHEDRINE	1 (0.8%)	2 (1.5%)	3 (1.1%)
SALMETEROL HYDROXYNAPHTHOATE	1 (0.8%)	2 (1.5%)	3 (1.1%)
ANTACID NOS	1 (0.8%)	1 (0.8%)	2 (0.8%)
CEFTRIAXONE SODIUM	1 (0.8%)	1 (0.8%)	2 (0.8%)
COUGH COLD PREPARATIONS NOS	1 (0.8%)	1 (0.8%)	2 (0.8%)
ETHINYLESTRADIOL	1 (0.8%)	1 (0.8%)	2 (0.8%)
MINOCYCLINE	1 (0.8%)	1 (0.8%)	2 (0.8%)
NORGESTIMATE	1 (0.8%)	1 (0.8%)	2 (0.8%)
OMEPRAZOLE	1 (0.8%)	1 (0.8%)	2 (0.8%)
PROCAINE HYDROCHLORIDE	1 (0.8%)	1 (0.8%)	2 (0.8%)
SODIUM CHLORIDE	1 (0.8%)	1 (0.8%)	2 (0.8%)
TETRACYCLINE	1 (0.8%)	1 (0.8%)	2 (0.8%)

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Table 13.9.2

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
(excluding Taper Phase)
Intention-To-Treat Population

Generic Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
TURPENTINE OIL	1 (0.8%)	1 (0.8%)	2 (0.8%)
AMPICILLIN	1 (0.8%)	0	1 (0.4%)
ANTIBIOTIC NOS	1 (0.8%)	0	1 (0.4%)
ANTIHISTAMINE, NOS	1 (0.8%)	0	1 (0.4%)
ATROPINE SULFATE	1 (0.8%)	0	1 (0.4%)
BENZOYL PEROXIDE	1 (0.8%)	0	1 (0.4%)
BETAMETHASONE	1 (0.8%)	0	1 (0.4%)
CALCIUM	1 (0.8%)	0	1 (0.4%)
CARISOPRODOL	1 (0.8%)	0	1 (0.4%)
CEFIXIME	1 (0.8%)	0	1 (0.4%)
CEFUROXIME SODIUM	1 (0.8%)	0	1 (0.4%)
CLEMASTINE FUMARATE	1 (0.8%)	0	1 (0.4%)
DEXAMETHASONE	1 (0.8%)	0	1 (0.4%)
DEXTRAN	1 (0.8%)	0	1 (0.4%)
DEXTROMETHORPHAN POLISTIREX	1 (0.8%)	0	1 (0.4%)
DIPHENOXYLATE HYDROCHLORIDE	1 (0.8%)	0	1 (0.4%)
DIRITHROMYCIN	1 (0.8%)	0	1 (0.4%)
DOXYLAMINE	1 (0.8%)	0	1 (0.4%)
FERROUS FUMARATE	1 (0.8%)	0	1 (0.4%)
FERROUS SULFATE	1 (0.8%)	0	1 (0.4%)
GUANFACINE	1 (0.8%)	0	1 (0.4%)
HYPROMELLOSE	1 (0.8%)	0	1 (0.4%)
ISOTRETINOIN	1 (0.8%)	0	1 (0.4%)
LEVONORGESTREL	1 (0.8%)	0	1 (0.4%)
LEVOTHYROXINE SODIUM	1 (0.8%)	0	1 (0.4%)
METHOCARBAMOL	1 (0.8%)	0	1 (0.4%)
METOCLOPRAMIDE	1 (0.8%)	0	1 (0.4%)
MINERALS NOS	1 (0.8%)	0	1 (0.4%)
MORPHINE SULFATE	1 (0.8%)	0	1 (0.4%)
MUSCLE RELAXANT, NOS	1 (0.8%)	0	1 (0.4%)
NAPROXEN	1 (0.8%)	0	1 (0.4%)
NASAL SPRAY	1 (0.8%)	0	1 (0.4%)
NEOMYCIN	1 (0.8%)	0	1 (0.4%)
OXYBUTYNIN	1 (0.8%)	0	1 (0.4%)
OXYTETRACYCLINE	1 (0.8%)	0	1 (0.4%)
PERMETHRIN	1 (0.8%)	0	1 (0.4%)
PHENOL	1 (0.8%)	0	1 (0.4%)
PROCHLORPERAZINE	1 (0.8%)	0	1 (0.4%)
PROTEINS NOS	1 (0.8%)	0	1 (0.4%)
ROFECOXIB	1 (0.8%)	0	1 (0.4%)
SALICYLIC ACID	1 (0.8%)	0	1 (0.4%)
SENNA	1 (0.8%)	0	1 (0.4%)
SULFADIAZINE SILVER	1 (0.8%)	0	1 (0.4%)
SULFAMETHOXAZOLE	1 (0.8%)	0	1 (0.4%)
SUMATRIPTAN	1 (0.8%)	0	1 (0.4%)
TOLTERODINE TARTRATE	1 (0.8%)	0	1 (0.4%)

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Table 13.9.2

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
(excluding Taper Phase)
Intention-To-Treat Population

Generic Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
TRIMETHOPRIM	1 (0.8%)	0	1 (0.4%)
TRIPROLIDINE HYDROCHLORIDE	1 (0.8%)	0	1 (0.4%)
YELLOW PHENOLPHTHALEIN	1 (0.8%)	0	1 (0.4%)
TRIAMCINOLONE ACETONIDE	0	3 (2.3%)	3 (1.1%)
BENZOCAINE	0	2 (1.5%)	2 (0.8%)
DESMOPRESSIN	0	2 (1.5%)	2 (0.8%)
NITROUS OXIDE	0	2 (1.5%)	2 (0.8%)
PENICILLIN NOS	0	2 (1.5%)	2 (0.8%)
PREDNISOLONE SODIUM PHOSPHATE	0	2 (1.5%)	2 (0.8%)
ALPRAZOLAM	0	1 (0.8%)	1 (0.4%)
AMINOACETIC ACID	0	1 (0.8%)	1 (0.4%)
AMPHETAMINE ASPARTATE	0	1 (0.8%)	1 (0.4%)
AMPHETAMINE SULFATE	0	1 (0.8%)	1 (0.4%)
ANTAZOLINE PHOSPHATE	0	1 (0.8%)	1 (0.4%)
BENTONITE	0	1 (0.8%)	1 (0.4%)
BENZALKONIUM CHLORIDE	0	1 (0.8%)	1 (0.4%)
BENZATHINE BENZYLPENICILLIN	0	1 (0.8%)	1 (0.4%)
BENZONATATE	0	1 (0.8%)	1 (0.4%)
BETAMETHASONE DIPROPIONATE	0	1 (0.8%)	1 (0.4%)
BROMPHENIRAMINE	0	1 (0.8%)	1 (0.4%)
BUTALBITAL	0	1 (0.8%)	1 (0.4%)
CALAMINE	0	1 (0.8%)	1 (0.4%)
CEFAZOLIN	0	1 (0.8%)	1 (0.4%)
CHLOROXYLENOL	0	1 (0.8%)	1 (0.4%)
CHLORPHENAMINE TANNATE	0	1 (0.8%)	1 (0.4%)
CLOTRIMAZOLE	0	1 (0.8%)	1 (0.4%)
DEXTROAMPHETAMINE SACCHARATE	0	1 (0.8%)	1 (0.4%)
DEXTROAMPHETAMINE SULFATE	0	1 (0.8%)	1 (0.4%)
DEXTROPROPOXYPHENE	0	1 (0.8%)	1 (0.4%)
DICHLORALPHENAZONE	0	1 (0.8%)	1 (0.4%)
EAR MEDICATION, NOS	0	1 (0.8%)	1 (0.4%)
ECONAZOLE NITRATE	0	1 (0.8%)	1 (0.4%)
ECTOPARASITICIDES, NOS INCLUDING SCABICIDES	0	1 (0.8%)	1 (0.4%)
ETHANOL	0	1 (0.8%)	1 (0.4%)
FLUORIDE NOS	0	1 (0.8%)	1 (0.4%)
GLYCEROL	0	1 (0.8%)	1 (0.4%)
HEPATITIS B VACCINE	0	1 (0.8%)	1 (0.4%)
HYDROXYZINE	0	1 (0.8%)	1 (0.4%)
INFLUENZA VIRUS VACCINE POLYVALENT	0	1 (0.8%)	1 (0.4%)
ISOMETHEPTENE	0	1 (0.8%)	1 (0.4%)
KAOLIN	0	1 (0.8%)	1 (0.4%)
LIDOCAINE	0	1 (0.8%)	1 (0.4%)
MEPYRAMINE TANNATE	0	1 (0.8%)	1 (0.4%)
METHYLPHENIDATE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
METHYLPREDNISOLONE SODIUM SUCCINATE	0	1 (0.8%)	1 (0.4%)
METOCLOPRAMIDE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)

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Table 13.9.2

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
(excluding Taper Phase)
Intention-To-Treat Population

Generic Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
MINERAL WAX	0	1 (0.8%)	1 (0.4%)
MINOCYCLINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
MIRTAZAPINE	0	1 (0.8%)	1 (0.4%)
MORPHINE	0	1 (0.8%)	1 (0.4%)
MUPIROCIN	0	1 (0.8%)	1 (0.4%)
NAPHAZOLINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
NIZATIDINE	0	1 (0.8%)	1 (0.4%)
OFLOXACIN	0	1 (0.8%)	1 (0.4%)
ONDANSETRON HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
OXYMETAZOLINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
PARAFFIN, LIQUID	0	1 (0.8%)	1 (0.4%)
PARAFFIN, SOFT	0	1 (0.8%)	1 (0.4%)
PECTIN	0	1 (0.8%)	1 (0.4%)
PETHIDINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
PHENOL, LIQUEFIED	0	1 (0.8%)	1 (0.4%)
PHENYLEPHRINE TANNATE	0	1 (0.8%)	1 (0.4%)
PHENYLMERCURIC ACETATE	0	1 (0.8%)	1 (0.4%)
PIRBUTEROL ACETATE	0	1 (0.8%)	1 (0.4%)
QUETIAPINE	0	1 (0.8%)	1 (0.4%)
RANITIDINE	0	1 (0.8%)	1 (0.4%)
SENNA FRUIT	0	1 (0.8%)	1 (0.4%)
SODIUM CITRATE	0	1 (0.8%)	1 (0.4%)
SORBITOL	0	1 (0.8%)	1 (0.4%)
TERBUTALINE SULFATE	0	1 (0.8%)	1 (0.4%)
TETANUS TOXOID	0	1 (0.8%)	1 (0.4%)
TRIAMCINOLONE	0	1 (0.8%)	1 (0.4%)
TRIMETHOBENZAMIDE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
UNKNOWN MEDICATION	0	1 (0.8%)	1 (0.4%)
VENLAFAXINE	0	1 (0.8%)	1 (0.4%)
WOOL WAX ALCOHOL	0	1 (0.8%)	1 (0.4%)
ZINC GLUCONATE	0	1 (0.8%)	1 (0.4%)
ZINC OXIDE	0	1 (0.8%)	1 (0.4%)

Table 13.9.3

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=78)	Placebo (N=78)	Total (N=156)
Total number of patients with at least one concomitant medication during taper or follow-up	Total	77 (98.7%)	77 (98.7%)	154 (98.7%)
ALIMENTARY TRACT/METAB	Total	17 (21.8%)	16 (20.5%)	33 (21.2%)
	ACETYLSALICYLIC ACID	1 (1.3%)	2 (2.6%)	3 (1.9%)
	ALUMINIUM HYDROXIDE	1 (1.3%)	1 (1.3%)	2 (1.3%)
	ASCORBIC ACID	3 (3.8%)	0	3 (1.9%)
	ATROPINE SULFATE	0	1 (1.3%)	1 (0.6%)
	BISMUTH SUBSALICYLATE	1 (1.3%)	3 (3.8%)	4 (2.6%)
	CALCIUM CARBONATE	1 (1.3%)	1 (1.3%)	2 (1.3%)
	DEXAMPHETAMINE SULFATE	1 (1.3%)	0	1 (0.6%)
	DICYCLOVERINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	DIMETICONE, ACTIVATED	2 (2.6%)	0	2 (1.3%)
	FAMOTIDINE	0	2 (2.6%)	2 (1.3%)
	FERROUS FUMARATE	1 (1.3%)	0	1 (0.6%)
	HYOSCINE HYDROBROMIDE	0	1 (1.3%)	1 (0.6%)
	HYOSCYAMINE SULFATE	0	1 (1.3%)	1 (0.6%)
	MAGNESIUM HYDROXIDE	1 (1.3%)	1 (1.3%)	2 (1.3%)
	MINERALS NOS	1 (1.3%)	0	1 (0.6%)
	NEOMYCIN SULFATE	1 (1.3%)	0	1 (0.6%)
	OMEPRAZOLE	1 (1.3%)	0	1 (0.6%)
	PHENOBARBITAL	0	1 (1.3%)	1 (0.6%)
	RANITIDINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	SENNA FRUIT	0	1 (1.3%)	1 (0.6%)
	TRIAMCINOLONE	0	1 (1.3%)	1 (0.6%)
	TRIAMCINOLONE ACETONIDE	0	1 (1.3%)	1 (0.6%)
	VITAMINS NOS	10 (12.8%)	6 (7.7%)	16 (10.3%)
ANTIINFECTIVES,SYSTEMIC	Total	13 (16.7%)	10 (12.8%)	23 (14.7%)
	AMOXICILLIN	2 (2.6%)	1 (1.3%)	3 (1.9%)
	AMOXICILLIN TRIHYDRATE	3 (3.8%)	0	3 (1.9%)
	ANTIBIOTIC NOS	1 (1.3%)	0	1 (0.6%)
	AZITHROMYCIN	0	1 (1.3%)	1 (0.6%)
	CEFALEXIN MONOHYDRATE	1 (1.3%)	1 (1.3%)	2 (1.3%)
	CEFPROZIL MONOHYDRATE	1 (1.3%)	1 (1.3%)	2 (1.3%)
	CLAVULANIC ACID	3 (3.8%)	0	3 (1.9%)
	CLINDAMYCIN	1 (1.3%)	0	1 (0.6%)
	DOXYCYCLINE	1 (1.3%)	0	1 (0.6%)
	ERYTHROMYCIN	1 (1.3%)	1 (1.3%)	2 (1.3%)
	FLUCONAZOLE	1 (1.3%)	0	1 (0.6%)
	HEPATITIS B VACCINE	0	1 (1.3%)	1 (0.6%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

Table 13.9.3

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

ATC Code Level 1	Generic Term(s)	Acute Study Treatment Group: Paroxetine (N=78)	Placebo (N=78)	Total (N=156)
ANTIINFECTIVES,SYSTEMIC	KETOCONAZOLE	0	1 (1.3%)	1 (0.6%)
	MINOCYCLINE	1 (1.3%)	1 (1.3%)	2 (1.3%)
	MINOCYCLINE HYDROCHLORIDE	0	1 (1.3%)	1 (0.6%)
	NEOMYCIN SULFATE	1 (1.3%)	0	1 (0.6%)
	OFLOXACIN	0	1 (1.3%)	1 (0.6%)
	TETRACYCLINE	1 (1.3%)	1 (1.3%)	2 (1.3%)
ANTINEOPLASTIC & IMMUNOSUP	Total	1 (1.3%)	0	1 (0.6%)
	MEDROXYPROGESTERONE ACETATE	1 (1.3%)	0	1 (0.6%)
BLOOD/BLOOD FORM ORGANS	Total	2 (2.6%)	3 (3.8%)	5 (3.2%)
	ACETYLSALICYLIC ACID	1 (1.3%)	2 (2.6%)	3 (1.9%)
	FERROUS SULFATE	1 (1.3%)	0	1 (0.6%)
	I.V. FLUIDS	0	1 (1.3%)	1 (0.6%)
CARDIOVASCULAR	Total	3 (3.8%)	2 (2.6%)	5 (3.2%)
	CLONIDINE	1 (1.3%)	0	1 (0.6%)
	CLONIDINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	GUANFACINE	1 (1.3%)	0	1 (0.6%)
	HYPERICUM EXTRACT	0	1 (1.3%)	1 (0.6%)
	PREDNISOLONE SODIUM PHOSPHATE	0	1 (1.3%)	1 (0.6%)
CENTRAL NERVOUS SYSTEM	Total	57 (73.1%)	48 (61.5%)	105 (67.3%)
	ACETYLSALICYLIC ACID	2 (2.6%)	3 (3.8%)	5 (3.2%)
	AMFEBUTAMONE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	AMPHETAMINE ASPARTATE	0	2 (2.6%)	2 (1.3%)
	AMPHETAMINE SULFATE	0	2 (2.6%)	2 (1.3%)
	BUTALBITAL	0	1 (1.3%)	1 (0.6%)
	CAFFEINE	1 (1.3%)	2 (2.6%)	3 (1.9%)
	CARBAMAZEPINE	0	1 (1.3%)	1 (0.6%)
	CHLORPROMAZINE HYDROCHLORIDE	0	1 (1.3%)	1 (0.6%)
	CINNAMEDRINE HYDROCHLORIDE	0	1 (1.3%)	1 (0.6%)
	CITALOPRAM	3 (3.8%)	1 (1.3%)	4 (2.6%)
	CLONIDINE	1 (1.3%)	0	1 (0.6%)
	CLONIDINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	DEXAMPHETAMINE SULFATE	1 (1.3%)	0	1 (0.6%)
	DEXTROAMPHETAMINE SACCHARATE	0	2 (2.6%)	2 (1.3%)
	DEXTROAMPHETAMINE SULFATE	0	2 (2.6%)	2 (1.3%)
	DICHLORALPHENAZONE	0	1 (1.3%)	1 (0.6%)
	DIPHENHYDRAMINE HYDROCHLORIDE	0	1 (1.3%)	1 (0.6%)
	FLUOXETINE	1 (1.3%)	1 (1.3%)	2 (1.3%)
	HYDROXYZINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)

The N’s in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

Table 13.9.3

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

		Acute Study Treatment Group		
ATC Code Level 1	Generic Term(s)	Paroxetine (N=78)	Placebo (N=78)	Total (N=156)
CENTRAL NERVOUS SYSTEM	HYPERICUM EXTRACT	0	1 (1.3%)	1 (0.6%)
	IBUPROFEN	12 (15.4%)	14 (17.9%)	26 (16.7%)
	IMIPRAMINE	0	1 (1.3%)	1 (0.6%)
	ISOMETHEPTENE	0	1 (1.3%)	1 (0.6%)
	METHYLPHENIDATE HYDROCHLORIDE	1 (1.3%)	3 (3.8%)	4 (2.6%)
	MIRTAZAPINE	0	1 (1.3%)	1 (0.6%)
	OLANZAPINE	2 (2.6%)	1 (1.3%)	3 (1.9%)
	PARACETAMOL	11 (14.1%)	8 (10.3%)	19 (12.2%)
	PAROXETINE	33 (42.3%)	21 (26.9%)	54 (34.6%)
	PROCHLORPERAZINE	1 (1.3%)	0	1 (0.6%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (1.3%)	1 (0.6%)
	QUETIAPINE	0	1 (1.3%)	1 (0.6%)
	RISPERIDONE	1 (1.3%)	6 (7.7%)	7 (4.5%)
	SERTRALINE HYDROCHLORIDE	1 (1.3%)	1 (1.3%)	2 (1.3%)
	VENLAFAXINE	0	1 (1.3%)	1 (0.6%)
DERMATOLOGICALS	Total	12 (15.4%)	21 (26.9%)	33 (21.2%)
	BACITRACIN	1 (1.3%)	0	1 (0.6%)
	BENZOYL PEROXIDE	1 (1.3%)	0	1 (0.6%)
	BETAMETHASONE DIPROPIONATE	0	1 (1.3%)	1 (0.6%)
	BUDESONIDE	2 (2.6%)	4 (5.1%)	6 (3.8%)
	CHLOROXYLENOL	0	1 (1.3%)	1 (0.6%)
	DIPHENHYDRAMINE	1 (1.3%)	1 (1.3%)	2 (1.3%)
	DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.3%)	6 (7.7%)	7 (4.5%)
	ECONAZOLE NITRATE	0	1 (1.3%)	1 (0.6%)
	ERYTHROMYCIN	1 (1.3%)	1 (1.3%)	2 (1.3%)
	FLUTICASONE PROPIONATE	2 (2.6%)	4 (5.1%)	6 (3.8%)
	GRISEOFULVIN	0	1 (1.3%)	1 (0.6%)
	HYDROCORTISONE	0	1 (1.3%)	1 (0.6%)
	ISOTRETINOIN	1 (1.3%)	0	1 (0.6%)
	KETOCONAZOLE	0	1 (1.3%)	1 (0.6%)
	MOMETASONE FUROATE	2 (2.6%)	0	2 (1.3%)
	NEOMYCIN SULFATE	2 (2.6%)	0	2 (1.3%)
	POLYMYXIN B SULFATE	1 (1.3%)	0	1 (0.6%)
	PREDNISOLONE SODIUM PHOSPHATE	0	1 (1.3%)	1 (0.6%)
	SALICYLIC ACID	1 (1.3%)	0	1 (0.6%)
	TETRACYCLINE	1 (1.3%)	1 (1.3%)	2 (1.3%)
	TRIAMCINOLONE	0	1 (1.3%)	1 (0.6%)
	TRIAMCINOLONE ACETONIDE	0	1 (1.3%)	1 (0.6%)
GU SYSTEM/SEX HORMONES	Total	6 (7.7%)	5 (6.4%)	11 (7.1%)
	ANTIBIOTIC NOS	1 (1.3%)	0	1 (0.6%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

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Table 13.9.3

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

		Acute Study Treatment Group		
ATC Code Level 1	Generic Term(s)	Paroxetine (N=78)	Placebo (N=78)	Total (N=156)
GU SYSTEM/SEX HORMONES	CICLOPIROX OLAMINE	1 (1.3%)	0	1 (0.6%)
	ECONAZOLE NITRATE	0	1 (1.3%)	1 (0.6%)
	ETHINYLESTRADIOL	1 (1.3%)	1 (1.3%)	2 (1.3%)
	HYPERICUM EXTRACT	0	1 (1.3%)	1 (0.6%)
	MEDROXYPROGESTERONE ACETATE	1 (1.3%)	0	1 (0.6%)
	MIFEPRISTONE	1 (1.3%)	0	1 (0.6%)
	NITROFURANTOIN	1 (1.3%)	1 (1.3%)	2 (1.3%)
	NORGESTIMATE	1 (1.3%)	1 (1.3%)	2 (1.3%)
	OFLOXACIN	0	1 (1.3%)	1 (0.6%)
	TOLTERODINE TARTRATE	1 (1.3%)	0	1 (0.6%)
MUSCULO-SKELETAL	Total	17 (21.8%)	14 (17.9%)	31 (19.9%)
	CELECOXIB	2 (2.6%)	0	2 (1.3%)
	IBUPROFEN	12 (15.4%)	14 (17.9%)	26 (16.7%)
	NAPROXEN	1 (1.3%)	0	1 (0.6%)
	NAPROXEN SODIUM	2 (2.6%)	0	2 (1.3%)
	ROFECOXIB	1 (1.3%)	0	1 (0.6%)
	SALICYLIC ACID	1 (1.3%)	0	1 (0.6%)
RESPIRATORY	Total	29 (37.2%)	33 (42.3%)	62 (39.7%)
	BROMPHENIRAMINE MALEATE	2 (2.6%)	0	2 (1.3%)
	BUDESONIDE	2 (2.6%)	4 (5.1%)	6 (3.8%)
	CETIRIZINE HYDROCHLORIDE	2 (2.6%)	4 (5.1%)	6 (3.8%)
	CHLORPHENAMINE MALEATE	1 (1.3%)	1 (1.3%)	2 (1.3%)
	CHLORPHENAMINE TANNATE	0	1 (1.3%)	1 (0.6%)
	COUGH COLD PREPARATIONS NOS	1 (1.3%)	0	1 (0.6%)
	CYPROHEPTADINE	0	1 (1.3%)	1 (0.6%)
	DEXTROMETHORPHAN HYDROBROMIDE	0	2 (2.6%)	2 (1.3%)
	DIMENHYDRINATE	1 (1.3%)	0	1 (0.6%)
	DIPHENHYDRAMINE	1 (1.3%)	1 (1.3%)	2 (1.3%)
	DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.3%)	6 (7.7%)	7 (4.5%)
	DOXYLAMINE SUCCINATE	0	1 (1.3%)	1 (0.6%)
	ETHANOL	0	1 (1.3%)	1 (0.6%)
	FEXOFENADINE HYDROCHLORIDE	4 (5.1%)	2 (2.6%)	6 (3.8%)
	FLUTICASONE PROPIONATE	2 (2.6%)	4 (5.1%)	6 (3.8%)
	GUAIFENESIN	1 (1.3%)	2 (2.6%)	3 (1.9%)
	IPECACUANHA, PREPARED	0	1 (1.3%)	1 (0.6%)
	LORATADINE	8 (10.3%)	6 (7.7%)	14 (9.0%)
	MEPYRAMINE TANNATE	0	1 (1.3%)	1 (0.6%)
	MOMETASONE FUROATE	2 (2.6%)	0	2 (1.3%)
	MONTELUKAST SODIUM	1 (1.3%)	3 (3.8%)	4 (2.6%)
	PARACETAMOL	0	2 (2.6%)	2 (1.3%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

Table 13.9.3

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

		Acute Study Treatment Group		
ATC Code Level 1	Generic Term(s)	Paroxetine (N=78)	Placebo (N=78)	Total (N=156)
RESPIRATORY	PHENYLEPHRINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	PHENYLEPHRINE TANNATE	0	1 (1.3%)	1 (0.6%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	2 (2.6%)	0	2 (1.3%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	3 (3.8%)	2 (2.6%)	5 (3.2%)
	PSEUDOEPHEDRINE SULFATE	1 (1.3%)	0	1 (0.6%)
	SALBUTAMOL	5 (6.4%)	6 (7.7%)	11 (7.1%)
	SALMETEROL HYDROXYNAPHTHOATE	0	2 (2.6%)	2 (1.3%)
	TRIAMCINOLONE ACETONIDE	0	1 (1.3%)	1 (0.6%)
	TRIPROLIDINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
SENSORY ORGANS	Total	4 (5.1%)	8 (10.3%)	12 (7.7%)
	ANTAZOLINE PHOSPHATE	0	1 (1.3%)	1 (0.6%)
	CLONIDINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	ERYTHROMYCIN	1 (1.3%)	1 (1.3%)	2 (1.3%)
	HYDROCORTISONE	0	1 (1.3%)	1 (0.6%)
	NAPHAZOLINE HYDROCHLORIDE	0	1 (1.3%)	1 (0.6%)
	NEOMYCIN SULFATE	1 (1.3%)	0	1 (0.6%)
	OFLOXACIN	0	1 (1.3%)	1 (0.6%)
	PREDNISOLONE SODIUM PHOSPHATE	0	1 (1.3%)	1 (0.6%)
	TETRACYCLINE	1 (1.3%)	1 (1.3%)	2 (1.3%)
	TRIAMCINOLONE	0	1 (1.3%)	1 (0.6%)
	TRIAMCINOLONE ACETONIDE	0	1 (1.3%)	1 (0.6%)
SYSTEMIC HORMONAL	Total	1 (1.3%)	7 (9.0%)	8 (5.1%)
	DESMOPRESSIN	0	3 (3.8%)	3 (1.9%)
	HYDROCORTISONE	0	1 (1.3%)	1 (0.6%)
	LEVOTHYROXINE SODIUM	1 (1.3%)	0	1 (0.6%)
	PREDNISOLONE SODIUM PHOSPHATE	0	1 (1.3%)	1 (0.6%)
	TRIAMCINOLONE	0	1 (1.3%)	1 (0.6%)
	TRIAMCINOLONE ACETONIDE	0	1 (1.3%)	1 (0.6%)
UNCLASSIFIABLE	Total	0	1 (1.3%)	1 (0.6%)
	UNKNOWN MEDICATION	0	1 (1.3%)	1 (0.6%)
VARIOUS	Total	1 (1.3%)	2 (2.6%)	3 (1.9%)
	HYPERICUM EXTRACT	0	1 (1.3%)	1 (0.6%)
	IPECACUANHA, PREPARED	0	1 (1.3%)	1 (0.6%)
	PROTEINS NOS	1 (1.3%)	0	1 (0.6%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

Table 13.9.4

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

	Acute Study Treatment Group		
Generic Term	Paroxetine (N=78)	Placebo (N=78)	Total (N=156)
Total number of patients with at least one concomitant medication during taper or follow-up	77 (98.7%)	77 (98.7%)	154 (98.7%)
PAROXETINE	33 (42.3%)	21 (26.9%)	54 (34.6%)
IBUPROFEN	12 (15.4%)	14 (17.9%)	26 (16.7%)
PARACETAMOL	11 (14.1%)	8 (10.3%)	19 (12.2%)
VITAMINS NOS	10 (12.8%)	6 (7.7%)	16 (10.3%)
LORATADINE	8 (10.3%)	6 (7.7%)	14 (9.0%)
SALBUTAMOL	5 (6.4%)	6 (7.7%)	11 (7.1%)
FEXOFENADINE HYDROCHLORIDE	4 (5.1%)	2 (2.6%)	6 (3.8%)
PSEUDOEPHEDRINE HYDROCHLORIDE	3 (3.8%)	2 (2.6%)	5 (3.2%)
CITALOPRAM	3 (3.8%)	1 (1.3%)	4 (2.6%)
AMOXICILLIN TRIHYDRATE	3 (3.8%)	0	3 (1.9%)
ASCORBIC ACID	3 (3.8%)	0	3 (1.9%)
CLAVULANIC ACID	3 (3.8%)	0	3 (1.9%)
BUDESONIDE	2 (2.6%)	4 (5.1%)	6 (3.8%)
CETIRIZINE HYDROCHLORIDE	2 (2.6%)	4 (5.1%)	6 (3.8%)
FLUTICASONE PROPIONATE	2 (2.6%)	4 (5.1%)	6 (3.8%)
ACETYLSALICYLIC ACID	2 (2.6%)	3 (3.8%)	5 (3.2%)
AMOXICILLIN	2 (2.6%)	1 (1.3%)	3 (1.9%)
OLANZAPINE	2 (2.6%)	1 (1.3%)	3 (1.9%)
BROMPHENIRAMINE MALEATE	2 (2.6%)	0	2 (1.3%)
CELECOXIB	2 (2.6%)	0	2 (1.3%)
DIMETICONE, ACTIVATED	2 (2.6%)	0	2 (1.3%)
MOMETASONE FUROATE	2 (2.6%)	0	2 (1.3%)
NAPROXEN SODIUM	2 (2.6%)	0	2 (1.3%)
NEOMYCIN SULFATE	2 (2.6%)	0	2 (1.3%)
PHENYLPROPANOLAMINE HYDROCHLORIDE	2 (2.6%)	0	2 (1.3%)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.3%)	6 (7.7%)	7 (4.5%)
RISPERIDONE	1 (1.3%)	6 (7.7%)	7 (4.5%)
BISMUTH SUBSALICYLATE	1 (1.3%)	3 (3.8%)	4 (2.6%)
METHYLPHENIDATE HYDROCHLORIDE	1 (1.3%)	3 (3.8%)	4 (2.6%)
MONTELUKAST SODIUM	1 (1.3%)	3 (3.8%)	4 (2.6%)
CAFFEINE	1 (1.3%)	2 (2.6%)	3 (1.9%)
GUAIFENESIN	1 (1.3%)	2 (2.6%)	3 (1.9%)
ALUMINIUM HYDROXIDE	1 (1.3%)	1 (1.3%)	2 (1.3%)
CALCIUM CARBONATE	1 (1.3%)	1 (1.3%)	2 (1.3%)
CEFALEXIN MONOHYDRATE	1 (1.3%)	1 (1.3%)	2 (1.3%)
CEFPROZIL MONOHYDRATE	1 (1.3%)	1 (1.3%)	2 (1.3%)
CHLORPHENAMINE MALEATE	1 (1.3%)	1 (1.3%)	2 (1.3%)
DIPHENHYDRAMINE	1 (1.3%)	1 (1.3%)	2 (1.3%)
ERYTHROMYCIN	1 (1.3%)	1 (1.3%)	2 (1.3%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

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Table 13.9.4

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

	Acute Study Treatment Group		
Generic Term	Paroxetine (N=78)	Placebo (N=78)	Total (N=156)
ETHINYLESTRADIOL	1 (1.3%)	1 (1.3%)	2 (1.3%)
FLUOXETINE	1 (1.3%)	1 (1.3%)	2 (1.3%)
MAGNESIUM HYDROXIDE	1 (1.3%)	1 (1.3%)	2 (1.3%)
MINOCYCLINE	1 (1.3%)	1 (1.3%)	2 (1.3%)
NITROFURANTOIN	1 (1.3%)	1 (1.3%)	2 (1.3%)
NORGESTIMATE	1 (1.3%)	1 (1.3%)	2 (1.3%)
SERTRALINE HYDROCHLORIDE	1 (1.3%)	1 (1.3%)	2 (1.3%)
TETRACYCLINE	1 (1.3%)	1 (1.3%)	2 (1.3%)
AMFEBUTAMONE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
ANTIBIOTIC NOS	1 (1.3%)	0	1 (0.6%)
BACITRACIN	1 (1.3%)	0	1 (0.6%)
BENZOYL PEROXIDE	1 (1.3%)	0	1 (0.6%)
CICLOPIROX OLAMINE	1 (1.3%)	0	1 (0.6%)
CLINDAMYCIN	1 (1.3%)	0	1 (0.6%)
CLONIDINE	1 (1.3%)	0	1 (0.6%)
CLONIDINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
COUGH COLD PREPARATIONS NOS	1 (1.3%)	0	1 (0.6%)
DEXAMPHETAMINE SULFATE	1 (1.3%)	0	1 (0.6%)
DICYCLOVERINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
DIMENHYDRINATE	1 (1.3%)	0	1 (0.6%)
DOXYCYCLINE	1 (1.3%)	0	1 (0.6%)
FERROUS FUMARATE	1 (1.3%)	0	1 (0.6%)
FERROUS SULFATE	1 (1.3%)	0	1 (0.6%)
FLUCONAZOLE	1 (1.3%)	0	1 (0.6%)
GUANFACINE	1 (1.3%)	0	1 (0.6%)
HYDROXYZINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
ISOTRETINOIN	1 (1.3%)	0	1 (0.6%)
LEVOTHYROXINE SODIUM	1 (1.3%)	0	1 (0.6%)
MEDROXYPROGESTERONE ACETATE	1 (1.3%)	0	1 (0.6%)
MIFEPRISTONE	1 (1.3%)	0	1 (0.6%)
MINERALS NOS	1 (1.3%)	0	1 (0.6%)
NAPROXEN	1 (1.3%)	0	1 (0.6%)
OMEPRAZOLE	1 (1.3%)	0	1 (0.6%)
PHENYLEPHRINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
POLYMYXIN B SULFATE	1 (1.3%)	0	1 (0.6%)
PROCHLORPERAZINE	1 (1.3%)	0	1 (0.6%)
PROTEINS NOS	1 (1.3%)	0	1 (0.6%)
PSEUDOEPHEDRINE SULFATE	1 (1.3%)	0	1 (0.6%)
RANITIDINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
ROFECOXIB	1 (1.3%)	0	1 (0.6%)
SALICYLIC ACID	1 (1.3%)	0	1 (0.6%)
TOLTERODINE TARTRATE	1 (1.3%)	0	1 (0.6%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

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Table 13.9.4

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

	Acute Study Treatment Group		
Generic Term	Paroxetine (N=78)	Placebo (N=78)	Total (N=156)
TRIPROLIDINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
DESMOPRESSIN	0	3 (3.8%)	3 (1.9%)
AMPHETAMINE ASPARTATE	0	2 (2.6%)	2 (1.3%)
AMPHETAMINE SULFATE	0	2 (2.6%)	2 (1.3%)
DEXTROAMPHETAMINE SACCHARATE	0	2 (2.6%)	2 (1.3%)
DEXTROAMPHETAMINE SULFATE	0	2 (2.6%)	2 (1.3%)
DEXTROMETHORPHAN HYDROBROMIDE	0	2 (2.6%)	2 (1.3%)
FAMOTIDINE	0	2 (2.6%)	2 (1.3%)
SALMETEROL HYDROXYNAPHTHOATE	0	2 (2.6%)	2 (1.3%)
ANTAZOLINE PHOSPHATE	0	1 (1.3%)	1 (0.6%)
ATROPINE SULFATE	0	1 (1.3%)	1 (0.6%)
AZITHROMYCIN	0	1 (1.3%)	1 (0.6%)
BETAMETHASONE DIPROPIONATE	0	1 (1.3%)	1 (0.6%)
BUTALBITAL	0	1 (1.3%)	1 (0.6%)
CARBAMAZEPINE	0	1 (1.3%)	1 (0.6%)
CHLOROXYLENOL	0	1 (1.3%)	1 (0.6%)
CHLORPHENAMINE TANNATE	0	1 (1.3%)	1 (0.6%)
CHLORPROMAZINE HYDROCHLORIDE	0	1 (1.3%)	1 (0.6%)
CINNAMEDRINE HYDROCHLORIDE	0	1 (1.3%)	1 (0.6%)
CYPROHEPTADINE	0	1 (1.3%)	1 (0.6%)
DICHLORALPHENAZONE	0	1 (1.3%)	1 (0.6%)
DOXYLAMINE SUCCINATE	0	1 (1.3%)	1 (0.6%)
ECONAZOLE NITRATE	0	1 (1.3%)	1 (0.6%)
ETHANOL	0	1 (1.3%)	1 (0.6%)
GRISEOFULVIN	0	1 (1.3%)	1 (0.6%)
HEPATITIS B VACCINE	0	1 (1.3%)	1 (0.6%)
HYDROCORTISONE	0	1 (1.3%)	1 (0.6%)
HYOSCINE HYDROBROMIDE	0	1 (1.3%)	1 (0.6%)
HYOSCYAMINE SULFATE	0	1 (1.3%)	1 (0.6%)
HYPERICUM EXTRACT	0	1 (1.3%)	1 (0.6%)
I.V. FLUIDS	0	1 (1.3%)	1 (0.6%)
IMIPRAMINE	0	1 (1.3%)	1 (0.6%)
IPECACUANHA, PREPARED	0	1 (1.3%)	1 (0.6%)
ISOMETHEPTENE	0	1 (1.3%)	1 (0.6%)
KETOCONAZOLE	0	1 (1.3%)	1 (0.6%)
MEPYRAMINE TANNATE	0	1 (1.3%)	1 (0.6%)
MINOCYCLINE HYDROCHLORIDE	0	1 (1.3%)	1 (0.6%)
MIRTAZAPINE	0	1 (1.3%)	1 (0.6%)
NAPHAZOLINE HYDROCHLORIDE	0	1 (1.3%)	1 (0.6%)
OFLOXACIN	0	1 (1.3%)	1 (0.6%)
PHENOBARBITAL	0	1 (1.3%)	1 (0.6%)
PHENYLEPHRINE TANNATE	0	1 (1.3%)	1 (0.6%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

Table 13.9.4

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase or Follow-up Phase
Intention-To-Treat Population entering the Taper Phase or Follow-Up Phase

	Acute Study Treatment Group		
Generic Term	Paroxetine (N=78)	Placebo (N=78)	Total (N=156)
PREDNISOLONE SODIUM PHOSPHATE	0	1 (1.3%)	1 (0.6%)
QUETIAPINE	0	1 (1.3%)	1 (0.6%)
SENNA FRUIT	0	1 (1.3%)	1 (0.6%)
TRIAMCINOLONE	0	1 (1.3%)	1 (0.6%)
TRIAMCINOLONE ACETONIDE	0	1 (1.3%)	1 (0.6%)
UNKNOWN MEDICATION	0	1 (1.3%)	1 (0.6%)
VENLAFAXINE	0	1 (1.3%)	1 (0.6%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase
Note:The numerator may be larger than the denominator, as it includes patients who did not enter the follow-up phase but had a concomitant medication which was started before the last dose of study/taper medication and has a missing stop date

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Table 13.10.1

Number (%) of Patients who Missed more than 3 Consecutive days of Open Label Study Medication at Each Visit
and Overall by Acute Study Treatment Group
Intention-To-Treat Population

Age Group : Children

	Acute Study Treatment Group					
	Paroxetine (N = 67)		Placebo (N = 72)		Total (N = 139)	
Visit	Missed > 3 Consecutive Days No	Yes	Missed > 3 Consecutive Days No	Yes	Missed > 3 Consecutive Days No	Yes
Week 1	62 (95.4%)	3 (4.6%)	71 (100.0%)	0	133(97.8%)	3 (2.2%)
Week 2	58 (100.0%)	0	68 (98.6%)	1 (1.4%)	126(99.2%)	1 (0.8%)
Week 3	60 (96.8%)	2 (3.2%)	64 (95.5%)	3 (4.5%)	124(96.1%)	5 (3.9%)
Week 4	58 (96.7%)	2 (3.3%)	59 (96.7%)	2 (3.3%)	117(96.7%)	4 (3.3%)
Week 6	56 (96.6%)	2 (3.4%)	58 (98.3%)	1 (1.7%)	114(97.4%)	3 (2.6%)
Week 8	50 (92.6%)	4 (7.4%)	49 (94.2%)	3 (5.8%)	99 (93.4%)	7 (6.6%)
Week 12	43 (91.5%)	4 (8.5%)	43 (91.5%)	4 (8.5%)	86 (91.5%)	8 (8.5%)
Week 16	35 (94.6%)	2 (5.4%)	37 (94.9%)	2 (5.1%)	72 (94.7%)	4 (5.3%)
Week 20	33 (100.0%)	0	31 (96.9%)	1 (3.1%)	64 (98.5%)	1 (1.5%)
Week 24	31 (93.9%)	2 (6.1%)	22 (91.7%)	2 (8.3%)	53 (93.0%)	4 (7.0%)
Overall*	49 (74.2%)	17 (25.8%)	54 (76.1%)	17 (23.9%)	103(75.2%)	34 (24.8%)

Note: Percentages are out of number of patients in each acute study treatment group who have this study medication information on the relevant CRF page, patients with unknown compliance and duration of study medication >3 days at that visit are considered non-compliant.
* Overall = Number of patients who miss >3 consecutive days at any point in the study.
Patients who miss >3 consecutive days on more than one occasion are only counted once.

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Table 13.10.1

Number (%) of Patients who Missed more than 3 Consecutive days of Open Label Study Medication at Each Visit
and Overall by Acute Study Treatment Group
Intention-To-Treat Population

Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine (N = 66)		Placebo (N = 58)		Total (N = 124)	
Visit	Missed > 3 Consecutive Days No	Yes	Missed > 3 Consecutive Days No	Yes	Missed > 3 Consecutive Days No	Yes
Week 1	63 (95.5%)	3 (4.5%)	56 (96.6%)	2 (3.4%)	119(96.0%)	5 (4.0%)
Week 2	63 (98.4%)	1 (1.6%)	52 (98.1%)	1 (1.9%)	115(98.3%)	2 (1.7%)
Week 3	56 (90.3%)	6 (9.7%)	51 (96.2%)	2 (3.8%)	107(93.0%)	8 (7.0%)
Week 4	58 (96.7%)	2 (3.3%)	48 (98.0%)	1 (2.0%)	106(97.2%)	3 (2.8%)
Week 6	58 (98.3%)	1 (1.7%)	46 (97.9%)	1 (2.1%)	104(98.1%)	2 (1.9%)
Week 8	54 (94.7%)	3 (5.3%)	40 (95.2%)	2 (4.8%)	94 (94.9%)	5 (5.1%)
Week 12	53 (96.4%)	2 (3.6%)	37 (97.4%)	1 (2.6%)	90 (96.8%)	3 (3.2%)
Week 16	47 (94.0%)	3 (6.0%)	33 (91.7%)	3 (8.3%)	80 (93.0%)	6 (7.0%)
Week 20	40 (97.6%)	1 (2.4%)	28 (96.6%)	1 (3.4%)	68 (97.1%)	2 (2.9%)
Week 24	35 (92.1%)	3 (7.9%)	23 (95.8%)	1 (4.2%)	58 (93.5%)	4 (6.5%)
Overall*	46 (69.7%)	20 (30.3%)	48 (82.8%)	10 (17.2%)	94 (75.8%)	30 (24.2%)

Note: Percentages are out of number of patients in each acute study treatment group who have this study medication information on the relevant CRF page, patients with unknown compliance and duration of study medication >3 days at that visit are considered non-compliant.
* Overall = Number of patients who miss >3 consecutive days at any point in the study.
Patients who miss >3 consecutive days on more than one occasion are only counted once.

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Table 13.10.1

Number (%) of Patients who Missed more than 3 Consecutive days of Open Label Study Medication at Each Visit
and Overall by Acute Study Treatment Group
Intention-To-Treat Population

Age Group : Total

	Acute Study Treatment Group					
	Paroxetine (N = 133)		Placebo (N = 130)		Total (N = 263)	
	Missed > 3 Consecutive Days		Missed > 3 Consecutive Days		Missed > 3 Consecutive Days	
Visit	No	Yes	No	Yes	No	Yes
Week 1	125(95.4%)	6 (4.6%)	127(98.4%)	2 (1.6%)	252(96.9%)	8 (3.1%)
Week 2	121(99.2%)	1 (0.8%)	120(98.4%)	2 (1.6%)	241(98.8%)	3 (1.2%)
Week 3	116(93.5%)	8 (6.5%)	115(95.8%)	5 (4.2%)	231(94.7%)	13 (5.3%)
Week 4	116(96.7%)	4 (3.3%)	107(97.3%)	3 (2.7%)	223(97.0%)	7 (3.0%)
Week 6	114(97.4%)	3 (2.6%)	104(98.1%)	2 (1.9%)	218(97.8%)	5 (2.2%)
Week 8	104(93.7%)	7 (6.3%)	89 (94.7%)	5 (5.3%)	193(94.1%)	12 (5.9%)
Week 12	96 (94.1%)	6 (5.9%)	80 (94.1%)	5 (5.9%)	176(94.1%)	11 (5.9%)
Week 16	82 (94.3%)	5 (5.7%)	70 (93.3%)	5 (6.7%)	152(93.8%)	10 (6.2%)
Week 20	73 (98.6%)	1 (1.4%)	59 (96.7%)	2 (3.3%)	132(97.8%)	3 (2.2%)
Week 24	66 (93.0%)	5 (7.0%)	45 (93.8%)	3 (6.3%)	111(93.3%)	8 (6.7%)
Overall*	95 (72.0%)	37 (28.0%)	102(79.1%)	27 (20.9%)	197(75.5%)	64 (24.5%)

Note: Percentages are out of number of patients in each acute study treatment group who have this study medication information on the relevant CRF page, patients with unknown compliance and duration of study medication >3 days at that visit are considered non-compliant.
* Overall = Number of patients who miss >3 consecutive days at any point in the study.
Patients who miss >3 consecutive days on more than one occasion are only counted once.

Table 13.10.2

Tablet Accountability (number (%) of patients) at Each Visit and Overall by Acute Study Treatment Group

Intention-To-Treat Population

Age Group : Children

	Paroxetine (N=67)		Placebo (N=72)		Total (N=139)	
	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)
Week 1	57 (90.5%)	6 (9.5%)	63 (92.6%)	5 (7.4%)	120 (91.6%)	11 (8.4%)
Week 2	49 (86.0%)	8 (14.0%)	61 (91.0%)	6 (9.0%)	110 (88.7%)	14 (11.3%)
Week 3	54 (91.5%)	5 (8.5%)	57 (89.1%)	7 (10.9%)	111 (90.2%)	12 (9.8%)
Week 4	48 (85.7%)	8 (14.3%)	49 (83.1%)	10 (16.9%)	97 (84.3%)	18 (15.7%)
Week 6	41 (80.4%)	10 (19.6%)	48 (81.4%)	11 (18.6%)	89 (80.9%)	21 (19.1%)
Week 8	38 (77.6%)	11 (22.4%)	40 (81.6%)	9 (18.4%)	78 (79.6%)	20 (20.4%)
Week 12	37 (88.1%)	5 (11.9%)	37 (86.0%)	6 (14.0%)	74 (87.1%)	11 (12.9%)
Week 16	33 (94.3%)	2 (5.7%)	29 (85.3%)	5 (14.7%)	62 (89.9%)	7 (10.1%)
Week 20	24 (82.8%)	5 (17.2%)	28 (93.3%)	2 (6.7%)	52 (88.1%)	7 (11.9%)
Week 24	24 (85.7%)	4 (14.3%)	19 (90.5%)	2 (9.5%)	43 (87.8%)	6 (12.2%)
Overall**	37 (94.9%)	2 (5.1%)	41 (87.2%)	6 (12.8%)	78 (90.7%)	8 (9.3%)

* Accountability at each visit is defined as the result of the following calculation falling within the 80%-120% band:
[(Total no. of Capsules Dispensed for the Visit - Total no. of Capsules Returned for the Visit) /
sum for each record in the CRF corresponding to the visit (No. of Days * No. of Capsules Per Day)] * 100

** Accountability overall is defined as the result of the following calculation falling within the 80%-120% band:
[(Total No. of Caps Dispensed - Total No. of Caps Returned) / {Sum for each visit (No. of Days * No. of Caps Per Day)}] * 100
Note: No. of Days = Stop Date - Start Date + 1

Note: Percentages are out of number of patients in each acute study treatment group who have this study medication information on the relevant CRF page.

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Table 13.10.2

Tablet Accountability (number (%) of patients) at Each Visit and Overall by Acute Study Treatment Group

Intention-To-Treat Population

Age Group : Adolescents

	Paroxetine (N=66)		Placebo (N=58)		Total (N=124)	
	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)
Week 1	50 (82.0%)	11 (18.0%)	44 (75.9%)	14 (24.1%)	94 (79.0%)	25 (21.0%)
Week 2	46 (76.7%)	14 (23.3%)	43 (81.1%)	10 (18.9%)	89 (78.8%)	24 (21.2%)
Week 3	50 (84.7%)	9 (15.3%)	44 (89.8%)	5 (10.2%)	94 (87.0%)	14 (13.0%)
Week 4	49 (83.1%)	10 (16.9%)	39 (84.8%)	7 (15.2%)	88 (83.8%)	17 (16.2%)
Week 6	48 (82.8%)	10 (17.2%)	41 (93.2%)	3 (6.8%)	89 (87.3%)	13 (12.7%)
Week 8	43 (81.1%)	10 (18.9%)	36 (85.7%)	6 (14.3%)	79 (83.2%)	16 (16.8%)
Week 12	42 (79.2%)	11 (20.8%)	30 (88.2%)	4 (11.8%)	72 (82.8%)	15 (17.2%)
Week 16	41 (87.2%)	6 (12.8%)	32 (94.1%)	2 (5.9%)	73 (90.1%)	8 (9.9%)
Week 20	34 (89.5%)	4 (10.5%)	24 (88.9%)	3 (11.1%)	58 (89.2%)	7 (10.8%)
Week 24	30 (81.1%)	7 (18.9%)	20 (87.0%)	3 (13.0%)	50 (83.3%)	10 (16.7%)
Overall**	42 (93.3%)	3 (6.7%)	38 (97.4%)	1 (2.6%)	80 (95.2%)	4 (4.8%)

* Accountability at each visit is defined as the result of the following calculation falling within the 80%-120% band:
[(Total no. of Capsules Dispensed for the Visit - Total no. of Capsules Returned for the Visit) /
sum for each record in the CRF corresponding to the visit (No. of Days * No. of Capsules Per Day)] * 100

** Accountability overall is defined as the result of the following calculation falling within the 80%-120% band:
[(Total No. of Caps Dispensed - Total No. of Caps Returned) / {Sum for each visit (No. of Days * No. of Caps Per Day)}] * 100

Note: No. of Days = Stop Date - Start Date + 1

Note: Percentages are out of number of patients in each acute study treatment group who have this study medication information on the relevant CRF page.

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Table 13.10.2

Tablet Accountability (number (%) of patients) at Each Visit and Overall by Acute Study Treatment Group

Intention-To-Treat Population

Age Group : Total

	Paroxetine (N=133)		Placebo (N=130)		Total (N=263)	
	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)
Week 1	107 (86.3%)	17 (13.7%)	107 (84.9%)	19 (15.1%)	214 (85.6%)	36 (14.4%)
Week 2	95 (81.2%)	22 (18.8%)	104 (86.7%)	16 (13.3%)	199 (84.0%)	38 (16.0%)
Week 3	104 (88.1%)	14 (11.9%)	101 (89.4%)	12 (10.6%)	205 (88.7%)	26 (11.3%)
Week 4	97 (84.3%)	18 (15.7%)	88 (83.8%)	17 (16.2%)	185 (84.1%)	35 (15.9%)
Week 6	89 (81.7%)	20 (18.3%)	89 (86.4%)	14 (13.6%)	178 (84.0%)	34 (16.0%)
Week 8	81 (79.4%)	21 (20.6%)	76 (83.5%)	15 (16.5%)	157 (81.3%)	36 (18.7%)
Week 12	79 (83.2%)	16 (16.8%)	67 (87.0%)	10 (13.0%)	146 (84.9%)	26 (15.1%)
Week 16	74 (90.2%)	8 (9.8%)	61 (89.7%)	7 (10.3%)	135 (90.0%)	15 (10.0%)
Week 20	58 (86.6%)	9 (13.4%)	52 (91.2%)	5 (8.8%)	110 (88.7%)	14 (11.3%)
Week 24	54 (83.1%)	11 (16.9%)	39 (88.6%)	5 (11.4%)	93 (85.3%)	16 (14.7%)
Overall**	79 (94.0%)	5 (6.0%)	79 (91.9%)	7 (8.1%)	158 (92.9%)	12 (7.1%)

* Accountability at each visit is defined as the result of the following calculation falling within the 80%-120% band:
[(Total no. of Capsules Dispensed for the Visit - Total no. of Capsules Returned for the Visit) /
sum for each record in the CRF corresponding to the visit (No. of Days * No. of Capsules Per Day)] * 100

** Accountability overall is defined as the result of the following calculation falling within the 80%-120% band:
[(Total No. of Caps Dispensed - Total No. of Caps Returned) / {Sum for each visit (No. of Days * No. of Caps Per Day)}] * 100

Note: No. of Days = Stop Date - Start Date + 1

Note: Percentages are out of number of patients in each acute study treatment group who have this study medication information on the relevant CRF page.

Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: MDD
Age Group: Children

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	59	78.7	7	9.3	8	10.7	1	1.3	0	0.0	75	100.0
Week 2	29	40.8	32	45.1	7	9.9	3	4.2	0	0.0	71	100.0
Week 3	19	27.5	28	40.6	20	29.0	2	2.9	0	0.0	69	100.0
Week 4	16	24.2	26	39.4	19	28.8	5	7.6	0	0.0	66	100.0
Week 6	13	20.3	25	39.1	19	29.7	6	9.4	1	1.6	64	100.0
Week 8	11	19.0	20	34.5	20	34.5	7	12.1	0	0.0	58	100.0
Week 12	9	17.3	18	34.6	17	32.7	7	13.5	1	1.9	52	100.0
Week 16	8	18.2	14	31.8	16	36.4	2	4.5	4	9.1	44	100.0
Week 20	5	14.7	11	32.4	10	29.4	5	14.7	3	8.8	34	100.0
Week 24	6	18.2	12	36.4	10	30.3	1	3.0	4	12.1	33	100.0

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Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: MDD
Age Group: Adolescents

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	51	70.8	10	13.9	11	15.3	0	0.0	0	0.0	72	100.0
Week 2	15	22.1	40	58.8	12	17.6	1	1.5	0	0.0	68	100.0
Week 3	8	11.9	33	49.3	23	34.3	3	4.5	0	0.0	67	100.0
Week 4	7	10.8	30	46.2	25	38.5	3	4.6	0	0.0	65	100.0
Week 6	5	8.1	29	46.8	25	40.3	1	1.6	2	3.2	62	100.0
Week 8	4	6.8	24	40.7	25	42.4	6	10.2	0	0.0	59	100.0
Week 12	3	5.4	22	39.3	23	41.1	7	12.5	1	1.8	56	100.0
Week 16	3	5.8	19	36.5	23	44.2	7	13.5	0	0.0	52	100.0
Week 20	4	8.9	17	37.8	12	26.7	11	24.4	1	2.2	45	100.0
Week 24	3	7.7	16	41.0	11	28.2	7	17.9	2	5.1	39	100.0

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Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: MDD
Age Group: Total

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	110	74.8	17	11.6	19	12.9	1	0.7	0	0.0	147	100.0
Week 2	44	31.7	72	51.8	19	13.7	4	2.9	0	0.0	139	100.0
Week 3	27	19.9	61	44.9	43	31.6	5	3.7	0	0.0	136	100.0
Week 4	23	17.6	56	42.7	44	33.6	8	6.1	0	0.0	131	100.0
Week 6	18	14.3	54	42.9	44	34.9	7	5.6	3	2.4	126	100.0
Week 8	15	12.8	44	37.6	45	38.5	13	11.1	0	0.0	117	100.0
Week 12	12	11.1	40	37.0	40	37.0	14	13.0	2	1.9	108	100.0
Week 16	11	11.5	33	34.4	39	40.6	9	9.4	4	4.2	96	100.0
Week 20	9	11.4	28	35.4	22	27.8	16	20.3	4	5.1	79	100.0
Week 24	9	12.5	28	38.9	21	29.2	8	11.1	6	8.3	72	100.0

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Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: OCD
Age Group: Children

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	59	93.7	3	4.8	1	1.6	0	0.0	0	0.0	63	100.0
Week 2	18	31.6	34	59.6	5	8.8	0	0.0	0	0.0	57	100.0
Week 3	11	18.3	32	53.3	15	25.0	2	3.3	0	0.0	60	100.0
Week 4	7	12.3	28	49.1	15	26.3	5	8.8	2	3.5	57	100.0
Week 6	7	13.0	21	38.9	16	29.6	7	13.0	3	5.6	54	100.0
Week 8	7	14.6	14	29.2	18	37.5	4	8.3	5	10.4	48	100.0
Week 12	4	9.5	16	38.1	13	31.0	5	11.9	4	9.5	42	100.0
Week 16	4	11.8	14	41.2	9	26.5	5	14.7	2	5.9	34	100.0
Week 20	5	16.1	13	41.9	8	25.8	4	12.9	1	3.2	31	100.0
Week 24	4	14.8	12	44.4	8	29.6	3	11.1	0	0.0	27	100.0

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Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: OCD
Age Group: Adolescents

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	46	88.5	4	7.7	2	3.8	0	0.0	0	0.0	52	100.0
Week 2	6	12.2	36	73.5	7	14.3	0	0.0	0	0.0	49	100.0
Week 3	2	4.1	20	40.8	23	46.9	4	8.2	0	0.0	49	100.0
Week 4	3	6.5	9	19.6	19	41.3	11	23.9	4	8.7	46	100.0
Week 6	1	2.2	8	17.4	14	30.4	13	28.3	10	21.7	46	100.0
Week 8	1	2.4	9	21.4	9	21.4	13	31.0	10	23.8	42	100.0
Week 12	1	2.7	7	18.9	8	21.6	8	21.6	13	35.1	37	100.0
Week 16	1	2.9	7	20.6	9	26.5	5	14.7	12	35.3	34	100.0
Week 20	1	3.6	5	17.9	5	17.9	6	21.4	11	39.3	28	100.0
Week 24	0	0.0	4	17.4	4	17.4	4	17.4	11	47.8	23	100.0

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Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: OCD
Age Group: Total

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	105	91.3	7	6.1	3	2.6	0	0.0	0	0.0	115	100.0
Week 2	24	22.6	70	66.0	12	11.3	0	0.0	0	0.0	106	100.0
Week 3	13	11.9	52	47.7	38	34.9	6	5.5	0	0.0	109	100.0
Week 4	10	9.7	37	35.9	34	33.0	16	15.5	6	5.8	103	100.0
Week 6	8	8.0	29	29.0	30	30.0	20	20.0	13	13.0	100	100.0
Week 8	8	8.9	23	25.6	27	30.0	17	18.9	15	16.7	90	100.0
Week 12	5	6.3	23	29.1	21	26.6	13	16.5	17	21.5	79	100.0
Week 16	5	7.4	21	30.9	18	26.5	10	14.7	14	20.6	68	100.0
Week 20	6	10.2	18	30.5	13	22.0	10	16.9	12	20.3	59	100.0
Week 24	4	8.0	16	32.0	12	24.0	7	14.0	11	22.0	50	100.0

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Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: Total
Age Group: Children

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	118	85.5	10	7.2	9	6.5	1	0.7	0	0.0	138	100.0
Week 2	47	36.7	66	51.6	12	9.4	3	2.3	0	0.0	128	100.0
Week 3	30	23.3	60	46.5	35	27.1	4	3.1	0	0.0	129	100.0
Week 4	23	18.7	54	43.9	34	27.6	10	8.1	2	1.6	123	100.0
Week 6	20	16.9	46	39.0	35	29.7	13	11.0	4	3.4	118	100.0
Week 8	18	17.0	34	32.1	38	35.8	11	10.4	5	4.7	106	100.0
Week 12	13	13.8	34	36.2	30	31.9	12	12.8	5	5.3	94	100.0
Week 16	12	15.4	28	35.9	25	32.1	7	9.0	6	7.7	78	100.0
Week 20	10	15.4	24	36.9	18	27.7	9	13.8	4	6.2	65	100.0
Week 24	10	16.7	24	40.0	18	30.0	4	6.7	4	6.7	60	100.0

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Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: Total
Age Group: Adolescents

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	97	78.2	14	11.3	13	10.5	0	0.0	0	0.0	124	100.0
Week 2	21	17.9	76	65.0	19	16.2	1	0.9	0	0.0	117	100.0
Week 3	10	8.6	53	45.7	46	39.7	7	6.0	0	0.0	116	100.0
Week 4	10	9.0	39	35.1	44	39.6	14	12.6	4	3.6	111	100.0
Week 6	6	5.6	37	34.3	39	36.1	14	13.0	12	11.1	108	100.0
Week 8	5	5.0	33	32.7	34	33.7	19	18.8	10	9.9	101	100.0
Week 12	4	4.3	29	31.2	31	33.3	15	16.1	14	15.1	93	100.0
Week 16	4	4.7	26	30.2	32	37.2	12	14.0	12	14.0	86	100.0
Week 20	5	6.8	22	30.1	17	23.3	17	23.3	12	16.4	73	100.0
Week 24	3	4.8	20	32.3	15	24.2	11	17.7	13	21.0	62	100.0

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Table 13.10.3

Number (%) of Patients Exposed to each Study Medication Dosage at each Visit

Intention-To-Treat Population
Primary Diagnosis: Total
Age Group: Total

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	215	82.1	24	9.2	22	8.4	1	0.4	0	0.0	262	100.0
Week 2	68	27.8	142	58.0	31	12.7	4	1.6	0	0.0	245	100.0
Week 3	40	16.3	113	46.1	81	33.1	11	4.5	0	0.0	245	100.0
Week 4	33	14.1	93	39.7	78	33.3	24	10.3	6	2.6	234	100.0
Week 6	26	11.5	83	36.7	74	32.7	27	11.9	16	7.1	226	100.0
Week 8	23	11.1	67	32.4	72	34.8	30	14.5	15	7.2	207	100.0
Week 12	17	9.1	63	33.7	61	32.6	27	14.4	19	10.2	187	100.0
Week 16	16	9.8	54	32.9	57	34.8	19	11.6	18	11.0	164	100.0
Week 20	15	10.9	46	33.3	35	25.4	26	18.8	16	11.6	138	100.0
Week 24	13	10.7	44	36.1	33	27.0	15	12.3	17	13.9	122	100.0

Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: MDD
Age Group: Children

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
12 (16.0%)	20 (26.7%)	29 (38.7%)	7 (9.3%)	7 (9.3%)	75 (100.0%)

BRL 29060 - 716

Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: MDD
Age Group: Adolescents

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
6 (8.3%)	15 (20.8%)	29 (40.3%)	17 (23.6%)	5 (6.9%)	72 (100.0%)

BRL 29060 - 716

Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: MDD
Age Group: Total

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
18 (12.2%)	35 (23.8%)	58 (39.5%)	24 (16.3%)	12 (8.2%)	147 (100.0%)

BRL 29060 - 716

Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: OCD
Age Group: Children

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
3 (4.7%)	24 (37.5%)	21 (32.8%)	10 (15.6%)	6 (9.4%)	64 (100.0%)

BRL 29060 - 716

Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: OCD
Age Group: Adolescents

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
3 (5.8%)	7 (13.5%)	10 (19.2%)	11 (21.2%)	21 (40.4%)	52 (100.0%)

BRL 29060 - 716

Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: OCD
Age Group: Total

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
6 (5.2%)	31 (26.7%)	31 (26.7%)	21 (18.1%)	27 (23.3%)	116 (100.0%)

BRL 29060 - 716

Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: Total
Age Group: Children

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
15 (10.8%)	44 (31.7%)	50 (36.0%)	17 (12.2%)	13 (9.4%)	139 (100.0%)

BRL 29060 - 716

Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: Total
Age Group: Adolescents

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
9 (7.3%)	22 (17.7%)	39 (31.5%)	28 (22.6%)	26 (21.0%)	124 (100.0%)

BRL 29060 - 716

Table 13.10.4

Number (%) of Patients by Maximum Daily Dosage of Open-Label Study Medication at any time During the Study

Intention-To-Treat Population
Primary Diagnosis: Total
Age Group: Total

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
24 (9.1%)	66 (25.1%)	89 (33.8%)	45 (17.1%)	39 (14.8%)	263 (100.0%)

Table 13.10.5.1b

Overall Duration of Exposure to Open-Label Study Medication (Excluding Taper Medication) by Acute Study Treatment Group

Intention-To-Treat Population

Age Group: Children

Days	Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
	------Acute Study Treatment Group-------		
>= 1	67 (100.0%)	72 (100.0%)	139 (100.0%)
> 7	65 (97.0%)	71 (98.6%)	136 (97.8%)
> 14	63 (94.0%)	69 (95.8%)	132 (95.0%)
> 21	62 (92.5%)	66 (91.7%)	128 (92.1%)
> 28	62 (92.5%)	64 (88.9%)	126 (90.6%)
> 42	56 (83.6%)	57 (79.2%)	113 (81.3%)
> 56	53 (79.1%)	50 (69.4%)	103 (74.1%)
> 70	45 (67.2%)	45 (62.5%)	90 (64.7%)
> 84	42 (62.7%)	41 (56.9%)	83 (59.7%)
> 112	36 (53.7%)	35 (48.6%)	71 (51.1%)
> 140	35 (52.2%)	27 (37.5%)	62 (44.6%)
> 168	22 (32.8%)	17 (23.6%)	39 (28.1%)
> 182	6 (9.0%)	6 (8.3%)	12 (8.6%)
Overall Mean	117.2	104.7	110.7
Minimum	2	2	2
Maximum	195	197	197

Note: Day 1 = Study 716 Baseline

BRL 29060 - 716

Table 13.10.5.1b

Overall Duration of Exposure to Open-Label Study Medication (Excluding Taper Medication) by Acute Study Treatment Group

Intention-To-Treat Population

Age Group: Adolescents

Days	Acute Study Treatment Group: Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
>= 1	66 (100.0%)	58 (100.0%)	124 (100.0%)
> 7	65 (98.5%)	57 (98.3%)	122 (98.4%)
> 14	65 (98.5%)	54 (93.1%)	119 (96.0%)
> 21	62 (93.9%)	53 (91.4%)	115 (92.7%)
> 28	61 (92.4%)	52 (89.7%)	113 (91.1%)
> 42	58 (87.9%)	45 (77.6%)	103 (83.1%)
> 56	56 (84.8%)	40 (69.0%)	96 (77.4%)
> 70	55 (83.3%)	36 (62.1%)	91 (73.4%)
> 84	54 (81.8%)	36 (62.1%)	90 (72.6%)
> 112	46 (69.7%)	32 (55.2%)	78 (62.9%)
> 140	39 (59.1%)	26 (44.8%)	65 (52.4%)
> 168	22 (33.3%)	16 (27.6%)	38 (30.6%)
> 182	5 (7.6%)	2 (3.4%)	7 (5.6%)
Overall Mean	133.0	110.3	122.4
Minimum	2	2	2
Maximum	187	204	204

Note: Day 1 = Study 716 Baseline

BRL 29060 - 716

Table 13.10.5.1b

Overall Duration of Exposure to Open-Label Study Medication (Excluding Taper Medication) by Acute Study Treatment Group

Intention-To-Treat Population

Age Group: Total

Days	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
>= 1	133 (100.0%)	130 (100.0%)	263 (100.0%)
> 7	130 (97.7%)	128 (98.5%)	258 (98.1%)
> 14	128 (96.2%)	123 (94.6%)	251 (95.4%)
> 21	124 (93.2%)	119 (91.5%)	243 (92.4%)
> 28	123 (92.5%)	116 (89.2%)	239 (90.9%)
> 42	114 (85.7%)	102 (78.5%)	216 (82.1%)
> 56	109 (82.0%)	90 (69.2%)	199 (75.7%)
> 70	100 (75.2%)	81 (62.3%)	181 (68.8%)
> 84	96 (72.2%)	77 (59.2%)	173 (65.8%)
> 112	82 (61.7%)	67 (51.5%)	149 (56.7%)
> 140	74 (55.6%)	53 (40.8%)	127 (48.3%)
> 168	44 (33.1%)	33 (25.4%)	77 (29.3%)
> 182	11 (8.3%)	8 (6.2%)	19 (7.2%)
Overall Mean	125.1	107.2	116.2
Minimum	2	2	2
Maximum	195	204	204

Note: Day 1 = Study 716 Baseline

Table 13.10.5.1d

Overall Duration of Exposure to Paroxetine Study Medication (Excluding Acute Study Taper Medication and Open-Label Taper Medication)

Pure Paroxetine Population

Age Group: Children

Days	Paroxetine (N=50)
>= 1	50 (100.0%)
> 7	50 (100.0%)
> 14	50 (100.0%)
> 21	50 (100.0%)
> 28	50 (100.0%)
> 42	50 (100.0%)
> 56	50 (100.0%)
> 70	49 (98.0%)
> 84	47 (94.0%)
> 112	43 (86.0%)
> 140	34 (68.0%)
> 168	28 (56.0%)
> 182	28 (56.0%)
> 196	28 (56.0%)
> 224	24 (48.0%)
> 238	13 (26.0%)
> 252	2 (4.0%)
> 266	0 (0.0%)
Overall Mean	186.7
Minimum	58
Maximum	264

Note: Day 1 = Acute Study Baseline

BRL 29060 - 716

Table 13.10.5.1d

Overall Duration of Exposure to Paroxetine Study Medication (Excluding Acute Study Taper Medication and Open-Label Taper Medication)

Pure Paroxetine Population

Age Group: Adolescents

Days	Paroxetine (N=46)
>= 1	46 (100.0%)
> 7	46 (100.0%)
> 14	46 (100.0%)
> 21	46 (100.0%)
> 28	46 (100.0%)
> 42	46 (100.0%)
> 56	46 (100.0%)
> 70	46 (100.0%)
> 84	44 (95.7%)
> 112	40 (87.0%)
> 140	38 (82.6%)
> 168	33 (71.7%)
> 182	31 (67.4%)
> 196	28 (60.9%)
> 224	21 (45.7%)
> 238	11 (23.9%)
> 252	3 (6.5%)
> 266	0 (0.0%)
Overall Mean	197.3
Minimum	73
Maximum	264

Note: Day 1 = Acute Study Baseline

BRL 29060 - 716

Table 13.10.5.1d

Overall Duration of Exposure to Paroxetine Study Medication (Excluding Acute Study Taper Medication and Open-Label Taper Medication)

Pure Paroxetine Population

Age Group: Total

Days	Paroxetine (N=96)
>= 1	96 (100.0%)
> 7	96 (100.0%)
> 14	96 (100.0%)
> 21	96 (100.0%)
> 28	96 (100.0%)
> 42	96 (100.0%)
> 56	96 (100.0%)
> 70	95 (99.0%)
> 84	91 (94.8%)
> 112	83 (86.5%)
> 140	72 (75.0%)
> 168	61 (63.5%)
> 182	59 (61.5%)
> 196	56 (58.3%)
> 224	45 (46.9%)
> 238	24 (25.0%)
> 252	5 (5.2%)
> 266	0 (0.0%)
Overall Mean	191.8
Minimum	58
Maximum	264

Note: Day 1 = Acute Study Baseline

Table 13.10.5.2b

Overall Duration of Exposure to Open-Label Study Medication (Including Taper Medication) by Acute Study Treatment Group

Intention-To-Treat Population

Age Group: Children

Days	Acute Study Treatment Group: Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
>= 1	67 (100.0%)	72 (100.0%)	139 (100.0%)
> 7	65 (97.0%)	71 (98.6%)	136 (97.8%)
> 14	63 (94.0%)	69 (95.8%)	132 (95.0%)
> 21	62 (92.5%)	67 (93.1%)	129 (92.8%)
> 28	62 (92.5%)	65 (90.3%)	127 (91.4%)
> 42	56 (83.6%)	57 (79.2%)	113 (81.3%)
> 56	53 (79.1%)	52 (72.2%)	105 (75.5%)
> 70	46 (68.7%)	48 (66.7%)	94 (67.6%)
> 84	42 (62.7%)	42 (58.3%)	84 (60.4%)
> 112	36 (53.7%)	35 (48.6%)	71 (51.1%)
> 140	35 (52.2%)	29 (40.3%)	64 (46.0%)
> 168	25 (37.3%)	19 (26.4%)	44 (31.7%)
> 182	12 (17.9%)	9 (12.5%)	21 (15.1%)
> 196	3 (4.5%)	2 (2.8%)	5 (3.6%)
Overall Mean	120.6	108.2	114.2
Minimum	2	2	2
Maximum	210	201	210

Note: Day 1 = Study 716 Baseline

BRL 29060 - 716

Table 13.10.5.2b

Overall Duration of Exposure to Open-Label Study Medication (Including Taper Medication) by Acute Study Treatment Group

Intention-To-Treat Population

Age Group: Adolescents

Days	Acute Study Treatment Group: Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
>= 1	66 (100.0%)	58 (100.0%)	124 (100.0%)
> 7	65 (98.5%)	57 (98.3%)	122 (98.4%)
> 14	65 (98.5%)	54 (93.1%)	119 (96.0%)
> 21	62 (93.9%)	53 (91.4%)	115 (92.7%)
> 28	61 (92.4%)	52 (89.7%)	113 (91.1%)
> 42	58 (87.9%)	46 (79.3%)	104 (83.9%)
> 56	56 (84.8%)	41 (70.7%)	97 (78.2%)
> 70	55 (83.3%)	36 (62.1%)	91 (73.4%)
> 84	54 (81.8%)	36 (62.1%)	90 (72.6%)
> 112	48 (72.7%)	32 (55.2%)	80 (64.5%)
> 140	41 (62.1%)	26 (44.8%)	67 (54.0%)
> 168	25 (37.9%)	17 (29.3%)	42 (33.9%)
> 182	13 (19.7%)	9 (15.5%)	22 (17.7%)
> 196	2 (3.0%)	2 (3.4%)	4 (3.2%)
Overall Mean	137.6	113.5	126.3
Minimum	2	2	2
Maximum	211	225	225

Note: Day 1 = Study 716 Baseline

BRL 29060 - 716

Table 13.10.5.2b

Overall Duration of Exposure to Open-Label Study Medication (Including Taper Medication) by Acute Study Treatment Group

Intention-To-Treat Population

Age Group: Total

Days	Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
	------Acute Study Treatment Group-------		
>= 1	133 (100.0%)	130 (100.0%)	263 (100.0%)
> 7	130 (97.7%)	128 (98.5%)	258 (98.1%)
> 14	128 (96.2%)	123 (94.6%)	251 (95.4%)
> 21	124 (93.2%)	120 (92.3%)	244 (92.8%)
> 28	123 (92.5%)	117 (90.0%)	240 (91.3%)
> 42	114 (85.7%)	103 (79.2%)	217 (82.5%)
> 56	109 (82.0%)	93 (71.5%)	202 (76.8%)
> 70	101 (75.9%)	84 (64.6%)	185 (70.3%)
> 84	96 (72.2%)	78 (60.0%)	174 (66.2%)
> 112	84 (63.2%)	67 (51.5%)	151 (57.4%)
> 140	76 (57.1%)	55 (42.3%)	131 (49.8%)
> 168	50 (37.6%)	36 (27.7%)	86 (32.7%)
> 182	25 (18.8%)	18 (13.8%)	43 (16.3%)
> 196	5 (3.8%)	4 (3.1%)	9 (3.4%)
Overall Mean	129.0	110.5	119.9
Minimum	2	2	2
Maximum	211	225	225

Note: Day 1 = Study 716 Baseline

Table 13.10.5.2d

Overall Duration of Exposure to Paroxetine Study Medication (Including Acute Study Taper Medication and Open-Label Taper Medication)

Pure Paroxetine Population

Age Group: Children

Days	Paroxetine (N=50)
>= 1	50 (100.0%)
> 7	50 (100.0%)
> 14	50 (100.0%)
> 21	50 (100.0%)
> 28	50 (100.0%)
> 42	50 (100.0%)
> 56	50 (100.0%)
> 70	49 (98.0%)
> 84	48 (96.0%)
> 112	44 (88.0%)
> 140	37 (74.0%)
> 168	32 (64.0%)
> 182	30 (60.0%)
> 196	28 (56.0%)
> 224	25 (50.0%)
> 238	22 (44.0%)
> 252	18 (36.0%)
> 266	10 (20.0%)
> 280	2 (4.0%)
> 294	0 (0.0%)
> 308	0 (0.0%)
> 322	0 (0.0%)
Overall Mean	202.5
Minimum	65
Maximum	289

Note: Day 1 = Acute Study Baseline

BRL 29060 - 716

Table 13.10.5.2d

Overall Duration of Exposure to Paroxetine Study Medication (Including Acute Study Taper Medication and Open-Label Taper Medication)

Pure Paroxetine Population

Age Group: Adolescents

Days	Paroxetine (N=46)
>= 1	46 (100.0%)
> 7	46 (100.0%)
> 14	46 (100.0%)
> 21	46 (100.0%)
> 28	46 (100.0%)
> 42	46 (100.0%)
> 56	46 (100.0%)
> 70	46 (100.0%)
> 84	45 (97.8%)
> 112	42 (91.3%)
> 140	41 (89.1%)
> 168	37 (80.4%)
> 182	34 (73.9%)
> 196	30 (65.2%)
> 224	28 (60.9%)
> 238	23 (50.0%)
> 252	16 (34.8%)
> 266	7 (15.2%)
> 280	4 (8.7%)
> 294	1 (2.2%)
> 308	0 (0.0%)
> 322	0 (0.0%)
Overall Mean	218.7
Minimum	74
Maximum	304

Note: Day 1 = Acute Study Baseline

BRL 29060 - 716

Table 13.10.5.2d

Overall Duration of Exposure to Paroxetine Study Medication (Including Acute Study Taper Medication and Open-Label Taper Medication)

Pure Paroxetine Population

Age Group: Total

Days	Paroxetine (N=96)
>= 1	96 (100.0%)
> 7	96 (100.0%)
> 14	96 (100.0%)
> 21	96 (100.0%)
> 28	96 (100.0%)
> 42	96 (100.0%)
> 56	96 (100.0%)
> 70	95 (99.0%)
> 84	93 (96.9%)
> 112	86 (89.6%)
> 140	78 (81.3%)
> 168	69 (71.9%)
> 182	64 (66.7%)
> 196	58 (60.4%)
> 224	53 (55.2%)
> 238	45 (46.9%)
> 252	34 (35.4%)
> 266	17 (17.7%)
> 280	6 (6.3%)
> 294	1 (1.0%)
> 308	0 (0.0%)
> 322	0 (0.0%)
Overall Mean	210.3
Minimum	65
Maximum	304

Note: Day 1 = Acute Study Baseline

Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : MDD
Age Group: : Children

Visit	N	Mean	Std Dev
Week 1	75	13.5	7.26
Week 2	71	17.7	7.96
Week 3	69	20.7	8.28
Week 4	66	22.0	8.98
Week 6	64	23.3	9.60
Week 8	58	24.0	9.35
Week 12	52	24.8	10.00
Week 16	44	25.5	11.30
Week 20	35	26.7	11.69
Week 24	33	25.5	12.01
Overall Mean	75	20.6	7.86

Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : MDD
Age Group: : Adolescents

Visit	N	Mean	Std Dev
Week 1	72	14.4	7.48
Week 2	68	19.9	6.80
Week 3	67	23.1	7.43
Week 4	65	23.7	7.41
Week 6	62	24.5	8.03
Week 8	59	25.6	7.72
Week 12	56	26.6	8.37
Week 16	52	26.5	7.89
Week 20	45	27.3	10.09
Week 24	39	27.2	10.25
Overall Mean	72	22.8	6.63

BRL 29060 - 716

Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : MDD
Age Group: : Total

Visit	N	Mean	Std Dev
Week 1	147	13.9	7.36
Week 2	139	18.8	7.47
Week 3	136	21.9	7.94
Week 4	131	22.8	8.25
Week 6	126	23.9	8.85
Week 8	117	24.8	8.57
Week 12	108	25.7	9.19
Week 16	96	26.0	9.57
Week 20	80	27.1	10.75
Week 24	72	26.4	11.04
Overall Mean	147	21.7	7.34

Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : OCD
Age Group: : Children

Visit	N	Mean	Std Dev
Week 1	63	10.8	3.26
Week 2	57	17.7	5.98
Week 3	60	21.3	7.47
Week 4	57	24.2	9.44
Week 6	54	25.9	10.55
Week 8	48	27.1	11.48
Week 12	42	27.4	11.06
Week 16	34	26.2	10.74
Week 20	31	24.5	10.28
Week 24	27	23.7	8.84
Overall Mean	64	21.3	7.47

BRL 29060 - 716

Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : OCD
Age Group: : Adolescents

Visit	N	Mean	Std Dev
Week 1	52	11.5	4.60
Week 2	49	20.2	5.20
Week 3	49	25.9	7.05
Week 4	46	30.9	10.29
Week 6	46	35.0	10.90
Week 8	42	35.2	11.53
Week 12	37	36.8	12.26
Week 16	34	35.9	12.58
Week 20	28	37.5	12.66
Week 24	23	39.6	11.86
Overall Mean	52	28.1	8.57

Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : OCD
Age Group: : Total

Visit	N	Mean	Std Dev
Week 1	115	11.1	3.92
Week 2	106	18.9	5.74
Week 3	109	23.4	7.60
Week 4	103	27.2	10.33
Week 6	100	30.1	11.59
Week 8	90	30.9	12.15
Week 12	79	31.8	12.48
Week 16	68	31.0	12.59
Week 20	59	30.7	13.11
Week 24	50	31.0	12.98
Overall Mean	116	24.3	8.63

Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : Total
Age Group: : Children

Visit	N	Mean	Std Dev
Week 1	138	12.2	5.92
Week 2	128	17.7	7.12
Week 3	129	21.0	7.89
Week 4	123	23.0	9.23
Week 6	118	24.5	10.09
Week 8	106	25.4	10.44
Week 12	94	26.0	10.51
Week 16	78	25.8	10.99
Week 20	66	25.7	11.02
Week 24	60	24.7	10.65
Overall Mean	139	20.9	7.66

Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : Total
Age Group: : Adolescents

Visit	N	Mean	Std Dev
Week 1	124	13.2	6.57
Week 2	117	20.0	6.16
Week 3	116	24.3	7.37
Week 4	111	26.7	9.37
Week 6	108	29.0	10.67
Week 8	101	29.6	10.58
Week 12	93	30.6	11.21
Week 16	86	30.2	10.95
Week 20	73	31.2	12.13
Week 24	62	31.8	12.35
Overall Mean	124	25.0	7.91

Table 13.10.6

Mean Daily Dosage (mg/day) of Paroxetine at Each Visit and Overall

Intention-To-Treat Population
Primary Diagnosis : Total
Age Group: : Total

Visit	N	Mean	Std Dev
Week 1	262	12.7	6.24
Week 2	245	18.8	6.76
Week 3	245	22.6	7.81
Week 4	234	24.7	9.46
Week 6	226	26.6	10.59
Week 8	207	27.4	10.69
Week 12	187	28.3	11.08
Week 16	164	28.1	11.16
Week 20	139	28.6	11.90
Week 24	122	28.3	12.04
Overall Mean	263	22.9	8.03

Table 13.10.7

Mean Daily Dosage (mg/day) of Paroxetine at Week 24 LOCF Endpoint for CY-BOCS/CDRS-R Total Score
by Primary Diagnosis and Age Group
Intention-To-Treat Population

Primary Diagnosis	Age Group	N	Mean	Std Dev
MDD (CDRS-R)	Children	50	25.8	12.63
	Adolescents	51	27.1	10.64
	Total	101	26.4	11.63
OCD (CY-BOCS)	Children	38	22.6	8.28
	Adolescents	32	35.6	13.90
	Total	70	28.6	12.89

Summary Statistics for the visit making up each patient’s LOCF assessment

11 Source Tables: Efficacy Results

Table 14.1.1b

Summary Statistics for Acute Study Baseline, Week 24, Week 24 LOCF and Change from Acute Study Baseline in CDRS-R Total Score by Age Group and Acute Study Treatment Group
Intention-To-Treat Population with Primary Diagnosis of MDD

		Paroxetine (N=81)			Placebo (N=66)			Total (N=147)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Baseline	N	39	42	81	36	30	66	75	72	147
	MEAN	57.5	63.1	60.4	59.7	61.3	60.4	58.6	62.4	60.4
	MEDIAN	58.0	62.0	59.0	58.5	61.0	60.5	58.0	61.5	59.0
	STDDEV	6.54	10.06	8.95	8.04	7.92	7.97	7.33	9.21	8.49
	MINIMUM	46	45	45	45	46	45	45	45	45
	MAXIMUM	78	84	84	82	87	87	82	87	87
	MISSING	0	0	0	0	0	0	0	0	0
Week 24	N	17	24	41	10	13	23	27	37	64
	MEAN	25.9	29.2	27.9	25.5	25.5	25.5	25.8	27.9	27.0
	MEDIAN	26.0	26.0	26.0	23.5	23.0	23.0	24.0	23.0	24.0
	STDDEV	6.04	10.72	9.13	6.64	8.54	7.60	6.14	10.05	8.62
	MINIMUM	18	18	18	18	20	18	18	18	18
	MAXIMUM	41	61	61	41	51	51	41	61	61
	MISSING	1	2	3	1	0	1	2	2	4
Week 24 LOCF	N	23	31	54	27	20	47	50	51	101
	MEAN	28.0	33.6	31.2	33.3	37.4	35.0	30.9	35.1	33.0
	MEDIAN	26.0	31.0	27.0	29.0	28.5	29.0	28.0	30.0	28.0
	STDDEV	8.62	14.36	12.46	12.89	19.90	16.18	11.33	16.66	14.36
	MINIMUM	18	18	18	18	20	18	18	18	18
	MAXIMUM	51	72	72	62	86	86	62	86	86
	MISSING	16	11	27	9	10	19	25	21	46
Change from Acute Baseline to Week 24	N	17	24	41	10	13	23	27	37	64
	MEAN	-34.0	-33.0	-33.4	-35.9	-33.5	-34.5	-34.7	-33.2	-33.8
	MEDIAN	-34.0	-37.0	-35.0	-33.5	-36.0	-36.0	-34.0	-36.0	-35.0
	STDDEV	9.51	15.20	13.01	12.39	10.01	10.90	10.47	13.46	12.22
	MINIMUM	-52	-54	-54	-60	-46	-60	-60	-54	-60
	MAXIMUM	-14	2	2	-22	-8	-8	-14	2	2
	MISSING	22	18	40	26	17	43	48	35	83
Change from Acute Baseline to Week 24 LOCF Endpoint	N	23	31	54	27	20	47	50	51	101
	MEAN	-30.6	-28.4	-29.3	-27.3	-24.2	-25.9	-28.8	-26.7	-27.7
	MEDIAN	-32.0	-30.0	-31.5	-25.0	-29.0	-26.0	-30.5	-30.0	-30.0
	STDDEV	11.53	17.63	15.25	15.78	16.18	15.85	13.95	17.04	15.55
	MINIMUM	-52	-54	-54	-60	-46	-60	-60	-54	-60
	MAXIMUM	-5	13	13	1	3	3	1	13	13

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.
Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

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Table 14.1.1b

Summary Statistics for Acute Study Baseline, Week 24, Week 24 LOCF and Change from Acute Study Baseline in CDRS-R Total Score by Age Group and Acute Study Treatment Group
Intention-To-Treat Population with Primary Diagnosis of MDD

		Paroxetine (N=81)			Placebo (N=66)			Total (N=147)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Change from Acute Baseline to Week 24 LOCF Endpoint	MISSING	16	11	27	9	10	19	25	21	46

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.
Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.1.1d

Summary Statistics for Acute Study Treatment Phase Endpoint, Week 24, Week 24 LOCF and Change from Acute Study Treatment Phase Endpoint in CDRS-R Total Score by Age Group
Pure Paroxetine Population with Primary Diagnosis of MDD

		Paroxetine (N=50)		
Visit	Statistic	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	25	25	50
	MEAN	33.2	34.5	33.9
	MEDIAN	31.0	31.0	31.0
	STDDEV	11.95	12.72	12.23
	MINIMUM	18	19	18
	MAXIMUM	63	71	71
	MISSING	0	0	0
Week 24	N	13	15	28
	MEAN	24.2	28.9	26.8
	MEDIAN	24.0	24.0	24.0
	STDDEV	4.36	12.29	9.61
	MINIMUM	18	18	18
	MAXIMUM	33	61	61
	MISSING	0	0	0
Week 24 LOCF	N	15	22	37
	MEAN	25.2	35.2	31.2
	MEDIAN	26.0	29.0	27.0
	STDDEV	4.87	16.13	13.63
	MINIMUM	18	18	18
	MAXIMUM	34	72	72
	MISSING	10	3	13
Change from Acute Study Treatment Phase Endpoint to Week 24	N	13	15	28
	MEAN	-8.2	-5.4	-6.7
	MEDIAN	-1.0	-3.0	-2.0
	STDDEV	13.87	15.11	14.35
	MINIMUM	-37	-30	-37
	MAXIMUM	3	30	30
	MISSING	12	10	22
Change from Acute Study Treatment Phase Endpoint to Week 24 LOCF	N	15	22	37
	MEAN	-8.3	0.5	-3.1
	MEDIAN	-2.0	-1.5	-2.0
	STDDEV	12.89	17.87	16.44
	MINIMUM	-37	-30	-37
	MAXIMUM	3	33	33
	MISSING	10	3	13

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.

Table 14.1.1e

Summary Statistics for Acute Study Treatment Phase Endpoint, Week 24, Week 24 LOCF and Change from Acute Study Treatment Phase Endpoint in CDRS-R Total Score by Age Group
Intention-to-Treat Population with Primary Diagnosis of MDD and Acute Study Treatment Group of Placebo

		Placebo (N=66)		
Visit	Statistic	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	36	29	65
	MEAN	32.7	36.6	34.4
	MEDIAN	31.5	35.0	33.0
	STDDEV	10.47	12.83	11.65
	MINIMUM	18	18	18
	MAXIMUM	51	65	65
	MISSING	0	1	1
Week 24	N	10	13	23
	MEAN	25.5	25.5	25.5
	MEDIAN	23.5	23.0	23.0
	STDDEV	6.64	8.54	7.60
	MINIMUM	18	20	18
	MAXIMUM	41	51	51
	MISSING	1	0	1
Week 24 LOCF	N	27	20	47
	MEAN	33.3	37.4	35.0
	MEDIAN	29.0	28.5	29.0
	STDDEV	12.89	19.90	16.18
	MINIMUM	18	20	18
	MAXIMUM	62	86	86
	MISSING	9	10	19
Change from Acute Study Treatment Phase Endpoint to Week 24	N	10	13	23
	MEAN	-8.3	-5.2	-6.6
	MEDIAN	-6.0	-7.0	-7.0
	STDDEV	10.30	14.97	12.96
	MINIMUM	-25	-31	-31
	MAXIMUM	3	29	29
	MISSING	26	17	43
Change from Acute Study Treatment Phase Endpoint to Week 24 LOCF	N	27	19	46
	MEAN	-0.3	1.1	0.3
	MEDIAN	-1.0	1.0	-0.5
	STDDEV	15.05	18.23	16.25
	MINIMUM	-25	-31	-31
	MAXIMUM	38	45	45
	MISSING	9	11	20

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.

Table 14.2.1b

Summary Statistics for Acute Study Baseline, Week 24, Week 24 LOCF and Change from Acute Study Baseline in CY-BOCS Total Score by Age Group and Acute Study Treatment Group
Intention-to-Treat Population with Primary Diagnosis of OCD

		Paroxetine (N=52)			Placebo (N=64)			Total (N=116)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Baseline	N	28	24	52	36	28	64	64	52	116
	MEAN	23.6	26.0	24.8	25.0	24.5	24.8	24.4	25.2	24.8
	MEDIAN	23.0	24.5	24.0	24.5	25.0	25.0	23.5	25.0	24.0
	STDDEV	4.36	4.89	4.73	5.11	4.46	4.81	4.81	4.69	4.75
	MINIMUM	18	19	18	16	16	16	16	16	16
	MAXIMUM	34	36	36	37	37	37	37	37	37
	MISSING	0	0	0	0	0	0	0	0	0
Week 24	N	13	11	24	11	10	21	24	21	45
	MEAN	7.9	7.7	7.8	8.3	10.2	9.2	8.1	8.9	8.5
	MEDIAN	10.0	7.0	8.0	8.0	9.5	8.0	8.5	8.0	8.0
	STDDEV	6.66	5.06	5.86	7.56	6.68	7.05	6.93	5.87	6.40
	MINIMUM	0	0	0	0	0	0	0	0	0
	MAXIMUM	17	18	18	23	22	23	23	22	23
	MISSING	2	0	2	1	1	2	3	1	4
Week 24 LOCF	N	17	15	32	21	17	38	38	32	70
	MEAN	8.7	8.7	8.7	12.9	14.8	13.7	11.0	11.9	11.4
	MEDIAN	10.0	7.0	8.0	15.0	14.0	14.5	11.5	10.5	11.0
	STDDEV	8.72	7.17	7.90	8.04	8.63	8.25	8.50	8.45	8.43
	MINIMUM	0	0	0	0	0	0	0	0	0
	MAXIMUM	31	28	31	24	34	34	31	34	34
	MISSING	11	9	20	15	11	26	26	20	46
Change from Acute Baseline to Week 24	N	13	11	24	11	10	21	24	21	45
	MEAN	-15.2	-17.5	-16.2	-16.9	-15.5	-16.2	-16.0	-16.5	-16.2
	MEDIAN	-14.0	-15.0	-15.0	-20.0	-16.0	-17.0	-15.5	-15.0	-15.0
	STDDEV	6.20	7.99	7.02	8.93	6.75	7.80	7.45	7.31	7.31
	MINIMUM	-25	-29	-29	-33	-23	-33	-33	-29	-33
	MAXIMUM	-7	-7	-7	-6	-6	-6	-6	-6	-6
	MISSING	15	13	28	25	18	43	40	31	71
Change from Acute Baseline to Week 24 LOCF Endpoint	N	17	15	32	21	17	38	38	32	70
	MEAN	-14.9	-16.8	-15.8	-10.5	-10.6	-10.6	-12.4	-13.5	-12.9
	MEDIAN	-17.0	-15.0	-16.0	-7.0	-9.0	-8.5	-11.5	-13.5	-12.5
	STDDEV	9.34	8.20	8.74	9.93	8.25	9.10	9.80	8.68	9.25
	MINIMUM	-27	-29	-29	-33	-23	-33	-33	-29	-33

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.2.1b

Summary Statistics for Acute Study Baseline, Week 24, Week 24 LOCF and Change from Acute Study Baseline
in CY-BOCS Total Score by Age Group and Acute Study Treatment Group
Intention-to-Treat Population with Primary Diagnosis of OCD

		Paroxetine (N=52)			Placebo (N=64)			Total (N=116)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Change from Acute Baseline to Week 24 LOCF Endpoint	MAXIMUM	12	-2	12	2	3	3	12	3	12
	MISSING	11	9	20	15	11	26	26	20	46

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.2.1d

Summary Statistics for Acute Study Treatment Phase Endpoint, Week 24, Week 24 LOCF and Change from Acute Study Treatment Phase Endpoint in CY-BOCS Total Score by Age Group
Pure Paroxetine Population with Primary Diagnosis of OCD

		Paroxetine (N=46)		
Visit	Statistic	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	25	21	46
	MEAN	12.1	16.6	14.2
	MEDIAN	13.0	17.0	14.0
	STDDEV	8.39	7.68	8.30
	MINIMUM	0	3	0
	MAXIMUM	34	34	34
	MISSING	0	0	0
Week 24	N	12	10	22
	MEAN	8.5	8.1	8.3
	MEDIAN	10.0	7.5	9.0
	STDDEV	6.61	5.17	5.87
	MINIMUM	0	0	0
	MAXIMUM	17	18	18
	MISSING	1	0	1
Week 24 LOCF	N	16	14	30
	MEAN	9.2	9.0	9.1
	MEDIAN	10.0	7.5	9.0
	STDDEV	8.77	7.32	7.99
	MINIMUM	0	0	0
	MAXIMUM	31	28	31
	MISSING	9	7	16
Change from Acute Study Treatment Phase Endpoint to Week 24	N	12	10	22
	MEAN	-1.9	-6.0	-3.8
	MEDIAN	-1.0	-6.5	-2.5
	STDDEV	5.02	3.80	4.87
	MINIMUM	-13	-10	-13
	MAXIMUM	4	2	4
	MISSING	13	11	24
Change from Acute Study Treatment Phase Endpoint to Week 24 LOCF	N	16	14	30
	MEAN	-1.8	-6.1	-3.8
	MEDIAN	-0.5	-6.5	-2.5
	STDDEV	7.73	3.92	6.54
	MINIMUM	-20	-12	-20
	MAXIMUM	15	2	15
	MISSING	9	7	16

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.

Table 14.2.1e

Summary Statistics for Acute Study Treatment Phase Endpoint, Week 24, Week 24 LOCF and Change from Acute Study Treatment Phase Endpoint in CY-BOCS Total Score by Age Group
Intention-to-Treat Population with Primary Diagnosis of OCD and Acute Study Treatment Group of Placebo

		Placebo (N=64)		
Visit	Statistic	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	35	28	63
	MEAN	16.7	18.0	17.3
	MEDIAN	16.0	19.0	18.0
	STDDEV	7.99	7.27	7.64
	MINIMUM	0	0	0
	MAXIMUM	33	36	36
	MISSING	1	0	1
Week 24	N	11	10	21
	MEAN	8.3	10.2	9.2
	MEDIAN	8.0	9.5	8.0
	STDDEV	7.56	6.68	7.05
	MINIMUM	0	0	0
	MAXIMUM	23	22	23
	MISSING	1	1	2
Week 24 LOCF	N	21	17	38
	MEAN	12.9	14.8	13.7
	MEDIAN	15.0	14.0	14.5
	STDDEV	8.04	8.63	8.25
	MINIMUM	0	0	0
	MAXIMUM	24	34	34
	MISSING	15	11	26
Change from Acute Study Treatment Phase Endpoint to Week 24	N	10	10	20
	MEAN	-4.4	-5.4	-4.9
	MEDIAN	-5.5	-5.0	-5.0
	STDDEV	8.50	6.48	7.38
	MINIMUM	-16	-18	-18
	MAXIMUM	10	3	10
	MISSING	26	18	44
Change from Acute Study Treatment Phase Endpoint to Week 24 LOCF	N	20	17	37
	MEAN	-2.0	-3.4	-2.6
	MEDIAN	-2.5	-2.0	-2.0
	STDDEV	7.06	6.07	6.57
	MINIMUM	-16	-18	-18
	MAXIMUM	10	6	10
	MISSING	16	11	27

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.

Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																			
Week 1	Not assessed (0)	1	2.9	2	5.4	3	4.2	0	.	0	.	0	.	1	1.5	2	3.2	3	2.3
	Very much improved (1)	12	35.3	7	18.9	19	26.8	7	21.2	4	15.4	11	18.6	19	28.4	11	17.5	30	23.1
	Much Improved (2)	8	23.5	8	21.6	16	22.5	12	36.4	5	19.2	17	28.8	20	29.9	13	20.6	33	25.4
	Minimally improved (3)	9	26.5	14	37.8	23	32.4	10	30.3	8	30.8	18	30.5	19	28.4	22	34.9	41	31.5
	No change (4)	3	8.8	2	5.4	5	7.0	2	6.1	9	34.6	11	18.6	5	7.5	11	17.5	16	12.3
	Minimally worse (5)	1	2.9	4	10.8	5	7.0	1	3.0	0	.	1	1.7	2	3.0	4	6.3	6	4.6
	Much worse (6)	0	.	0	.	0	.	1	3.0	0	.	1	1.7	1	1.5	0	.	1	0.8
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	34	100.0	37	100.0	71	100.0	33	100.0	26	100.0	59	100.0	67	100.0	63	100.0	130	100.0
Week 2	Not assessed (0)	0	.	3	7.7	3	4.2	0	.	0	.	0	.	0	.	3	4.7	3	2.3

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Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																			
Week 2	Very much improved (1)	14	42.4	11	28.2	25	34.7	11	34.4	4	16.0	15	26.3	25	38.5	15	23.4	40	31.0
	Much Improved (2)	4	12.1	9	23.1	13	18.1	9	28.1	11	44.0	20	35.1	13	20.0	20	31.3	33	25.6
	Minimally improved (3)	11	33.3	13	33.3	24	33.3	7	21.9	6	24.0	13	22.8	18	27.7	19	29.7	37	28.7
	No change (4)	2	6.1	1	2.6	3	4.2	2	6.3	4	16.0	6	10.5	4	6.2	5	7.8	9	7.0
	Minimally worse (5)	2	6.1	1	2.6	3	4.2	1	3.1	0	.	1	1.8	3	4.6	1	1.6	4	3.1
	Much worse (6)	0	.	1	2.6	1	1.4	2	6.3	0	.	2	3.5	2	3.1	1	1.6	3	2.3
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	33	100.0	39	100.0	72	100.0	32	100.0	25	100.0	57	100.0	65	100.0	64	100.0	129	100.0
Week 3	Not assessed (0)	0	.	3	7.9	3	4.2	0	.	0	.	0	.	0	.	3	5.0	3	2.4
	Very much improved (1)	14	42.4	7	18.4	21	29.6	10	32.3	3	13.6	13	24.5	24	37.5	10	16.7	34	27.4

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Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																			
Week 3	Much Improved (2)	12	36.4	15	39.5	27	38.0	13	41.9	11	50.0	24	45.3	25	39.1	26	43.3	51	41.1
	Minimally improved (3)	6	18.2	10	26.3	16	22.5	7	22.6	4	18.2	11	20.8	13	20.3	14	23.3	27	21.8
	No change (4)	1	3.0	3	7.9	4	5.6	0	.	3	13.6	3	5.7	1	1.6	6	10.0	7	5.6
	Minimally worse (5)	0	.	0	.	0	.	1	3.2	1	4.5	2	3.8	1	1.6	1	1.7	2	1.6
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	33	100.0	38	100.0	71	100.0	31	100.0	22	100.0	53	100.0	64	100.0	60	100.0	124	100.0
Week 4	Not assessed (0)	0	.	2	5.4	2	2.7	0	.	0	.	0	.	0	.	2	3.3	2	1.6
	Very much improved (1)	14	38.9	11	29.7	25	34.2	12	38.7	4	16.7	16	29.1	26	38.8	15	24.6	41	32.0
	Much Improved (2)	13	36.1	17	45.9	30	41.1	9	29.0	11	45.8	20	36.4	22	32.8	28	45.9	50	39.1

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Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																			
Week 4	Minimally improved (3)	8	22.2	4	10.8	12	16.4	4	12.9	5	20.8	9	16.4	12	17.9	9	14.8	21	16.4
	No change (4)	1	2.8	2	5.4	3	4.1	3	9.7	3	12.5	6	10.9	4	6.0	5	8.2	9	7.0
	Minimally worse (5)	0	.	1	2.7	1	1.4	3	9.7	0	.	3	5.5	3	4.5	1	1.6	4	3.1
	Much worse (6)	0	.	0	.	0	.	0	.	1	4.2	1	1.8	0	.	1	1.6	1	0.8
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	36	100.0	37	100.0	73	100.0	31	100.0	24	100.0	55	100.0	67	100.0	61	100.0	128	100.0
Week 8	Not assessed (0)	0	.	2	6.1	2	3.2	0	.	0	.	0	.	0	.	2	3.8	2	1.8
	Very much improved (1)	12	41.4	10	30.3	22	35.5	11	40.7	6	30.0	17	36.2	23	41.1	16	30.2	39	35.8
	Much Improved (2)	9	31.0	17	51.5	26	41.9	11	40.7	9	45.0	20	42.6	20	35.7	26	49.1	46	42.2
	Minimally improved (3)	7	24.1	3	9.1	10	16.1	3	11.1	3	15.0	6	12.8	10	17.9	6	11.3	16	14.7

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Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																			
Week 8	No change (4)	1	3.4	1	3.0	2	3.2	2	7.4	2	10.0	4	8.5	3	5.4	3	5.7	6	5.5
	Minimally worse (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	29	100.0	33	100.0	62	100.0	27	100.0	20	100.0	47	100.0	56	100.0	53	100.0	109	100.0
Week 12	Not assessed (0)	0	.	2	5.9	2	3.4	0	.	0	.	0	.	0	.	2	3.8	2	2.0
	Very much improved (1)	9	37.5	13	38.2	22	37.9	6	27.3	6	31.6	12	29.3	15	32.6	19	35.8	34	34.3
	Much Improved (2)	11	45.8	16	47.1	27	46.6	11	50.0	10	52.6	21	51.2	22	47.8	26	49.1	48	48.5
	Minimally improved (3)	0	.	0	.	0	.	0	.	2	10.5	2	4.9	0	.	2	3.8	2	2.0
	No change (4)	3	12.5	1	2.9	4	6.9	5	22.7	1	5.3	6	14.6	8	17.4	2	3.8	10	10.1
	Minimally worse (5)	1	4.2	1	2.9	2	3.4	0	.	0	.	0	.	1	2.2	1	1.9	2	2.0

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Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
Visit		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 12	Much worse (6)	0	.	1	2.9	1	1.7	0	.	0	.	0	.	0	.	1	1.9	1	1.0
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	24	100.0	34	100.0	58	100.0	22	100.0	19	100.0	41	100.0	46	100.0	53	100.0	99	100.0
Week 16	Not assessed (0)	1	5.3	1	3.2	2	4.0	0	.	0	.	0	.	1	2.5	1	2.1	2	2.3
	Very much improved (1)	7	36.8	11	35.5	18	36.0	6	28.6	4	25.0	10	27.0	13	32.5	15	31.9	28	32.2
	Much Improved (2)	9	47.4	13	41.9	22	44.0	12	57.1	8	50.0	20	54.1	21	52.5	21	44.7	42	48.3
	Minimally improved (3)	1	5.3	4	12.9	5	10.0	0	.	2	12.5	2	5.4	1	2.5	6	12.8	7	8.0
	No change (4)	1	5.3	2	6.5	3	6.0	3	14.3	1	6.3	4	10.8	4	10.0	3	6.4	7	8.0
	Minimally worse (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Much worse (6)	0	.	0	.	0	.	0	.	1	6.3	1	2.7	0	.	1	2.1	1	1.1
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.

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Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
Visit	Total	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 16		19	100.0	31	100.0	50	100.0	21	100.0	16	100.0	37	100.0	40	100.0	47	100.0	87	100.0
Week 20	Not assessed (0)	1	5.3	1	3.8	2	4.4	0	.	0	.	0	.	1	2.8	1	2.6	2	2.7
	Very much improved (1)	10	52.6	13	50.0	23	51.1	6	35.3	6	46.2	12	40.0	16	44.4	19	48.7	35	46.7
	Much Improved (2)	8	42.1	10	38.5	18	40.0	8	47.1	5	38.5	13	43.3	16	44.4	15	38.5	31	41.3
	Minimally improved (3)	0	.	1	3.8	1	2.2	0	.	1	7.7	1	3.3	0	.	2	5.1	2	2.7
	No change (4)	0	.	0	.	0	.	2	11.8	0	.	2	6.7	2	5.6	0	.	2	2.7
	Minimally worse (5)	0	.	1	3.8	1	2.2	1	5.9	0	.	1	3.3	1	2.8	1	2.6	2	2.7
	Much worse (6)	0	.	0	.	0	.	0	.	1	7.7	1	3.3	0	.	1	2.6	1	1.3
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	19	100.0	26	100.0	45	100.0	17	100.0	13	100.0	30	100.0	36	100.0	39	100.0	75	100.0
Week 24	Not assessed (0)	1	5.9	1	4.0	2	4.8	0	.	0	.	0	.	1	3.7	1	2.6	2	3.1

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Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																			
Week 24	Very much improved (1)	11	64.7	12	48.0	23	54.8	3	30.0	6	46.2	9	39.1	14	51.9	18	47.4	32	49.2
	Much Improved (2)	5	29.4	10	40.0	15	35.7	6	60.0	6	46.2	12	52.2	11	40.7	16	42.1	27	41.5
	Minimally improved (3)	0	.	1	4.0	1	2.4	1	10.0	0	.	1	4.3	1	3.7	1	2.6	2	3.1
	No change (4)	0	.	1	4.0	1	2.4	0	.	1	7.7	1	4.3	0	.	2	5.3	2	3.1
	Minimally worse (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	17	100.0	25	100.0	42	100.0	10	100.0	13	100.0	23	100.0	27	100.0	38	100.0	65	100.0
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much improved (1)	16	43.2	17	41.5	33	42.3	9	25.7	6	20.7	15	23.4	25	34.7	23	32.9	48	33.8

(CONTINUED)

Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																			
Week 24 LOCF	Much Improved (2)	13	35.1	12	29.3	25	32.1	16	45.7	11	37.9	27	42.2	29	40.3	23	32.9	52	36.6
	Minimally improved (3)	4	10.8	7	17.1	11	14.1	5	14.3	4	13.8	9	14.1	9	12.5	11	15.7	20	14.1
	No change (4)	3	8.1	3	7.3	6	7.7	4	11.4	4	13.8	8	12.5	7	9.7	7	10.0	14	9.9
	Minimally worse (5)	0	.	0	.	0	.	1	2.9	2	6.9	3	4.7	1	1.4	2	2.9	3	2.1
	Much worse (6)	1	2.7	1	2.4	2	2.6	0	.	2	6.9	2	3.1	1	1.4	3	4.3	4	2.8
	Very much worse (7)	0	.	1	2.4	1	1.3	0	.	0	.	0	.	0	.	1	1.4	1	0.7
	Total	37	100.0	41	100.0	78	100.0	35	100.0	29	100.0	64	100.0	72	100.0	70	100.0	142	100.0

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Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																			
Week 1	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much improved (1)	4	18.2	5	21.7	9	20.0	2	6.7	0	.	2	3.7	6	11.5	5	10.6	11	11.1
	Much Improved (2)	7	31.8	5	21.7	12	26.7	9	30.0	1	4.2	10	18.5	16	30.8	6	12.8	22	22.2
	Minimally improved (3)	5	22.7	5	21.7	10	22.2	11	36.7	11	45.8	22	40.7	16	30.8	16	34.0	32	32.3
	No change (4)	5	22.7	6	26.1	11	24.4	6	20.0	11	45.8	17	31.5	11	21.2	17	36.2	28	28.3
	Minimally worse (5)	1	4.5	2	8.7	3	6.7	1	3.3	1	4.2	2	3.7	2	3.8	3	6.4	5	5.1
	Much worse (6)	0	.	0	.	0	.	1	3.3	0	.	1	1.9	1	1.9	0	.	1	1.0
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	22	100.0	23	100.0	45	100.0	30	100.0	24	100.0	54	100.0	52	100.0	47	100.0	99	100.0
Week 2	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.

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Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																			
Week 2	Very much improved (1)	3	15.0	5	25.0	8	20.0	5	16.1	0	.	5	9.1	8	15.7	5	11.4	13	13.7
	Much Improved (2)	8	40.0	6	30.0	14	35.0	9	29.0	7	29.2	16	29.1	17	33.3	13	29.5	30	31.6
	Minimally improved (3)	5	25.0	5	25.0	10	25.0	9	29.0	11	45.8	20	36.4	14	27.5	16	36.4	30	31.6
	No change (4)	3	15.0	4	20.0	7	17.5	6	19.4	5	20.8	11	20.0	9	17.6	9	20.5	18	18.9
	Minimally worse (5)	1	5.0	0	.	1	2.5	2	6.5	1	4.2	3	5.5	3	5.9	1	2.3	4	4.2
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	20	100.0	20	100.0	40	100.0	31	100.0	24	100.0	55	100.0	51	100.0	44	100.0	95	100.0
Week 3	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much improved (1)	7	31.8	5	27.8	12	30.0	5	14.7	2	8.7	7	12.3	12	21.4	7	17.1	19	19.6

(CONTINUED)

Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																			
Week 3	Much Improved (2)	7	31.8	5	27.8	12	30.0	13	38.2	11	47.8	24	42.1	20	35.7	16	39.0	36	37.1
	Minimally improved (3)	6	27.3	5	27.8	11	27.5	12	35.3	7	30.4	19	33.3	18	32.1	12	29.3	30	30.9
	No change (4)	1	4.5	2	11.1	3	7.5	4	11.8	3	13.0	7	12.3	5	8.9	5	12.2	10	10.3
	Minimally worse (5)	0	.	1	5.6	1	2.5	0	.	0	.	0	.	0	.	1	2.4	1	1.0
	Much worse (6)	1	4.5	0	.	1	2.5	0	.	0	.	0	.	1	1.8	0	.	1	1.0
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	22	100.0	18	100.0	40	100.0	34	100.0	23	100.0	57	100.0	56	100.0	41	100.0	97	100.0
Week 4	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much improved (1)	8	30.8	5	21.7	13	26.5	7	23.3	2	8.0	9	16.4	15	26.8	7	14.6	22	21.2
	Much Improved (2)	10	38.5	10	43.5	20	40.8	11	36.7	13	52.0	24	43.6	21	37.5	23	47.9	44	42.3

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Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																			
Week 4	Minimally improved (3)	7	26.9	6	26.1	13	26.5	7	23.3	6	24.0	13	23.6	14	25.0	12	25.0	26	25.0
	No change (4)	0	.	2	8.7	2	4.1	5	16.7	4	16.0	9	16.4	5	8.9	6	12.5	11	10.6
	Minimally worse (5)	1	3.8	0	.	1	2.0	0	.	0	.	0	.	1	1.8	0	.	1	1.0
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	26	100.0	23	100.0	49	100.0	30	100.0	25	100.0	55	100.0	56	100.0	48	100.0	104	100.0
Week 8	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much improved (1)	8	34.8	8	38.1	16	36.4	9	40.9	4	23.5	13	33.3	17	37.8	12	31.6	29	34.9
	Much Improved (2)	8	34.8	7	33.3	15	34.1	6	27.3	6	35.3	12	30.8	14	31.1	13	34.2	27	32.5
	Minimally improved (3)	5	21.7	5	23.8	10	22.7	5	22.7	5	29.4	10	25.6	10	22.2	10	26.3	20	24.1

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Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																			
Week 8	No change (4)	0	.	1	4.8	1	2.3	1	4.5	1	5.9	2	5.1	1	2.2	2	5.3	3	3.6
	Minimally worse (5)	2	8.7	0	.	2	4.5	1	4.5	0	.	1	2.6	3	6.7	0	.	3	3.6
	Much worse (6)	0	.	0	.	0	.	0	.	1	5.9	1	2.6	0	.	1	2.6	1	1.2
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	23	100.0	21	100.0	44	100.0	22	100.0	17	100.0	39	100.0	45	100.0	38	100.0	83	100.0
Week 12	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much improved (1)	9	52.9	6	37.5	15	45.5	10	47.6	7	50.0	17	48.6	19	50.0	13	43.3	32	47.1
	Much Improved (2)	5	29.4	7	43.8	12	36.4	4	19.0	5	35.7	9	25.7	9	23.7	12	40.0	21	30.9
	Minimally improved (3)	2	11.8	2	12.5	4	12.1	2	9.5	2	14.3	4	11.4	4	10.5	4	13.3	8	11.8
	No change (4)	0	.	0	.	0	.	3	14.3	0	.	3	8.6	3	7.9	0	.	3	4.4
	Minimally worse (5)	1	5.9	1	6.3	2	6.1	2	9.5	0	.	2	5.7	3	7.9	1	3.3	4	5.9

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Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
Visit		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 12	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	17	100.0	16	100.0	33	100.0	21	100.0	14	100.0	35	100.0	38	100.0	30	100.0	68	100.0
Week 16	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much improved (1)	8	53.3	4	26.7	12	40.0	7	50.0	8	50.0	15	50.0	15	51.7	12	38.7	27	45.0
	Much Improved (2)	4	26.7	7	46.7	11	36.7	3	21.4	7	43.8	10	33.3	7	24.1	14	45.2	21	35.0
	Minimally improved (3)	2	13.3	4	26.7	6	20.0	3	21.4	1	6.3	4	13.3	5	17.2	5	16.1	10	16.7
	No change (4)	1	6.7	0	.	1	3.3	1	7.1	0	.	1	3.3	2	6.9	0	.	2	3.3
	Minimally worse (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.

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Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit	Total																		
Week 16		15	100.0	15	100.0	30	100.0	14	100.0	16	100.0	30	100.0	29	100.0	31	100.0	60	100.0
Week 20	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much improved (1)	7	58.3	2	18.2	9	39.1	9	69.2	6	50.0	15	60.0	16	64.0	8	34.8	24	50.0
	Much Improved (2)	4	33.3	5	45.5	9	39.1	3	23.1	4	33.3	7	28.0	7	28.0	9	39.1	16	33.3
	Minimally improved (3)	1	8.3	3	27.3	4	17.4	0	.	1	8.3	1	4.0	1	4.0	4	17.4	5	10.4
	No change (4)	0	.	0	.	0	.	1	7.7	1	8.3	2	8.0	1	4.0	1	4.3	2	4.2
	Minimally worse (5)	0	.	1	9.1	1	4.3	0	.	0	.	0	.	0	.	1	4.3	1	2.1
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	12	100.0	11	100.0	23	100.0	13	100.0	12	100.0	25	100.0	25	100.0	23	100.0	48	100.0
Week 24	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.

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Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																			
Week 24	Very much improved (1)	8	53.3	6	54.5	14	53.8	8	66.7	5	45.5	13	56.5	16	59.3	11	50.0	27	55.1
	Much Improved (2)	5	33.3	3	27.3	8	30.8	3	25.0	5	45.5	8	34.8	8	29.6	8	36.4	16	32.7
	Minimally improved (3)	2	13.3	1	9.1	3	11.5	1	8.3	0	.	1	4.3	3	11.1	1	4.5	4	8.2
	No change (4)	0	.	1	9.1	1	3.8	0	.	1	9.1	1	4.3	0	.	2	9.1	2	4.1
	Minimally worse (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Much worse (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	15	100.0	11	100.0	26	100.0	12	100.0	11	100.0	23	100.0	27	100.0	22	100.0	49	100.0
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Very much improved (1)	11	39.3	11	47.8	22	43.1	11	31.4	7	25.0	18	28.6	22	34.9	18	35.3	40	35.1

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Table 14.3.1

Number and Percentage of patients in each category of CGI Global Improvement at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Visit																			
Week 24 LOCF	Much Improved (2)	9	32.1	6	26.1	15	29.4	10	28.6	12	42.9	22	34.9	19	30.2	18	35.3	37	32.5
	Minimally improved (3)	5	17.9	5	21.7	10	19.6	8	22.9	3	10.7	11	17.5	13	20.6	8	15.7	21	18.4
	No change (4)	1	3.6	1	4.3	2	3.9	5	14.3	4	14.3	9	14.3	6	9.5	5	9.8	11	9.6
	Minimally worse (5)	2	7.1	0	.	2	3.9	1	2.9	0	.	1	1.6	3	4.8	0	.	3	2.6
	Much worse (6)	0	.	0	.	0	.	0	.	2	7.1	2	3.2	0	.	2	3.9	2	1.8
	Very much worse (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	28	100.0	23	100.0	51	100.0	35	100.0	28	100.0	63	100.0	63	100.0	51	100.0	114	100.0

Table 14.3.2

Proportion of Responders for CGI Global Improvement at each visit by Acute Study Treatment Group

Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Children

	Acute Study Treatment Group								
	Paroxetine (N = 39)			Placebo (N = 36)			Total (N = 75)		
	n	%	N	n	%	N	n	%	N
Visit									
Week 1	20	60.6	33	19	57.6	33	39	59.1	66
Week 2	18	54.5	33	20	62.5	32	38	58.5	65
Week 3	26	78.8	33	23	74.2	31	49	76.6	64
Week 4	27	75.0	36	21	67.7	31	48	71.6	67
Week 8	21	72.4	29	22	81.5	27	43	76.8	56
Week 12	20	83.3	24	17	77.3	22	37	80.4	46
Week 16	16	88.9	18	18	85.7	21	34	87.2	39
Week 20	18	100.0	18	14	82.4	17	32	91.4	35
Week 24	16	100.0	16	9	90.0	10	25	96.2	26
Week 24 LOCF	29	78.4	37	25	71.4	35	54	75.0	72

Note: Responders are patients who have a score of 1 or 2

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Table 14.3.2

Proportion of Responders for CGI Global Improvement at each visit by Acute Study Treatment Group

Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Adolescent

	Acute Study Treatment Group								
	Paroxetine (N = 42)			Placebo (N = 30)			Total (N = 72)		
	n	%	N	n	%	N	n	%	N
Visit									
Week 1	15	42.9	35	9	34.6	26	24	39.3	61
Week 2	20	55.6	36	15	60.0	25	35	57.4	61
Week 3	22	62.9	35	14	63.6	22	36	63.2	57
Week 4	28	80.0	35	15	62.5	24	43	72.9	59
Week 8	27	87.1	31	15	75.0	20	42	82.4	51
Week 12	29	90.6	32	16	84.2	19	45	88.2	51
Week 16	24	80.0	30	12	75.0	16	36	78.3	46
Week 20	23	92.0	25	11	84.6	13	34	89.5	38
Week 24	22	91.7	24	12	92.3	13	34	91.9	37
Week 24 LOCF	29	70.7	41	17	58.6	29	46	65.7	70

Note: Responders are patients who have a score of 1 or 2

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Table 14.3.2

Proportion of Responders for CGI Global Improvement at each visit by Acute Study Treatment Group

Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Total

	Acute Study Treatment Group								
	Paroxetine (N = 81)			Placebo (N = 66)			Total (N = 147)		
	n	%	N	n	%	N	n	%	N
Visit									
Week 1	35	51.5	68	28	47.5	59	63	49.6	127
Week 2	38	55.1	69	35	61.4	57	73	57.9	126
Week 3	48	70.6	68	37	69.8	53	85	70.2	121
Week 4	55	77.5	71	36	65.5	55	91	72.2	126
Week 8	48	80.0	60	37	78.7	47	85	79.4	107
Week 12	49	87.5	56	33	80.5	41	82	84.5	97
Week 16	40	83.3	48	30	81.1	37	70	82.4	85
Week 20	41	95.3	43	25	83.3	30	66	90.4	73
Week 24	38	95.0	40	21	91.3	23	59	93.7	63
Week 24 LOCF	58	74.4	78	42	65.6	64	100	70.4	142

Note: Responders are patients who have a score of 1 or 2

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Table 14.3.2

Proportion of Responders for CGI Global Improvement at each visit by Acute Study Treatment Group

Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Children

	Acute Study Treatment Group								
	Paroxetine (N = 28)			Placebo (N = 36)			Total (N = 64)		
	n	%	N	n	%	N	n	%	N
Visit									
Week 1	11	50.0	22	11	36.7	30	22	42.3	52
Week 2	11	55.0	20	14	45.2	31	25	49.0	51
Week 3	14	63.6	22	18	52.9	34	32	57.1	56
Week 4	18	69.2	26	18	60.0	30	36	64.3	56
Week 8	16	69.6	23	15	68.2	22	31	68.9	45
Week 12	14	82.4	17	14	66.7	21	28	73.7	38
Week 16	12	80.0	15	10	71.4	14	22	75.9	29
Week 20	11	91.7	12	12	92.3	13	23	92.0	25
Week 24	13	86.7	15	11	91.7	12	24	88.9	27
Week 24 LOCF	20	71.4	28	21	60.0	35	41	65.1	63

Note: Responders are patients who have a score of 1 or 2

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Table 14.3.2

Proportion of Responders for CGI Global Improvement at each visit by Acute Study Treatment Group

Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Adolescent

	Acute Study Treatment Group								
	Paroxetine (N = 24)			Placebo (N = 28)			Total (N = 52)		
	n	%	N	n	%	N	n	%	N
Visit									
Week 1	10	43.5	23	1	4.2	24	11	23.4	47
Week 2	11	55.0	20	7	29.2	24	18	40.9	44
Week 3	10	55.6	18	13	56.5	23	23	56.1	41
Week 4	15	65.2	23	15	60.0	25	30	62.5	48
Week 8	15	71.4	21	10	58.8	17	25	65.8	38
Week 12	13	81.3	16	12	85.7	14	25	83.3	30
Week 16	11	73.3	15	15	93.8	16	26	83.9	31
Week 20	7	63.6	11	10	83.3	12	17	73.9	23
Week 24	9	81.8	11	10	90.9	11	19	86.4	22
Week 24 LOCF	17	73.9	23	19	67.9	28	36	70.6	51

Note: Responders are patients who have a score of 1 or 2

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Table 14.3.2

Proportion of Responders for CGI Global Improvement at each visit by Acute Study Treatment Group

Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Total

	Acute Study Treatment Group								
	Paroxetine (N = 52)			Placebo (N = 64)			Total (N = 116)		
	n	%	N	n	%	N	n	%	N
Visit									
Week 1	21	46.7	45	12	22.2	54	33	33.3	99
Week 2	22	55.0	40	21	38.2	55	43	45.3	95
Week 3	24	60.0	40	31	54.4	57	55	56.7	97
Week 4	33	67.3	49	33	60.0	55	66	63.5	104
Week 8	31	70.5	44	25	64.1	39	56	67.5	83
Week 12	27	81.8	33	26	74.3	35	53	77.9	68
Week 16	23	76.7	30	25	83.3	30	48	80.0	60
Week 20	18	78.3	23	22	88.0	25	40	83.3	48
Week 24	22	84.6	26	21	91.3	23	43	87.8	49
Week 24 LOCF	37	72.5	51	40	63.5	63	77	67.5	114

Note: Responders are patients who have a score of 1 or 2

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Acute Baseline	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Borderline mentally ill (2)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Mildly ill (3)	0	.	1	2.4	1	1.2	2	5.6	0	.	2	3.0	2	2.7	1	1.4	3	2.0
	Moderately ill (4)	31	79.5	30	71.4	61	75.3	26	72.2	22	73.3	48	72.7	57	76.0	52	72.2	109	74.1
	Markedly ill (5)	7	17.9	8	19.0	15	18.5	7	19.4	8	26.7	15	22.7	14	18.7	16	22.2	30	20.4
	Severely ill (6)	1	2.6	3	7.1	4	4.9	1	2.8	0	.	1	1.5	2	2.7	3	4.2	5	3.4
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

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Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Acute Baseline	Total	39	100.0	42	100.0	81	100.0	36	100.0	30	100.0	66	100.0	75	100.0	72	100.0	147	100.0
Week 1	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	8	23.5	6	16.2	14	19.7	5	15.2	2	7.7	7	11.9	13	19.4	8	12.7	21	16.2
	Borderline mentally ill (2)	6	17.6	6	16.2	12	16.9	6	18.2	8	30.8	14	23.7	12	17.9	14	22.2	26	20.0
	Mildly ill (3)	11	32.4	11	29.7	22	31.0	10	30.3	5	19.2	15	25.4	21	31.3	16	25.4	37	28.5
	Moderately ill (4)	7	20.6	13	35.1	20	28.2	11	33.3	11	42.3	22	37.3	18	26.9	24	38.1	42	32.3
	Markedly ill (5)	2	5.9	1	2.7	3	4.2	1	3.0	0	.	1	1.7	3	4.5	1	1.6	4	3.1
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

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Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 1	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	34	100.0	37	100.0	71	100.0	33	100.0	26	100.0	59	100.0	67	100.0	63	100.0	130	100.0
Week 2	Not assessed (0)	0	.	1	2.6	1	1.4	0	.	0	.	0	.	0	.	1	1.6	1	0.8
	Normal, not at all ill (1)	9	27.3	9	23.1	18	25.0	8	25.0	4	16.0	12	21.1	17	26.2	13	20.3	30	23.3
	Borderline mentally ill (2)	6	18.2	8	20.5	14	19.4	4	12.5	5	20.0	9	15.8	10	15.4	13	20.3	23	17.8
	Mildly ill (3)	8	24.2	9	23.1	17	23.6	10	31.3	9	36.0	19	33.3	18	27.7	18	28.1	36	27.9
	Moderately ill (4)	9	27.3	10	25.6	19	26.4	8	25.0	7	28.0	15	26.3	17	26.2	17	26.6	34	26.4
	Markedly ill (5)	1	3.0	2	5.1	3	4.2	2	6.3	0	.	2	3.5	3	4.6	2	3.1	5	3.9

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

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Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 2	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	33	100.0	39	100.0	72	100.0	32	100.0	25	100.0	57	100.0	65	100.0	64	100.0	129	100.0
Week 3	Not assessed (0)	0	.	1	2.6	1	1.4	0	.	0	.	0	.	0	.	1	1.7	1	0.8
	Normal, not at all ill (1)	8	24.2	6	15.8	14	19.7	8	25.8	4	18.2	12	22.6	16	25.0	10	16.7	26	21.0
	Borderline mentally ill (2)	11	33.3	11	28.9	22	31.0	6	19.4	5	22.7	11	20.8	17	26.6	16	26.7	33	26.6
	Mildly ill (3)	8	24.2	16	42.1	24	33.8	11	35.5	8	36.4	19	35.8	19	29.7	24	40.0	43	34.7
	Moderately ill (4)	6	18.2	4	10.5	10	14.1	6	19.4	5	22.7	11	20.8	12	18.8	9	15.0	21	16.9

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

BRL 29060 - 716

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 3	Markedly ill (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	33	100.0	38	100.0	71	100.0	31	100.0	22	100.0	53	100.0	64	100.0	60	100.0	124	100.0
Week 4	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	9	25.0	8	21.6	17	23.3	8	25.8	3	12.5	11	20.0	17	25.4	11	18.0	28	21.9
	Borderline mentally ill (2)	15	41.7	14	37.8	29	39.7	10	32.3	9	37.5	19	34.5	25	37.3	23	37.7	48	37.5
	Mildly ill (3)	6	16.7	10	27.0	16	21.9	7	22.6	7	29.2	14	25.5	13	19.4	17	27.9	30	23.4

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 4	Moderately ill (4)	5	13.9	3	8.1	8	11.0	5	16.1	4	16.7	9	16.4	10	14.9	7	11.5	17	13.3
	Markedly ill (5)	1	2.8	2	5.4	3	4.1	1	3.2	1	4.2	2	3.6	2	3.0	3	4.9	5	3.9
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	36	100.0	37	100.0	73	100.0	31	100.0	24	100.0	55	100.0	67	100.0	61	100.0	128	100.0
Week 8	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	8	27.6	10	30.3	18	29.0	7	25.9	5	25.0	12	25.5	15	26.8	15	28.3	30	27.5
	Borderline mentally ill (2)	7	24.1	13	39.4	20	32.3	9	33.3	7	35.0	16	34.0	16	28.6	20	37.7	36	33.0

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

BRL 29060 - 716

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 8	Mildly ill (3)	9	31.0	8	24.2	17	27.4	7	25.9	5	25.0	12	25.5	16	28.6	13	24.5	29	26.6
	Moderately ill (4)	4	13.8	2	6.1	6	9.7	4	14.8	3	15.0	7	14.9	8	14.3	5	9.4	13	11.9
	Markedly ill (5)	1	3.4	0	.	1	1.6	0	.	0	.	0	.	1	1.8	0	.	1	0.9
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	29	100.0	33	100.0	62	100.0	27	100.0	20	100.0	47	100.0	56	100.0	53	100.0	109	100.0
Week 12	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	5	20.8	11	32.4	16	27.6	5	22.7	7	36.8	12	29.3	10	21.7	18	34.0	28	28.3

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

BRL 29060 - 716

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 12	Borderline mentally ill (2)	7	29.2	10	29.4	17	29.3	7	31.8	6	31.6	13	31.7	14	30.4	16	30.2	30	30.3
	Mildly ill (3)	10	41.7	10	29.4	20	34.5	8	36.4	2	10.5	10	24.4	18	39.1	12	22.6	30	30.3
	Moderately ill (4)	0	.	2	5.9	2	3.4	1	4.5	4	21.1	5	12.2	1	2.2	6	11.3	7	7.1
	Markedly ill (5)	2	8.3	1	2.9	3	5.2	1	4.5	0	.	1	2.4	3	6.5	1	1.9	4	4.0
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	24	100.0	34	100.0	58	100.0	22	100.0	19	100.0	41	100.0	46	100.0	53	100.0	99	100.0
Week 16	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

BRL 29060 - 716

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 16	Normal, not at all ill (1)	5	26.3	10	32.3	15	30.0	3	14.3	7	43.8	10	27.0	8	20.0	17	36.2	25	28.7
	Borderline mentally ill (2)	7	36.8	10	32.3	17	34.0	9	42.9	5	31.3	14	37.8	16	40.0	15	31.9	31	35.6
	Mildly ill (3)	6	31.6	6	19.4	12	24.0	7	33.3	0	.	7	18.9	13	32.5	6	12.8	19	21.8
	Moderately ill (4)	1	5.3	5	16.1	6	12.0	2	9.5	4	25.0	6	16.2	3	7.5	9	19.1	12	13.8
	Markedly ill (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	19	100.0	31	100.0	50	100.0	21	100.0	16	100.0	37	100.0	40	100.0	47	100.0	87	100.0

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

BRL 29060 - 716

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 20	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	9	47.4	11	42.3	20	44.4	3	17.6	4	30.8	7	23.3	12	33.3	15	38.5	27	36.0
	Borderline mentally ill (2)	6	31.6	10	38.5	16	35.6	9	52.9	5	38.5	14	46.7	15	41.7	15	38.5	30	40.0
	Mildly ill (3)	4	21.1	4	15.4	8	17.8	4	23.5	2	15.4	6	20.0	8	22.2	6	15.4	14	18.7
	Moderately ill (4)	0	.	1	3.8	1	2.2	1	5.9	1	7.7	2	6.7	1	2.8	2	5.1	3	4.0
	Markedly ill (5)	0	.	0	.	0	.	0	.	1	7.7	1	3.3	0	.	1	2.6	1	1.3
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 20	Total	19	100.0	26	100.0	45	100.0	17	100.0	13	100.0	30	100.0	36	100.0	39	100.0	75	100.0
Week 24	Not assessed (0)	0	.	1	4.0	1	2.4	0	.	0	.	0	.	0	.	1	2.6	1	1.5
	Normal, not at all ill (1)	8	47.1	9	36.0	17	40.5	2	20.0	5	38.5	7	30.4	10	37.0	14	36.8	24	36.9
	Borderline mentally ill (2)	8	47.1	9	36.0	17	40.5	4	40.0	4	30.8	8	34.8	12	44.4	13	34.2	25	38.5
	Mildly ill (3)	1	5.9	4	16.0	5	11.9	2	20.0	3	23.1	5	21.7	3	11.1	7	18.4	10	15.4
	Moderately ill (4)	0	.	1	4.0	1	2.4	2	20.0	0	.	2	8.7	2	7.4	1	2.6	3	4.6
	Markedly ill (5)	0	.	1	4.0	1	2.4	0	.	1	7.7	1	4.3	0	.	2	5.3	2	3.1
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

BRL 29060 - 716

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 24 LOCF	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	17	100.0	25	100.0	42	100.0	10	100.0	13	100.0	23	100.0	27	100.0	38	100.0	65	100.0
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	10	27.0	15	35.7	25	31.6	6	17.1	6	20.7	12	18.8	16	22.2	21	29.6	37	25.9
	Borderline mentally ill (2)	15	40.5	11	26.2	26	32.9	13	37.1	7	24.1	20	31.3	28	38.9	18	25.4	46	32.2
	Mildly ill (3)	8	21.6	6	14.3	14	17.7	6	17.1	5	17.2	11	17.2	14	19.4	11	15.5	25	17.5
	Moderately ill (4)	3	8.1	7	16.7	10	12.7	9	25.7	8	27.6	17	26.6	12	16.7	15	21.1	27	18.9
	Markedly ill (5)	1	2.7	2	4.8	3	3.8	1	2.9	3	10.3	4	6.3	2	2.8	5	7.0	7	4.9

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

BRL 29060 - 716

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 24 LOCF	Severely ill (6)	0	.	1	2.4	1	1.3	0	.	0	.	0	.	0	.	1	1.4	1	0.7
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	37	100.0	42	100.0	79	100.0	35	100.0	29	100.0	64	100.0	72	100.0	71	100.0	143	100.0

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Acute Baseline	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Borderline mentally ill (2)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Mildly ill (3)	0	.	0	.	0	.	1	2.8	1	3.6	2	3.1	1	1.6	1	1.9	2	1.7
	Moderately ill (4)	18	64.3	11	45.8	29	55.8	17	47.2	9	32.1	26	40.6	35	54.7	20	38.5	55	47.4
	Markedly ill (5)	9	32.1	11	45.8	20	38.5	11	30.6	15	53.6	26	40.6	20	31.3	26	50.0	46	39.7
	Severely ill (6)	1	3.6	2	8.3	3	5.8	7	19.4	3	10.7	10	15.6	8	12.5	5	9.6	13	11.2
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Acute Baseline	Total	28	100.0	24	100.0	52	100.0	36	100.0	28	100.0	64	100.0	64	100.0	52	100.0	116	100.0
Week 1	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	3	13.6	1	4.3	4	8.9	1	3.3	0	.	1	1.9	4	7.7	1	2.1	5	5.1
	Borderline mentally ill (2)	2	9.1	3	13.0	5	11.1	1	3.3	1	4.2	2	3.7	3	5.8	4	8.5	7	7.1
	Mildly ill (3)	5	22.7	5	21.7	10	22.2	6	20.0	1	4.2	7	13.0	11	21.2	6	12.8	17	17.2
	Moderately ill (4)	8	36.4	9	39.1	17	37.8	16	53.3	15	62.5	31	57.4	24	46.2	24	51.1	48	48.5
	Markedly ill (5)	4	18.2	5	21.7	9	20.0	5	16.7	6	25.0	11	20.4	9	17.3	11	23.4	20	20.2
	Severely ill (6)	0	.	0	.	0	.	1	3.3	1	4.2	2	3.7	1	1.9	1	2.1	2	2.0

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 1	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	22	100.0	23	100.0	45	100.0	30	100.0	24	100.0	54	100.0	52	100.0	47	100.0	99	100.0
Week 2	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	1	5.0	2	10.0	3	7.5	3	9.7	0	.	3	5.5	4	7.8	2	4.5	6	6.3
	Borderline mentally ill (2)	5	25.0	4	20.0	9	22.5	2	6.5	2	8.3	4	7.3	7	13.7	6	13.6	13	13.7
	Mildly ill (3)	4	20.0	5	25.0	9	22.5	9	29.0	4	16.7	13	23.6	13	25.5	9	20.5	22	23.2
	Moderately ill (4)	9	45.0	7	35.0	16	40.0	10	32.3	15	62.5	25	45.5	19	37.3	22	50.0	41	43.2
	Markedly ill (5)	1	5.0	2	10.0	3	7.5	6	19.4	2	8.3	8	14.5	7	13.7	4	9.1	11	11.6

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 2	Severely ill (6)	0	.	0	.	0	.	1	3.2	1	4.2	2	3.6	1	2.0	1	2.3	2	2.1
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	20	100.0	20	100.0	40	100.0	31	100.0	24	100.0	55	100.0	51	100.0	44	100.0	95	100.0
Week 3	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	3	13.6	2	11.1	5	12.5	3	8.8	2	8.7	5	8.8	6	10.7	4	9.8	10	10.3
	Borderline mentally ill (2)	4	18.2	3	16.7	7	17.5	1	2.9	2	8.7	3	5.3	5	8.9	5	12.2	10	10.3
	Mildly ill (3)	6	27.3	4	22.2	10	25.0	12	35.3	8	34.8	20	35.1	18	32.1	12	29.3	30	30.9
	Moderately ill (4)	8	36.4	6	33.3	14	35.0	13	38.2	8	34.8	21	36.8	21	37.5	14	34.1	35	36.1

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 3	Markedly ill (5)	1	4.5	3	16.7	4	10.0	5	14.7	2	8.7	7	12.3	6	10.7	5	12.2	11	11.3
	Severely ill (6)	0	.	0	.	0	.	0	.	1	4.3	1	1.8	0	.	1	2.4	1	1.0
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	22	100.0	18	100.0	40	100.0	34	100.0	23	100.0	57	100.0	56	100.0	41	100.0	97	100.0
Week 4	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	4	15.4	4	17.4	8	16.3	4	13.3	1	4.0	5	9.1	8	14.3	5	10.4	13	12.5
	Borderline mentally ill (2)	4	15.4	3	13.0	7	14.3	3	10.0	3	12.0	6	10.9	7	12.5	6	12.5	13	12.5
	Mildly ill (3)	9	34.6	6	26.1	15	30.6	11	36.7	7	28.0	18	32.7	20	35.7	13	27.1	33	31.7

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

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Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 4	Moderately ill (4)	6	23.1	7	30.4	13	26.5	11	36.7	11	44.0	22	40.0	17	30.4	18	37.5	35	33.7
	Markedly ill (5)	3	11.5	3	13.0	6	12.2	1	3.3	2	8.0	3	5.5	4	7.1	5	10.4	9	8.7
	Severely ill (6)	0	.	0	.	0	.	0	.	1	4.0	1	1.8	0	.	1	2.1	1	1.0
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	26	100.0	23	100.0	49	100.0	30	100.0	25	100.0	55	100.0	56	100.0	48	100.0	104	100.0
Week 8	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	3	13.0	6	28.6	9	20.5	5	22.7	2	11.8	7	17.9	8	17.8	8	21.1	16	19.3
	Borderline mentally ill (2)	5	21.7	2	9.5	7	15.9	3	13.6	3	17.6	6	15.4	8	17.8	5	13.2	13	15.7

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 8	Mildly ill (3)	8	34.8	6	28.6	14	31.8	8	36.4	6	35.3	14	35.9	16	35.6	12	31.6	28	33.7
	Moderately ill (4)	5	21.7	5	23.8	10	22.7	4	18.2	5	29.4	9	23.1	9	20.0	10	26.3	19	22.9
	Markedly ill (5)	2	8.7	2	9.5	4	9.1	2	9.1	0	.	2	5.1	4	8.9	2	5.3	6	7.2
	Severely ill (6)	0	.	0	.	0	.	0	.	1	5.9	1	2.6	0	.	1	2.6	1	1.2
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	23	100.0	21	100.0	44	100.0	22	100.0	17	100.0	39	100.0	45	100.0	38	100.0	83	100.0
Week 12	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	4	23.5	3	18.8	7	21.2	4	19.0	3	21.4	7	20.0	8	21.1	6	20.0	14	20.6

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 12	Borderline mentally ill (2)	4	23.5	3	18.8	7	21.2	3	14.3	4	28.6	7	20.0	7	18.4	7	23.3	14	20.6
	Mildly ill (3)	7	41.2	7	43.8	14	42.4	8	38.1	6	42.9	14	40.0	15	39.5	13	43.3	28	41.2
	Moderately ill (4)	1	5.9	3	18.8	4	12.1	6	28.6	0	.	6	17.1	7	18.4	3	10.0	10	14.7
	Markedly ill (5)	1	5.9	0	.	1	3.0	0	.	0	.	0	.	1	2.6	0	.	1	1.5
	Severely ill (6)	0	.	0	.	0	.	0	.	1	7.1	1	2.9	0	.	1	3.3	1	1.5
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	17	100.0	16	100.0	33	100.0	21	100.0	14	100.0	35	100.0	38	100.0	30	100.0	68	100.0
Week 16	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 16	Normal, not at all ill (1)	3	20.0	2	13.3	5	16.7	4	28.6	5	31.3	9	30.0	7	24.1	7	22.6	14	23.3
	Borderline mentally ill (2)	5	33.3	3	20.0	8	26.7	3	21.4	1	6.3	4	13.3	8	27.6	4	12.9	12	20.0
	Mildly ill (3)	6	40.0	5	33.3	11	36.7	4	28.6	8	50.0	12	40.0	10	34.5	13	41.9	23	38.3
	Moderately ill (4)	1	6.7	3	20.0	4	13.3	3	21.4	1	6.3	4	13.3	4	13.8	4	12.9	8	13.3
	Markedly ill (5)	0	.	2	13.3	2	6.7	0	.	0	.	0	.	0	.	2	6.5	2	3.3
	Severely ill (6)	0	.	0	.	0	.	0	.	1	6.3	1	3.3	0	.	1	3.2	1	1.7
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	15	100.0	15	100.0	30	100.0	14	100.0	16	100.0	30	100.0	29	100.0	31	100.0	60	100.0

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 20	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	6	50.0	2	18.2	8	34.8	4	30.8	4	33.3	8	32.0	10	40.0	6	26.1	16	33.3
	Borderline mentally ill (2)	1	8.3	2	18.2	3	13.0	2	15.4	1	8.3	3	12.0	3	12.0	3	13.0	6	12.5
	Mildly ill (3)	5	41.7	5	45.5	10	43.5	6	46.2	4	33.3	10	40.0	11	44.0	9	39.1	20	41.7
	Moderately ill (4)	0	.	1	9.1	1	4.3	1	7.7	3	25.0	4	16.0	1	4.0	4	17.4	5	10.4
	Markedly ill (5)	0	.	1	9.1	1	4.3	0	.	0	.	0	.	0	.	1	4.3	1	2.1
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 20	Total	12	100.0	11	100.0	23	100.0	13	100.0	12	100.0	25	100.0	25	100.0	23	100.0	48	100.0
Week 24	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	5	33.3	3	27.3	8	30.8	4	33.3	2	18.2	6	26.1	9	33.3	5	22.7	14	28.6
	Borderline mentally ill (2)	3	20.0	4	36.4	7	26.9	3	25.0	2	18.2	5	21.7	6	22.2	6	27.3	12	24.5
	Mildly ill (3)	7	46.7	3	27.3	10	38.5	5	41.7	5	45.5	10	43.5	12	44.4	8	36.4	20	40.8
	Moderately ill (4)	0	.	1	9.1	1	3.8	0	.	2	18.2	2	8.7	0	.	3	13.6	3	6.1
	Markedly ill (5)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 24	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	15	100.0	11	100.0	26	100.0	12	100.0	11	100.0	23	100.0	27	100.0	22	100.0	49	100.0
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Normal, not at all ill (1)	7	25.0	7	30.4	14	27.5	5	14.3	3	10.7	8	12.7	12	19.0	10	19.6	22	19.3
	Borderline mentally ill (2)	4	14.3	5	21.7	9	17.6	3	8.6	4	14.3	7	11.1	7	11.1	9	17.6	16	14.0
	Mildly ill (3)	10	35.7	6	26.1	16	31.4	15	42.9	10	35.7	25	39.7	25	39.7	16	31.4	41	36.0
	Moderately ill (4)	6	21.4	3	13.0	9	17.6	10	28.6	8	28.6	18	28.6	16	25.4	11	21.6	27	23.7
	Markedly ill (5)	1	3.6	2	8.7	3	5.9	2	5.7	2	7.1	4	6.3	3	4.8	4	7.8	7	6.1

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.1b

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Week 24 LOCF	Severely ill (6)	0	.	0	.	0	.	0	.	1	3.6	1	1.6	0	.	1	2.0	1	0.9
	Among the most extremely ill patients (7)	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.	0	.
	Total	28	100.0	23	100.0	51	100.0	35	100.0	28	100.0	63	100.0	63	100.0	51	100.0	114	100.0

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Acute Study Treatment Phase Endpoint	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	6	24.0	5	20.0	11	22.0
	Borderline mentally ill (2)	9	36.0	7	28.0	16	32.0
	Mildly ill (3)	3	12.0	7	28.0	10	20.0
	Moderately ill (4)	5	20.0	5	20.0	10	20.0
	Markedly ill (5)	2	8.0	1	4.0	3	6.0
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	25	100.0	25	100.0	50	100.0
Week 1	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	14.3	1	4.8	4	9.5
	Borderline mentally ill (2)	5	23.8	3	14.3	8	19.0
	Mildly ill (3)	5	23.8	7	33.3	12	28.6
	Moderately ill (4)	6	28.6	10	47.6	16	38.1
	Markedly ill (5)	2	9.5	0	.	2	4.8
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	21	100.0	21	100.0	42	100.0

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Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 2	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	19.0	3	13.6	7	16.3
	Borderline mentally ill (2)	3	14.3	5	22.7	8	18.6
	Mildly ill (3)	6	28.6	7	31.8	13	30.2
	Moderately ill (4)	7	33.3	7	31.8	14	32.6
	Markedly ill (5)	1	4.8	0	.	1	2.3
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	21	100.0	22	100.0	43	100.0
Week 3	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	20.0	2	8.3	6	13.6
	Borderline mentally ill (2)	6	30.0	9	37.5	15	34.1
	Mildly ill (3)	4	20.0	11	45.8	15	34.1
	Moderately ill (4)	6	30.0	2	8.3	8	18.2
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	20	100.0	24	100.0	44	100.0

(CONTINUED)

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Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 4	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	17.4	2	9.1	6	13.3
	Borderline mentally ill (2)	9	39.1	10	45.5	19	42.2
	Mildly ill (3)	5	21.7	7	31.8	12	26.7
	Moderately ill (4)	5	21.7	1	4.5	6	13.3
	Markedly ill (5)	0	.	2	9.1	2	4.4
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	23	100.0	22	100.0	45	100.0
Week 8	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	15.0	6	30.0	9	22.5
	Borderline mentally ill (2)	6	30.0	6	30.0	12	30.0
	Mildly ill (3)	8	40.0	6	30.0	14	35.0
	Moderately ill (4)	3	15.0	2	10.0	5	12.5
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	20	100.0	20	100.0	40	100.0

(CONTINUED)

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Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 12	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	23.5	5	25.0	9	24.3
	Borderline mentally ill (2)	4	23.5	7	35.0	11	29.7
	Mildly ill (3)	8	47.1	7	35.0	15	40.5
	Moderately ill (4)	0	.	1	5.0	1	2.7
	Markedly ill (5)	1	5.9	0	.	1	2.7
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	17	100.0	20	100.0	37	100.0
Week 16	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	26.7	4	21.1	8	23.5
	Borderline mentally ill (2)	5	33.3	6	31.6	11	32.4
	Mildly ill (3)	5	33.3	6	31.6	11	32.4
	Moderately ill (4)	1	6.7	3	15.8	4	11.8
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	15	100.0	19	100.0	34	100.0

(CONTINUED)

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Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 20	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	38.5	4	26.7	9	32.1
	Borderline mentally ill (2)	5	38.5	7	46.7	12	42.9
	Mildly ill (3)	3	23.1	3	20.0	6	21.4
	Moderately ill (4)	0	.	1	6.7	1	3.6
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	13	100.0	15	100.0	28	100.0
Week 24	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	38.5	4	26.7	9	32.1
	Borderline mentally ill (2)	7	53.8	7	46.7	14	50.0
	Mildly ill (3)	1	7.7	3	20.0	4	14.3
	Moderately ill (4)	0	.	1	6.7	1	3.6
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	13	100.0	15	100.0	28	100.0

(CONTINUED)

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Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	20.8	5	20.0	10	20.4
	Borderline mentally ill (2)	11	45.8	9	36.0	20	40.8
	Mildly ill (3)	6	25.0	5	20.0	11	22.4
	Moderately ill (4)	2	8.3	5	20.0	7	14.3
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	1	4.0	1	2.0
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	24	100.0	25	100.0	49	100.0

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Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Paroxetine (N = 46)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Acute Study Treatment Phase Endpoint	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	20.0	0	.	5	10.9
	Borderline mentally ill (2)	5	20.0	4	19.0	9	19.6
	Mildly ill (3)	6	24.0	6	28.6	12	26.1
	Moderately ill (4)	8	32.0	6	28.6	14	30.4
	Markedly ill (5)	1	4.0	5	23.8	6	13.0
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	25	100.0	21	100.0	46	100.0
Week 1	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	15.0	0	.	3	7.5
	Borderline mentally ill (2)	2	10.0	2	10.0	4	10.0
	Mildly ill (3)	5	25.0	5	25.0	10	25.0
	Moderately ill (4)	7	35.0	8	40.0	15	37.5
	Markedly ill (5)	3	15.0	5	25.0	8	20.0
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	20	100.0	20	100.0	40	100.0

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Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Paroxetine (N = 46)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 2	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	1	5.6	1	5.9	2	5.7
	Borderline mentally ill (2)	4	22.2	3	17.6	7	20.0
	Mildly ill (3)	4	22.2	5	29.4	9	25.7
	Moderately ill (4)	8	44.4	6	35.3	14	40.0
	Markedly ill (5)	1	5.6	2	11.8	3	8.6
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	18	100.0	17	100.0	35	100.0
Week 3	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	15.0	1	6.7	4	11.4
	Borderline mentally ill (2)	3	15.0	2	13.3	5	14.3
	Mildly ill (3)	6	30.0	4	26.7	10	28.6
	Moderately ill (4)	8	40.0	5	33.3	13	37.1
	Markedly ill (5)	0	.	3	20.0	3	8.6
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	20	100.0	15	100.0	35	100.0

(CONTINUED)

Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Paroxetine (N = 46)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 4	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	16.7	3	15.0	7	15.9
	Borderline mentally ill (2)	4	16.7	2	10.0	6	13.6
	Mildly ill (3)	8	33.3	6	30.0	14	31.8
	Moderately ill (4)	6	25.0	6	30.0	12	27.3
	Markedly ill (5)	2	8.3	3	15.0	5	11.4
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	24	100.0	20	100.0	44	100.0
Week 8	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	14.3	5	27.8	8	20.5
	Borderline mentally ill (2)	4	19.0	2	11.1	6	15.4
	Mildly ill (3)	8	38.1	5	27.8	13	33.3
	Moderately ill (4)	4	19.0	4	22.2	8	20.5
	Markedly ill (5)	2	9.5	2	11.1	4	10.3
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	21	100.0	18	100.0	39	100.0

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Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Paroxetine (N = 46)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 12	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	26.7	2	15.4	6	21.4
	Borderline mentally ill (2)	3	20.0	3	23.1	6	21.4
	Mildly ill (3)	6	40.0	6	46.2	12	42.9
	Moderately ill (4)	1	6.7	2	15.4	3	10.7
	Markedly ill (5)	1	6.7	0	.	1	3.6
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	15	100.0	13	100.0	28	100.0
Week 16	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	23.1	2	14.3	5	18.5
	Borderline mentally ill (2)	4	30.8	3	21.4	7	25.9
	Mildly ill (3)	5	38.5	5	35.7	10	37.0
	Moderately ill (4)	1	7.7	3	21.4	4	14.8
	Markedly ill (5)	0	.	1	7.1	1	3.7
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	13	100.0	14	100.0	27	100.0

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Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Paroxetine (N = 46)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 20	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	50.0	1	10.0	6	30.0
	Borderline mentally ill (2)	1	10.0	2	20.0	3	15.0
	Mildly ill (3)	4	40.0	5	50.0	9	45.0
	Moderately ill (4)	0	.	1	10.0	1	5.0
	Markedly ill (5)	0	.	1	10.0	1	5.0
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	10	100.0	10	100.0	20	100.0
Week 24	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	30.8	3	30.0	7	30.4
	Borderline mentally ill (2)	3	23.1	3	30.0	6	26.1
	Mildly ill (3)	6	46.2	3	30.0	9	39.1
	Moderately ill (4)	0	.	1	10.0	1	4.3
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	13	100.0	10	100.0	23	100.0

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Table 14.4.1d

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Paroxetine (N = 46)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	6	24.0	6	30.0	12	26.7
	Borderline mentally ill (2)	4	16.0	4	20.0	8	17.8
	Mildly ill (3)	9	36.0	6	30.0	15	33.3
	Moderately ill (4)	5	20.0	2	10.0	7	15.6
	Markedly ill (5)	1	4.0	2	10.0	3	6.7
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	25	100.0	20	100.0	45	100.0

Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Acute Study Treatment Phase Endpoint	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	6	16.7	5	17.2	11	16.9
	Borderline mentally ill (2)	7	19.4	7	24.1	14	21.5
	Mildly ill (3)	6	16.7	6	20.7	12	18.5
	Moderately ill (4)	16	44.4	11	37.9	27	41.5
	Markedly ill (5)	1	2.8	0	.	1	1.5
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	36	100.0	29	100.0	65	100.0
Week 1	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	15.2	2	7.7	7	11.9
	Borderline mentally ill (2)	6	18.2	8	30.8	14	23.7
	Mildly ill (3)	10	30.3	5	19.2	15	25.4
	Moderately ill (4)	11	33.3	11	42.3	22	37.3
	Markedly ill (5)	1	3.0	0	.	1	1.7
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	33	100.0	26	100.0	59	100.0

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Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 2	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	8	25.0	4	16.0	12	21.1
	Borderline mentally ill (2)	4	12.5	5	20.0	9	15.8
	Mildly ill (3)	10	31.3	9	36.0	19	33.3
	Moderately ill (4)	8	25.0	7	28.0	15	26.3
	Markedly ill (5)	2	6.3	0	.	2	3.5
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	32	100.0	25	100.0	57	100.0
Week 3	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	8	25.8	4	18.2	12	22.6
	Borderline mentally ill (2)	6	19.4	5	22.7	11	20.8
	Mildly ill (3)	11	35.5	8	36.4	19	35.8
	Moderately ill (4)	6	19.4	5	22.7	11	20.8
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	31	100.0	22	100.0	53	100.0

(CONTINUED)

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Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 4	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	8	25.8	3	12.5	11	20.0
	Borderline mentally ill (2)	10	32.3	9	37.5	19	34.5
	Mildly ill (3)	7	22.6	7	29.2	14	25.5
	Moderately ill (4)	5	16.1	4	16.7	9	16.4
	Markedly ill (5)	1	3.2	1	4.2	2	3.6
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	31	100.0	24	100.0	55	100.0
Week 8	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	7	25.9	5	25.0	12	25.5
	Borderline mentally ill (2)	9	33.3	7	35.0	16	34.0
	Mildly ill (3)	7	25.9	5	25.0	12	25.5
	Moderately ill (4)	4	14.8	3	15.0	7	14.9
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	27	100.0	20	100.0	47	100.0

(CONTINUED)

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Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 12	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	22.7	7	36.8	12	29.3
	Borderline mentally ill (2)	7	31.8	6	31.6	13	31.7
	Mildly ill (3)	8	36.4	2	10.5	10	24.4
	Moderately ill (4)	1	4.5	4	21.1	5	12.2
	Markedly ill (5)	1	4.5	0	.	1	2.4
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	22	100.0	19	100.0	41	100.0
Week 16	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	14.3	7	43.8	10	27.0
	Borderline mentally ill (2)	9	42.9	5	31.3	14	37.8
	Mildly ill (3)	7	33.3	0	.	7	18.9
	Moderately ill (4)	2	9.5	4	25.0	6	16.2
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	21	100.0	16	100.0	37	100.0

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Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 20	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	17.6	4	30.8	7	23.3
	Borderline mentally ill (2)	9	52.9	5	38.5	14	46.7
	Mildly ill (3)	4	23.5	2	15.4	6	20.0
	Moderately ill (4)	1	5.9	1	7.7	2	6.7
	Markedly ill (5)	0	.	1	7.7	1	3.3
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	17	100.0	13	100.0	30	100.0
Week 24	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	2	20.0	5	38.5	7	30.4
	Borderline mentally ill (2)	4	40.0	4	30.8	8	34.8
	Mildly ill (3)	2	20.0	3	23.1	5	21.7
	Moderately ill (4)	2	20.0	0	.	2	8.7
	Markedly ill (5)	0	.	1	7.7	1	4.3
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	10	100.0	13	100.0	23	100.0

(CONTINUED)

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Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	6	17.1	6	20.7	12	18.8
	Borderline mentally ill (2)	13	37.1	7	24.1	20	31.3
	Mildly ill (3)	6	17.1	5	17.2	11	17.2
	Moderately ill (4)	9	25.7	8	27.6	17	26.6
	Markedly ill (5)	1	2.9	3	10.3	4	6.3
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	35	100.0	29	100.0	64	100.0

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Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 64)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Acute Study Treatment Phase Endpoint	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	8.6	1	3.6	4	6.3
	Borderline mentally ill (2)	5	14.3	2	7.1	7	11.1
	Mildly ill (3)	8	22.9	5	17.9	13	20.6
	Moderately ill (4)	14	40.0	15	53.6	29	46.0
	Markedly ill (5)	5	14.3	4	14.3	9	14.3
	Severely ill (6)	0	.	1	3.6	1	1.6
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	35	100.0	28	100.0	63	100.0
Week 1	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	1	3.3	0	.	1	1.9
	Borderline mentally ill (2)	1	3.3	1	4.2	2	3.7
	Mildly ill (3)	6	20.0	1	4.2	7	13.0
	Moderately ill (4)	16	53.3	15	62.5	31	57.4
	Markedly ill (5)	5	16.7	6	25.0	11	20.4
	Severely ill (6)	1	3.3	1	4.2	2	3.7
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	30	100.0	24	100.0	54	100.0

(CONTINUED)

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Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 64)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 2	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	9.7	0	.	3	5.5
	Borderline mentally ill (2)	2	6.5	2	8.3	4	7.3
	Mildly ill (3)	9	29.0	4	16.7	13	23.6
	Moderately ill (4)	10	32.3	15	62.5	25	45.5
	Markedly ill (5)	6	19.4	2	8.3	8	14.5
	Severely ill (6)	1	3.2	1	4.2	2	3.6
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	31	100.0	24	100.0	55	100.0
Week 3	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	3	8.8	2	8.7	5	8.8
	Borderline mentally ill (2)	1	2.9	2	8.7	3	5.3
	Mildly ill (3)	12	35.3	8	34.8	20	35.1
	Moderately ill (4)	13	38.2	8	34.8	21	36.8
	Markedly ill (5)	5	14.7	2	8.7	7	12.3
	Severely ill (6)	0	.	1	4.3	1	1.8
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	34	100.0	23	100.0	57	100.0

(CONTINUED)

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Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 64)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 4	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	13.3	1	4.0	5	9.1
	Borderline mentally ill (2)	3	10.0	3	12.0	6	10.9
	Mildly ill (3)	11	36.7	7	28.0	18	32.7
	Moderately ill (4)	11	36.7	11	44.0	22	40.0
	Markedly ill (5)	1	3.3	2	8.0	3	5.5
	Severely ill (6)	0	.	1	4.0	1	1.8
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	30	100.0	25	100.0	55	100.0
Week 8	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	22.7	2	11.8	7	17.9
	Borderline mentally ill (2)	3	13.6	3	17.6	6	15.4
	Mildly ill (3)	8	36.4	6	35.3	14	35.9
	Moderately ill (4)	4	18.2	5	29.4	9	23.1
	Markedly ill (5)	2	9.1	0	.	2	5.1
	Severely ill (6)	0	.	1	5.9	1	2.6
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	22	100.0	17	100.0	39	100.0

(CONTINUED)

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Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 64)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 12	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	19.0	3	21.4	7	20.0
	Borderline mentally ill (2)	3	14.3	4	28.6	7	20.0
	Mildly ill (3)	8	38.1	6	42.9	14	40.0
	Moderately ill (4)	6	28.6	0	.	6	17.1
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	1	7.1	1	2.9
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	21	100.0	14	100.0	35	100.0
Week 16	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	28.6	5	31.3	9	30.0
	Borderline mentally ill (2)	3	21.4	1	6.3	4	13.3
	Mildly ill (3)	4	28.6	8	50.0	12	40.0
	Moderately ill (4)	3	21.4	1	6.3	4	13.3
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	1	6.3	1	3.3
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	14	100.0	16	100.0	30	100.0

(CONTINUED)

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Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 64)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 20	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	30.8	4	33.3	8	32.0
	Borderline mentally ill (2)	2	15.4	1	8.3	3	12.0
	Mildly ill (3)	6	46.2	4	33.3	10	40.0
	Moderately ill (4)	1	7.7	3	25.0	4	16.0
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	13	100.0	12	100.0	25	100.0
Week 24	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	4	33.3	2	18.2	6	26.1
	Borderline mentally ill (2)	3	25.0	2	18.2	5	21.7
	Mildly ill (3)	5	41.7	5	45.5	10	43.5
	Moderately ill (4)	0	.	2	18.2	2	8.7
	Markedly ill (5)	0	.	0	.	0	.
	Severely ill (6)	0	.	0	.	0	.
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	12	100.0	11	100.0	23	100.0

(CONTINUED)

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Table 14.4.1e

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score at Each Visit
by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 64)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 24 LOCF	Not assessed (0)	0	.	0	.	0	.
	Normal, not at all ill (1)	5	14.3	3	10.7	8	12.7
	Borderline mentally ill (2)	3	8.6	4	14.3	7	11.1
	Mildly ill (3)	15	42.9	10	35.7	25	39.7
	Moderately ill (4)	10	28.6	8	28.6	18	28.6
	Markedly ill (5)	2	5.7	2	7.1	4	6.3
	Severely ill (6)	0	.	1	3.6	1	1.6
	Among the most extremely ill patients (7)	0	.	0	.	0	.
	Total	35	100.0	28	100.0	63	100.0

Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 1	-4	2	5.9	0	.	2	2.8	2	6.1	1	3.8	3	5.1	4	6.0	1	1.6	5	3.8
	-3	7	20.6	9	24.3	16	22.5	7	21.2	3	11.5	10	16.9	14	20.9	12	19.0	26	20.0
	-2	8	23.5	7	18.9	15	21.1	4	12.1	7	26.9	11	18.6	12	17.9	14	22.2	26	20.0
	-1	9	26.5	11	29.7	20	28.2	8	24.2	7	26.9	15	25.4	17	25.4	18	28.6	35	26.9
	0	7	20.6	9	24.3	16	22.5	10	30.3	8	30.8	18	30.5	17	25.4	17	27.0	34	26.2
	1	1	2.9	1	2.7	2	2.8	2	6.1	0	.	2	3.4	3	4.5	1	1.6	4	3.1
	Total	34	100.0	37	100.0	71	100.0	33	100.0	26	100.0	59	100.0	67	100.0	63	100.0	130	100.0
Week 2	-5	0	.	0	.	0	.	1	3.1	0	.	1	1.8	1	1.5	0	.	1	0.8
	-4	2	6.1	1	2.6	3	4.2	2	6.3	3	12.0	5	8.8	4	6.2	4	6.3	8	6.2
	-3	8	24.2	11	28.2	19	26.4	8	25.0	1	4.0	9	15.8	16	24.6	12	18.8	28	21.7
	-2	7	21.2	9	23.1	16	22.2	1	3.1	7	28.0	8	14.0	8	12.3	16	25.0	24	18.6
	-1	8	24.2	7	17.9	15	20.8	11	34.4	9	36.0	20	35.1	19	29.2	16	25.0	35	27.1
	0	7	21.2	10	25.6	17	23.6	7	21.9	5	20.0	12	21.1	14	21.5	15	23.4	29	22.5

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

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Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 2	1	1	3.0	0	.	1	1.4	2	6.3	0	.	2	3.5	3	4.6	0	.	3	2.3
	Missing	0	.	1	2.6	1	1.4	0	.	0	.	0	.	0	.	1	1.6	1	0.8
	Total	33	100.0	39	100.0	72	100.0	32	100.0	25	100.0	57	100.0	65	100.0	64	100.0	129	100.0
Week 3	-4	3	9.1	0	.	3	4.2	4	12.9	3	13.6	7	13.2	7	10.9	3	5.0	10	8.1
	-3	8	24.2	12	31.6	20	28.2	6	19.4	1	4.5	7	13.2	14	21.9	13	21.7	27	21.8
	-2	10	30.3	9	23.7	19	26.8	5	16.1	7	31.8	12	22.6	15	23.4	16	26.7	31	25.0
	-1	6	18.2	11	28.9	17	23.9	9	29.0	8	36.4	17	32.1	15	23.4	19	31.7	34	27.4
	0	6	18.2	5	13.2	11	15.5	7	22.6	3	13.6	10	18.9	13	20.3	8	13.3	21	16.9
	Missing	0	.	1	2.6	1	1.4	0	.	0	.	0	.	0	.	1	1.7	1	0.8
	Total	33	100.0	38	100.0	71	100.0	31	100.0	22	100.0	53	100.0	64	100.0	60	100.0	124	100.0
Week 4	-4	4	11.1	2	5.4	6	8.2	3	9.7	2	8.3	5	9.1	7	10.4	4	6.6	11	8.6
	-3	8	22.2	11	29.7	19	26.0	7	22.6	3	12.5	10	18.2	15	22.4	14	23.0	29	22.7
	-2	12	33.3	13	35.1	25	34.2	9	29.0	8	33.3	17	30.9	21	31.3	21	34.4	42	32.8

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

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Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 4	-1	6	16.7	5	13.5	11	15.1	7	22.6	7	29.2	14	25.5	13	19.4	12	19.7	25	19.5
	0	6	16.7	5	13.5	11	15.1	4	12.9	3	12.5	7	12.7	10	14.9	8	13.1	18	14.1
	1	0	.	1	2.7	1	1.4	1	3.2	1	4.2	2	3.6	1	1.5	2	3.3	3	2.3
	Total	36	100.0	37	100.0	73	100.0	31	100.0	24	100.0	55	100.0	67	100.0	61	100.0	128	100.0
Week 8	-4	2	6.9	3	9.1	5	8.1	2	7.4	4	20.0	6	12.8	4	7.1	7	13.2	11	10.1
	-3	9	31.0	12	36.4	21	33.9	7	25.9	1	5.0	8	17.0	16	28.6	13	24.5	29	26.6
	-2	5	17.2	11	33.3	16	25.8	9	33.3	8	40.0	17	36.2	14	25.0	19	35.8	33	30.3
	-1	8	27.6	5	15.2	13	21.0	4	14.8	5	25.0	9	19.1	12	21.4	10	18.9	22	20.2
	0	5	17.2	2	6.1	7	11.3	5	18.5	2	10.0	7	14.9	10	17.9	4	7.5	14	12.8
	Total	29	100.0	33	100.0	62	100.0	27	100.0	20	100.0	47	100.0	56	100.0	53	100.0	109	100.0
Week 12	-4	2	8.3	4	11.8	6	10.3	1	4.5	2	10.5	3	7.3	3	6.5	6	11.3	9	9.1
	-3	3	12.5	10	29.4	13	22.4	4	18.2	7	36.8	11	26.8	7	15.2	17	32.1	24	24.2
	-2	8	33.3	9	26.5	17	29.3	9	40.9	5	26.3	14	34.1	17	37.0	14	26.4	31	31.3

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

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Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 12	-1	10	41.7	10	29.4	20	34.5	6	27.3	2	10.5	8	19.5	16	34.8	12	22.6	28	28.3
	0	1	4.2	0	.	1	1.7	2	9.1	3	15.8	5	12.2	3	6.5	3	5.7	6	6.1
	1	0	.	1	2.9	1	1.7	0	.	0	.	0	.	0	.	1	1.9	1	1.0
	Total	24	100.0	34	100.0	58	100.0	22	100.0	19	100.0	41	100.0	46	100.0	53	100.0	99	100.0
Week 16	-5	0	.	1	3.2	1	2.0	0	.	0	.	0	.	0	.	1	2.1	1	1.1
	-4	3	15.8	2	6.5	5	10.0	0	.	3	18.8	3	8.1	3	7.5	5	10.6	8	9.2
	-3	2	10.5	9	29.0	11	22.0	4	19.0	4	25.0	8	21.6	6	15.0	13	27.7	19	21.8
	-2	8	42.1	11	35.5	19	38.0	11	52.4	5	31.3	16	43.2	19	47.5	16	34.0	35	40.2
	-1	6	31.6	4	12.9	10	20.0	3	14.3	2	12.5	5	13.5	9	22.5	6	12.8	15	17.2
	0	0	.	3	9.7	3	6.0	3	14.3	2	12.5	5	13.5	3	7.5	5	10.6	8	9.2
	1	0	.	1	3.2	1	2.0	0	.	0	.	0	.	0	.	1	2.1	1	1.1
	Total	19	100.0	31	100.0	50	100.0	21	100.0	16	100.0	37	100.0	40	100.0	47	100.0	87	100.0
Week 20	-5	0	.	1	3.8	1	2.2	0	.	0	.	0	.	0	.	1	2.6	1	1.3

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

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Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 20	-4	3	15.8	3	11.5	6	13.3	1	5.9	1	7.7	2	6.7	4	11.1	4	10.3	8	10.7
	-3	7	36.8	10	38.5	17	37.8	4	23.5	4	30.8	8	26.7	11	30.6	14	35.9	25	33.3
	-2	6	31.6	7	26.9	13	28.9	7	41.2	5	38.5	12	40.0	13	36.1	12	30.8	25	33.3
	-1	3	15.8	4	15.4	7	15.6	4	23.5	1	7.7	5	16.7	7	19.4	5	12.8	12	16.0
	0	0	.	1	3.8	1	2.2	1	5.9	1	7.7	2	6.7	1	2.8	2	5.1	3	4.0
	1	0	.	0	.	0	.	0	.	1	7.7	1	3.3	0	.	1	2.6	1	1.3
	Total	19	100.0	26	100.0	45	100.0	17	100.0	13	100.0	30	100.0	36	100.0	39	100.0	75	100.0
Week 24	-5	1	5.9	1	4.0	2	4.8	0	.	0	.	0	.	1	3.7	1	2.6	2	3.1
	-4	2	11.8	2	8.0	4	9.5	1	10.0	2	15.4	3	13.0	3	11.1	4	10.5	7	10.8
	-3	6	35.3	9	36.0	15	35.7	1	10.0	4	30.8	5	21.7	7	25.9	13	34.2	20	30.8
	-2	7	41.2	6	24.0	13	31.0	5	50.0	3	23.1	8	34.8	12	44.4	9	23.7	21	32.3
	-1	1	5.9	4	16.0	5	11.9	1	10.0	3	23.1	4	17.4	2	7.4	7	18.4	9	13.8
	0	0	.	1	4.0	1	2.4	2	20.0	1	7.7	3	13.0	2	7.4	2	5.3	4	6.2

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

BRL 29060 - 716

Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Major Depressive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 81)						Placebo (N = 66)						Total (N = 147)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 24	1	0	.	1	4.0	1	2.4	0	.	0	.	0	.	0	.	1	2.6	1	1.5
	Missing	0	.	1	4.0	1	2.4	0	.	0	.	0	.	0	.	1	2.6	1	1.5
	Total	17	100.0	25	100.0	42	100.0	10	100.0	13	100.0	23	100.0	27	100.0	38	100.0	65	100.0
Week 24 LOCF	-5	1	2.7	1	2.4	2	2.5	0	.	0	.	0	.	1	1.4	1	1.4	2	1.4
	-4	2	5.4	4	9.5	6	7.6	4	11.4	3	10.3	7	10.9	6	8.3	7	9.9	13	9.1
	-3	10	27.0	13	31.0	23	29.1	5	14.3	4	13.8	9	14.1	15	20.8	17	23.9	32	22.4
	-2	12	32.4	9	21.4	21	26.6	10	28.6	7	24.1	17	26.6	22	30.6	16	22.5	38	26.6
	-1	8	21.6	8	19.0	16	20.3	6	17.1	6	20.7	12	18.8	14	19.4	14	19.7	28	19.6
	0	4	10.8	4	9.5	8	10.1	10	28.6	7	24.1	17	26.6	14	19.4	11	15.5	25	17.5
	1	0	.	2	4.8	2	2.5	0	.	2	6.9	2	3.1	0	.	4	5.6	4	2.8
	2	0	.	1	2.4	1	1.3	0	.	0	.	0	.	0	.	1	1.4	1	0.7
	Total	37	100.0	42	100.0	79	100.0	35	100.0	29	100.0	64	100.0	72	100.0	71	100.0	143	100.0

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 1	-4	1	4.5	0	.	1	2.2	1	3.3	1	4.2	2	3.7	2	3.8	1	2.1	3	3.0
	-3	3	13.6	1	4.3	4	8.9	3	10.0	0	.	3	5.6	6	11.5	1	2.1	7	7.1
	-2	3	13.6	7	30.4	10	22.2	3	10.0	1	4.2	4	7.4	6	11.5	8	17.0	14	14.1
	-1	6	27.3	7	30.4	13	28.9	8	26.7	7	29.2	15	27.8	14	26.9	14	29.8	28	28.3
	0	7	31.8	7	30.4	14	31.1	14	46.7	15	62.5	29	53.7	21	40.4	22	46.8	43	43.4
	1	2	9.1	1	4.3	3	6.7	0	.	0	.	0	.	2	3.8	1	2.1	3	3.0
	2	0	.	0	.	0	.	1	3.3	0	.	1	1.9	1	1.9	0	.	1	1.0
	Total	22	100.0	23	100.0	45	100.0	30	100.0	24	100.0	54	100.0	52	100.0	47	100.0	99	100.0
Week 2	-5	0	.	1	5.0	1	2.5	1	3.2	0	.	1	1.8	1	2.0	1	2.3	2	2.1
	-4	0	.	0	.	0	.	2	6.5	1	4.2	3	5.5	2	3.9	1	2.3	3	3.2
	-3	2	10.0	2	10.0	4	10.0	2	6.5	2	8.3	4	7.3	4	7.8	4	9.1	8	8.4
	-2	6	30.0	4	20.0	10	25.0	4	12.9	1	4.2	5	9.1	10	19.6	5	11.4	15	15.8
	-1	5	25.0	8	40.0	13	32.5	10	32.3	9	37.5	19	34.5	15	29.4	17	38.6	32	33.7

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

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Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 2	0	7	35.0	5	25.0	12	30.0	11	35.5	11	45.8	22	40.0	18	35.3	16	36.4	34	35.8
	1	0	.	0	.	0	.	1	3.2	0	.	1	1.8	1	2.0	0	.	1	1.1
	Total	20	100.0	20	100.0	40	100.0	31	100.0	24	100.0	55	100.0	51	100.0	44	100.0	95	100.0
Week 3	-5	0	.	0	.	0	.	1	2.9	1	4.3	2	3.5	1	1.8	1	2.4	2	2.1
	-4	0	.	1	5.6	1	2.5	1	2.9	1	4.3	2	3.5	1	1.8	2	4.9	3	3.1
	-3	3	13.6	3	16.7	6	15.0	3	8.8	1	4.3	4	7.0	6	10.7	4	9.8	10	10.3
	-2	9	40.9	1	5.6	10	25.0	6	17.6	4	17.4	10	17.5	15	26.8	5	12.2	20	20.6
	-1	5	22.7	10	55.6	15	37.5	13	38.2	11	47.8	24	42.1	18	32.1	21	51.2	39	40.2
	0	4	18.2	2	11.1	6	15.0	9	26.5	5	21.7	14	24.6	13	23.2	7	17.1	20	20.6
	1	1	4.5	1	5.6	2	5.0	0	.	0	.	0	.	1	1.8	1	2.4	2	2.1
	2	0	.	0	.	0	.	1	2.9	0	.	1	1.8	1	1.8	0	.	1	1.0
	Total	22	100.0	18	100.0	40	100.0	34	100.0	23	100.0	57	100.0	56	100.0	41	100.0	97	100.0
Week 4	-5	0	.	1	4.3	1	2.0	2	6.7	0	.	2	3.6	2	3.6	1	2.1	3	2.9

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 4	-4	0	.	1	4.3	1	2.0	2	6.7	2	8.0	4	7.3	2	3.6	3	6.3	5	4.8
	-3	5	19.2	2	8.7	7	14.3	1	3.3	1	4.0	2	3.6	6	10.7	3	6.3	9	8.7
	-2	8	30.8	5	21.7	13	26.5	8	26.7	5	20.0	13	23.6	16	28.6	10	20.8	26	25.0
	-1	7	26.9	10	43.5	17	34.7	11	36.7	10	40.0	21	38.2	18	32.1	20	41.7	38	36.5
	0	4	15.4	4	17.4	8	16.3	5	16.7	7	28.0	12	21.8	9	16.1	11	22.9	20	19.2
	1	2	7.7	0	.	2	4.1	1	3.3	0	.	1	1.8	3	5.4	0	.	3	2.9
	Total	26	100.0	23	100.0	49	100.0	30	100.0	25	100.0	55	100.0	56	100.0	48	100.0	104	100.0
Week 8	-5	0	.	1	4.8	1	2.3	2	9.1	1	5.9	3	7.7	2	4.4	2	5.3	4	4.8
	-4	0	.	2	9.5	2	4.5	2	9.1	1	5.9	3	7.7	2	4.4	3	7.9	5	6.0
	-3	4	17.4	4	19.0	8	18.2	2	9.1	0	.	2	5.1	6	13.3	4	10.5	10	12.0
	-2	9	39.1	3	14.3	12	27.3	6	27.3	8	47.1	14	35.9	15	33.3	11	28.9	26	31.3
	-1	5	21.7	8	38.1	13	29.5	6	27.3	4	23.5	10	25.6	11	24.4	12	31.6	23	27.7
	0	4	17.4	3	14.3	7	15.9	3	13.6	3	17.6	6	15.4	7	15.6	6	15.8	13	15.7

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

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Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 8	1	1	4.3	0	.	1	2.3	0	.	0	.	0	.	1	2.2	0	.	1	1.2
	Missing	0	.	0	.	0	.	1	4.5	0	.	1	2.6	1	2.2	0	.	1	1.2
	Total	23	100.0	21	100.0	44	100.0	22	100.0	17	100.0	39	100.0	45	100.0	38	100.0	83	100.0
Week 12	-5	0	.	1	6.3	1	3.0	1	4.8	1	7.1	2	5.7	1	2.6	2	6.7	3	4.4
	-4	0	.	0	.	0	.	1	4.8	2	14.3	3	8.6	1	2.6	2	6.7	3	4.4
	-3	5	29.4	4	25.0	9	27.3	2	9.5	0	.	2	5.7	7	18.4	4	13.3	11	16.2
	-2	5	29.4	4	25.0	9	27.3	9	42.9	7	50.0	16	45.7	14	36.8	11	36.7	25	36.8
	-1	6	35.3	5	31.3	11	33.3	6	28.6	3	21.4	9	25.7	12	31.6	8	26.7	20	29.4
	0	0	.	2	12.5	2	6.1	2	9.5	1	7.1	3	8.6	2	5.3	3	10.0	5	7.4
	1	1	5.9	0	.	1	3.0	0	.	0	.	0	.	1	2.6	0	.	1	1.5
	Total	17	100.0	16	100.0	33	100.0	21	100.0	14	100.0	35	100.0	38	100.0	30	100.0	68	100.0
Week 16	-5	0	.	1	6.7	1	3.3	1	7.1	1	6.3	2	6.7	1	3.4	2	6.5	3	5.0
	-4	0	.	0	.	0	.	1	7.1	2	12.5	3	10.0	1	3.4	2	6.5	3	5.0

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

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Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 16	-3	3	20.0	2	13.3	5	16.7	3	21.4	2	12.5	5	16.7	6	20.7	4	12.9	10	16.7
	-2	8	53.3	5	33.3	13	43.3	5	35.7	5	31.3	10	33.3	13	44.8	10	32.3	23	38.3
	-1	4	26.7	3	20.0	7	23.3	2	14.3	4	25.0	6	20.0	6	20.7	7	22.6	13	21.7
	0	0	.	3	20.0	3	10.0	2	14.3	2	12.5	4	13.3	2	6.9	5	16.1	7	11.7
	1	0	.	1	6.7	1	3.3	0	.	0	.	0	.	0	.	1	3.2	1	1.7
	Total	15	100.0	15	100.0	30	100.0	14	100.0	16	100.0	30	100.0	29	100.0	31	100.0	60	100.0
Week 20	-5	0	.	1	9.1	1	4.3	1	7.7	0	.	1	4.0	1	4.0	1	4.3	2	4.2
	-4	0	.	0	.	0	.	1	7.7	2	16.7	3	12.0	1	4.0	2	8.7	3	6.3
	-3	6	50.0	2	18.2	8	34.8	3	23.1	2	16.7	5	20.0	9	36.0	4	17.4	13	27.1
	-2	3	25.0	2	18.2	5	21.7	4	30.8	5	41.7	9	36.0	7	28.0	7	30.4	14	29.2
	-1	3	25.0	5	45.5	8	34.8	3	23.1	0	.	3	12.0	6	24.0	5	21.7	11	22.9
	0	0	.	1	9.1	1	4.3	1	7.7	3	25.0	4	16.0	1	4.0	4	17.4	5	10.4
	Total	12	100.0	11	100.0	23	100.0	13	100.0	12	100.0	25	100.0	25	100.0	23	100.0	48	100.0

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 24	-5	0	.	0	.	0	.	1	8.3	0	.	1	4.3	1	3.7	0	.	1	2.0
	-4	0	.	1	9.1	1	3.8	1	8.3	2	18.2	3	13.0	1	3.7	3	13.6	4	8.2
	-3	5	33.3	4	36.4	9	34.6	3	25.0	0	.	3	13.0	8	29.6	4	18.2	12	24.5
	-2	6	40.0	3	27.3	9	34.6	5	41.7	7	63.6	12	52.2	11	40.7	10	45.5	21	42.9
	-1	4	26.7	3	27.3	7	26.9	2	16.7	0	.	2	8.7	6	22.2	3	13.6	9	18.4
	0	0	.	0	.	0	.	0	.	2	18.2	2	8.7	0	.	2	9.1	2	4.1
	Total	15	100.0	11	100.0	26	100.0	12	100.0	11	100.0	23	100.0	27	100.0	22	100.0	49	100.0
Week 24 LOCF	-5	0	.	1	4.3	1	2.0	2	5.7	1	3.6	3	4.8	2	3.2	2	3.9	4	3.5
	-4	1	3.6	1	4.3	2	3.9	1	2.9	2	7.1	3	4.8	2	3.2	3	5.9	5	4.4
	-3	7	25.0	8	34.8	15	29.4	4	11.4	0	.	4	6.3	11	17.5	8	15.7	19	16.7
	-2	8	28.6	4	17.4	12	23.5	12	34.3	12	42.9	24	38.1	20	31.7	16	31.4	36	31.6
	-1	9	32.1	8	34.8	17	33.3	10	28.6	6	21.4	16	25.4	19	30.2	14	27.5	33	28.9
	0	2	7.1	1	4.3	3	5.9	5	14.3	7	25.0	12	19.0	7	11.1	8	15.7	15	13.2

(CONTINUED)

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.2b

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Baseline,
by Age Group and Acute Study Treatment Group
Intention-To-Treat Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Acute Study Treatment Group																	
		Paroxetine (N = 52)						Placebo (N = 64)						Total (N = 116)					
		Children		Adolescents		Total		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Change from acute study baseline to																			
Week 24 LOCF	1	1	3.6	0	.	1	2.0	0	.	0	.	0	.	1	1.6	0	.	1	0.9
	2	0	.	0	.	0	.	1	2.9	0	.	1	1.6	1	1.6	0	.	1	0.9
	Total	28	100.0	23	100.0	51	100.0	35	100.0	28	100.0	63	100.0	63	100.0	51	100.0	114	100.0

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.2d

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
Change from acute study treatment phase endpoint to:		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 1	-1	1	4.8	2	9.5	3	7.1
	0	11	52.4	9	42.9	20	47.6
	1	7	33.3	7	33.3	14	33.3
	2	1	4.8	2	9.5	3	7.1
	3	0	.	1	4.8	1	2.4
	4	1	4.8	0	.	1	2.4
	Total	21	100.0	21	100.0	42	100.0
Week 2	-2	0	.	1	4.5	1	2.3
	-1	3	14.3	4	18.2	7	16.3
	0	10	47.6	10	45.5	20	46.5
	1	5	23.8	5	22.7	10	23.3
	2	2	9.5	2	9.1	4	9.3
	4	1	4.8	0	.	1	2.3
	Total	21	100.0	22	100.0	43	100.0
Week 3	-3	1	5.0	1	4.2	2	4.5
	-2	0	.	1	4.2	1	2.3
	-1	3	15.0	5	20.8	8	18.2
	0	10	50.0	11	45.8	21	47.7
	1	5	25.0	5	20.8	10	22.7
	2	1	5.0	1	4.2	2	4.5

(CONTINUED)

Table 14.4.2d

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
Change from acute study treatment phase endpoint to:		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 3	Total	20	100.0	24	100.0	44	100.0
Week 4	-3	1	4.3	0	.	1	2.2
	-2	2	8.7	2	9.1	4	8.9
	-1	1	4.3	3	13.6	4	8.9
	0	13	56.5	12	54.5	25	55.6
	1	4	17.4	4	18.2	8	17.8
	2	1	4.3	1	4.5	2	4.4
	3	1	4.3	0	.	1	2.2
	Total	23	100.0	22	100.0	45	100.0
Week 8	-2	2	10.0	2	10.0	4	10.0
	-1	2	10.0	6	30.0	8	20.0
	0	13	65.0	12	60.0	25	62.5
	1	1	5.0	0	.	1	2.5
	2	1	5.0	0	.	1	2.5
	3	1	5.0	0	.	1	2.5
	Total	20	100.0	20	100.0	40	100.0
Week 12	-2	2	11.8	3	15.0	5	13.5
	-1	1	5.9	3	15.0	4	10.8
	0	9	52.9	10	50.0	19	51.4
	1	3	17.6	4	20.0	7	18.9

(CONTINUED)

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Table 14.4.2d

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

Change from acute study treatment phase endpoint to:		Paroxetine (N = 50)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 12	2	2	11.8	0	.	2	5.4
	Total	17	100.0	20	100.0	37	100.0
Week 16	-4	0	.	1	5.3	1	2.9
	-2	2	13.3	2	10.5	4	11.8
	-1	3	20.0	3	15.8	6	17.6
	0	7	46.7	7	36.8	14	41.2
	1	1	6.7	3	15.8	4	11.8
	2	2	13.3	3	15.8	5	14.7
	Total	15	100.0	19	100.0	34	100.0
Week 20	-4	0	.	1	6.7	1	3.6
	-2	3	23.1	2	13.3	5	17.9
	-1	3	23.1	4	26.7	7	25.0
	0	4	30.8	6	40.0	10	35.7
	1	3	23.1	2	13.3	5	17.9
	Total	13	100.0	15	100.0	28	100.0
Week 24	-4	1	7.7	0	.	1	3.6
	-3	0	.	1	6.7	1	3.6
	-2	1	7.7	2	13.3	3	10.7
	-1	2	15.4	5	33.3	7	25.0
	0	7	53.8	5	33.3	12	42.9

(CONTINUED)

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Table 14.4.2d

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Pure Paroxetine Population

Primary Diagnosis : Major Depressive Disorder

		Paroxetine (N = 50)					
Change from acute study treatment phase endpoint to:		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 24	1	2	15.4	2	13.3	4	14.3
	Total	13	100.0	15	100.0	28	100.0
Week 24 LOCF	-4	1	4.2	0	.	1	2.0
	-3	0	.	1	4.0	1	2.0
	-2	2	8.3	2	8.0	4	8.2
	-1	3	12.5	6	24.0	9	18.4
	0	13	54.2	8	32.0	21	42.9
	1	4	16.7	5	20.0	9	18.4
	2	1	4.2	2	8.0	3	6.1
	3	0	.	1	4.0	1	2.0
	Total	24	100.0	25	100.0	49	100.0

Table 14.4.2d

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Paroxetine (N = 46)					
Change from acute study treatment phase endpoint to:		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 1	-1	2	10.0	0	.	2	5.0
	0	10	50.0	16	80.0	26	65.0
	1	4	20.0	2	10.0	6	15.0
	2	4	20.0	2	10.0	6	15.0
	Total	20	100.0	20	100.0	40	100.0
Week 2	-3	0	.	1	5.9	1	2.9
	-1	1	5.6	3	17.6	4	11.4
	0	10	55.6	11	64.7	21	60.0
	1	4	22.2	1	5.9	5	14.3
	2	3	16.7	1	5.9	4	11.4
	Total	18	100.0	17	100.0	35	100.0
Week 3	-2	0	.	1	6.7	1	2.9
	-1	3	15.0	4	26.7	7	20.0
	0	13	65.0	6	40.0	19	54.3
	1	4	20.0	4	26.7	8	22.9
	Total	20	100.0	15	100.0	35	100.0
Week 4	-3	0	.	1	5.0	1	2.3
	-2	1	4.2	1	5.0	2	4.5
	-1	2	8.3	3	15.0	5	11.4
	0	18	75.0	13	65.0	31	70.5

(CONTINUED)

Table 14.4.2d

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

Change from acute study treatment phase endpoint to:		Paroxetine (N = 46)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 4	1	1	4.2	2	10.0	3	6.8
	2	2	8.3	0	.	2	4.5
	Total	24	100.0	20	100.0	44	100.0
Week 8	-3	0	.	2	11.1	2	5.1
	-2	2	9.5	2	11.1	4	10.3
	-1	1	4.8	3	16.7	4	10.3
	0	12	57.1	9	50.0	21	53.8
	1	4	19.0	2	11.1	6	15.4
	2	2	9.5	0	.	2	5.1
	Total	21	100.0	18	100.0	39	100.0
Week 12	-3	2	13.3	1	7.7	3	10.7
	-2	0	.	2	15.4	2	7.1
	-1	2	13.3	2	15.4	4	14.3
	0	7	46.7	7	53.8	14	50.0
	1	3	20.0	1	7.7	4	14.3
	2	1	6.7	0	.	1	3.6
	Total	15	100.0	13	100.0	28	100.0
Week 16	-3	1	7.7	1	7.1	2	7.4
	-2	2	15.4	1	7.1	3	11.1
	-1	1	7.7	2	14.3	3	11.1

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Table 14.4.2d

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Pure Paroxetine Population

Primary Diagnosis : Obsessive-Compulsive Disorder

		Paroxetine (N = 46)					
Change from acute study treatment phase endpoint to:		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 16	0	5	38.5	10	71.4	15	55.6
	1	4	30.8	0	.	4	14.8
	Total	13	100.0	14	100.0	27	100.0
Week 20	-3	1	10.0	1	10.0	2	10.0
	-2	1	10.0	0	.	1	5.0
	-1	3	30.0	3	30.0	6	30.0
	0	5	50.0	6	60.0	11	55.0
	Total	10	100.0	10	100.0	20	100.0
Week 24	-2	2	15.4	3	30.0	5	21.7
	-1	3	23.1	5	50.0	8	34.8
	0	7	53.8	2	20.0	9	39.1
	1	1	7.7	0	.	1	4.3
	Total	13	100.0	10	100.0	23	100.0
Week 24 LOCF	-3	0	.	1	5.0	1	2.2
	-2	3	12.0	4	20.0	7	15.6
	-1	3	12.0	9	45.0	12	26.7
	0	15	60.0	6	30.0	21	46.7
	1	3	12.0	0	.	3	6.7
	2	1	4.0	0	.	1	2.2
	Total	25	100.0	20	100.0	45	100.0

Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
Change from acute study treatment phase endpoint to:		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 1	-2	1	3.0	0	.	1	1.7
	-1	9	27.3	2	7.7	11	18.6
	0	20	60.6	18	69.2	38	64.4
	1	3	9.1	4	15.4	7	11.9
	2	0	.	1	3.8	1	1.7
	Missing	0	.	1	3.8	1	1.7
	Total	33	100.0	26	100.0	59	100.0
Week 2	-3	1	3.1	1	4.0	2	3.5
	-1	12	37.5	5	20.0	17	29.8
	0	15	46.9	13	52.0	28	49.1
	1	4	12.5	4	16.0	8	14.0
	2	0	.	1	4.0	1	1.8
	Missing	0	.	1	4.0	1	1.8
	Total	32	100.0	25	100.0	57	100.0
Week 3	-4	1	3.2	0	.	1	1.9
	-3	1	3.2	0	.	1	1.9
	-2	2	6.5	0	.	2	3.8
	-1	10	32.3	7	31.8	17	32.1
	0	15	48.4	11	50.0	26	49.1
	1	1	3.2	1	4.5	2	3.8

(CONTINUED)

Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

Change from acute study treatment phase endpoint to:		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 3	2	1	3.2	2	9.1	3	5.7
	Missing	0	.	1	4.5	1	1.9
	Total	31	100.0	22	100.0	53	100.0
Week 4	-4	1	3.2	0	.	1	1.8
	-3	1	3.2	0	.	1	1.8
	-2	4	12.9	0	.	4	7.3
	-1	9	29.0	7	29.2	16	29.1
	0	13	41.9	12	50.0	25	45.5
	1	1	3.2	4	16.7	5	9.1
	2	2	6.5	0	.	2	3.6
	Missing	0	.	1	4.2	1	1.8
	Total	31	100.0	24	100.0	55	100.0
Week 8	-4	1	3.7	0	.	1	2.1
	-3	2	7.4	0	.	2	4.3
	-2	3	11.1	1	5.0	4	8.5
	-1	5	18.5	10	50.0	15	31.9
	0	14	51.9	7	35.0	21	44.7
	1	1	3.7	0	.	1	2.1
	2	0	.	1	5.0	1	2.1
	3	1	3.7	0	.	1	2.1

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Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

Change from acute study treatment phase endpoint to:		Placebo (N = 66)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 8	Missing	0	.	1	5.0	1	2.1
	Total	27	100.0	20	100.0	47	100.0
Week 12	-4	1	4.5	0	.	1	2.4
	-3	2	9.1	1	5.3	3	7.3
	-2	3	13.6	2	10.5	5	12.2
	-1	7	31.8	5	26.3	12	29.3
	0	6	27.3	10	52.6	16	39.0
	1	2	9.1	0	.	2	4.9
	3	1	4.5	0	.	1	2.4
	Missing	0	.	1	5.3	1	2.4
	Total	22	100.0	19	100.0	41	100.0
Week 16	-3	1	4.8	0	.	1	2.7
	-2	6	28.6	4	25.0	10	27.0
	-1	4	19.0	4	25.0	8	21.6
	0	9	42.9	6	37.5	15	40.5
	1	1	4.8	0	.	1	2.7
	2	0	.	1	6.3	1	2.7
	Missing	0	.	1	6.3	1	2.7
	Total	21	100.0	16	100.0	37	100.0
Week 20	-3	2	11.8	0	.	2	6.7

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Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
Change from acute study treatment phase endpoint to:		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 20	-2	4	23.5	3	23.1	7	23.3
	-1	6	35.3	2	15.4	8	26.7
	0	5	29.4	4	30.8	9	30.0
	1	0	.	2	15.4	2	6.7
	2	0	.	2	15.4	2	6.7
	Total	17	100.0	13	100.0	30	100.0
Week 24	-4	1	10.0	0	.	1	4.3
	-2	2	20.0	2	15.4	4	17.4
	-1	2	20.0	4	30.8	6	26.1
	0	5	50.0	4	30.8	9	39.1
	1	0	.	1	7.7	1	4.3
	2	0	.	1	7.7	1	4.3
	3	0	.	1	7.7	1	4.3
	Total	10	100.0	13	100.0	23	100.0
Week 24 LOCF	-4	1	2.9	0	.	1	1.6
	-2	5	14.3	2	6.9	7	10.9
	-1	8	22.9	6	20.7	14	21.9
	0	18	51.4	13	44.8	31	48.4
	1	1	2.9	5	17.2	6	9.4
	2	0	.	1	3.4	1	1.6

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Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group

Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Major Depressive Disorder

		Placebo (N = 66)					
Change from acute study treatment phase endpoint to:		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 24 LOCF	3	2	5.7	1	3.4	3	4.7
	Missing	0	.	1	3.4	1	1.6
	Total	35	100.0	29	100.0	64	100.0

Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 64)					
Change from acute study treatment phase endpoint to:		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 1	-1	4	13.3	2	8.3	6	11.1
	0	14	46.7	14	58.3	28	51.9
	1	6	20.0	5	20.8	11	20.4
	2	2	6.7	3	12.5	5	9.3
	3	3	10.0	0	.	3	5.6
	Missing	1	3.3	0	.	1	1.9
	Total	30	100.0	24	100.0	54	100.0
Week 2	-2	0	.	1	4.2	1	1.8
	-1	6	19.4	2	8.3	8	14.5
	0	17	54.8	16	66.7	33	60.0
	1	4	12.9	3	12.5	7	12.7
	2	2	6.5	2	8.3	4	7.3
	3	1	3.2	0	.	1	1.8
	Missing	1	3.2	0	.	1	1.8
	Total	31	100.0	24	100.0	55	100.0
Week 3	-2	0	.	2	8.7	2	3.5
	-1	9	26.5	5	21.7	14	24.6
	0	14	41.2	14	60.9	28	49.1
	1	7	20.6	1	4.3	8	14.0
	2	2	5.9	1	4.3	3	5.3

(CONTINUED)

Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 64)					
Change from acute study treatment phase endpoint to:		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 3	3	1	2.9	0	.	1	1.8
	Missing	1	2.9	0	.	1	1.8
	Total	34	100.0	23	100.0	57	100.0
Week 4	-3	1	3.3	0	.	1	1.8
	-1	8	26.7	9	36.0	17	30.9
	0	15	50.0	14	56.0	29	52.7
	1	4	13.3	1	4.0	5	9.1
	2	1	3.3	1	4.0	2	3.6
	Missing	1	3.3	0	.	1	1.8
	Total	30	100.0	25	100.0	55	100.0
Week 8	-3	1	4.5	0	.	1	2.6
	-2	2	9.1	4	23.5	6	15.4
	-1	5	22.7	5	29.4	10	25.6
	0	9	40.9	6	35.3	15	38.5
	1	3	13.6	2	11.8	5	12.8
	Missing	2	9.1	0	.	2	5.1
	Total	22	100.0	17	100.0	39	100.0
Week 12	-2	4	19.0	4	28.6	8	22.9
	-1	6	28.6	8	57.1	14	40.0
	0	7	33.3	2	14.3	9	25.7

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Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

Change from acute study treatment phase endpoint to:		Placebo (N = 64)					
		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 12	1	1	4.8	0	.	1	2.9
	2	2	9.5	0	.	2	5.7
	Missing	1	4.8	0	.	1	2.9
	Total	21	100.0	14	100.0	35	100.0
Week 16	-3	0	.	1	6.3	1	3.3
	-2	3	21.4	3	18.8	6	20.0
	-1	2	14.3	9	56.3	11	36.7
	0	6	42.9	3	18.8	9	30.0
	1	1	7.1	0	.	1	3.3
	2	1	7.1	0	.	1	3.3
	Missing	1	7.1	0	.	1	3.3
	Total	14	100.0	16	100.0	30	100.0
Week 20	-3	0	.	1	8.3	1	4.0
	-2	3	23.1	3	25.0	6	24.0
	-1	2	15.4	4	33.3	6	24.0
	0	5	38.5	4	33.3	9	36.0
	1	1	7.7	0	.	1	4.0
	2	1	7.7	0	.	1	4.0
	Missing	1	7.7	0	.	1	4.0
	Total	13	100.0	12	100.0	25	100.0

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Table 14.4.2e

Number and Percentage of Patients by Change in CGI Severity of Illness from Acute Study Treatment Phase Endpoint, by Age Group
Intention-to-Treat Population with Acute Study Treatment Group of Placebo

Primary Diagnosis : Obsessive-Compulsive Disorder

		Placebo (N = 64)					
Change from acute study treatment phase endpoint to:		Children		Adolescents		Total	
		n	%	n	%	n	%
Week 24	-2	4	33.3	2	18.2	6	26.1
	-1	1	8.3	6	54.5	7	30.4
	0	4	33.3	3	27.3	7	30.4
	1	2	16.7	0	.	2	8.7
	Missing	1	8.3	0	.	1	4.3
	Total	12	100.0	11	100.0	23	100.0
Week 24 LOCF	-3	1	2.9	0	.	1	1.6
	-2	5	14.3	5	17.9	10	15.9
	-1	7	20.0	9	32.1	16	25.4
	0	14	40.0	12	42.9	26	41.3
	1	6	17.1	2	7.1	8	12.7
	3	1	2.9	0	.	1	1.6
	Missing	1	2.9	0	.	1	1.6
	Total	35	100.0	28	100.0	63	100.0

Table 14.4.3b

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CGI Severity of Illness Score
at Each Visit by Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Children

	Acute Study Treatment Group														
	Paroxetine (N = 39)					Placebo (N = 36)					Total (N = 75)				
	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N
Acute Baseline	4.2	4.0	4	6	39	4.2	4.0	3	6	36	4.2	4.0	3	6	75
Change from Acute Study Baseline to 716:															
Week 1	-1.6	-1.5	-4	1	34	-1.3	-1.0	-4	1	33	-1.4	-1.0	-4	1	67
Week 2	-1.6	-2.0	-4	1	33	-1.5	-1.0	-5	1	32	-1.6	-1.0	-5	1	65
Week 3	-1.9	-2.0	-4	0	33	-1.7	-1.0	-4	0	31	-1.8	-2.0	-4	0	64
Week 4	-1.9	-2.0	-4	0	36	-1.8	-2.0	-4	1	31	-1.9	-2.0	-4	1	67
Week 8	-1.8	-2.0	-4	0	29	-1.9	-2.0	-4	0	27	-1.9	-2.0	-4	0	56
Week 12	-1.8	-2.0	-4	0	24	-1.8	-2.0	-4	0	22	-1.8	-2.0	-4	0	46
Week 16	-2.1	-2.0	-4	-1	19	-1.8	-2.0	-3	0	21	-1.9	-2.0	-4	0	40
Week 20	-2.5	-3.0	-4	-1	19	-2.0	-2.0	-4	0	17	-2.3	-2.0	-4	0	36
Week 24	-2.7	-3.0	-5	-1	17	-1.8	-2.0	-4	0	10	-2.4	-2.0	-5	0	27
Week 24 LOCF	-2.0	-2.0	-5	0	37	-1.6	-2.0	-4	0	35	-1.8	-2.0	-5	0	72

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.3b

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CGI Severity of Illness Score
at Each Visit by Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Adolescent

	Acute Study Treatment Group														
	Paroxetine (N = 42)					Placebo (N = 30)					Total (N = 72)				
	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N
Acute Baseline	4.3	4.0	3	6	42	4.3	4.0	4	5	30	4.3	4.0	3	6	72
Change from Acute Study Baseline to 716:															
Week 1	-1.4	-1.0	-3	1	37	-1.3	-1.0	-4	0	26	-1.3	-1.0	-4	1	63
Week 2	-1.6	-2.0	-4	0	38	-1.5	-1.0	-4	0	25	-1.6	-2.0	-4	0	63
Week 3	-1.8	-2.0	-3	0	37	-1.7	-1.5	-4	0	22	-1.7	-2.0	-4	0	59
Week 4	-1.9	-2.0	-4	1	37	-1.6	-2.0	-4	1	24	-1.8	-2.0	-4	1	61
Week 8	-2.3	-2.0	-4	0	33	-2.0	-2.0	-4	0	20	-2.2	-2.0	-4	0	53
Week 12	-2.1	-2.0	-4	1	34	-2.2	-2.0	-4	0	19	-2.2	-2.0	-4	1	53
Week 16	-2.1	-2.0	-5	1	31	-2.3	-2.0	-4	0	16	-2.1	-2.0	-5	1	47
Week 20	-2.5	-3.0	-5	0	26	-2.0	-2.0	-4	1	13	-2.3	-2.0	-5	1	39
Week 24	-2.3	-2.5	-5	1	24	-2.2	-2.0	-4	0	13	-2.3	-2.0	-5	1	37
Week 24 LOCF	-2.0	-2.0	-5	2	42	-1.4	-1.0	-4	1	29	-1.7	-2.0	-5	2	71

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

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Table 14.4.3b

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CGI Severity of Illness Score
at Each Visit by Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Total

	Acute Study Treatment Group														
	Paroxetine (N = 81)					Placebo (N = 66)					Total (N = 147)				
	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N
Acute Baseline	4.3	4.0	3	6	81	4.2	4.0	3	6	66	4.3	4.0	3	6	147
Change from Acute Study Baseline to 716:															
Week 1	-1.5	-1.0	-4	1	71	-1.3	-1.0	-4	1	59	-1.4	-1.0	-4	1	130
Week 2	-1.6	-2.0	-4	1	71	-1.5	-1.0	-5	1	57	-1.6	-1.0	-5	1	128
Week 3	-1.8	-2.0	-4	0	70	-1.7	-1.0	-4	0	53	-1.8	-2.0	-4	0	123
Week 4	-1.9	-2.0	-4	1	73	-1.7	-2.0	-4	1	55	-1.9	-2.0	-4	1	128
Week 8	-2.1	-2.0	-4	0	62	-1.9	-2.0	-4	0	47	-2.0	-2.0	-4	0	109
Week 12	-2.0	-2.0	-4	1	58	-2.0	-2.0	-4	0	41	-2.0	-2.0	-4	1	99
Week 16	-2.1	-2.0	-5	1	50	-2.0	-2.0	-4	0	37	-2.0	-2.0	-5	1	87
Week 20	-2.5	-3.0	-5	0	45	-2.0	-2.0	-4	1	30	-2.3	-2.0	-5	1	75
Week 24	-2.5	-3.0	-5	1	41	-2.0	-2.0	-4	0	23	-2.3	-2.0	-5	1	64
Week 24 LOCF	-2.0	-2.0	-5	2	79	-1.5	-2.0	-4	1	64	-1.8	-2.0	-5	2	143

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.3b

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CGI Severity of Illness Score
at Each Visit by Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Children

	Acute Study Treatment Group														
	Paroxetine (N = 28)					Placebo (N = 36)					Total (N = 64)				
	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N
Acute Baseline	4.4	4.0	4	6	28	4.7	4.5	3	6	36	4.5	4.0	3	6	64
Change from Acute Study Baseline to 716:															
Week 1	-1.0	-1.0	-4	1	22	-0.8	-0.5	-4	2	30	-0.9	-1.0	-4	2	52
Week 2	-1.2	-1.0	-3	0	20	-1.2	-1.0	-5	1	31	-1.2	-1.0	-5	1	51
Week 3	-1.4	-2.0	-3	1	22	-1.2	-1.0	-5	2	34	-1.3	-1.0	-5	2	56
Week 4	-1.4	-1.5	-3	1	26	-1.6	-1.0	-5	1	30	-1.5	-1.0	-5	1	56
Week 8	-1.5	-2.0	-3	1	23	-2.0	-2.0	-5	0	21	-1.7	-2.0	-5	1	44
Week 12	-1.8	-2.0	-3	1	17	-1.9	-2.0	-5	0	21	-1.8	-2.0	-5	1	38
Week 16	-1.9	-2.0	-3	-1	15	-2.1	-2.0	-5	0	14	-2.0	-2.0	-5	0	29
Week 20	-2.3	-2.5	-3	-1	12	-2.2	-2.0	-5	0	13	-2.2	-2.0	-5	0	25
Week 24	-2.1	-2.0	-3	-1	15	-2.5	-2.0	-5	-1	12	-2.3	-2.0	-5	-1	27
Week 24 LOCF	-1.8	-2.0	-4	1	28	-1.7	-2.0	-5	2	35	-1.7	-2.0	-5	2	63

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

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Table 14.4.3b

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CGI Severity of Illness Score
at Each Visit by Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Adolescent

	Acute Study Treatment Group														
	Paroxetine (N = 24)					Placebo (N = 28)					Total (N = 52)				
	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N
Acute Baseline	4.6	5.0	4	6	24	4.7	5.0	3	6	28	4.7	5.0	3	6	52
Change from Acute Study Baseline to 716:															
Week 1	-1.0	-1.0	-3	1	23	-0.5	0.0	-4	0	24	-0.8	-1.0	-4	1	47
Week 2	-1.4	-1.0	-5	0	20	-0.9	-1.0	-4	0	24	-1.1	-1.0	-5	0	44
Week 3	-1.3	-1.0	-4	1	18	-1.3	-1.0	-5	0	23	-1.3	-1.0	-5	1	41
Week 4	-1.5	-1.0	-5	0	23	-1.2	-1.0	-4	0	25	-1.4	-1.0	-5	0	48
Week 8	-1.9	-1.0	-5	0	21	-1.7	-2.0	-5	0	17	-1.8	-2.0	-5	0	38
Week 12	-1.9	-2.0	-5	0	16	-2.1	-2.0	-5	0	14	-2.0	-2.0	-5	0	30
Week 16	-1.5	-2.0	-5	1	15	-2.1	-2.0	-5	0	16	-1.8	-2.0	-5	1	31
Week 20	-1.8	-1.0	-5	0	11	-2.0	-2.0	-4	0	12	-1.9	-2.0	-5	0	23
Week 24	-2.3	-2.0	-4	-1	11	-2.0	-2.0	-4	0	11	-2.1	-2.0	-4	0	22
Week 24 LOCF	-2.1	-2.0	-5	0	23	-1.5	-2.0	-5	0	28	-1.8	-2.0	-5	0	51

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.3b

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline in CGI Severity of Illness Score
at Each Visit by Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Total

	Acute Study Treatment Group														
	Paroxetine (N = 52)					Placebo (N = 64)					Total (N = 116)				
	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N	Mean	Median	Min	Max	N
Acute Baseline	4.5	4.0	4	6	52	4.7	5.0	3	6	64	4.6	5.0	3	6	116
Change from Acute Study Baseline to 716:															
Week 1	-1.0	-1.0	-4	1	45	-0.7	0.0	-4	2	54	-0.8	-1.0	-4	2	99
Week 2	-1.3	-1.0	-5	0	40	-1.0	-1.0	-5	1	55	-1.1	-1.0	-5	1	95
Week 3	-1.4	-1.0	-4	1	40	-1.3	-1.0	-5	2	57	-1.3	-1.0	-5	2	97
Week 4	-1.4	-1.0	-5	1	49	-1.4	-1.0	-5	1	55	-1.4	-1.0	-5	1	104
Week 8	-1.7	-2.0	-5	1	44	-1.9	-2.0	-5	0	38	-1.8	-2.0	-5	1	82
Week 12	-1.8	-2.0	-5	1	33	-2.0	-2.0	-5	0	35	-1.9	-2.0	-5	1	68
Week 16	-1.7	-2.0	-5	1	30	-2.1	-2.0	-5	0	30	-1.9	-2.0	-5	1	60
Week 20	-2.0	-2.0	-5	0	23	-2.1	-2.0	-5	0	25	-2.1	-2.0	-5	0	48
Week 24	-2.2	-2.0	-4	-1	26	-2.3	-2.0	-5	0	23	-2.2	-2.0	-5	0	49
Week 24 LOCF	-1.9	-2.0	-5	1	51	-1.6	-2.0	-5	2	63	-1.7	-2.0	-5	2	114

Note: Study 715 data is collected at Acute Study Screening rather than Acute Study Baseline

Table 14.4.3d

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Pure Paroxetine Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Children

	Acute Study Treatment Group				
	Paroxetine (N = 25)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	2.5	2.0	1	5	25
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.6	0.0	-1	4	21
Week 2	0.5	0.0	-1	4	21
Week 3	0.1	0.0	-3	2	20
Week 4	0.0	0.0	-3	3	23
Week 8	0.0	0.0	-2	3	20
Week 12	0.1	0.0	-2	2	17
Week 16	-0.1	0.0	-2	2	15
Week 20	-0.5	0.0	-2	1	13
Week 24	-0.5	0.0	-4	1	13
Week 24 LOCF	-0.2	0.0	-4	2	24

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Table 14.4.3d

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Pure Paroxetine Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Adolescent

	Acute Study Treatment Group				
	Paroxetine (N = 25)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	2.6	3.0	1	5	25
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.6	0.0	-1	3	21
Week 2	0.1	0.0	-2	2	22
Week 3	-0.1	0.0	-3	2	24
Week 4	-0.0	0.0	-2	2	22
Week 8	-0.5	0.0	-2	0	20
Week 12	-0.3	0.0	-2	1	20
Week 16	-0.1	0.0	-4	2	19
Week 20	-0.7	0.0	-4	1	15
Week 24	-0.7	-1.0	-3	1	15
Week 24 LOCF	-0.0	0.0	-3	3	25

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Table 14.4.3d

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Pure Paroxetine Population
Primary Diagnosis : Major Depressive Disorder
Age Group : Total

	Acute Study Treatment Group				
	Paroxetine (N = 50)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	2.6	2.0	1	5	50
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.6	0.0	-1	4	42
Week 2	0.3	0.0	-2	4	43
Week 3	-0.0	0.0	-3	2	44
Week 4	0.0	0.0	-3	3	45
Week 8	-0.3	0.0	-2	3	40
Week 12	-0.1	0.0	-2	2	37
Week 16	-0.1	0.0	-4	2	34
Week 20	-0.6	0.0	-4	1	28
Week 24	-0.6	0.0	-4	1	28
Week 24 LOCF	-0.1	0.0	-4	3	49

Table 14.4.3d

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Pure Paroxetine Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Children

	Acute Study Treatment Group				
	Paroxetine (N = 25)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	2.8	3.0	1	5	25
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.5	0.0	-1	2	20
Week 2	0.5	0.0	-1	2	18
Week 3	0.1	0.0	-1	1	20
Week 4	0.0	0.0	-2	2	24
Week 8	0.1	0.0	-2	2	21
Week 12	-0.2	0.0	-3	2	15
Week 16	-0.3	0.0	-3	1	13
Week 20	-0.8	-0.5	-3	0	10
Week 24	-0.5	0.0	-2	1	13
Week 24 LOCF	-0.2	0.0	-2	2	25

Table 14.4.3d

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Pure Paroxetine Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Adolescent

	Acute Study Treatment Group				
	Paroxetine (N = 21)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	3.6	4.0	2	5	21
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.3	0.0	0	2	20
Week 2	-0.2	0.0	-3	2	17
Week 3	-0.1	0.0	-2	1	15
Week 4	-0.3	0.0	-3	1	20
Week 8	-0.6	0.0	-3	1	18
Week 12	-0.6	0.0	-3	1	13
Week 16	-0.5	0.0	-3	0	14
Week 20	-0.6	0.0	-3	0	10
Week 24	-1.1	-1.0	-2	0	10
Week 24 LOCF	-1.0	-1.0	-3	0	20

Table 14.4.3d

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Pure Paroxetine Population
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Total

	Acute Study Treatment Group				
	Paroxetine (N = 46)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	3.2	3.0	1	5	46
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.4	0.0	-1	2	40
Week 2	0.2	0.0	-3	2	35
Week 3	-0.0	0.0	-2	1	35
Week 4	-0.1	0.0	-3	2	44
Week 8	-0.2	0.0	-3	2	39
Week 12	-0.4	0.0	-3	2	28
Week 16	-0.4	0.0	-3	1	27
Week 20	-0.7	0.0	-3	0	20
Week 24	-0.7	-1.0	-2	1	23
Week 24 LOCF	-0.5	0.0	-3	2	45

Table 14.4.3e

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Intention-to-Treat Population with Acute Study Treatment Group of Placebo
Primary Diagnosis : Major Depressive Disorder
Age Group : Children

	Acute Study Treatment Group				
	Placebo (N = 36)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	3.0	3.0	1	5	36
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	-0.2	0.0	-2	1	33
Week 2	-0.3	0.0	-3	1	32
Week 3	-0.6	0.0	-4	2	31
Week 4	-0.6	0.0	-4	2	31
Week 8	-0.6	0.0	-4	3	27
Week 12	-0.8	-1.0	-4	3	22
Week 16	-0.9	-1.0	-3	1	21
Week 20	-1.2	-1.0	-3	0	17
Week 24	-1.0	-0.5	-4	0	10
Week 24 LOCF	-0.4	0.0	-4	3	35

Table 14.4.3e

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Intention-to-Treat Population with Acute Study Treatment Group of Placebo
Primary Diagnosis : Major Depressive Disorder
Age Group : Adolescent

	Acute Study Treatment Group				
	Placebo (N = 30)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	2.8	3.0	1	4	29
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.2	0.0	-1	2	25
Week 2	-0.1	0.0	-3	2	24
Week 3	-0.1	0.0	-1	2	21
Week 4	-0.1	0.0	-1	1	23
Week 8	-0.5	-1.0	-2	2	19
Week 12	-0.7	0.0	-3	0	18
Week 16	-0.7	-1.0	-2	2	15
Week 20	-0.2	0.0	-2	2	13
Week 24	-0.2	0.0	-2	3	13
Week 24 LOCF	0.0	0.0	-2	3	28

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Table 14.4.3e

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Intention-to-Treat Population with Acute Study Treatment Group of Placebo
Primary Diagnosis : Major Depressive Disorder
Age Group : Total

	Acute Study Treatment Group				
	Placebo (N = 66)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	2.9	3.0	1	5	65
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	-0.1	0.0	-2	2	58
Week 2	-0.2	0.0	-3	2	56
Week 3	-0.4	0.0	-4	2	52
Week 4	-0.4	0.0	-4	2	54
Week 8	-0.6	0.0	-4	3	46
Week 12	-0.8	-1.0	-4	3	40
Week 16	-0.8	-1.0	-3	2	36
Week 20	-0.7	-1.0	-3	2	30
Week 24	-0.5	0.0	-4	3	23
Week 24 LOCF	-0.2	0.0	-4	3	63

Table 14.4.3e

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Intention-to-Treat Population with Acute Study Treatment Group of Placebo
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Children

	Acute Study Treatment Group				
	Placebo (N = 36)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	3.4	4.0	1	5	35
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.5	0.0	-1	3	29
Week 2	0.2	0.0	-1	3	30
Week 3	0.2	0.0	-1	3	33
Week 4	-0.2	0.0	-3	2	29
Week 8	-0.5	0.0	-3	1	20
Week 12	-0.5	-0.5	-2	2	20
Week 16	-0.4	0.0	-2	2	13
Week 20	-0.4	0.0	-2	2	12
Week 24	-0.6	0.0	-2	1	11
Week 24 LOCF	-0.3	0.0	-3	3	34

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Table 14.4.3e

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Intention-to-Treat Population with Acute Study Treatment Group of Placebo
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Adolescent

	Acute Study Treatment Group				
	Placebo (N = 28)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	3.8	4.0	1	6	28
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.4	0.0	-1	2	24
Week 2	0.1	0.0	-2	2	24
Week 3	-0.3	0.0	-2	2	23
Week 4	-0.2	0.0	-1	2	25
Week 8	-0.6	-1.0	-2	1	17
Week 12	-1.1	-1.0	-2	0	14
Week 16	-1.1	-1.0	-3	0	16
Week 20	-1.1	-1.0	-3	0	12
Week 24	-0.9	-1.0	-2	0	11
Week 24 LOCF	-0.6	-0.5	-2	1	28

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Table 14.4.3e

Summary Statistics for Acute Study Treatment Phase Endpoint and Change from Acute Study Treatment Phase Endpoint in CGI Severity of Illness Score at Each Visit
Intention-to-Treat Population with Acute Study Treatment Group of Placebo
Primary Diagnosis : Obsessive-Compulsive Disorder
Age Group : Total

	Acute Study Treatment Group				
	Placebo (N = 64)				
	Mean	Median	Minimum	Maximum	N
Acute Study Treatment Phase Endpoint	3.6	4.0	1	6	63
Change from Acute Study Treatment Phase Endpoint to 716:					
Week 1	0.5	0.0	-1	3	53
Week 2	0.1	0.0	-2	3	54
Week 3	-0.0	0.0	-2	3	56
Week 4	-0.2	0.0	-3	2	54
Week 8	-0.5	0.0	-3	1	37
Week 12	-0.7	-1.0	-2	2	34
Week 16	-0.8	-1.0	-3	2	29
Week 20	-0.8	-1.0	-3	2	24
Week 24	-0.8	-1.0	-2	1	22
Week 24 LOCF	-0.5	0.0	-3	3	62

Table 14.5.1

Summary Statistics for Change in CDRS-R Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of MDD

Dose Level At Treatment Phase Endpoint : 2 (20mg)

		Paroxetine (N=16)			Placebo (N=15)			Total (N=31)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	9	7	16	8	7	15	17	14	31
	MEAN	34.9	27.9	31.8	28.5	29.0	28.7	31.9	28.4	30.3
	MEDIAN	35.0	27.0	30.5	26.0	21.0	24.0	31.0	26.0	28.0
	STDDEV	12.73	8.13	11.22	9.91	11.94	10.50	11.61	9.83	10.81
	MINIMUM	20	19	19	18	18	18	18	18	18
	MAXIMUM	56	42	56	42	46	46	56	46	56
	MISSING	0	0	0	0	0	0	0	0	0
716 Baseline	N	8	7	15	8	7	15	16	14	30
	MEAN	39.8	30.3	35.3	32.9	29.1	31.1	36.3	29.7	33.2
	MEDIAN	35.0	30.0	31.0	34.0	24.0	33.0	34.5	28.5	32.0
	STDDEV	16.76	6.26	13.46	16.31	9.94	13.38	16.37	8.00	13.36
	MINIMUM	20	22	20	17	19	17	17	19	17
	MAXIMUM	66	42	66	68	44	68	68	44	68
	MISSING	1	0	1	0	0	0	1	0	1
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	8	7	15	8	7	15	16	14	30
	MEAN	7.1	2.4	4.9	4.4	0.1	2.4	5.8	1.3	3.7
	MEDIAN	2.5	0.0	2.0	0.0	-1.0	0.0	0.0	0.0	0.0
	STDDEV	12.09	4.08	9.28	16.69	3.24	12.19	14.15	3.73	10.72
	MINIMUM	-4	-2	-4	-9	-3	-9	-9	-3	-9
	MAXIMUM	30	8	30	44	6	44	44	8	44
	MISSING	1	0	1	0	0	0	1	0	1

Note: Patients who complete Paroxetine study 701 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.
Note: Study 715 patients do not have a treatment phase endpoint assessment, therefore are included as 'Missing/Uneval.'

Table 14.5.1

Summary Statistics for Change in CDRS-R Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of MDD

Dose Level At Treatment Phase Endpoint : 3 (30mg)

		Paroxetine (N=49)			Placebo (N=22)			Total (N=71)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	7	11	18	10	12	22	17	23	40
	MEAN	26.3	32.8	30.3	32.3	38.6	35.7	29.8	35.8	33.3
	MEDIAN	24.0	30.0	27.0	28.5	34.0	33.0	25.0	33.0	30.5
	STDDEV	7.11	13.61	11.73	12.55	10.87	11.82	10.81	12.33	11.95
	MINIMUM	21	20	20	19	25	19	19	20	19
	MAXIMUM	42	71	71	51	61	61	51	71	71
	MISSING	14	17	31	0	0	0	14	17	31
716 Baseline	N	18	27	45	10	12	22	28	39	67
	MEAN	28.3	35.8	32.8	33.8	40.3	37.4	30.3	37.2	34.3
	MEDIAN	26.5	34.0	29.0	33.0	35.5	35.0	27.0	35.0	29.0
	STDDEV	8.55	12.79	11.77	11.19	11.79	11.73	9.74	12.51	11.86
	MINIMUM	20	20	20	17	28	17	17	20	17
	MAXIMUM	56	72	72	52	56	56	56	72	72
	MISSING	3	1	4	0	0	0	3	1	4
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	5	10	15	10	12	22	15	22	37
	MEAN	3.4	-1.7	0.0	1.5	1.8	1.6	2.1	0.2	1.0
	MEDIAN	3.0	-2.0	0.0	0.5	2.0	1.5	1.0	0.0	0.0
	STDDEV	11.37	11.94	11.61	7.59	6.20	6.69	8.65	9.18	8.90
	MINIMUM	-14	-24	-24	-10	-7	-10	-14	-24	-24
	MAXIMUM	15	24	24	18	14	18	18	24	24
	MISSING	16	18	34	0	0	0	16	18	34

Note: Patients who complete Paroxetine study 701 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.
Note: Study 715 patients do not have a treatment phase endpoint assessment, therefore are included as 'Missing/Uneval.'

Table 14.5.1

Summary Statistics for Change in CDRS-R Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of MDD

Dose Level At Treatment Phase Endpoint : 4 (40mg)

		Paroxetine (N=10)			Placebo (N=6)			Total (N=16)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	5	5	10	2	4	6	7	9	16
	MEAN	43.2	43.6	43.4	42.0	38.5	39.7	42.9	41.3	42.0
	MEDIAN	41.0	48.0	43.5	42.0	39.0	42.0	42.0	42.0	42.0
	STDDEV	13.33	12.42	12.15	0.00	13.30	10.46	10.90	12.28	11.34
	MINIMUM	26	29	26	42	22	22	26	22	22
	MAXIMUM	63	57	63	42	54	54	63	57	63
	MISSING	0	0	0	0	0	0	0	0	0
716 Baseline	N	5	5	10	2	3	5	7	8	15
	MEAN	43.2	49.2	46.2	52.5	47.3	49.4	45.9	48.5	47.3
	MEDIAN	42.0	50.0	46.0	52.5	50.0	50.0	44.0	50.0	48.0
	STDDEV	19.41	10.03	14.91	10.61	14.19	11.70	17.04	10.77	13.58
	MINIMUM	27	33	27	45	32	32	27	32	27
	MAXIMUM	75	58	75	60	60	60	75	60	75
	MISSING	0	0	0	0	1	1	0	1	1
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	5	5	10	2	3	5	7	8	15
	MEAN	0.0	5.6	2.8	10.5	8.0	9.0	3.0	6.5	4.9
	MEDIAN	1.0	4.0	3.0	10.5	10.0	10.0	3.0	5.0	4.0
	STDDEV	9.30	6.23	8.02	10.61	11.14	9.59	10.13	7.69	8.77
	MINIMUM	-13	0	-13	3	-4	-4	-13	-4	-13
	MAXIMUM	12	16	16	18	18	18	18	18	18
	MISSING	0	0	0	0	1	1	0	1	1

Note: Patients who complete Paroxetine study 701 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.
Note: Study 715 patients do not have a treatment phase endpoint assessment, therefore are included as 'Missing/Uneval.'

Table 14.5.1

Summary Statistics for Change in CDRS-R Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of MDD

Dose Level At Treatment Phase Endpoint : 5 (50mg)

		Paroxetine (N=3)			Placebo (N=12)			Total (N=15)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	1	2	3	6	5	11	7	7	14
	MEAN	29.0	44.5	39.3	42.0	44.0	42.9	40.1	44.1	42.1
	MEDIAN	29.0	44.5	39.0	40.5	41.0	41.0	39.0	41.0	40.0
	STDDEV	.	7.78	10.50	6.00	15.30	10.62	7.36	12.89	10.29
	MINIMUM	29	39	29	35	26	26	29	26	26
	MAXIMUM	29	50	50	51	65	65	51	65	65
	MISSING	0	0	0	0	1	1	0	1	1
716 Baseline	N	1	2	3	6	6	12	7	8	15
	MEAN	55.0	43.5	47.3	45.8	51.2	48.5	47.1	49.3	48.3
	MEDIAN	55.0	43.5	48.0	43.5	55.0	47.0	46.0	48.0	48.0
	STDDEV	.	6.36	8.02	9.28	17.95	13.91	9.15	15.76	12.70
	MINIMUM	55	39	39	38	28	28	38	28	28
	MAXIMUM	55	48	55	63	73	73	63	73	73
	MISSING	0	0	0	0	0	0	0	0	0
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	1	2	3	6	5	11	7	7	14
	MEAN	26.0	-1.0	8.0	3.8	10.8	7.0	7.0	7.4	7.2
	MEDIAN	26.0	-1.0	0.0	0.0	8.0	2.0	0.0	2.0	1.0
	STDDEV	.	1.41	15.62	8.93	13.55	11.25	11.69	12.49	11.62
	MINIMUM	26	-2	-2	-3	-5	-5	-3	-5	-5
	MAXIMUM	26	0	26	21	28	28	26	28	28
	MISSING	0	0	0	0	1	1	0	1	1

Note: Patients who complete Paroxetine study 701 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.
Note: Study 715 patients do not have a treatment phase endpoint assessment, therefore are included as 'Missing/Uneval.'

Table 14.5.2

Summary Statistics for Change in CY-BOCS Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of OCD

Dose Level At Treatment Phase Endpoint : 2 (20mg)

		Paroxetine (N=12)			Placebo (N=7)			Total (N=19)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	10	2	12	5	2	7	15	4	19
	MEAN	7.2	17.0	8.8	17.2	20.0	18.0	10.5	18.5	12.2
	MEDIAN	7.0	17.0	11.5	14.0	20.0	16.0	13.0	19.5	13.0
	STDDEV	6.58	4.24	7.18	7.85	1.41	6.58	8.32	3.11	8.16
	MINIMUM	0	14	0	12	19	12	0	14	0
	MAXIMUM	16	20	20	31	21	31	31	21	31
	MISSING	0	0	0	0	0	0	0	0	0
716 Baseline	N	10	2	12	5	2	7	15	4	19
	MEAN	8.7	15.0	9.8	21.4	18.0	20.4	12.9	16.5	13.7
	MEDIAN	7.0	15.0	9.5	17.0	18.0	17.0	12.0	16.5	14.0
	STDDEV	8.53	1.41	8.10	9.21	1.41	7.72	10.46	2.08	9.38
	MINIMUM	0	14	0	12	17	12	0	14	0
	MAXIMUM	27	16	27	34	19	34	34	19	34
	MISSING	0	0	0	0	0	0	0	0	0
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	10	2	12	5	2	7	15	4	19
	MEAN	1.5	-2.0	0.9	4.2	-2.0	2.4	2.4	-2.0	1.5
	MEDIAN	0.5	-2.0	0.5	3.0	-2.0	0.0	1.0	-2.0	0.0
	STDDEV	5.19	5.66	5.18	6.22	2.83	6.02	5.49	3.65	5.39
	MINIMUM	-7	-6	-7	0	-4	-4	-7	-6	-7
	MAXIMUM	11	2	11	15	0	15	15	2	15
	MISSING	0	0	0	0	0	0	0	0	0

Note: Patients who complete Paroxetine study 704 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.
Note: Study 715 patients do not have a treatment phase endpoint assessment, therefore are included as 'Missing/Uneval.'

Table 14.5.2

Summary Statistics for Change in CY-BOCS Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of OCD

Dose Level At Treatment Phase Endpoint : 3 (30mg)

		Paroxetine (N=12)			Placebo (N=8)			Total (N=20)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	5	1	6	4	4	8	9	5	14
	MEAN	15.2	11.0	14.5	19.3	10.5	14.9	17.0	10.6	14.7
	MEDIAN	15.0	11.0	13.0	18.5	11.5	16.0	15.0	11.0	15.0
	STDDEV	6.38	.	5.96	5.74	9.04	8.43	6.10	7.83	7.21
	MINIMUM	8	11	8	14	0	0	8	0	0
	MAXIMUM	23	11	23	26	19	26	26	19	26
	MISSING	3	3	6	0	0	0	3	3	6
716 Baseline	N	8	4	12	3	4	7	11	8	19
	MEAN	17.3	14.0	16.2	20.3	17.3	18.6	18.1	15.6	17.1
	MEDIAN	19.5	16.0	19.5	22.0	20.0	21.0	20.0	20.0	20.0
	STDDEV	5.99	10.13	7.31	4.73	12.28	9.25	5.63	10.57	7.91
	MINIMUM	9	1	1	15	0	0	9	0	0
	MAXIMUM	24	23	24	24	29	29	24	29	29
	MISSING	0	0	0	1	0	1	1	0	1
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	5	1	6	3	4	7	8	5	13
	MEAN	2.8	0.0	2.3	-0.3	6.8	3.7	1.6	5.4	3.1
	MEDIAN	0.0	0.0	0.0	0.0	2.0	0.0	0.0	0.0	0.0
	STDDEV	6.22	.	5.68	1.53	11.00	8.69	5.04	9.99	7.19
	MINIMUM	-3	0	-3	-2	0	-2	-3	0	-3
	MAXIMUM	13	0	13	1	23	23	13	23	23
	MISSING	3	3	6	1	0	1	4	3	7

Note: Patients who complete Paroxetine study 704 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.
Note: Study 715 patients do not have a treatment phase endpoint assessment, therefore are included as 'Missing/Uneval.'

Table 14.5.2

Summary Statistics for Change in CY-BOCS Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of OCD

Dose Level At Treatment Phase Endpoint : 4 (40mg)

		Paroxetine (N=11)			Placebo (N=14)			Total (N=25)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	3	8	11	10	4	14	13	12	25
	MEAN	13.3	16.6	15.7	15.7	19.8	16.9	15.2	17.7	16.4
	MEDIAN	12.0	19.0	19.0	18.0	18.0	18.0	16.0	19.0	19.0
	STDDEV	6.11	6.02	5.93	8.54	12.69	9.55	7.87	8.33	8.03
	MINIMUM	8	9	8	2	7	2	2	7	2
	MAXIMUM	20	24	24	27	36	36	27	36	36
	MISSING	0	0	0	0	0	0	0	0	0
716 Baseline	N	2	6	8	10	4	14	12	10	22
	MEAN	20.5	16.7	17.6	17.1	22.8	18.7	17.7	19.1	18.3
	MEDIAN	20.5	17.5	19.5	20.0	21.0	20.0	20.0	18.0	20.0
	STDDEV	0.71	5.28	4.81	7.34	9.39	8.04	6.77	7.40	6.93
	MINIMUM	20	10	10	6	14	6	6	10	6
	MAXIMUM	21	22	22	27	35	35	27	35	35
	MISSING	1	2	3	0	0	0	1	2	3
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	2	6	8	10	4	14	12	10	22
	MEAN	6.5	-0.8	1.0	1.4	3.0	1.9	2.3	0.7	1.5
	MEDIAN	6.5	0.0	0.0	0.0	1.5	0.5	0.0	0.5	0.0
	STDDEV	9.19	2.86	5.42	3.44	4.83	3.76	4.61	4.03	4.33
	MINIMUM	0	-6	-6	-3	-1	-3	-3	-6	-6
	MAXIMUM	13	2	13	9	10	10	13	10	13
	MISSING	1	2	3	0	0	0	1	2	3

Note: Patients who complete Paroxetine study 704 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.
Note: Study 715 patients do not have a treatment phase endpoint assessment, therefore are included as 'Missing/Uneval.'

Table 14.5.2

Summary Statistics for Change in CY-BOCS Total Score from Acute Study Treatment Phase Endpoint to Study 716 Baseline
by Dose Level, Acute Study Treatment Group and Age Group
Intention-To-Treat Population with Primary Diagnosis of OCD

Dose Level At Treatment Phase Endpoint : 5 (50mg)

		Paroxetine (N=14)			Placebo (N=33)			Total (N=47)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total	Children	Adolescents	Total
Acute Study Treatment Phase Endpoint	N	5	9	14	14	18	32	19	27	46
	MEAN	20.0	18.7	19.1	18.4	19.1	18.8	18.8	18.9	18.9
	MEDIAN	19.0	17.0	18.0	19.0	19.0	19.0	19.0	19.0	19.0
	STDDEV	8.75	9.03	8.61	7.32	5.03	6.04	7.50	6.46	6.83
	MINIMUM	10	9	9	6	9	6	6	9	6
	MAXIMUM	34	34	34	33	26	33	34	34	34
	MISSING	0	0	0	1	0	1	1	0	1
716 Baseline	N	5	9	14	15	18	33	20	27	47
	MEAN	23.6	21.7	22.4	21.3	22.0	21.7	21.9	21.9	21.9
	MEDIAN	22.0	21.0	21.5	23.0	22.5	23.0	22.5	22.0	22.0
	STDDEV	7.16	9.29	8.35	7.26	4.27	5.73	7.11	6.20	6.53
	MINIMUM	16	8	8	7	15	7	7	8	7
	MAXIMUM	35	34	35	31	27	31	35	34	35
	MISSING	0	0	0	0	0	0	0	0	0
Change from Acute Study Treatment Phase Endpoint to 716 Baseline	N	5	9	14	14	18	32	19	27	46
	MEAN	3.6	3.0	3.2	2.3	2.9	2.7	2.6	3.0	2.8
	MEDIAN	1.0	0.0	0.5	0.0	3.0	1.0	0.0	1.0	1.0
	STDDEV	6.54	5.22	5.48	7.13	4.09	5.53	6.82	4.40	5.46
	MINIMUM	-1	-1	-1	-9	-4	-9	-9	-4	-9
	MAXIMUM	15	14	15	15	10	15	15	14	15
	MISSING	0	0	0	1	0	1	1	0	1

Note: Patients who complete Paroxetine study 704 at dosage level 1 (10mg/day) do not taper and therefore are excluded as their treatment phase endpoint is the same day as their study 716 baseline assessment.
Note: Study 715 patients do not have a treatment phase endpoint assessment, therefore are included as 'Missing/Uneval.'

12 Source Tables: Safety Results

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BRL-29060

Paroxetine

Narrative Location Table

Table 15.0
Protocol 716

SB Document Number: BRL-029060/RSD-101C1P/1

Issue Date: 16 September 2002

Patient Number	Serious Adverse Event	Adverse Event Leading to Withdrawal	Vital Sign Value of Clinical Concern and Associated Adverse Event	Laboratory Value of Clinical Concern and Associated Adverse Event
716.002.27191			15.2.3	
716.004.25403		15.1.10		
716.004.25405	15.1.9			
716.006.25418		15.1.10		X
716.008.25644		15.1.10		
716.010.25371		15.1.10		
716.010.25606		15.1.10		
716.013.00701	15.1.9			
716.014.25651		15.1.10		
716.014.25652	15.1.9	X		
716.015.25464		15.1.10		
716.015.25466		15.1.10		
716.015.25469		15.1.10		
716.015.27043		15.1.10		
716.016.25447		15.1.10		
716.016.25450		15.1.10		
716.016.27017		15.1.10		
716.016.27019		15.1.10		
716.016.27021		15.1.10		
716.017.00004	15.1.9			
716.019.25751	15.1.9			
716.019.25752	15.1.9	X		
716.020.25458	15.1.9	X		
716.025.25802	15.1.9	X		
716.025.25822		15.1.10		
716.025.27059		15.1.10		
716.025.27060		15.1.10		
716.028.25962			15.2.3	
716.028.27683	15.1.9			
716.028.27685	15.1.9			
716.043.27696		15.1.10		
716.044.27655		15.1.10		
716.044.27656	15.1.9	X		
716.047.27156		15.1.10		
716.049.28149	15.1.9			
716.151.25607	15.1.9			
716.159.25628			15.2.3	
716.164.25721		15.1.10		
716.165.25664		15.1.10		X
716.167.25696				15.3.3
716.167.25903			15.2.3	
716.169.25781				15.3.3
716.176.25668			15.2.3	
716.176.25794		15.1.10		

Patient Number	Serious Adverse Event	Adverse Event Leading to Withdrawal	Vital Sign Value of Clinical Concern and Associated Adverse Event	Laboratory Value of Clinical Concern and Associated Adverse Event
716.176.25795			15.2.3	
716.176.27164				15.3.3
716.176.27171			15.2.3	
716.176.27172				15.3.3
716.176.27678	15.1.9			
716.180.25776		15.1.10		
716.183.25901		15.1.10		
716.192.25868				15.3.3
716.192.25870		15.1.10		
716.192.25872			15.2.3	
716.201.00109	15.1.9	X		
716.201.00110		15.1.10		

X indicates that the patient had narratives for two different reasons, and the narratives are combined for that patient in the numbered table.

Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	9 (11.1%)	8 (12.1%)	17 (11.6%)
Body as a Whole	TOTAL	4 (4.9%)	4 (6.1%)	8 (5.4%)
	HEADACHE	2 (2.5%)	2 (3.0%)	4 (2.7%)
	ABSCESS	1 (1.2%)	0	1 (0.7%)
	INFECTION	1 (1.2%)	0	1 (0.7%)
	ABDOMINAL PAIN	0	1 (1.5%)	1 (0.7%)
	TRAUMA	0	1 (1.5%)	1 (0.7%)
Respiratory System	TOTAL	3 (3.7%)	1 (1.5%)	4 (2.7%)
	COUGH INCREASED	2 (2.5%)	0	2 (1.4%)
	RESPIRATORY DISORDER	1 (1.2%)	0	1 (0.7%)
	RHINITIS	1 (1.2%)	0	1 (0.7%)
	SINUSITIS	0	1 (1.5%)	1 (0.7%)
Endocrine System	TOTAL	1 (1.2%)	0	1 (0.7%)
	THYROID DISORDER	1 (1.2%)	0	1 (0.7%)
Hemic and Lymphatic System	TOTAL	1 (1.2%)	0	1 (0.7%)
	PURPURA	1 (1.2%)	0	1 (0.7%)
Digestive System	TOTAL	0	2 (3.0%)	2 (1.4%)
	GASTROINTESTINAL DISORDER	0	1 (1.5%)	1 (0.7%)
	NAUSEA	0	1 (1.5%)	1 (0.7%)
Special Senses	TOTAL	0	1 (1.5%)	1 (0.7%)
	OTITIS MEDIA	0	1 (1.5%)	1 (0.7%)
Urogenital System	TOTAL	0	1 (1.5%)	1 (0.7%)
	ALBUMINURIA	0	1 (1.5%)	1 (0.7%)

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Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	12 (23.1%)	11 (17.2%)	23 (19.8%)
Body as a Whole	TOTAL	8 (15.4%)	4 (6.3%)	12 (10.3%)
	HEADACHE	4 (7.7%)	2 (3.1%)	6 (5.2%)
	TRAUMA	2 (3.8%)	1 (1.6%)	3 (2.6%)
	FEVER	2 (3.8%)	0	2 (1.7%)
	ABDOMINAL PAIN	1 (1.9%)	0	1 (0.9%)
	BACK PAIN	1 (1.9%)	0	1 (0.9%)
	INFECTION	0	1 (1.6%)	1 (0.9%)
Respiratory System	TOTAL	3 (5.8%)	3 (4.7%)	6 (5.2%)
	RHINITIS	2 (3.8%)	0	2 (1.7%)
	PHARYNGITIS	1 (1.9%)	1 (1.6%)	2 (1.7%)
	SINUSITIS	0	2 (3.1%)	2 (1.7%)
Digestive System	TOTAL	1 (1.9%)	2 (3.1%)	3 (2.6%)
	NAUSEA	0	2 (3.1%)	2 (1.7%)
	DIARRHEA	1 (1.9%)	0	1 (0.9%)
	VOMITING	0	1 (1.6%)	1 (0.9%)
Hemic and Lymphatic System	TOTAL	1 (1.9%)	0	1 (0.9%)
	PURPURA	1 (1.9%)	0	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	1 (1.9%)	1 (1.6%)	2 (1.7%)
	WEIGHT GAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
Endocrine System	TOTAL	0	1 (1.6%)	1 (0.9%)
	THYROID DISORDER	0	1 (1.6%)	1 (0.9%)
Nervous System	TOTAL	0	1 (1.6%)	1 (0.9%)
	ANXIETY	0	1 (1.6%)	1 (0.9%)

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Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
TOTAL	TOTAL	21 (15.8%)	19 (14.6%)	40 (15.2%)
Body as a Whole	TOTAL	12 (9.0%)	8 (6.2%)	20 (7.6%)
	HEADACHE	6 (4.5%)	4 (3.1%)	10 (3.8%)
	TRAUMA	2 (1.5%)	2 (1.5%)	4 (1.5%)
	FEVER	2 (1.5%)	0	2 (0.8%)
	ABDOMINAL PAIN	1 (0.8%)	1 (0.8%)	2 (0.8%)
	INFECTION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	ABSCESS	1 (0.8%)	0	1 (0.4%)
	BACK PAIN	1 (0.8%)	0	1 (0.4%)
Respiratory System	TOTAL	6 (4.5%)	4 (3.1%)	10 (3.8%)
	RHINITIS	3 (2.3%)	0	3 (1.1%)
	SINUSITIS	0	3 (2.3%)	3 (1.1%)
	COUGH INCREASED	2 (1.5%)	0	2 (0.8%)
	PHARYNGITIS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	RESPIRATORY DISORDER	1 (0.8%)	0	1 (0.4%)
Hemic and Lymphatic System	TOTAL	2 (1.5%)	0	2 (0.8%)
	PURPURA	2 (1.5%)	0	2 (0.8%)
Digestive System	TOTAL	1 (0.8%)	4 (3.1%)	5 (1.9%)
	NAUSEA	0	3 (2.3%)	3 (1.1%)
	DIARRHEA	1 (0.8%)	0	1 (0.4%)
	GASTROINTESTINAL DISORDER	0	1 (0.8%)	1 (0.4%)
	VOMITING	0	1 (0.8%)	1 (0.4%)
Endocrine System	TOTAL	1 (0.8%)	1 (0.8%)	2 (0.8%)
	THYROID DISORDER	1 (0.8%)	1 (0.8%)	2 (0.8%)
Metabolic and Nutritional Disorders	TOTAL	1 (0.8%)	1 (0.8%)	2 (0.8%)
	WEIGHT GAIN	1 (0.8%)	1 (0.8%)	2 (0.8%)
Nervous System	TOTAL	0	1 (0.8%)	1 (0.4%)
	ANXIETY	0	1 (0.8%)	1 (0.4%)
Special Senses	TOTAL	0	1 (0.8%)	1 (0.4%)
	OTITIS MEDIA	0	1 (0.8%)	1 (0.4%)
Urogenital System	TOTAL	0	1 (0.8%)	1 (0.4%)
	ALBUMINURIA	0	1 (0.8%)	1 (0.4%)

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Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.0.1

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	1 (1.2%)	1 (1.5%)	2 (1.4%)
Urogenital System	TOTAL	1 (1.2%)	0	1 (0.7%)
	KIDNEY FUNCTION ABNORMAL	1 (1.2%)	0	1 (0.7%)
Body as a Whole	TOTAL	0	1 (1.5%)	1 (0.7%)
	ABDOMINAL PAIN	0	1 (1.5%)	1 (0.7%)

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Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	1 (1.9%)	2 (3.1%)	3 (2.6%)
Respiratory System	TOTAL	1 (1.9%)	1 (1.6%)	2 (1.7%)
	EPISTAXIS	1 (1.9%)	0	1 (0.9%)
	RHINITIS	0	1 (1.6%)	1 (0.9%)
Skin and Appendages	TOTAL	0	1 (1.6%)	1 (0.9%)
	ECZEMA	0	1 (1.6%)	1 (0.9%)

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Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
TOTAL	TOTAL	2 (1.5%)	3 (2.3%)	5 (1.9%)
Respiratory System	TOTAL	1 (0.8%)	1 (0.8%)	2 (0.8%)
	EPISTAXIS	1 (0.8%)	0	1 (0.4%)
	RHINITIS	0	1 (0.8%)	1 (0.4%)
Urogenital System	TOTAL	1 (0.8%)	0	1 (0.4%)
	KIDNEY FUNCTION ABNORMAL	1 (0.8%)	0	1 (0.4%)
Body as a Whole	TOTAL	0	1 (0.8%)	1 (0.4%)
	ABDOMINAL PAIN	0	1 (0.8%)	1 (0.4%)
Skin and Appendages	TOTAL	0	1 (0.8%)	1 (0.4%)
	ECZEMA	0	1 (0.8%)	1 (0.4%)

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Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.0.2

Number (%) of Patients with Adverse Experiences Prior to Start of Acute Study Treatment and Ongoing into study 716
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	24 (29.6%)	11 (16.7%)	35 (23.8%)
Nervous System	TOTAL	11 (13.6%)	5 (7.6%)	16 (10.9%)
	SOMNOLENCE	4 (4.9%)	3 (4.5%)	7 (4.8%)
	HYPERKINESIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
	CONCENTRATION IMPAIRED	2 (2.5%)	0	2 (1.4%)
	ANXIETY	1 (1.2%)	1 (1.5%)	2 (1.4%)
	DEPRESSION	1 (1.2%)	1 (1.5%)	2 (1.4%)
	INSOMNIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	AGITATION	1 (1.2%)	0	1 (0.7%)
	DIZZINESS	1 (1.2%)	0	1 (0.7%)
	MYOCLONUS	1 (1.2%)	0	1 (0.7%)
	NERVOUSNESS	1 (1.2%)	0	1 (0.7%)
Body as a Whole	TOTAL	8 (9.9%)	1 (1.5%)	9 (6.1%)
	TRAUMA	3 (3.7%)	0	3 (2.0%)
	ASTHENIA	2 (2.5%)	0	2 (1.4%)
	INFECTION	2 (2.5%)	0	2 (1.4%)
	PAIN	1 (1.2%)	0	1 (0.7%)
	ALLERGIC REACTION	0	1 (1.5%)	1 (0.7%)
Respiratory System	TOTAL	3 (3.7%)	4 (6.1%)	7 (4.8%)
	PHARYNGITIS	1 (1.2%)	1 (1.5%)	2 (1.4%)
	RESPIRATORY DISORDER	1 (1.2%)	1 (1.5%)	2 (1.4%)
	RHINITIS	1 (1.2%)	1 (1.5%)	2 (1.4%)
	BRONCHITIS	0	1 (1.5%)	1 (0.7%)
Digestive System	TOTAL	2 (2.5%)	1 (1.5%)	3 (2.0%)
	DYSPEPSIA	1 (1.2%)	0	1 (0.7%)
	NAUSEA	1 (1.2%)	0	1 (0.7%)
	DECREASED APPETITE	0	1 (1.5%)	1 (0.7%)
Cardiovascular System	TOTAL	1 (1.2%)	2 (3.0%)	3 (2.0%)
	CARDIAC DISORDERS	1 (1.2%)	0	1 (0.7%)
	MIGRAINE	0	1 (1.5%)	1 (0.7%)
	PALPITATION	0	1 (1.5%)	1 (0.7%)
	TACHYCARDIA	0	1 (1.5%)	1 (0.7%)
Hemic and Lymphatic System	TOTAL	1 (1.2%)	0	1 (0.7%)
	PURPURA	1 (1.2%)	0	1 (0.7%)
Skin and Appendages	TOTAL	1 (1.2%)	0	1 (0.7%)
	SWEATING	1 (1.2%)	0	1 (0.7%)

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Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
Special Senses	TOTAL	1 (1.2%)	0	1 (0.7%)
	OTITIS MEDIA	1 (1.2%)	0	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.5%)	1 (0.7%)
	SGPT INCREASED	0	1 (1.5%)	1 (0.7%)
	WEIGHT GAIN	0	1 (1.5%)	1 (0.7%)
Urogenital System	TOTAL	0	1 (1.5%)	1 (0.7%)
	ALBUMINURIA	0	1 (1.5%)	1 (0.7%)
	HAEMATURIA	0	1 (1.5%)	1 (0.7%)

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Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	1 (3.0%)	0	1 (1.6%)
Urogenital System	TOTAL	1 (3.0%)	0	1 (1.6%)
	MENSTRUAL DISORDER	1 (3.0%)	0	1 (1.6%)

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Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	16 (30.8%)	13 (20.3%)	29 (25.0%)
Nervous System	TOTAL	7 (13.5%)	5 (7.8%)	12 (10.3%)
	NERVOUSNESS	3 (5.8%)	2 (3.1%)	5 (4.3%)
	INSOMNIA	2 (3.8%)	0	2 (1.7%)
	SOMNOLENCE	2 (3.8%)	0	2 (1.7%)
	DEPERSONALIZATION	1 (1.9%)	0	1 (0.9%)
	DEPRESSION	1 (1.9%)	0	1 (0.9%)
	TREMOR	1 (1.9%)	0	1 (0.9%)
	VERTIGO	1 (1.9%)	0	1 (0.9%)
	DIZZINESS	0	1 (1.6%)	1 (0.9%)
	HYPERKINESIA	0	1 (1.6%)	1 (0.9%)
	MANIC REACTION	0	1 (1.6%)	1 (0.9%)
	NYSTAGMUS	0	1 (1.6%)	1 (0.9%)
Body as a Whole	TOTAL	4 (7.7%)	6 (9.4%)	10 (8.6%)
	ALLERGIC REACTION	1 (1.9%)	3 (4.7%)	4 (3.4%)
	ASTHENIA	1 (1.9%)	2 (3.1%)	3 (2.6%)
	ABDOMINAL PAIN	1 (1.9%)	0	1 (0.9%)
	HEADACHE	1 (1.9%)	0	1 (0.9%)
	INFECTION	0	1 (1.6%)	1 (0.9%)
Digestive System	TOTAL	3 (5.8%)	3 (4.7%)	6 (5.2%)
	DECREASED APPETITE	1 (1.9%)	2 (3.1%)	3 (2.6%)
	NAUSEA	1 (1.9%)	1 (1.6%)	2 (1.7%)
	DIARRHEA	1 (1.9%)	0	1 (0.9%)
	FLATULENCE	1 (1.9%)	0	1 (0.9%)
	CONSTIPATION	0	1 (1.6%)	1 (0.9%)
Respiratory System	TOTAL	3 (5.8%)	1 (1.6%)	4 (3.4%)
	RHINITIS	2 (3.8%)	1 (1.6%)	3 (2.6%)
	COUGH INCREASED	1 (1.9%)	0	1 (0.9%)
	RESPIRATORY DISORDER	1 (1.9%)	0	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	2 (3.8%)	0	2 (1.7%)
	WEIGHT GAIN	2 (3.8%)	0	2 (1.7%)
Cardiovascular System	TOTAL	1 (1.9%)	1 (1.6%)	2 (1.7%)
	HYPERTENSION	1 (1.9%)	0	1 (0.9%)
	VASODILATATION	0	1 (1.6%)	1 (0.9%)
Endocrine System	TOTAL	1 (1.9%)	0	1 (0.9%)
	THYROID DISORDER	1 (1.9%)	0	1 (0.9%)

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Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
Musculoskeletal System	TOTAL	1 (1.9%)	0	1 (0.9%)
	MYALGIA	1 (1.9%)	0	1 (0.9%)
Skin and Appendages	TOTAL	1 (1.9%)	2 (3.1%)	3 (2.6%)
	ACNE	1 (1.9%)	0	1 (0.9%)
	FUNGAL DERMATITIS	0	1 (1.6%)	1 (0.9%)
	RASH	0	1 (1.6%)	1 (0.9%)
Special Senses	TOTAL	1 (1.9%)	2 (3.1%)	3 (2.6%)
	KERATOCONJUNCTIVITIS	1 (1.9%)	0	1 (0.9%)
	EAR DISORDER	0	1 (1.6%)	1 (0.9%)
	EAR PAIN	0	1 (1.6%)	1 (0.9%)
	OTITIS MEDIA	0	1 (1.6%)	1 (0.9%)
Urogenital System	TOTAL	1 (1.9%)	1 (1.6%)	2 (1.7%)
	URINARY INCONTINENCE	1 (1.9%)	0	1 (0.9%)
	HAEMATURIA	0	1 (1.6%)	1 (0.9%)
Hemic and Lymphatic System	TOTAL	0	1 (1.6%)	1 (0.9%)
	LEUKOPENIA	0	1 (1.6%)	1 (0.9%)

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Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (2.4%)	1 (1.5%)
Urogenital System	TOTAL	0	1 (2.4%)	1 (1.5%)
	ABNORMAL EJACULATION	0	1 (2.4%)	1 (1.5%)

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Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
TOTAL	TOTAL	40 (30.1%)	24 (18.5%)	64 (24.3%)
Nervous System	TOTAL	18 (13.5%)	10 (7.7%)	28 (10.6%)
	SOMNOLENCE	6 (4.5%)	3 (2.3%)	9 (3.4%)
	NERVOUSNESS	4 (3.0%)	2 (1.5%)	6 (2.3%)
	INSOMNIA	3 (2.3%)	1 (0.8%)	4 (1.5%)
	HYPERKINESIA	2 (1.5%)	2 (1.5%)	4 (1.5%)
	DEPRESSION	2 (1.5%)	1 (0.8%)	3 (1.1%)
	CONCENTRATION IMPAIRED	2 (1.5%)	0	2 (0.8%)
	ANXIETY	1 (0.8%)	1 (0.8%)	2 (0.8%)
	DIZZINESS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	AGITATION	1 (0.8%)	0	1 (0.4%)
	DEPERSONALIZATION	1 (0.8%)	0	1 (0.4%)
	MYOCLONUS	1 (0.8%)	0	1 (0.4%)
	TREMOR	1 (0.8%)	0	1 (0.4%)
	VERTIGO	1 (0.8%)	0	1 (0.4%)
	MANIC REACTION	0	1 (0.8%)	1 (0.4%)
	NYSTAGMUS	0	1 (0.8%)	1 (0.4%)
Body as a Whole	TOTAL	12 (9.0%)	7 (5.4%)	19 (7.2%)
	ASTHENIA	3 (2.3%)	2 (1.5%)	5 (1.9%)
	ALLERGIC REACTION	1 (0.8%)	4 (3.1%)	5 (1.9%)
	TRAUMA	3 (2.3%)	0	3 (1.1%)
	INFECTION	2 (1.5%)	1 (0.8%)	3 (1.1%)
	ABDOMINAL PAIN	1 (0.8%)	0	1 (0.4%)
	HEADACHE	1 (0.8%)	0	1 (0.4%)
	PAIN	1 (0.8%)	0	1 (0.4%)
Respiratory System	TOTAL	6 (4.5%)	5 (3.8%)	11 (4.2%)
	RHINITIS	3 (2.3%)	2 (1.5%)	5 (1.9%)
	RESPIRATORY DISORDER	2 (1.5%)	1 (0.8%)	3 (1.1%)
	PHARYNGITIS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	COUGH INCREASED	1 (0.8%)	0	1 (0.4%)
	BRONCHITIS	0	1 (0.8%)	1 (0.4%)
Digestive System	TOTAL	5 (3.8%)	4 (3.1%)	9 (3.4%)
	DECREASED APPETITE	1 (0.8%)	3 (2.3%)	4 (1.5%)
	NAUSEA	2 (1.5%)	1 (0.8%)	3 (1.1%)
	DIARRHEA	1 (0.8%)	0	1 (0.4%)
	DYSPEPSIA	1 (0.8%)	0	1 (0.4%)
	FLATULENCE	1 (0.8%)	0	1 (0.4%)
	CONSTIPATION	0	1 (0.8%)	1 (0.4%)
Cardiovascular System	TOTAL	2 (1.5%)	3 (2.3%)	5 (1.9%)

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Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Cardiovascular System	CARDIAC DISORDERS	1 (0.8%)	0	1 (0.4%)
	HYPERTENSION	1 (0.8%)	0	1 (0.4%)
	MIGRAINE	0	1 (0.8%)	1 (0.4%)
	PALPITATION	0	1 (0.8%)	1 (0.4%)
	TACHYCARDIA	0	1 (0.8%)	1 (0.4%)
	VASODILATATION	0	1 (0.8%)	1 (0.4%)
Metabolic and Nutritional Disorders	TOTAL	2 (1.5%)	1 (0.8%)	3 (1.1%)
	WEIGHT GAIN	2 (1.5%)	1 (0.8%)	3 (1.1%)
	SGPT INCREASED	0	1 (0.8%)	1 (0.4%)
Skin and Appendages	TOTAL	2 (1.5%)	2 (1.5%)	4 (1.5%)
	ACNE	1 (0.8%)	0	1 (0.4%)
	SWEATING	1 (0.8%)	0	1 (0.4%)
	FUNGAL DERMATITIS	0	1 (0.8%)	1 (0.4%)
	RASH	0	1 (0.8%)	1 (0.4%)
Special Senses	TOTAL	2 (1.5%)	2 (1.5%)	4 (1.5%)
	OTITIS MEDIA	1 (0.8%)	1 (0.8%)	2 (0.8%)
	KERATOCONJUNCTIVITIS	1 (0.8%)	0	1 (0.4%)
	EAR DISORDER	0	1 (0.8%)	1 (0.4%)
	EAR PAIN	0	1 (0.8%)	1 (0.4%)
Endocrine System	TOTAL	1 (0.8%)	0	1 (0.4%)
	THYROID DISORDER	1 (0.8%)	0	1 (0.4%)
Hemic and Lymphatic System	TOTAL	1 (0.8%)	1 (0.8%)	2 (0.8%)
	PURPURA	1 (0.8%)	0	1 (0.4%)
	LEUKOPENIA	0	1 (0.8%)	1 (0.4%)
Musculoskeletal System	TOTAL	1 (0.8%)	0	1 (0.4%)
	MYALGIA	1 (0.8%)	0	1 (0.4%)
Urogenital System	TOTAL	1 (0.8%)	2 (1.5%)	3 (1.1%)
	HAEMATURIA	0	2 (1.5%)	2 (0.8%)
	URINARY INCONTINENCE	1 (0.8%)	0	1 (0.4%)
	ALBUMINURIA	0	1 (0.8%)	1 (0.4%)

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Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (1.3%)	1 (0.7%)
Urogenital System	TOTAL	0	1 (1.3%)	1 (0.7%)
	ABNORMAL EJACULATION	0	1 (1.3%)	1 (0.7%)

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Table 15.1.1.0.3

Number (%) of Patients with Adverse Experiences During the Acute Study Treatment Phase (Including Taper) and Ongoing into study 716 by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	1 (1.6%)	0	1 (0.9%)
Urogenital System	TOTAL	1 (1.6%)	0	1 (0.9%)
	MENSTRUAL DISORDER	1 (1.6%)	0	1 (0.9%)

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
TOTAL	TOTAL	32 (82.1%)	25 (69.4%)	57 (76.0%)
Body as a Whole	TOTAL	21 (53.8%)	15 (41.7%)	36 (48.0%)
	TRAUMA	11 (28.2%)	4 (11.1%)	15 (20.0%)
	INFECTION	5 (12.8%)	9 (25.0%)	14 (18.7%)
	HEADACHE	9 (23.1%)	4 (11.1%)	13 (17.3%)
	ABDOMINAL PAIN	7 (17.9%)	3 (8.3%)	10 (13.3%)
	FEVER	5 (12.8%)	2 (5.6%)	7 (9.3%)
	ALLERGIC REACTION	3 (7.7%)	2 (5.6%)	5 (6.7%)
	PAIN	3 (7.7%)	1 (2.8%)	4 (5.3%)
	ASTHENIA	2 (5.1%)	2 (5.6%)	4 (5.3%)
	BACK PAIN	0	3 (8.3%)	3 (4.0%)
	FACE EDEMA	2 (5.1%)	0	2 (2.7%)
Respiratory System	TOTAL	20 (51.3%)	13 (36.1%)	33 (44.0%)
	RESPIRATORY DISORDER	9 (23.1%)	6 (16.7%)	15 (20.0%)
	PHARYNGITIS	8 (20.5%)	4 (11.1%)	12 (16.0%)
	RHINITIS	4 (10.3%)	3 (8.3%)	7 (9.3%)
	COUGH INCREASED	3 (7.7%)	1 (2.8%)	4 (5.3%)
	SINUSITIS	3 (7.7%)	1 (2.8%)	4 (5.3%)
	EPISTAXIS	0	2 (5.6%)	2 (2.7%)
	ASTHMA	0	1 (2.8%)	1 (1.3%)
	BRONCHITIS	0	1 (2.8%)	1 (1.3%)
	PNEUMONIA	0	1 (2.8%)	1 (1.3%)
	YAWN	0	1 (2.8%)	1 (1.3%)
Digestive System	TOTAL	15 (38.5%)	11 (30.6%)	26 (34.7%)
	VOMITING	7 (17.9%)	4 (11.1%)	11 (14.7%)
	DYSPEPSIA	4 (10.3%)	3 (8.3%)	7 (9.3%)
	DIARRHEA	2 (5.1%)	1 (2.8%)	3 (4.0%)
	NAUSEA	1 (2.6%)	2 (5.6%)	3 (4.0%)
	DRY MOUTH	2 (5.1%)	0	2 (2.7%)
	DECREASED APPETITE	1 (2.6%)	1 (2.8%)	2 (2.7%)
	TOOTH CARIES	0	2 (5.6%)	2 (2.7%)
	CONSTIPATION	1 (2.6%)	0	1 (1.3%)
	INCREASED APPETITE	1 (2.6%)	0	1 (1.3%)
	STOMATITIS	1 (2.6%)	0	1 (1.3%)
	GASTROENTERITIS	0	1 (2.8%)	1 (1.3%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (2.8%)	1 (1.3%)
Nervous System	TOTAL	13 (33.3%)	12 (33.3%)	25 (33.3%)
	NERVOUSNESS	5 (12.8%)	0	5 (6.7%)
	HOSTILITY	4 (10.3%)	1 (2.8%)	5 (6.7%)
	INSOMNIA	1 (2.6%)	3 (8.3%)	4 (5.3%)

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
Nervous System	DEPRESSION	2 (5.1%)	1 (2.8%)	3 (4.0%)
	HYPERKINESIA	2 (5.1%)	1 (2.8%)	3 (4.0%)
	AGITATION	1 (2.6%)	2 (5.6%)	3 (4.0%)
	HALLUCINATIONS	1 (2.6%)	1 (2.8%)	2 (2.7%)
	HYPESTHESIA	0	2 (5.6%)	2 (2.7%)
	CONVULSION	1 (2.6%)	0	1 (1.3%)
	EMOTIONAL LABILITY	1 (2.6%)	0	1 (1.3%)
	NEUROSIS	1 (2.6%)	0	1 (1.3%)
	VESTIBULAR DISORDER	1 (2.6%)	0	1 (1.3%)
	ANXIETY	0	1 (2.8%)	1 (1.3%)
	CONCENTRATION IMPAIRED	0	1 (2.8%)	1 (1.3%)
	DIZZINESS	0	1 (2.8%)	1 (1.3%)
	EUPHORIA	0	1 (2.8%)	1 (1.3%)
	PARALYSIS	0	1 (2.8%)	1 (1.3%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.3%)
	TREMOR	0	1 (2.8%)	1 (1.3%)
Skin and Appendages	TOTAL	6 (15.4%)	4 (11.1%)	10 (13.3%)
	CONTACT DERMATITIS	2 (5.1%)	1 (2.8%)	3 (4.0%)
	RASH	1 (2.6%)	2 (5.6%)	3 (4.0%)
	ACNE	2 (5.1%)	0	2 (2.7%)
	HERPES ZOSTER	1 (2.6%)	0	1 (1.3%)
	MACULOPAPULAR RASH	0	1 (2.8%)	1 (1.3%)
	PRURITUS	0	1 (2.8%)	1 (1.3%)
Metabolic and Nutritional Disorders	TOTAL	5 (12.8%)	4 (11.1%)	9 (12.0%)
	WEIGHT GAIN	4 (10.3%)	3 (8.3%)	7 (9.3%)
	DEHYDRATION	1 (2.6%)	1 (2.8%)	2 (2.7%)
Musculoskeletal System	TOTAL	3 (7.7%)	1 (2.8%)	4 (5.3%)
	ARTHRALGIA	2 (5.1%)	0	2 (2.7%)
	TENDINOUS DISORDER	1 (2.6%)	0	1 (1.3%)
	ARTHROSIS	0	1 (2.8%)	1 (1.3%)
	MYALGIA	0	1 (2.8%)	1 (1.3%)
Special Senses	TOTAL	2 (5.1%)	2 (5.6%)	4 (5.3%)
	OTITIS MEDIA	2 (5.1%)	1 (2.8%)	3 (4.0%)
	ABNORMAL VISION	0	1 (2.8%)	1 (1.3%)
Urogenital System	TOTAL	2 (5.1%)	3 (8.3%)	5 (6.7%)
	URINARY INCONTINENCE	1 (2.6%)	2 (5.6%)	3 (4.0%)
	PYURIA	1 (2.6%)	0	1 (1.3%)
	ALBUMINURIA	0	1 (2.8%)	1 (1.3%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
Urogenital System	CYSTITIS	0	1 (2.8%)	1 (1.3%)
	HAEMATURIA	0	1 (2.8%)	1 (1.3%)
Hemic and Lymphatic System	TOTAL	1 (2.6%)	2 (5.6%)	3 (4.0%)
	LEUKOPENIA	1 (2.6%)	2 (5.6%)	3 (4.0%)
	ANEMIA	0	1 (2.8%)	1 (1.3%)
Cardiovascular System	TOTAL	0	3 (8.3%)	3 (4.0%)
	BUNDLE BRANCH BLOCK	0	1 (2.8%)	1 (1.3%)
	MIGRAINE	0	1 (2.8%)	1 (1.3%)
	SYNCOPE	0	1 (2.8%)	1 (1.3%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	22 (78.6%)	30 (83.3%)	52 (81.3%)
Body as a Whole	TOTAL	14 (50.0%)	17 (47.2%)	31 (48.4%)
	HEADACHE	9 (32.1%)	8 (22.2%)	17 (26.6%)
	TRAUMA	4 (14.3%)	4 (11.1%)	8 (12.5%)
	ABDOMINAL PAIN	2 (7.1%)	5 (13.9%)	7 (10.9%)
	INFECTION	3 (10.7%)	3 (8.3%)	6 (9.4%)
	FEVER	3 (10.7%)	1 (2.8%)	4 (6.3%)
	PAIN	2 (7.1%)	1 (2.8%)	3 (4.7%)
	ABSCESS	1 (3.6%)	0	1 (1.6%)
	BACK PAIN	1 (3.6%)	0	1 (1.6%)
	ALLERGIC REACTION	0	1 (2.8%)	1 (1.6%)
	SPINA BIFIDA	0	1 (2.8%)	1 (1.6%)
Digestive System	TOTAL	9 (32.1%)	6 (16.7%)	15 (23.4%)
	NAUSEA	5 (17.9%)	1 (2.8%)	6 (9.4%)
	DECREASED APPETITE	2 (7.1%)	2 (5.6%)	4 (6.3%)
	DIARRHEA	3 (10.7%)	0	3 (4.7%)
	DYSPEPSIA	2 (7.1%)	1 (2.8%)	3 (4.7%)
	GINGIVITIS	1 (3.6%)	1 (2.8%)	2 (3.1%)
	TOOTH DISORDER	1 (3.6%)	0	1 (1.6%)
	VOMITING	1 (3.6%)	0	1 (1.6%)
	FLATULENCE	0	1 (2.8%)	1 (1.6%)
	GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
	TOOTH CARIES	0	1 (2.8%)	1 (1.6%)
Nervous System	TOTAL	8 (28.6%)	22 (61.1%)	30 (46.9%)
	NERVOUSNESS	1 (3.6%)	9 (25.0%)	10 (15.6%)
	HYPERKINESIA	5 (17.9%)	4 (11.1%)	9 (14.1%)
	INSOMNIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
	HOSTILITY	1 (3.6%)	4 (11.1%)	5 (7.8%)
	ANXIETY	1 (3.6%)	3 (8.3%)	4 (6.3%)
	DIZZINESS	1 (3.6%)	2 (5.6%)	3 (4.7%)
	SOMNOLENCE	1 (3.6%)	2 (5.6%)	3 (4.7%)
	AGITATION	1 (3.6%)	1 (2.8%)	2 (3.1%)
	MYOCLONUS	1 (3.6%)	1 (2.8%)	2 (3.1%)
	VERTIGO	0	2 (5.6%)	2 (3.1%)
	CONCENTRATION IMPAIRED	1 (3.6%)	0	1 (1.6%)
	DEPRESSION	1 (3.6%)	0	1 (1.6%)
	EMOTIONAL LABILITY	1 (3.6%)	0	1 (1.6%)
	DYSKINESIA	0	1 (2.8%)	1 (1.6%)
	LACK OF EMOTION	0	1 (2.8%)	1 (1.6%)
	MANIC REACTION	0	1 (2.8%)	1 (1.6%)
	PSYCHOSIS	0	1 (2.8%)	1 (1.6%)

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Body System	Preferred Term			
Nervous System	TREMOR	0	1 (2.8%)	1 (1.6%)
Respiratory System	TOTAL	8 (28.6%)	10 (27.8%)	18 (28.1%)
	RESPIRATORY DISORDER	2 (7.1%)	8 (22.2%)	10 (15.6%)
	PHARYNGITIS	5 (17.9%)	3 (8.3%)	8 (12.5%)
	RHINITIS	4 (14.3%)	4 (11.1%)	8 (12.5%)
	COUGH INCREASED	2 (7.1%)	1 (2.8%)	3 (4.7%)
	SINUSITIS	2 (7.1%)	1 (2.8%)	3 (4.7%)
	ASTHMA	1 (3.6%)	0	1 (1.6%)
Special Senses	TOTAL	5 (17.9%)	4 (11.1%)	9 (14.1%)
	OTITIS MEDIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
	OTITIS EXTERNA	2 (7.1%)	1 (2.8%)	3 (4.7%)
	EAR PAIN	1 (3.6%)	1 (2.8%)	2 (3.1%)
Hemic and Lymphatic System	TOTAL	2 (7.1%)	0	2 (3.1%)
	ANEMIA	1 (3.6%)	0	1 (1.6%)
	PURPURA	1 (3.6%)	0	1 (1.6%)
Skin and Appendages	TOTAL	2 (7.1%)	3 (8.3%)	5 (7.8%)
	CONTACT DERMATITIS	0	2 (5.6%)	2 (3.1%)
	RASH	0	2 (5.6%)	2 (3.1%)
	ACNE	1 (3.6%)	0	1 (1.6%)
	MACULOPAPULAR RASH	1 (3.6%)	0	1 (1.6%)
	FUNGAL DERMATITIS	0	1 (2.8%)	1 (1.6%)
	HERPES SIMPLEX	0	1 (2.8%)	1 (1.6%)
Urogenital System	TOTAL	2 (7.1%)	2 (5.6%)	4 (6.3%)
	ALBUMINURIA	2 (7.1%)	0	2 (3.1%)
	URINARY INCONTINENCE	0	2 (5.6%)	2 (3.1%)
	GLYCOSURIA	1 (3.6%)	0	1 (1.6%)
Cardiovascular System	TOTAL	1 (3.6%)	3 (8.3%)	4 (6.3%)
	VASODILATATION	0	3 (8.3%)	3 (4.7%)
	HAEMATOMA	1 (3.6%)	0	1 (1.6%)
Musculoskeletal System	TOTAL	1 (3.6%)	0	1 (1.6%)
	MYALGIA	1 (3.6%)	0	1 (1.6%)
Metabolic and Nutritional Disorders	TOTAL	0	3 (8.3%)	3 (4.7%)
	WEIGHT GAIN	0	3 (8.3%)	3 (4.7%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
TOTAL	TOTAL	1 (6.3%)	1 (7.7%)	2 (6.9%)
Urogenital System	TOTAL	1 (6.3%)	1 (7.7%)	2 (6.9%)
	DYSMENORRHEA	1 (6.3%)	1 (7.7%)	2 (6.9%)
	UTERUS DISORDERS	0	1 (7.7%)	1 (3.4%)

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
TOTAL	TOTAL	54 (80.6%)	55 (76.4%)	109 (78.4%)
Body as a Whole	TOTAL	35 (52.2%)	32 (44.4%)	67 (48.2%)
	HEADACHE	18 (26.9%)	12 (16.7%)	30 (21.6%)
	TRAUMA	15 (22.4%)	8 (11.1%)	23 (16.5%)
	INFECTION	8 (11.9%)	12 (16.7%)	20 (14.4%)
	ABDOMINAL PAIN	9 (13.4%)	8 (11.1%)	17 (12.2%)
	FEVER	8 (11.9%)	3 (4.2%)	11 (7.9%)
	PAIN	5 (7.5%)	2 (2.8%)	7 (5.0%)
	ALLERGIC REACTION	3 (4.5%)	3 (4.2%)	6 (4.3%)
	ASTHENIA	2 (3.0%)	2 (2.8%)	4 (2.9%)
	BACK PAIN	1 (1.5%)	3 (4.2%)	4 (2.9%)
	FACE EDEMA	2 (3.0%)	0	2 (1.4%)
	ABSCESS	1 (1.5%)	0	1 (0.7%)
	SPINA BIFIDA	0	1 (1.4%)	1 (0.7%)
Respiratory System	TOTAL	28 (41.8%)	23 (31.9%)	51 (36.7%)
	RESPIRATORY DISORDER	11 (16.4%)	14 (19.4%)	25 (18.0%)
	PHARYNGITIS	13 (19.4%)	7 (9.7%)	20 (14.4%)
	RHINITIS	8 (11.9%)	7 (9.7%)	15 (10.8%)
	COUGH INCREASED	5 (7.5%)	2 (2.8%)	7 (5.0%)
	SINUSITIS	5 (7.5%)	2 (2.8%)	7 (5.0%)
	ASTHMA	1 (1.5%)	1 (1.4%)	2 (1.4%)
	EPISTAXIS	0	2 (2.8%)	2 (1.4%)
	BRONCHITIS	0	1 (1.4%)	1 (0.7%)
	PNEUMONIA	0	1 (1.4%)	1 (0.7%)
	YAWN	0	1 (1.4%)	1 (0.7%)
Digestive System	TOTAL	24 (35.8%)	17 (23.6%)	41 (29.5%)
	VOMITING	8 (11.9%)	4 (5.6%)	12 (8.6%)
	DYSPEPSIA	6 (9.0%)	4 (5.6%)	10 (7.2%)
	NAUSEA	6 (9.0%)	3 (4.2%)	9 (6.5%)
	DIARRHEA	5 (7.5%)	1 (1.4%)	6 (4.3%)
	DECREASED APPETITE	3 (4.5%)	3 (4.2%)	6 (4.3%)
	TOOTH CARIES	0	3 (4.2%)	3 (2.2%)
	DRY MOUTH	2 (3.0%)	0	2 (1.4%)
	GINGIVITIS	1 (1.5%)	1 (1.4%)	2 (1.4%)
	GASTROENTERITIS	0	2 (2.8%)	2 (1.4%)
	CONSTIPATION	1 (1.5%)	0	1 (0.7%)
	INCREASED APPETITE	1 (1.5%)	0	1 (0.7%)
	STOMATITIS	1 (1.5%)	0	1 (0.7%)
	TOOTH DISORDER	1 (1.5%)	0	1 (0.7%)
	FLATULENCE	0	1 (1.4%)	1 (0.7%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.4%)	1 (0.7%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
Nervous System	TOTAL	21 (31.3%)	34 (47.2%)	55 (39.6%)
	NERVOUSNESS	6 (9.0%)	9 (12.5%)	15 (10.8%)
	HYPERKINESIA	7 (10.4%)	5 (6.9%)	12 (8.6%)
	HOSTILITY	5 (7.5%)	5 (6.9%)	10 (7.2%)
	INSOMNIA	4 (6.0%)	5 (6.9%)	9 (6.5%)
	AGITATION	2 (3.0%)	3 (4.2%)	5 (3.6%)
	ANXIETY	1 (1.5%)	4 (5.6%)	5 (3.6%)
	DEPRESSION	3 (4.5%)	1 (1.4%)	4 (2.9%)
	DIZZINESS	1 (1.5%)	3 (4.2%)	4 (2.9%)
	SOMNOLENCE	1 (1.5%)	3 (4.2%)	4 (2.9%)
	EMOTIONAL LABILITY	2 (3.0%)	0	2 (1.4%)
	CONCENTRATION IMPAIRED	1 (1.5%)	1 (1.4%)	2 (1.4%)
	HALLUCINATIONS	1 (1.5%)	1 (1.4%)	2 (1.4%)
	MYOCLONUS	1 (1.5%)	1 (1.4%)	2 (1.4%)
	HYPESTHESIA	0	2 (2.8%)	2 (1.4%)
	TREMOR	0	2 (2.8%)	2 (1.4%)
	VERTIGO	0	2 (2.8%)	2 (1.4%)
	CONVULSION	1 (1.5%)	0	1 (0.7%)
	NEUROSIS	1 (1.5%)	0	1 (0.7%)
	VESTIBULAR DISORDER	1 (1.5%)	0	1 (0.7%)
	DYSKINESIA	0	1 (1.4%)	1 (0.7%)
	EUPHORIA	0	1 (1.4%)	1 (0.7%)
	LACK OF EMOTION	0	1 (1.4%)	1 (0.7%)
	MANIC REACTION	0	1 (1.4%)	1 (0.7%)
	PARALYSIS	0	1 (1.4%)	1 (0.7%)
	PSYCHOSIS	0	1 (1.4%)	1 (0.7%)
Skin and Appendages	TOTAL	8 (11.9%)	7 (9.7%)	15 (10.8%)
	CONTACT DERMATITIS	2 (3.0%)	3 (4.2%)	5 (3.6%)
	RASH	1 (1.5%)	4 (5.6%)	5 (3.6%)
	ACNE	3 (4.5%)	0	3 (2.2%)
	MACULOPAPULAR RASH	1 (1.5%)	1 (1.4%)	2 (1.4%)
	HERPES ZOSTER	1 (1.5%)	0	1 (0.7%)
	FUNGAL DERMATITIS	0	1 (1.4%)	1 (0.7%)
	HERPES SIMPLEX	0	1 (1.4%)	1 (0.7%)
	PRURITUS	0	1 (1.4%)	1 (0.7%)
Special Senses	TOTAL	7 (10.4%)	6 (8.3%)	13 (9.4%)
	OTITIS MEDIA	5 (7.5%)	3 (4.2%)	8 (5.8%)
	OTITIS EXTERNA	2 (3.0%)	1 (1.4%)	3 (2.2%)
	EAR PAIN	1 (1.5%)	1 (1.4%)	2 (1.4%)
	ABNORMAL VISION	0	1 (1.4%)	1 (0.7%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Metabolic and Nutritional Disorders	TOTAL	5 (7.5%)	7 (9.7%)	12 (8.6%)
	WEIGHT GAIN	4 (6.0%)	6 (8.3%)	10 (7.2%)
	DEHYDRATION	1 (1.5%)	1 (1.4%)	2 (1.4%)
Musculoskeletal System	TOTAL	4 (6.0%)	1 (1.4%)	5 (3.6%)
	ARTHRALGIA	2 (3.0%)	0	2 (1.4%)
	MYALGIA	1 (1.5%)	1 (1.4%)	2 (1.4%)
	TENDINOUS DISORDER	1 (1.5%)	0	1 (0.7%)
	ARTHROSIS	0	1 (1.4%)	1 (0.7%)
Urogenital System	TOTAL	4 (6.0%)	5 (6.9%)	9 (6.5%)
	URINARY INCONTINENCE	1 (1.5%)	4 (5.6%)	5 (3.6%)
	ALBUMINURIA	2 (3.0%)	1 (1.4%)	3 (2.2%)
	GLYCOSURIA	1 (1.5%)	0	1 (0.7%)
	PYURIA	1 (1.5%)	0	1 (0.7%)
	CYSTITIS	0	1 (1.4%)	1 (0.7%)
	HAEMATURIA	0	1 (1.4%)	1 (0.7%)
Hemic and Lymphatic System	TOTAL	3 (4.5%)	2 (2.8%)	5 (3.6%)
	LEUKOPENIA	1 (1.5%)	2 (2.8%)	3 (2.2%)
	ANEMIA	1 (1.5%)	1 (1.4%)	2 (1.4%)
	PURPURA	1 (1.5%)	0	1 (0.7%)
Cardiovascular System	TOTAL	1 (1.5%)	6 (8.3%)	7 (5.0%)
	VASODILATATION	0	3 (4.2%)	3 (2.2%)
	HAEMATOMA	1 (1.5%)	0	1 (0.7%)
	BUNDLE BRANCH BLOCK	0	1 (1.4%)	1 (0.7%)
	MIGRAINE	0	1 (1.4%)	1 (0.7%)
	SYNCOPE	0	1 (1.4%)	1 (0.7%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	1 (2.9%)	1 (3.7%)	2 (3.2%)
Urogenital System	TOTAL	1 (2.9%)	1 (3.7%)	2 (3.2%)
	DYSMENORRHEA	1 (2.9%)	1 (3.7%)	2 (3.2%)
	UTERUS DISORDERS	0	1 (3.7%)	1 (1.6%)

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Body System	Preferred Term			
TOTAL	TOTAL	34 (81.0%)	19 (63.3%)	53 (73.6%)
Body as a Whole	TOTAL	22 (52.4%)	9 (30.0%)	31 (43.1%)
	HEADACHE	11 (26.2%)	6 (20.0%)	17 (23.6%)
	TRAUMA	6 (14.3%)	2 (6.7%)	8 (11.1%)
	INFECTION	3 (7.1%)	2 (6.7%)	5 (6.9%)
	ALLERGIC REACTION	4 (9.5%)	0	4 (5.6%)
	ABDOMINAL PAIN	3 (7.1%)	1 (3.3%)	4 (5.6%)
	FEVER	3 (7.1%)	1 (3.3%)	4 (5.6%)
	ASTHENIA	1 (2.4%)	3 (10.0%)	4 (5.6%)
	BACK PAIN	3 (7.1%)	0	3 (4.2%)
	CHEST PAIN	3 (7.1%)	0	3 (4.2%)
	MALAISE	1 (2.4%)	0	1 (1.4%)
	PAIN	0	1 (3.3%)	1 (1.4%)
Nervous System	TOTAL	19 (45.2%)	10 (33.3%)	29 (40.3%)
	EMOTIONAL LABILITY	6 (14.3%)	3 (10.0%)	9 (12.5%)
	SOMNOLENCE	5 (11.9%)	2 (6.7%)	7 (9.7%)
	INSOMNIA	3 (7.1%)	2 (6.7%)	5 (6.9%)
	DIZZINESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
	NERVOUSNESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
	AGITATION	2 (4.8%)	1 (3.3%)	3 (4.2%)
	ANXIETY	1 (2.4%)	1 (3.3%)	2 (2.8%)
	DEPRESSION	1 (2.4%)	0	1 (1.4%)
	LACK OF EMOTION	1 (2.4%)	0	1 (1.4%)
	PARESTHESIA	1 (2.4%)	0	1 (1.4%)
	VERTIGO	1 (2.4%)	0	1 (1.4%)
	CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.4%)
	HALLUCINATIONS	0	1 (3.3%)	1 (1.4%)
	HOSTILITY	0	1 (3.3%)	1 (1.4%)
	LIBIDO DECREASED	0	1 (3.3%)	1 (1.4%)
	TREMOR	0	1 (3.3%)	1 (1.4%)
	WITHDRAWAL SYNDROME	0	1 (3.3%)	1 (1.4%)
Respiratory System	TOTAL	16 (38.1%)	9 (30.0%)	25 (34.7%)
	RESPIRATORY DISORDER	7 (16.7%)	7 (23.3%)	14 (19.4%)
	PHARYNGITIS	4 (9.5%)	1 (3.3%)	5 (6.9%)
	RHINITIS	4 (9.5%)	1 (3.3%)	5 (6.9%)
	ASTHMA	3 (7.1%)	2 (6.7%)	5 (6.9%)
	BRONCHITIS	2 (4.8%)	2 (6.7%)	4 (5.6%)
	SINUSITIS	3 (7.1%)	0	3 (4.2%)
	COUGH INCREASED	1 (2.4%)	1 (3.3%)	2 (2.8%)
	DYSPNEA	1 (2.4%)	0	1 (1.4%)
	PNEUMONIA	1 (2.4%)	0	1 (1.4%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Body System	Preferred Term			
Digestive System	TOTAL	13 (31.0%)	7 (23.3%)	20 (27.8%)
	NAUSEA	7 (16.7%)	2 (6.7%)	9 (12.5%)
	VOMITING	5 (11.9%)	0	5 (6.9%)
	DIARRHEA	3 (7.1%)	1 (3.3%)	4 (5.6%)
	DYSPEPSIA	3 (7.1%)	1 (3.3%)	4 (5.6%)
	DECREASED APPETITE	1 (2.4%)	2 (6.7%)	3 (4.2%)
	TOOTH CARIES	1 (2.4%)	1 (3.3%)	2 (2.8%)
	INCREASED APPETITE	0	2 (6.7%)	2 (2.8%)
	DRY MOUTH	1 (2.4%)	0	1 (1.4%)
	GASTRITIS	1 (2.4%)	0	1 (1.4%)
	HEMATEMESIS	1 (2.4%)	0	1 (1.4%)
	GASTROINTESTINAL DISORDER	0	1 (3.3%)	1 (1.4%)
Skin and Appendages	TOTAL	5 (11.9%)	2 (6.7%)	7 (9.7%)
	CONTACT DERMATITIS	2 (4.8%)	0	2 (2.8%)
	ACNE	1 (2.4%)	1 (3.3%)	2 (2.8%)
	PRURITUS	1 (2.4%)	1 (3.3%)	2 (2.8%)
	FUNGAL DERMATITIS	1 (2.4%)	0	1 (1.4%)
	FURUNCULOSIS	1 (2.4%)	0	1 (1.4%)
Urogenital System	TOTAL	4 (9.5%)	1 (3.3%)	5 (6.9%)
	ALBUMINURIA	3 (7.1%)	1 (3.3%)	4 (5.6%)
	HAEMATURIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
	URINARY TRACT INFECTION	1 (2.4%)	0	1 (1.4%)
Hemic and Lymphatic System	TOTAL	2 (4.8%)	0	2 (2.8%)
	LEUKOPENIA	1 (2.4%)	0	1 (1.4%)
	LYMPHADENOPATHY	1 (2.4%)	0	1 (1.4%)
Metabolic and Nutritional Disorders	TOTAL	2 (4.8%)	3 (10.0%)	5 (6.9%)
	WEIGHT GAIN	1 (2.4%)	3 (10.0%)	4 (5.6%)
	WEIGHT LOSS	1 (2.4%)	0	1 (1.4%)
Musculoskeletal System	TOTAL	1 (2.4%)	0	1 (1.4%)
	MYALGIA	1 (2.4%)	0	1 (1.4%)
Special Senses	TOTAL	1 (2.4%)	0	1 (1.4%)
	OTITIS MEDIA	1 (2.4%)	0	1 (1.4%)
Cardiovascular System	TOTAL	0	1 (3.3%)	1 (1.4%)
	SYNCOPE	0	1 (3.3%)	1 (1.4%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	3 (21.4%)	2 (13.3%)	5 (17.2%)
Urogenital System	TOTAL	3 (21.4%)	2 (13.3%)	5 (17.2%)
	DYSMENORRHEA	3 (21.4%)	0	3 (10.3%)
	FEMALE GENITAL DISORDERS	0	1 (6.7%)	1 (3.4%)
	MENSTRUAL DISORDER	0	1 (6.7%)	1 (3.4%)

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	18 (75.0%)	19 (67.9%)	37 (71.2%)
Body as a Whole	TOTAL	14 (58.3%)	15 (53.6%)	29 (55.8%)
	HEADACHE	10 (41.7%)	9 (32.1%)	19 (36.5%)
	INFECTION	5 (20.8%)	3 (10.7%)	8 (15.4%)
	ALLERGIC REACTION	4 (16.7%)	3 (10.7%)	7 (13.5%)
	ASTHENIA	3 (12.5%)	4 (14.3%)	7 (13.5%)
	ABDOMINAL PAIN	3 (12.5%)	3 (10.7%)	6 (11.5%)
	TRAUMA	1 (4.2%)	4 (14.3%)	5 (9.6%)
	FEVER	0	2 (7.1%)	2 (3.8%)
	ABNORMAL LABORATORY VALUE	1 (4.2%)	0	1 (1.9%)
	PAIN	1 (4.2%)	0	1 (1.9%)
	BACK PAIN	0	1 (3.6%)	1 (1.9%)
Nervous System	TOTAL	9 (37.5%)	9 (32.1%)	18 (34.6%)
	INSOMNIA	3 (12.5%)	4 (14.3%)	7 (13.5%)
	NEUROSIS	3 (12.5%)	1 (3.6%)	4 (7.7%)
	HOSTILITY	1 (4.2%)	3 (10.7%)	4 (7.7%)
	NERVOUSNESS	1 (4.2%)	3 (10.7%)	4 (7.7%)
	DIZZINESS	2 (8.3%)	1 (3.6%)	3 (5.8%)
	EMOTIONAL LABILITY	2 (8.3%)	1 (3.6%)	3 (5.8%)
	HYPERKINESIA	1 (4.2%)	2 (7.1%)	3 (5.8%)
	ABNORMAL DREAMS	1 (4.2%)	1 (3.6%)	2 (3.8%)
	ANXIETY	1 (4.2%)	1 (3.6%)	2 (3.8%)
	SOMNOLENCE	1 (4.2%)	1 (3.6%)	2 (3.8%)
	AGITATION	0	2 (7.1%)	2 (3.8%)
	CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.9%)
	MANIC REACTION	1 (4.2%)	0	1 (1.9%)
	VERTIGO	1 (4.2%)	0	1 (1.9%)
	DEPRESSION	0	1 (3.6%)	1 (1.9%)
	TREMOR	0	1 (3.6%)	1 (1.9%)
Respiratory System	TOTAL	9 (37.5%)	8 (28.6%)	17 (32.7%)
	RESPIRATORY DISORDER	4 (16.7%)	5 (17.9%)	9 (17.3%)
	SINUSITIS	3 (12.5%)	0	3 (5.8%)
	ASTHMA	1 (4.2%)	2 (7.1%)	3 (5.8%)
	PHARYNGITIS	1 (4.2%)	2 (7.1%)	3 (5.8%)
	RHINITIS	1 (4.2%)	1 (3.6%)	2 (3.8%)
	BRONCHITIS	1 (4.2%)	0	1 (1.9%)
	PLEURA DISORDER	1 (4.2%)	0	1 (1.9%)
	EPISTAXIS	0	1 (3.6%)	1 (1.9%)
	PNEUMONIA	0	1 (3.6%)	1 (1.9%)
Digestive System	TOTAL	4 (16.7%)	11 (39.3%)	15 (28.8%)

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
Digestive System	NAUSEA	1 (4.2%)	6 (21.4%)	7 (13.5%)
	CONSTIPATION	1 (4.2%)	1 (3.6%)	2 (3.8%)
	DIARRHEA	1 (4.2%)	1 (3.6%)	2 (3.8%)
	TOOTH DISORDER	1 (4.2%)	1 (3.6%)	2 (3.8%)
	DECREASED APPETITE	0	2 (7.1%)	2 (3.8%)
	DRY MOUTH	0	2 (7.1%)	2 (3.8%)
	DYSPEPSIA	0	2 (7.1%)	2 (3.8%)
	FLATULENCE	0	1 (3.6%)	1 (1.9%)
	ULCERATIVE STOMATITIS	0	1 (3.6%)	1 (1.9%)
Urogenital System	TOTAL	4 (16.7%)	0	4 (7.7%)
	ALBUMINURIA	3 (12.5%)	0	3 (5.8%)
	DYSURIA	1 (4.2%)	0	1 (1.9%)
	HAEMATURIA	1 (4.2%)	0	1 (1.9%)
Musculoskeletal System	TOTAL	3 (12.5%)	1 (3.6%)	4 (7.7%)
	ARTHRALGIA	2 (8.3%)	1 (3.6%)	3 (5.8%)
	ARTHROSIS	1 (4.2%)	0	1 (1.9%)
Metabolic and Nutritional Disorders	TOTAL	2 (8.3%)	1 (3.6%)	3 (5.8%)
	WEIGHT GAIN	2 (8.3%)	0	2 (3.8%)
	WEIGHT LOSS	0	1 (3.6%)	1 (1.9%)
Special Senses	TOTAL	2 (8.3%)	3 (10.7%)	5 (9.6%)
	BLEPHARITIS	1 (4.2%)	0	1 (1.9%)
	EYE PAIN	1 (4.2%)	0	1 (1.9%)
	ABNORMAL VISION	0	1 (3.6%)	1 (1.9%)
	OTITIS MEDIA	0	1 (3.6%)	1 (1.9%)
	PHOTOPHOBIA	0	1 (3.6%)	1 (1.9%)
Skin and Appendages	TOTAL	1 (4.2%)	4 (14.3%)	5 (9.6%)
	ACNE	1 (4.2%)	2 (7.1%)	3 (5.8%)
	CONTACT DERMATITIS	0	1 (3.6%)	1 (1.9%)
	RASH	0	1 (3.6%)	1 (1.9%)
	SWEATING	0	1 (3.6%)	1 (1.9%)
	URTICARIA	0	1 (3.6%)	1 (1.9%)
Cardiovascular System	TOTAL	0	2 (7.1%)	2 (3.8%)
	SYNCOPE	0	1 (3.6%)	1 (1.9%)
	VASODILATATION	0	1 (3.6%)	1 (1.9%)
Hemic and Lymphatic System	TOTAL	0	2 (7.1%)	2 (3.8%)
	EOSINOPHILIA	0	1 (3.6%)	1 (1.9%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
Hemic and Lymphatic System	LEUKOCYTOSIS	0	1 (3.6%)	1 (1.9%)
	MONOCYTOSIS	0	1 (3.6%)	1 (1.9%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	3 (25.0%)	0	3 (14.3%)
Urogenital System	TOTAL	3 (25.0%)	0	3 (14.3%)
	DYSMENORRHEA	3 (25.0%)	0	3 (14.3%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
TOTAL	TOTAL	52 (78.8%)	38 (65.5%)	90 (72.6%)
Body as a Whole	TOTAL	36 (54.5%)	24 (41.4%)	60 (48.4%)
	HEADACHE	21 (31.8%)	15 (25.9%)	36 (29.0%)
	INFECTION	8 (12.1%)	5 (8.6%)	13 (10.5%)
	TRAUMA	7 (10.6%)	6 (10.3%)	13 (10.5%)
	ALLERGIC REACTION	8 (12.1%)	3 (5.2%)	11 (8.9%)
	ASTHENIA	4 (6.1%)	7 (12.1%)	11 (8.9%)
	ABDOMINAL PAIN	6 (9.1%)	4 (6.9%)	10 (8.1%)
	FEVER	3 (4.5%)	3 (5.2%)	6 (4.8%)
	BACK PAIN	3 (4.5%)	1 (1.7%)	4 (3.2%)
	CHEST PAIN	3 (4.5%)	0	3 (2.4%)
	PAIN	1 (1.5%)	1 (1.7%)	2 (1.6%)
	ABNORMAL LABORATORY VALUE	1 (1.5%)	0	1 (0.8%)
	MALAISE	1 (1.5%)	0	1 (0.8%)
Nervous System	TOTAL	28 (42.4%)	19 (32.8%)	47 (37.9%)
	EMOTIONAL LABILITY	8 (12.1%)	4 (6.9%)	12 (9.7%)
	INSOMNIA	6 (9.1%)	6 (10.3%)	12 (9.7%)
	SOMNOLENCE	6 (9.1%)	3 (5.2%)	9 (7.3%)
	NERVOUSNESS	4 (6.1%)	4 (6.9%)	8 (6.5%)
	DIZZINESS	5 (7.6%)	2 (3.4%)	7 (5.6%)
	AGITATION	2 (3.0%)	3 (5.2%)	5 (4.0%)
	HOSTILITY	1 (1.5%)	4 (6.9%)	5 (4.0%)
	NEUROSIS	3 (4.5%)	1 (1.7%)	4 (3.2%)
	ANXIETY	2 (3.0%)	2 (3.4%)	4 (3.2%)
	HYPERKINESIA	1 (1.5%)	2 (3.4%)	3 (2.4%)
	VERTIGO	2 (3.0%)	0	2 (1.6%)
	ABNORMAL DREAMS	1 (1.5%)	1 (1.7%)	2 (1.6%)
	CONCENTRATION IMPAIRED	1 (1.5%)	1 (1.7%)	2 (1.6%)
	DEPRESSION	1 (1.5%)	1 (1.7%)	2 (1.6%)
	TREMOR	0	2 (3.4%)	2 (1.6%)
	LACK OF EMOTION	1 (1.5%)	0	1 (0.8%)
	MANIC REACTION	1 (1.5%)	0	1 (0.8%)
	PARESTHESIA	1 (1.5%)	0	1 (0.8%)
	HALLUCINATIONS	0	1 (1.7%)	1 (0.8%)
	LIBIDO DECREASED	0	1 (1.7%)	1 (0.8%)
	WITHDRAWAL SYNDROME	0	1 (1.7%)	1 (0.8%)
Respiratory System	TOTAL	25 (37.9%)	17 (29.3%)	42 (33.9%)
	RESPIRATORY DISORDER	11 (16.7%)	12 (20.7%)	23 (18.5%)
	PHARYNGITIS	5 (7.6%)	3 (5.2%)	8 (6.5%)
	ASTHMA	4 (6.1%)	4 (6.9%)	8 (6.5%)
	RHINITIS	5 (7.6%)	2 (3.4%)	7 (5.6%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
Respiratory System	SINUSITIS	6 (9.1%)	0	6 (4.8%)
	BRONCHITIS	3 (4.5%)	2 (3.4%)	5 (4.0%)
	COUGH INCREASED	1 (1.5%)	1 (1.7%)	2 (1.6%)
	PNEUMONIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
	DYSPNEA	1 (1.5%)	0	1 (0.8%)
	PLEURA DISORDER	1 (1.5%)	0	1 (0.8%)
	EPISTAXIS	0	1 (1.7%)	1 (0.8%)
Digestive System	TOTAL	17 (25.8%)	18 (31.0%)	35 (28.2%)
	NAUSEA	8 (12.1%)	8 (13.8%)	16 (12.9%)
	DIARRHEA	4 (6.1%)	2 (3.4%)	6 (4.8%)
	DYSPEPSIA	3 (4.5%)	3 (5.2%)	6 (4.8%)
	VOMITING	5 (7.6%)	0	5 (4.0%)
	DECREASED APPETITE	1 (1.5%)	4 (6.9%)	5 (4.0%)
	DRY MOUTH	1 (1.5%)	2 (3.4%)	3 (2.4%)
	CONSTIPATION	1 (1.5%)	1 (1.7%)	2 (1.6%)
	TOOTH CARIES	1 (1.5%)	1 (1.7%)	2 (1.6%)
	TOOTH DISORDER	1 (1.5%)	1 (1.7%)	2 (1.6%)
	INCREASED APPETITE	0	2 (3.4%)	2 (1.6%)
	GASTRITIS	1 (1.5%)	0	1 (0.8%)
	HEMATEMESIS	1 (1.5%)	0	1 (0.8%)
	FLATULENCE	0	1 (1.7%)	1 (0.8%)
	GASTROINTESTINAL DISORDER	0	1 (1.7%)	1 (0.8%)
	ULCERATIVE STOMATITIS	0	1 (1.7%)	1 (0.8%)
Urogenital System	TOTAL	8 (12.1%)	1 (1.7%)	9 (7.3%)
	ALBUMINURIA	6 (9.1%)	1 (1.7%)	7 (5.6%)
	HAEMATURIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
	DYSURIA	1 (1.5%)	0	1 (0.8%)
	URINARY TRACT INFECTION	1 (1.5%)	0	1 (0.8%)
Skin and Appendages	TOTAL	6 (9.1%)	6 (10.3%)	12 (9.7%)
	ACNE	2 (3.0%)	3 (5.2%)	5 (4.0%)
	CONTACT DERMATITIS	2 (3.0%)	1 (1.7%)	3 (2.4%)
	PRURITUS	1 (1.5%)	1 (1.7%)	2 (1.6%)
	FUNGAL DERMATITIS	1 (1.5%)	0	1 (0.8%)
	FURUNCULOSIS	1 (1.5%)	0	1 (0.8%)
	RASH	0	1 (1.7%)	1 (0.8%)
	SWEATING	0	1 (1.7%)	1 (0.8%)
	URTICARIA	0	1 (1.7%)	1 (0.8%)
Metabolic and Nutritional Disorders	TOTAL	4 (6.1%)	4 (6.9%)	8 (6.5%)
	WEIGHT GAIN	3 (4.5%)	3 (5.2%)	6 (4.8%)

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	WEIGHT LOSS	1 (1.5%)	1 (1.7%)	2 (1.6%)
Musculoskeletal System	TOTAL	4 (6.1%)	1 (1.7%)	5 (4.0%)
	ARTHRALGIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
	ARTHROSIS	1 (1.5%)	0	1 (0.8%)
	MYALGIA	1 (1.5%)	0	1 (0.8%)
Special Senses	TOTAL	3 (4.5%)	3 (5.2%)	6 (4.8%)
	OTITIS MEDIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
	BLEPHARITIS	1 (1.5%)	0	1 (0.8%)
	EYE PAIN	1 (1.5%)	0	1 (0.8%)
	ABNORMAL VISION	0	1 (1.7%)	1 (0.8%)
	PHOTOPHOBIA	0	1 (1.7%)	1 (0.8%)
Hemic and Lymphatic System	TOTAL	2 (3.0%)	2 (3.4%)	4 (3.2%)
	LEUKOPENIA	1 (1.5%)	0	1 (0.8%)
	LYMPHADENOPATHY	1 (1.5%)	0	1 (0.8%)
	EOSINOPHILIA	0	1 (1.7%)	1 (0.8%)
	LEUKOCYTOSIS	0	1 (1.7%)	1 (0.8%)
	MONOCYTOSIS	0	1 (1.7%)	1 (0.8%)
Cardiovascular System	TOTAL	0	3 (5.2%)	3 (2.4%)
	SYNCOPE	0	2 (3.4%)	2 (1.6%)
	VASODILATATION	0	1 (1.7%)	1 (0.8%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=26)	 Placebo (N=24)	 Total (N=50)
TOTAL	TOTAL	6 (23.1%)	2 (8.3%)	8 (16.0%)
Urogenital System	TOTAL	6 (23.1%)	2 (8.3%)	8 (16.0%)
	DYSMENORRHEA	6 (23.1%)	0	6 (12.0%)
	FEMALE GENITAL DISORDERS	0	1 (4.2%)	1 (2.0%)
	MENSTRUAL DISORDER	0	1 (4.2%)	1 (2.0%)

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	66 (81.5%)	44 (66.7%)	110 (74.8%)
Body as a Whole	TOTAL	43 (53.1%)	24 (36.4%)	67 (45.6%)
	HEADACHE	20 (24.7%)	10 (15.2%)	30 (20.4%)
	TRAUMA	17 (21.0%)	6 (9.1%)	23 (15.6%)
	INFECTION	8 (9.9%)	11 (16.7%)	19 (12.9%)
	ABDOMINAL PAIN	10 (12.3%)	4 (6.1%)	14 (9.5%)
	FEVER	8 (9.9%)	3 (4.5%)	11 (7.5%)
	ALLERGIC REACTION	7 (8.6%)	2 (3.0%)	9 (6.1%)
	ASTHENIA	3 (3.7%)	5 (7.6%)	8 (5.4%)
	BACK PAIN	3 (3.7%)	3 (4.5%)	6 (4.1%)
	PAIN	3 (3.7%)	2 (3.0%)	5 (3.4%)
	CHEST PAIN	3 (3.7%)	0	3 (2.0%)
	FACE EDEMA	2 (2.5%)	0	2 (1.4%)
	MALAISE	1 (1.2%)	0	1 (0.7%)
Respiratory System	TOTAL	36 (44.4%)	22 (33.3%)	58 (39.5%)
	RESPIRATORY DISORDER	16 (19.8%)	13 (19.7%)	29 (19.7%)
	PHARYNGITIS	12 (14.8%)	5 (7.6%)	17 (11.6%)
	RHINITIS	8 (9.9%)	4 (6.1%)	12 (8.2%)
	SINUSITIS	6 (7.4%)	1 (1.5%)	7 (4.8%)
	COUGH INCREASED	4 (4.9%)	2 (3.0%)	6 (4.1%)
	ASTHMA	3 (3.7%)	3 (4.5%)	6 (4.1%)
	BRONCHITIS	2 (2.5%)	3 (4.5%)	5 (3.4%)
	PNEUMONIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	EPISTAXIS	0	2 (3.0%)	2 (1.4%)
	DYSPNEA	1 (1.2%)	0	1 (0.7%)
	YAWN	0	1 (1.5%)	1 (0.7%)
Nervous System	TOTAL	32 (39.5%)	22 (33.3%)	54 (36.7%)
	EMOTIONAL LABILITY	7 (8.6%)	3 (4.5%)	10 (6.8%)
	NERVOUSNESS	8 (9.9%)	1 (1.5%)	9 (6.1%)
	INSOMNIA	4 (4.9%)	5 (7.6%)	9 (6.1%)
	SOMNOLENCE	5 (6.2%)	3 (4.5%)	8 (5.4%)
	HOSTILITY	4 (4.9%)	2 (3.0%)	6 (4.1%)
	AGITATION	3 (3.7%)	3 (4.5%)	6 (4.1%)
	DIZZINESS	3 (3.7%)	2 (3.0%)	5 (3.4%)
	DEPRESSION	3 (3.7%)	1 (1.5%)	4 (2.7%)
	HYPERKINESIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
	ANXIETY	1 (1.2%)	2 (3.0%)	3 (2.0%)
	HALLUCINATIONS	1 (1.2%)	2 (3.0%)	3 (2.0%)
	CONCENTRATION IMPAIRED	0	2 (3.0%)	2 (1.4%)
	HYPESTHESIA	0	2 (3.0%)	2 (1.4%)
	TREMOR	0	2 (3.0%)	2 (1.4%)

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
Nervous System	CONVULSION	1 (1.2%)	0	1 (0.7%)
	LACK OF EMOTION	1 (1.2%)	0	1 (0.7%)
	NEUROSIS	1 (1.2%)	0	1 (0.7%)
	PARESTHESIA	1 (1.2%)	0	1 (0.7%)
	VERTIGO	1 (1.2%)	0	1 (0.7%)
	VESTIBULAR DISORDER	1 (1.2%)	0	1 (0.7%)
	EUPHORIA	0	1 (1.5%)	1 (0.7%)
	LIBIDO DECREASED	0	1 (1.5%)	1 (0.7%)
	PARALYSIS	0	1 (1.5%)	1 (0.7%)
	WITHDRAWAL SYNDROME	0	1 (1.5%)	1 (0.7%)
Digestive System	TOTAL	28 (34.6%)	18 (27.3%)	46 (31.3%)
	VOMITING	12 (14.8%)	4 (6.1%)	16 (10.9%)
	NAUSEA	8 (9.9%)	4 (6.1%)	12 (8.2%)
	DYSPEPSIA	7 (8.6%)	4 (6.1%)	11 (7.5%)
	DIARRHEA	5 (6.2%)	2 (3.0%)	7 (4.8%)
	DECREASED APPETITE	2 (2.5%)	3 (4.5%)	5 (3.4%)
	TOOTH CARIES	1 (1.2%)	3 (4.5%)	4 (2.7%)
	DRY MOUTH	3 (3.7%)	0	3 (2.0%)
	INCREASED APPETITE	1 (1.2%)	2 (3.0%)	3 (2.0%)
	CONSTIPATION	1 (1.2%)	0	1 (0.7%)
	GASTRITIS	1 (1.2%)	0	1 (0.7%)
	HEMATEMESIS	1 (1.2%)	0	1 (0.7%)
	STOMATITIS	1 (1.2%)	0	1 (0.7%)
	GASTROENTERITIS	0	1 (1.5%)	1 (0.7%)
	GASTROINTESTINAL DISORDER	0	1 (1.5%)	1 (0.7%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.7%)
Skin and Appendages	TOTAL	11 (13.6%)	6 (9.1%)	17 (11.6%)
	CONTACT DERMATITIS	4 (4.9%)	1 (1.5%)	5 (3.4%)
	ACNE	3 (3.7%)	1 (1.5%)	4 (2.7%)
	PRURITUS	1 (1.2%)	2 (3.0%)	3 (2.0%)
	RASH	1 (1.2%)	2 (3.0%)	3 (2.0%)
	FUNGAL DERMATITIS	1 (1.2%)	0	1 (0.7%)
	FURUNCULOSIS	1 (1.2%)	0	1 (0.7%)
	HERPES ZOSTER	1 (1.2%)	0	1 (0.7%)
	MACULOPAPULAR RASH	0	1 (1.5%)	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	7 (8.6%)	7 (10.6%)	14 (9.5%)
	WEIGHT GAIN	5 (6.2%)	6 (9.1%)	11 (7.5%)
	DEHYDRATION	1 (1.2%)	1 (1.5%)	2 (1.4%)
	WEIGHT LOSS	1 (1.2%)	0	1 (0.7%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
Urogenital System	TOTAL	6 (7.4%)	4 (6.1%)	10 (6.8%)
	ALBUMINURIA	3 (3.7%)	2 (3.0%)	5 (3.4%)
	HAEMATURIA	1 (1.2%)	2 (3.0%)	3 (2.0%)
	URINARY INCONTINENCE	1 (1.2%)	2 (3.0%)	3 (2.0%)
	PYURIA	1 (1.2%)	0	1 (0.7%)
	URINARY TRACT INFECTION	1 (1.2%)	0	1 (0.7%)
	CYSTITIS	0	1 (1.5%)	1 (0.7%)
Musculoskeletal System	TOTAL	4 (4.9%)	1 (1.5%)	5 (3.4%)
	ARTHRALGIA	2 (2.5%)	0	2 (1.4%)
	MYALGIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	TENDINOUS DISORDER	1 (1.2%)	0	1 (0.7%)
	ARTHROSIS	0	1 (1.5%)	1 (0.7%)
Hemic and Lymphatic System	TOTAL	3 (3.7%)	2 (3.0%)	5 (3.4%)
	LEUKOPENIA	2 (2.5%)	2 (3.0%)	4 (2.7%)
	LYMPHADENOPATHY	1 (1.2%)	0	1 (0.7%)
	ANEMIA	0	1 (1.5%)	1 (0.7%)
Special Senses	TOTAL	3 (3.7%)	2 (3.0%)	5 (3.4%)
	OTITIS MEDIA	3 (3.7%)	1 (1.5%)	4 (2.7%)
	ABNORMAL VISION	0	1 (1.5%)	1 (0.7%)
Cardiovascular System	TOTAL	0	4 (6.1%)	4 (2.7%)
	SYNCOPE	0	2 (3.0%)	2 (1.4%)
	BUNDLE BRANCH BLOCK	0	1 (1.5%)	1 (0.7%)
	MIGRAINE	0	1 (1.5%)	1 (0.7%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	3 (9.1%)	2 (6.9%)	5 (8.1%)
Urogenital System	TOTAL	3 (9.1%)	2 (6.9%)	5 (8.1%)
	DYSMENORRHEA	3 (9.1%)	0	3 (4.8%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.6%)
	MENSTRUAL DISORDER	0	1 (3.4%)	1 (1.6%)

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	40 (76.9%)	49 (76.6%)	89 (76.7%)
Body as a Whole	TOTAL	28 (53.8%)	32 (50.0%)	60 (51.7%)
	HEADACHE	19 (36.5%)	17 (26.6%)	36 (31.0%)
	INFECTION	8 (15.4%)	6 (9.4%)	14 (12.1%)
	ABDOMINAL PAIN	5 (9.6%)	8 (12.5%)	13 (11.2%)
	TRAUMA	5 (9.6%)	8 (12.5%)	13 (11.2%)
	ALLERGIC REACTION	4 (7.7%)	4 (6.3%)	8 (6.9%)
	ASTHENIA	3 (5.8%)	4 (6.3%)	7 (6.0%)
	FEVER	3 (5.8%)	3 (4.7%)	6 (5.2%)
	PAIN	3 (5.8%)	1 (1.6%)	4 (3.4%)
	BACK PAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
	ABNORMAL LABORATORY VALUE	1 (1.9%)	0	1 (0.9%)
	ABSCESS	1 (1.9%)	0	1 (0.9%)
	SPINA BIFIDA	0	1 (1.6%)	1 (0.9%)
Nervous System	TOTAL	17 (32.7%)	31 (48.4%)	48 (41.4%)
	NERVOUSNESS	2 (3.8%)	12 (18.8%)	14 (12.1%)
	HYPERKINESIA	6 (11.5%)	6 (9.4%)	12 (10.3%)
	INSOMNIA	6 (11.5%)	6 (9.4%)	12 (10.3%)
	HOSTILITY	2 (3.8%)	7 (10.9%)	9 (7.8%)
	DIZZINESS	3 (5.8%)	3 (4.7%)	6 (5.2%)
	ANXIETY	2 (3.8%)	4 (6.3%)	6 (5.2%)
	SOMNOLENCE	2 (3.8%)	3 (4.7%)	5 (4.3%)
	EMOTIONAL LABILITY	3 (5.8%)	1 (1.6%)	4 (3.4%)
	NEUROSIS	3 (5.8%)	1 (1.6%)	4 (3.4%)
	AGITATION	1 (1.9%)	3 (4.7%)	4 (3.4%)
	VERTIGO	1 (1.9%)	2 (3.1%)	3 (2.6%)
	CONCENTRATION IMPAIRED	2 (3.8%)	0	2 (1.7%)
	ABNORMAL DREAMS	1 (1.9%)	1 (1.6%)	2 (1.7%)
	DEPRESSION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	MANIC REACTION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	MYOCLONUS	1 (1.9%)	1 (1.6%)	2 (1.7%)
	TREMOR	0	2 (3.1%)	2 (1.7%)
	DYSKINESIA	0	1 (1.6%)	1 (0.9%)
	LACK OF EMOTION	0	1 (1.6%)	1 (0.9%)
	PSYCHOSIS	0	1 (1.6%)	1 (0.9%)
Respiratory System	TOTAL	17 (32.7%)	18 (28.1%)	35 (30.2%)
	RESPIRATORY DISORDER	6 (11.5%)	13 (20.3%)	19 (16.4%)
	PHARYNGITIS	6 (11.5%)	5 (7.8%)	11 (9.5%)
	RHINITIS	5 (9.6%)	5 (7.8%)	10 (8.6%)
	SINUSITIS	5 (9.6%)	1 (1.6%)	6 (5.2%)
	ASTHMA	2 (3.8%)	2 (3.1%)	4 (3.4%)

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
Respiratory System	COUGH INCREASED	2 (3.8%)	1 (1.6%)	3 (2.6%)
	BRONCHITIS	1 (1.9%)	0	1 (0.9%)
	PLEURA DISORDER	1 (1.9%)	0	1 (0.9%)
	EPISTAXIS	0	1 (1.6%)	1 (0.9%)
	PNEUMONIA	0	1 (1.6%)	1 (0.9%)
Digestive System	TOTAL	13 (25.0%)	17 (26.6%)	30 (25.9%)
	NAUSEA	6 (11.5%)	7 (10.9%)	13 (11.2%)
	DECREASED APPETITE	2 (3.8%)	4 (6.3%)	6 (5.2%)
	DIARRHEA	4 (7.7%)	1 (1.6%)	5 (4.3%)
	DYSPEPSIA	2 (3.8%)	3 (4.7%)	5 (4.3%)
	TOOTH DISORDER	2 (3.8%)	1 (1.6%)	3 (2.6%)
	CONSTIPATION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	GINGIVITIS	1 (1.9%)	1 (1.6%)	2 (1.7%)
	DRY MOUTH	0	2 (3.1%)	2 (1.7%)
	FLATULENCE	0	2 (3.1%)	2 (1.7%)
	VOMITING	1 (1.9%)	0	1 (0.9%)
	GASTROENTERITIS	0	1 (1.6%)	1 (0.9%)
	TOOTH CARIES	0	1 (1.6%)	1 (0.9%)
	ULCERATIVE STOMATITIS	0	1 (1.6%)	1 (0.9%)
Special Senses	TOTAL	7 (13.5%)	7 (10.9%)	14 (12.1%)
	OTITIS MEDIA	3 (5.8%)	3 (4.7%)	6 (5.2%)
	OTITIS EXTERNA	2 (3.8%)	1 (1.6%)	3 (2.6%)
	EAR PAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
	BLEPHARITIS	1 (1.9%)	0	1 (0.9%)
	EYE PAIN	1 (1.9%)	0	1 (0.9%)
	ABNORMAL VISION	0	1 (1.6%)	1 (0.9%)
	PHOTOPHOBIA	0	1 (1.6%)	1 (0.9%)
Urogenital System	TOTAL	6 (11.5%)	2 (3.1%)	8 (6.9%)
	ALBUMINURIA	5 (9.6%)	0	5 (4.3%)
	URINARY INCONTINENCE	0	2 (3.1%)	2 (1.7%)
	DYSURIA	1 (1.9%)	0	1 (0.9%)
	GLYCOSURIA	1 (1.9%)	0	1 (0.9%)
	HAEMATURIA	1 (1.9%)	0	1 (0.9%)
Musculoskeletal System	TOTAL	4 (7.7%)	1 (1.6%)	5 (4.3%)
	ARTHRALGIA	2 (3.8%)	1 (1.6%)	3 (2.6%)
	ARTHROSIS	1 (1.9%)	0	1 (0.9%)
	MYALGIA	1 (1.9%)	0	1 (0.9%)
Skin and Appendages	TOTAL	3 (5.8%)	7 (10.9%)	10 (8.6%)
	ACNE	2 (3.8%)	2 (3.1%)	4 (3.4%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
Skin and Appendages	CONTACT DERMATITIS	0	3 (4.7%)	3 (2.6%)
	RASH	0	3 (4.7%)	3 (2.6%)
	MACULOPAPULAR RASH	1 (1.9%)	0	1 (0.9%)
	FUNGAL DERMATITIS	0	1 (1.6%)	1 (0.9%)
	HERPES SIMPLEX	0	1 (1.6%)	1 (0.9%)
	SWEATING	0	1 (1.6%)	1 (0.9%)
	URTICARIA	0	1 (1.6%)	1 (0.9%)
Hemic and Lymphatic System	TOTAL	2 (3.8%)	2 (3.1%)	4 (3.4%)
	ANEMIA	1 (1.9%)	0	1 (0.9%)
	PURPURA	1 (1.9%)	0	1 (0.9%)
	EOSINOPHILIA	0	1 (1.6%)	1 (0.9%)
	LEUKOCYTOSIS	0	1 (1.6%)	1 (0.9%)
	MONOCYTOSIS	0	1 (1.6%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	2 (3.8%)	4 (6.3%)	6 (5.2%)
	WEIGHT GAIN	2 (3.8%)	3 (4.7%)	5 (4.3%)
	WEIGHT LOSS	0	1 (1.6%)	1 (0.9%)
Cardiovascular System	TOTAL	1 (1.9%)	5 (7.8%)	6 (5.2%)
	VASODILATATION	0	4 (6.3%)	4 (3.4%)
	HAEMATOMA	1 (1.9%)	0	1 (0.9%)
	SYNCOPE	0	1 (1.6%)	1 (0.9%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	4 (14.3%)	1 (4.5%)	5 (10.0%)
Urogenital System	TOTAL	4 (14.3%)	1 (4.5%)	5 (10.0%)
	DYSMENORRHEA	4 (14.3%)	1 (4.5%)	5 (10.0%)
	UTERUS DISORDERS	0	1 (4.5%)	1 (2.0%)

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
TOTAL	TOTAL	106 (79.7%)	93 (71.5%)	199 (75.7%)
Body as a Whole	TOTAL	71 (53.4%)	56 (43.1%)	127 (48.3%)
	HEADACHE	39 (29.3%)	27 (20.8%)	66 (25.1%)
	TRAUMA	22 (16.5%)	14 (10.8%)	36 (13.7%)
	INFECTION	16 (12.0%)	17 (13.1%)	33 (12.5%)
	ABDOMINAL PAIN	15 (11.3%)	12 (9.2%)	27 (10.3%)
	ALLERGIC REACTION	11 (8.3%)	6 (4.6%)	17 (6.5%)
	FEVER	11 (8.3%)	6 (4.6%)	17 (6.5%)
	ASTHENIA	6 (4.5%)	9 (6.9%)	15 (5.7%)
	PAIN	6 (4.5%)	3 (2.3%)	9 (3.4%)
	BACK PAIN	4 (3.0%)	4 (3.1%)	8 (3.0%)
	CHEST PAIN	3 (2.3%)	0	3 (1.1%)
	FACE EDEMA	2 (1.5%)	0	2 (0.8%)
	ABNORMAL LABORATORY VALUE	1 (0.8%)	0	1 (0.4%)
	ABSCESS	1 (0.8%)	0	1 (0.4%)
	MALAISE	1 (0.8%)	0	1 (0.4%)
	SPINA BIFIDA	0	1 (0.8%)	1 (0.4%)
Respiratory System	TOTAL	53 (39.8%)	40 (30.8%)	93 (35.4%)
	RESPIRATORY DISORDER	22 (16.5%)	26 (20.0%)	48 (18.3%)
	PHARYNGITIS	18 (13.5%)	10 (7.7%)	28 (10.6%)
	RHINITIS	13 (9.8%)	9 (6.9%)	22 (8.4%)
	SINUSITIS	11 (8.3%)	2 (1.5%)	13 (4.9%)
	ASTHMA	5 (3.8%)	5 (3.8%)	10 (3.8%)
	COUGH INCREASED	6 (4.5%)	3 (2.3%)	9 (3.4%)
	BRONCHITIS	3 (2.3%)	3 (2.3%)	6 (2.3%)
	PNEUMONIA	1 (0.8%)	2 (1.5%)	3 (1.1%)
	EPISTAXIS	0	3 (2.3%)	3 (1.1%)
	DYSPNEA	1 (0.8%)	0	1 (0.4%)
	PLEURA DISORDER	1 (0.8%)	0	1 (0.4%)
	YAWN	0	1 (0.8%)	1 (0.4%)
Nervous System	TOTAL	49 (36.8%)	53 (40.8%)	102 (38.8%)
	NERVOUSNESS	10 (7.5%)	13 (10.0%)	23 (8.7%)
	INSOMNIA	10 (7.5%)	11 (8.5%)	21 (8.0%)
	HYPERKINESIA	8 (6.0%)	7 (5.4%)	15 (5.7%)
	HOSTILITY	6 (4.5%)	9 (6.9%)	15 (5.7%)
	EMOTIONAL LABILITY	10 (7.5%)	4 (3.1%)	14 (5.3%)
	SOMNOLENCE	7 (5.3%)	6 (4.6%)	13 (4.9%)
	DIZZINESS	6 (4.5%)	5 (3.8%)	11 (4.2%)
	AGITATION	4 (3.0%)	6 (4.6%)	10 (3.8%)
	ANXIETY	3 (2.3%)	6 (4.6%)	9 (3.4%)
	DEPRESSION	4 (3.0%)	2 (1.5%)	6 (2.3%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Nervous System	NEUROSIS	4 (3.0%)	1 (0.8%)	5 (1.9%)
	CONCENTRATION IMPAIRED	2 (1.5%)	2 (1.5%)	4 (1.5%)
	VERTIGO	2 (1.5%)	2 (1.5%)	4 (1.5%)
	TREMOR	0	4 (3.1%)	4 (1.5%)
	HALLUCINATIONS	1 (0.8%)	2 (1.5%)	3 (1.1%)
	ABNORMAL DREAMS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	LACK OF EMOTION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	MANIC REACTION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	MYOCLONUS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	HYPESTHESIA	0	2 (1.5%)	2 (0.8%)
	CONVULSION	1 (0.8%)	0	1 (0.4%)
	PARESTHESIA	1 (0.8%)	0	1 (0.4%)
	VESTIBULAR DISORDER	1 (0.8%)	0	1 (0.4%)
	DYSKINESIA	0	1 (0.8%)	1 (0.4%)
	EUPHORIA	0	1 (0.8%)	1 (0.4%)
	LIBIDO DECREASED	0	1 (0.8%)	1 (0.4%)
	PARALYSIS	0	1 (0.8%)	1 (0.4%)
	PSYCHOSIS	0	1 (0.8%)	1 (0.4%)
	WITHDRAWAL SYNDROME	0	1 (0.8%)	1 (0.4%)
Digestive System	TOTAL	41 (30.8%)	35 (26.9%)	76 (28.9%)
	NAUSEA	14 (10.5%)	11 (8.5%)	25 (9.5%)
	VOMITING	13 (9.8%)	4 (3.1%)	17 (6.5%)
	DYSPEPSIA	9 (6.8%)	7 (5.4%)	16 (6.1%)
	DIARRHEA	9 (6.8%)	3 (2.3%)	12 (4.6%)
	DECREASED APPETITE	4 (3.0%)	7 (5.4%)	11 (4.2%)
	DRY MOUTH	3 (2.3%)	2 (1.5%)	5 (1.9%)
	TOOTH CARIES	1 (0.8%)	4 (3.1%)	5 (1.9%)
	CONSTIPATION	2 (1.5%)	1 (0.8%)	3 (1.1%)
	TOOTH DISORDER	2 (1.5%)	1 (0.8%)	3 (1.1%)
	INCREASED APPETITE	1 (0.8%)	2 (1.5%)	3 (1.1%)
	GINGIVITIS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	FLATULENCE	0	2 (1.5%)	2 (0.8%)
	GASTROENTERITIS	0	2 (1.5%)	2 (0.8%)
	GASTRITIS	1 (0.8%)	0	1 (0.4%)
	HEMATEMESIS	1 (0.8%)	0	1 (0.4%)
	STOMATITIS	1 (0.8%)	0	1 (0.4%)
	GASTROINTESTINAL DISORDER	0	1 (0.8%)	1 (0.4%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (0.8%)	1 (0.4%)
	ULCERATIVE STOMATITIS	0	1 (0.8%)	1 (0.4%)
Skin and Appendages	TOTAL	14 (10.5%)	13 (10.0%)	27 (10.3%)
	ACNE	5 (3.8%)	3 (2.3%)	8 (3.0%)
	CONTACT DERMATITIS	4 (3.0%)	4 (3.1%)	8 (3.0%)

Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Skin and Appendages	RASH	1 (0.8%)	5 (3.8%)	6 (2.3%)
	PRURITUS	1 (0.8%)	2 (1.5%)	3 (1.1%)
	FUNGAL DERMATITIS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	MACULOPAPULAR RASH	1 (0.8%)	1 (0.8%)	2 (0.8%)
	FURUNCULOSIS	1 (0.8%)	0	1 (0.4%)
	HERPES ZOSTER	1 (0.8%)	0	1 (0.4%)
	HERPES SIMPLEX	0	1 (0.8%)	1 (0.4%)
	SWEATING	0	1 (0.8%)	1 (0.4%)
	URTICARIA	0	1 (0.8%)	1 (0.4%)
Urogenital System	TOTAL	12 (9.0%)	6 (4.6%)	18 (6.8%)
	ALBUMINURIA	8 (6.0%)	2 (1.5%)	10 (3.8%)
	URINARY INCONTINENCE	1 (0.8%)	4 (3.1%)	5 (1.9%)
	HAEMATURIA	2 (1.5%)	2 (1.5%)	4 (1.5%)
	DYSURIA	1 (0.8%)	0	1 (0.4%)
	GLYCOSURIA	1 (0.8%)	0	1 (0.4%)
	PYURIA	1 (0.8%)	0	1 (0.4%)
	URINARY TRACT INFECTION	1 (0.8%)	0	1 (0.4%)
	CYSTITIS	0	1 (0.8%)	1 (0.4%)
Special Senses	TOTAL	10 (7.5%)	9 (6.9%)	19 (7.2%)
	OTITIS MEDIA	6 (4.5%)	4 (3.1%)	10 (3.8%)
	OTITIS EXTERNA	2 (1.5%)	1 (0.8%)	3 (1.1%)
	EAR PAIN	1 (0.8%)	1 (0.8%)	2 (0.8%)
	ABNORMAL VISION	0	2 (1.5%)	2 (0.8%)
	BLEPHARITIS	1 (0.8%)	0	1 (0.4%)
	EYE PAIN	1 (0.8%)	0	1 (0.4%)
	PHOTOPHOBIA	0	1 (0.8%)	1 (0.4%)
Metabolic and Nutritional Disorders	TOTAL	9 (6.8%)	11 (8.5%)	20 (7.6%)
	WEIGHT GAIN	7 (5.3%)	9 (6.9%)	16 (6.1%)
	DEHYDRATION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	WEIGHT LOSS	1 (0.8%)	1 (0.8%)	2 (0.8%)
Musculoskeletal System	TOTAL	8 (6.0%)	2 (1.5%)	10 (3.8%)
	ARTHRALGIA	4 (3.0%)	1 (0.8%)	5 (1.9%)
	MYALGIA	2 (1.5%)	1 (0.8%)	3 (1.1%)
	ARTHROSIS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	TENDINOUS DISORDER	1 (0.8%)	0	1 (0.4%)
Hemic and Lymphatic System	TOTAL	5 (3.8%)	4 (3.1%)	9 (3.4%)
	LEUKOPENIA	2 (1.5%)	2 (1.5%)	4 (1.5%)
	ANEMIA	1 (0.8%)	1 (0.8%)	2 (0.8%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Hemic and Lymphatic System	LYMPHADENOPATHY	1 (0.8%)	0	1 (0.4%)
	PURPURA	1 (0.8%)	0	1 (0.4%)
	EOSINOPHILIA	0	1 (0.8%)	1 (0.4%)
	LEUKOCYTOSIS	0	1 (0.8%)	1 (0.4%)
	MONOCYTOSIS	0	1 (0.8%)	1 (0.4%)
Cardiovascular System	TOTAL	1 (0.8%)	9 (6.9%)	10 (3.8%)
	VASODILATATION	0	4 (3.1%)	4 (1.5%)
	SYNCOPE	0	3 (2.3%)	3 (1.1%)
	HAEMATOMA	1 (0.8%)	0	1 (0.4%)
	BUNDLE BRANCH BLOCK	0	1 (0.8%)	1 (0.4%)
	MIGRAINE	0	1 (0.8%)	1 (0.4%)

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	7 (11.5%)	3 (5.9%)	10 (8.9%)
Urogenital System	TOTAL	7 (11.5%)	3 (5.9%)	10 (8.9%)
	DYSMENORRHEA	7 (11.5%)	1 (2.0%)	8 (7.1%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (0.9%)
	MENSTRUAL DISORDER	0	1 (2.0%)	1 (0.9%)
	UTERUS DISORDERS	0	1 (2.0%)	1 (0.9%)

Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
TOTAL	32 (82.1%)	25 (69.4%)	57 (76.0%)
TRAUMA	11 (28.2%)	4 (11.1%)	15 (20.0%)
RESPIRATORY DISORDER	9 (23.1%)	6 (16.7%)	15 (20.0%)
INFECTION	5 (12.8%)	9 (25.0%)	14 (18.7%)
HEADACHE	9 (23.1%)	4 (11.1%)	13 (17.3%)
PHARYNGITIS	8 (20.5%)	4 (11.1%)	12 (16.0%)
VOMITING	7 (17.9%)	4 (11.1%)	11 (14.7%)
ABDOMINAL PAIN	7 (17.9%)	3 (8.3%)	10 (13.3%)
FEVER	5 (12.8%)	2 (5.6%)	7 (9.3%)
DYSPEPSIA	4 (10.3%)	3 (8.3%)	7 (9.3%)
RHINITIS	4 (10.3%)	3 (8.3%)	7 (9.3%)
WEIGHT GAIN	4 (10.3%)	3 (8.3%)	7 (9.3%)
NERVOUSNESS	5 (12.8%)	0	5 (6.7%)
HOSTILITY	4 (10.3%)	1 (2.8%)	5 (6.7%)
ALLERGIC REACTION	3 (7.7%)	2 (5.6%)	5 (6.7%)
COUGH INCREASED	3 (7.7%)	1 (2.8%)	4 (5.3%)
PAIN	3 (7.7%)	1 (2.8%)	4 (5.3%)
SINUSITIS	3 (7.7%)	1 (2.8%)	4 (5.3%)
ASTHENIA	2 (5.1%)	2 (5.6%)	4 (5.3%)
INSOMNIA	1 (2.6%)	3 (8.3%)	4 (5.3%)
CONTACT DERMATITIS	2 (5.1%)	1 (2.8%)	3 (4.0%)
DEPRESSION	2 (5.1%)	1 (2.8%)	3 (4.0%)
DIARRHEA	2 (5.1%)	1 (2.8%)	3 (4.0%)
HYPERKINESIA	2 (5.1%)	1 (2.8%)	3 (4.0%)
OTITIS MEDIA	2 (5.1%)	1 (2.8%)	3 (4.0%)
AGITATION	1 (2.6%)	2 (5.6%)	3 (4.0%)
LEUKOPENIA	1 (2.6%)	2 (5.6%)	3 (4.0%)
NAUSEA	1 (2.6%)	2 (5.6%)	3 (4.0%)
RASH	1 (2.6%)	2 (5.6%)	3 (4.0%)
URINARY INCONTINENCE	1 (2.6%)	2 (5.6%)	3 (4.0%)
BACK PAIN	0	3 (8.3%)	3 (4.0%)
ACNE	2 (5.1%)	0	2 (2.7%)
ARTHRALGIA	2 (5.1%)	0	2 (2.7%)
DRY MOUTH	2 (5.1%)	0	2 (2.7%)
FACE EDEMA	2 (5.1%)	0	2 (2.7%)
DECREASED APPETITE	1 (2.6%)	1 (2.8%)	2 (2.7%)
HALLUCINATIONS	1 (2.6%)	1 (2.8%)	2 (2.7%)
EPISTAXIS	0	2 (5.6%)	2 (2.7%)
HYPESTHESIA	0	2 (5.6%)	2 (2.7%)
TOOTH CARIES	0	2 (5.6%)	2 (2.7%)
CONSTIPATION	1 (2.6%)	0	1 (1.3%)
EMOTIONAL LABILITY	1 (2.6%)	0	1 (1.3%)
INCREASED APPETITE	1 (2.6%)	0	1 (1.3%)
NEUROSIS	1 (2.6%)	0	1 (1.3%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Preferred Term			
ABNORMAL VISION	0	1 (2.8%)	1 (1.3%)
ALBUMINURIA	0	1 (2.8%)	1 (1.3%)
ANXIETY	0	1 (2.8%)	1 (1.3%)
ASTHMA	0	1 (2.8%)	1 (1.3%)
BRONCHITIS	0	1 (2.8%)	1 (1.3%)
CONCENTRATION IMPAIRED	0	1 (2.8%)	1 (1.3%)
DIZZINESS	0	1 (2.8%)	1 (1.3%)
GASTROENTERITIS	0	1 (2.8%)	1 (1.3%)
HAEMATURIA	0	1 (2.8%)	1 (1.3%)
MYALGIA	0	1 (2.8%)	1 (1.3%)
PNEUMONIA	0	1 (2.8%)	1 (1.3%)
PRURITUS	0	1 (2.8%)	1 (1.3%)
SOMNOLENCE	0	1 (2.8%)	1 (1.3%)
SYNCOPE	0	1 (2.8%)	1 (1.3%)
TREMOR	0	1 (2.8%)	1 (1.3%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
TOTAL	0	0	0

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
TOTAL	0	0	0

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
TOTAL	22 (78.6%)	29 (80.6%)	51 (79.7%)
HEADACHE	9 (32.1%)	8 (22.2%)	17 (26.6%)
RESPIRATORY DISORDER	2 (7.1%)	8 (22.2%)	10 (15.6%)
NERVOUSNESS	1 (3.6%)	9 (25.0%)	10 (15.6%)
HYPERKINESIA	5 (17.9%)	4 (11.1%)	9 (14.1%)
PHARYNGITIS	5 (17.9%)	3 (8.3%)	8 (12.5%)
RHINITIS	4 (14.3%)	4 (11.1%)	8 (12.5%)
TRAUMA	4 (14.3%)	4 (11.1%)	8 (12.5%)
ABDOMINAL PAIN	2 (7.1%)	5 (13.9%)	7 (10.9%)
NAUSEA	5 (17.9%)	1 (2.8%)	6 (9.4%)
INFECTION	3 (10.7%)	3 (8.3%)	6 (9.4%)
INSOMNIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
OTITIS MEDIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
HOSTILITY	1 (3.6%)	4 (11.1%)	5 (7.8%)
FEVER	3 (10.7%)	1 (2.8%)	4 (6.3%)
DECREASED APPETITE	2 (7.1%)	2 (5.6%)	4 (6.3%)
ANXIETY	1 (3.6%)	3 (8.3%)	4 (6.3%)
DIARRHEA	3 (10.7%)	0	3 (4.7%)
COUGH INCREASED	2 (7.1%)	1 (2.8%)	3 (4.7%)
DYSPEPSIA	2 (7.1%)	1 (2.8%)	3 (4.7%)
OTITIS EXTERNA	2 (7.1%)	1 (2.8%)	3 (4.7%)
PAIN	2 (7.1%)	1 (2.8%)	3 (4.7%)
SINUSITIS	2 (7.1%)	1 (2.8%)	3 (4.7%)
DIZZINESS	1 (3.6%)	2 (5.6%)	3 (4.7%)
SOMNOLENCE	1 (3.6%)	2 (5.6%)	3 (4.7%)
VASODILATATION	0	3 (8.3%)	3 (4.7%)
WEIGHT GAIN	0	3 (8.3%)	3 (4.7%)
ALBUMINURIA	2 (7.1%)	0	2 (3.1%)
AGITATION	1 (3.6%)	1 (2.8%)	2 (3.1%)
CONTACT DERMATITIS	0	2 (5.6%)	2 (3.1%)
RASH	0	2 (5.6%)	2 (3.1%)
URINARY INCONTINENCE	0	2 (5.6%)	2 (3.1%)
VERTIGO	0	2 (5.6%)	2 (3.1%)
ACNE	1 (3.6%)	0	1 (1.6%)
ASTHMA	1 (3.6%)	0	1 (1.6%)
BACK PAIN	1 (3.6%)	0	1 (1.6%)
CONCENTRATION IMPAIRED	1 (3.6%)	0	1 (1.6%)
DEPRESSION	1 (3.6%)	0	1 (1.6%)
EMOTIONAL LABILITY	1 (3.6%)	0	1 (1.6%)
MYALGIA	1 (3.6%)	0	1 (1.6%)
TOOTH DISORDER	1 (3.6%)	0	1 (1.6%)
VOMITING	1 (3.6%)	0	1 (1.6%)
ALLERGIC REACTION	0	1 (2.8%)	1 (1.6%)
FLATULENCE	0	1 (2.8%)	1 (1.6%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
TOOTH CARIES	0	1 (2.8%)	1 (1.6%)
TREMOR	0	1 (2.8%)	1 (1.6%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
TOTAL	0	0	0

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
Preferred Term			
TOTAL	1 (6.3%)	1 (7.7%)	2 (6.9%)
DYSMENORRHEA	1 (6.3%)	1 (7.7%)	2 (6.9%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
TOTAL	54 (80.6%)	54 (75.0%)	108 (77.7%)
HEADACHE	18 (26.9%)	12 (16.7%)	30 (21.6%)
RESPIRATORY DISORDER	11 (16.4%)	14 (19.4%)	25 (18.0%)
TRAUMA	15 (22.4%)	8 (11.1%)	23 (16.5%)
PHARYNGITIS	13 (19.4%)	7 (9.7%)	20 (14.4%)
INFECTION	8 (11.9%)	12 (16.7%)	20 (14.4%)
ABDOMINAL PAIN	9 (13.4%)	8 (11.1%)	17 (12.2%)
RHINITIS	8 (11.9%)	7 (9.7%)	15 (10.8%)
NERVOUSNESS	6 (9.0%)	9 (12.5%)	15 (10.8%)
VOMITING	8 (11.9%)	4 (5.6%)	12 (8.6%)
HYPERKINESIA	7 (10.4%)	5 (6.9%)	12 (8.6%)
FEVER	8 (11.9%)	3 (4.2%)	11 (7.9%)
DYSPEPSIA	6 (9.0%)	4 (5.6%)	10 (7.2%)
HOSTILITY	5 (7.5%)	5 (6.9%)	10 (7.2%)
WEIGHT GAIN	4 (6.0%)	6 (8.3%)	10 (7.2%)
NAUSEA	6 (9.0%)	3 (4.2%)	9 (6.5%)
INSOMNIA	4 (6.0%)	5 (6.9%)	9 (6.5%)
OTITIS MEDIA	5 (7.5%)	3 (4.2%)	8 (5.8%)
COUGH INCREASED	5 (7.5%)	2 (2.8%)	7 (5.0%)
PAIN	5 (7.5%)	2 (2.8%)	7 (5.0%)
SINUSITIS	5 (7.5%)	2 (2.8%)	7 (5.0%)
DIARRHEA	5 (7.5%)	1 (1.4%)	6 (4.3%)
ALLERGIC REACTION	3 (4.5%)	3 (4.2%)	6 (4.3%)
DECREASED APPETITE	3 (4.5%)	3 (4.2%)	6 (4.3%)
AGITATION	2 (3.0%)	3 (4.2%)	5 (3.6%)
CONTACT DERMATITIS	2 (3.0%)	3 (4.2%)	5 (3.6%)
ANXIETY	1 (1.5%)	4 (5.6%)	5 (3.6%)
RASH	1 (1.5%)	4 (5.6%)	5 (3.6%)
URINARY INCONTINENCE	1 (1.5%)	4 (5.6%)	5 (3.6%)
DEPRESSION	3 (4.5%)	1 (1.4%)	4 (2.9%)
ASTHENIA	2 (3.0%)	2 (2.8%)	4 (2.9%)
BACK PAIN	1 (1.5%)	3 (4.2%)	4 (2.9%)
DIZZINESS	1 (1.5%)	3 (4.2%)	4 (2.9%)
SOMNOLENCE	1 (1.5%)	3 (4.2%)	4 (2.9%)
ACNE	3 (4.5%)	0	3 (2.2%)
ALBUMINURIA	2 (3.0%)	1 (1.4%)	3 (2.2%)
OTITIS EXTERNA	2 (3.0%)	1 (1.4%)	3 (2.2%)
LEUKOPENIA	1 (1.5%)	2 (2.8%)	3 (2.2%)
TOOTH CARIES	0	3 (4.2%)	3 (2.2%)
VASODILATATION	0	3 (4.2%)	3 (2.2%)
ARTHRALGIA	2 (3.0%)	0	2 (1.4%)
DRY MOUTH	2 (3.0%)	0	2 (1.4%)
EMOTIONAL LABILITY	2 (3.0%)	0	2 (1.4%)
FACE EDEMA	2 (3.0%)	0	2 (1.4%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
ASTHMA	1 (1.5%)	1 (1.4%)	2 (1.4%)
CONCENTRATION IMPAIRED	1 (1.5%)	1 (1.4%)	2 (1.4%)
HALLUCINATIONS	1 (1.5%)	1 (1.4%)	2 (1.4%)
MYALGIA	1 (1.5%)	1 (1.4%)	2 (1.4%)
EPISTAXIS	0	2 (2.8%)	2 (1.4%)
GASTROENTERITIS	0	2 (2.8%)	2 (1.4%)
HYPESTHESIA	0	2 (2.8%)	2 (1.4%)
TREMOR	0	2 (2.8%)	2 (1.4%)
VERTIGO	0	2 (2.8%)	2 (1.4%)
CONSTIPATION	1 (1.5%)	0	1 (0.7%)
INCREASED APPETITE	1 (1.5%)	0	1 (0.7%)
NEUROSIS	1 (1.5%)	0	1 (0.7%)
TOOTH DISORDER	1 (1.5%)	0	1 (0.7%)
ABNORMAL VISION	0	1 (1.4%)	1 (0.7%)
BRONCHITIS	0	1 (1.4%)	1 (0.7%)
FLATULENCE	0	1 (1.4%)	1 (0.7%)
HAEMATURIA	0	1 (1.4%)	1 (0.7%)
PNEUMONIA	0	1 (1.4%)	1 (0.7%)
PRURITUS	0	1 (1.4%)	1 (0.7%)
SYNCOPE	0	1 (1.4%)	1 (0.7%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
TOTAL	0	0	0

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
TOTAL	1 (2.9%)	1 (3.7%)	2 (3.2%)
DYSMENORRHEA	1 (2.9%)	1 (3.7%)	2 (3.2%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
TOTAL	34 (81.0%)	18 (60.0%)	52 (72.2%)
HEADACHE	11 (26.2%)	6 (20.0%)	17 (23.6%)
RESPIRATORY DISORDER	7 (16.7%)	7 (23.3%)	14 (19.4%)
NAUSEA	7 (16.7%)	2 (6.7%)	9 (12.5%)
EMOTIONAL LABILITY	6 (14.3%)	3 (10.0%)	9 (12.5%)
TRAUMA	6 (14.3%)	2 (6.7%)	8 (11.1%)
SOMNOLENCE	5 (11.9%)	2 (6.7%)	7 (9.7%)
VOMITING	5 (11.9%)	0	5 (6.9%)
PHARYNGITIS	4 (9.5%)	1 (3.3%)	5 (6.9%)
RHINITIS	4 (9.5%)	1 (3.3%)	5 (6.9%)
ASTHMA	3 (7.1%)	2 (6.7%)	5 (6.9%)
INFECTION	3 (7.1%)	2 (6.7%)	5 (6.9%)
INSOMNIA	3 (7.1%)	2 (6.7%)	5 (6.9%)
ALLERGIC REACTION	4 (9.5%)	0	4 (5.6%)
ABDOMINAL PAIN	3 (7.1%)	1 (3.3%)	4 (5.6%)
ALBUMINURIA	3 (7.1%)	1 (3.3%)	4 (5.6%)
DIARRHEA	3 (7.1%)	1 (3.3%)	4 (5.6%)
DIZZINESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
DYSPEPSIA	3 (7.1%)	1 (3.3%)	4 (5.6%)
FEVER	3 (7.1%)	1 (3.3%)	4 (5.6%)
NERVOUSNESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
BRONCHITIS	2 (4.8%)	2 (6.7%)	4 (5.6%)
ASTHENIA	1 (2.4%)	3 (10.0%)	4 (5.6%)
WEIGHT GAIN	1 (2.4%)	3 (10.0%)	4 (5.6%)
BACK PAIN	3 (7.1%)	0	3 (4.2%)
CHEST PAIN	3 (7.1%)	0	3 (4.2%)
SINUSITIS	3 (7.1%)	0	3 (4.2%)
AGITATION	2 (4.8%)	1 (3.3%)	3 (4.2%)
DECREASED APPETITE	1 (2.4%)	2 (6.7%)	3 (4.2%)
CONTACT DERMATITIS	2 (4.8%)	0	2 (2.8%)
ACNE	1 (2.4%)	1 (3.3%)	2 (2.8%)
ANXIETY	1 (2.4%)	1 (3.3%)	2 (2.8%)
COUGH INCREASED	1 (2.4%)	1 (3.3%)	2 (2.8%)
HAEMATURIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
PRURITUS	1 (2.4%)	1 (3.3%)	2 (2.8%)
TOOTH CARIES	1 (2.4%)	1 (3.3%)	2 (2.8%)
INCREASED APPETITE	0	2 (6.7%)	2 (2.8%)
DEPRESSION	1 (2.4%)	0	1 (1.4%)
DRY MOUTH	1 (2.4%)	0	1 (1.4%)
LEUKOPENIA	1 (2.4%)	0	1 (1.4%)
MYALGIA	1 (2.4%)	0	1 (1.4%)
OTITIS MEDIA	1 (2.4%)	0	1 (1.4%)
PNEUMONIA	1 (2.4%)	0	1 (1.4%)
VERTIGO	1 (2.4%)	0	1 (1.4%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Preferred Term			
CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.4%)
HALLUCINATIONS	0	1 (3.3%)	1 (1.4%)
HOSTILITY	0	1 (3.3%)	1 (1.4%)
PAIN	0	1 (3.3%)	1 (1.4%)
SYNCOPE	0	1 (3.3%)	1 (1.4%)
TREMOR	0	1 (3.3%)	1 (1.4%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
Preferred Term			
TOTAL	3 (21.4%)	0	3 (10.3%)
DYSMENORRHEA	3 (21.4%)	0	3 (10.3%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
TOTAL	18 (75.0%)	19 (67.9%)	37 (71.2%)
HEADACHE	10 (41.7%)	9 (32.1%)	19 (36.5%)
RESPIRATORY DISORDER	4 (16.7%)	5 (17.9%)	9 (17.3%)
INFECTION	5 (20.8%)	3 (10.7%)	8 (15.4%)
ALLERGIC REACTION	4 (16.7%)	3 (10.7%)	7 (13.5%)
ASTHENIA	3 (12.5%)	4 (14.3%)	7 (13.5%)
INSOMNIA	3 (12.5%)	4 (14.3%)	7 (13.5%)
NAUSEA	1 (4.2%)	6 (21.4%)	7 (13.5%)
ABDOMINAL PAIN	3 (12.5%)	3 (10.7%)	6 (11.5%)
TRAUMA	1 (4.2%)	4 (14.3%)	5 (9.6%)
NEUROSIS	3 (12.5%)	1 (3.6%)	4 (7.7%)
HOSTILITY	1 (4.2%)	3 (10.7%)	4 (7.7%)
NERVOUSNESS	1 (4.2%)	3 (10.7%)	4 (7.7%)
ALBUMINURIA	3 (12.5%)	0	3 (5.8%)
SINUSITIS	3 (12.5%)	0	3 (5.8%)
ARTHRALGIA	2 (8.3%)	1 (3.6%)	3 (5.8%)
DIZZINESS	2 (8.3%)	1 (3.6%)	3 (5.8%)
EMOTIONAL LABILITY	2 (8.3%)	1 (3.6%)	3 (5.8%)
ACNE	1 (4.2%)	2 (7.1%)	3 (5.8%)
ASTHMA	1 (4.2%)	2 (7.1%)	3 (5.8%)
HYPERKINESIA	1 (4.2%)	2 (7.1%)	3 (5.8%)
PHARYNGITIS	1 (4.2%)	2 (7.1%)	3 (5.8%)
WEIGHT GAIN	2 (8.3%)	0	2 (3.8%)
ANXIETY	1 (4.2%)	1 (3.6%)	2 (3.8%)
CONSTIPATION	1 (4.2%)	1 (3.6%)	2 (3.8%)
DIARRHEA	1 (4.2%)	1 (3.6%)	2 (3.8%)
RHINITIS	1 (4.2%)	1 (3.6%)	2 (3.8%)
SOMNOLENCE	1 (4.2%)	1 (3.6%)	2 (3.8%)
TOOTH DISORDER	1 (4.2%)	1 (3.6%)	2 (3.8%)
AGITATION	0	2 (7.1%)	2 (3.8%)
DECREASED APPETITE	0	2 (7.1%)	2 (3.8%)
DRY MOUTH	0	2 (7.1%)	2 (3.8%)
DYSPEPSIA	0	2 (7.1%)	2 (3.8%)
FEVER	0	2 (7.1%)	2 (3.8%)
BRONCHITIS	1 (4.2%)	0	1 (1.9%)
CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.9%)
HAEMATURIA	1 (4.2%)	0	1 (1.9%)
PAIN	1 (4.2%)	0	1 (1.9%)
VERTIGO	1 (4.2%)	0	1 (1.9%)
ABNORMAL VISION	0	1 (3.6%)	1 (1.9%)
BACK PAIN	0	1 (3.6%)	1 (1.9%)
CONTACT DERMATITIS	0	1 (3.6%)	1 (1.9%)
DEPRESSION	0	1 (3.6%)	1 (1.9%)
EPISTAXIS	0	1 (3.6%)	1 (1.9%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
FLATULENCE	0	1 (3.6%)	1 (1.9%)
OTITIS MEDIA	0	1 (3.6%)	1 (1.9%)
PNEUMONIA	0	1 (3.6%)	1 (1.9%)
RASH	0	1 (3.6%)	1 (1.9%)
SYNCOPE	0	1 (3.6%)	1 (1.9%)
TREMOR	0	1 (3.6%)	1 (1.9%)
VASODILATATION	0	1 (3.6%)	1 (1.9%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
TOTAL	3 (25.0%)	0	3 (14.3%)
DYSMENORRHEA	3 (25.0%)	0	3 (14.3%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
TOTAL	52 (78.8%)	37 (63.8%)	89 (71.8%)
HEADACHE	21 (31.8%)	15 (25.9%)	36 (29.0%)
RESPIRATORY DISORDER	11 (16.7%)	12 (20.7%)	23 (18.5%)
NAUSEA	8 (12.1%)	8 (13.8%)	16 (12.9%)
INFECTION	8 (12.1%)	5 (8.6%)	13 (10.5%)
TRAUMA	7 (10.6%)	6 (10.3%)	13 (10.5%)
EMOTIONAL LABILITY	8 (12.1%)	4 (6.9%)	12 (9.7%)
INSOMNIA	6 (9.1%)	6 (10.3%)	12 (9.7%)
ALLERGIC REACTION	8 (12.1%)	3 (5.2%)	11 (8.9%)
ASTHENIA	4 (6.1%)	7 (12.1%)	11 (8.9%)
ABDOMINAL PAIN	6 (9.1%)	4 (6.9%)	10 (8.1%)
SOMNOLENCE	6 (9.1%)	3 (5.2%)	9 (7.3%)
PHARYNGITIS	5 (7.6%)	3 (5.2%)	8 (6.5%)
ASTHMA	4 (6.1%)	4 (6.9%)	8 (6.5%)
NERVOUSNESS	4 (6.1%)	4 (6.9%)	8 (6.5%)
ALBUMINURIA	6 (9.1%)	1 (1.7%)	7 (5.6%)
DIZZINESS	5 (7.6%)	2 (3.4%)	7 (5.6%)
RHINITIS	5 (7.6%)	2 (3.4%)	7 (5.6%)
SINUSITIS	6 (9.1%)	0	6 (4.8%)
DIARRHEA	4 (6.1%)	2 (3.4%)	6 (4.8%)
DYSPEPSIA	3 (4.5%)	3 (5.2%)	6 (4.8%)
FEVER	3 (4.5%)	3 (5.2%)	6 (4.8%)
WEIGHT GAIN	3 (4.5%)	3 (5.2%)	6 (4.8%)
VOMITING	5 (7.6%)	0	5 (4.0%)
BRONCHITIS	3 (4.5%)	2 (3.4%)	5 (4.0%)
ACNE	2 (3.0%)	3 (5.2%)	5 (4.0%)
AGITATION	2 (3.0%)	3 (5.2%)	5 (4.0%)
DECREASED APPETITE	1 (1.5%)	4 (6.9%)	5 (4.0%)
HOSTILITY	1 (1.5%)	4 (6.9%)	5 (4.0%)
BACK PAIN	3 (4.5%)	1 (1.7%)	4 (3.2%)
NEUROSIS	3 (4.5%)	1 (1.7%)	4 (3.2%)
ANXIETY	2 (3.0%)	2 (3.4%)	4 (3.2%)
CHEST PAIN	3 (4.5%)	0	3 (2.4%)
ARTHRALGIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
CONTACT DERMATITIS	2 (3.0%)	1 (1.7%)	3 (2.4%)
HAEMATURIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
DRY MOUTH	1 (1.5%)	2 (3.4%)	3 (2.4%)
HYPERKINESIA	1 (1.5%)	2 (3.4%)	3 (2.4%)
VERTIGO	2 (3.0%)	0	2 (1.6%)
CONCENTRATION IMPAIRED	1 (1.5%)	1 (1.7%)	2 (1.6%)
CONSTIPATION	1 (1.5%)	1 (1.7%)	2 (1.6%)
COUGH INCREASED	1 (1.5%)	1 (1.7%)	2 (1.6%)
DEPRESSION	1 (1.5%)	1 (1.7%)	2 (1.6%)
OTITIS MEDIA	1 (1.5%)	1 (1.7%)	2 (1.6%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
PAIN	1 (1.5%)	1 (1.7%)	2 (1.6%)
PNEUMONIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
PRURITUS	1 (1.5%)	1 (1.7%)	2 (1.6%)
TOOTH CARIES	1 (1.5%)	1 (1.7%)	2 (1.6%)
TOOTH DISORDER	1 (1.5%)	1 (1.7%)	2 (1.6%)
INCREASED APPETITE	0	2 (3.4%)	2 (1.6%)
SYNCOPE	0	2 (3.4%)	2 (1.6%)
TREMOR	0	2 (3.4%)	2 (1.6%)
LEUKOPENIA	1 (1.5%)	0	1 (0.8%)
MYALGIA	1 (1.5%)	0	1 (0.8%)
ABNORMAL VISION	0	1 (1.7%)	1 (0.8%)
EPISTAXIS	0	1 (1.7%)	1 (0.8%)
FLATULENCE	0	1 (1.7%)	1 (0.8%)
HALLUCINATIONS	0	1 (1.7%)	1 (0.8%)
RASH	0	1 (1.7%)	1 (0.8%)
VASODILATATION	0	1 (1.7%)	1 (0.8%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
TOTAL	0	0	0

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
TOTAL	6 (23.1%)	0	6 (12.0%)
DYSMENORRHEA	6 (23.1%)	0	6 (12.0%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
TOTAL	66 (81.5%)	43 (65.2%)	109 (74.1%)
HEADACHE	20 (24.7%)	10 (15.2%)	30 (20.4%)
RESPIRATORY DISORDER	16 (19.8%)	13 (19.7%)	29 (19.7%)
TRAUMA	17 (21.0%)	6 (9.1%)	23 (15.6%)
INFECTION	8 (9.9%)	11 (16.7%)	19 (12.9%)
PHARYNGITIS	12 (14.8%)	5 (7.6%)	17 (11.6%)
VOMITING	12 (14.8%)	4 (6.1%)	16 (10.9%)
ABDOMINAL PAIN	10 (12.3%)	4 (6.1%)	14 (9.5%)
NAUSEA	8 (9.9%)	4 (6.1%)	12 (8.2%)
RHINITIS	8 (9.9%)	4 (6.1%)	12 (8.2%)
FEVER	8 (9.9%)	3 (4.5%)	11 (7.5%)
DYSPEPSIA	7 (8.6%)	4 (6.1%)	11 (7.5%)
WEIGHT GAIN	5 (6.2%)	6 (9.1%)	11 (7.5%)
EMOTIONAL LABILITY	7 (8.6%)	3 (4.5%)	10 (6.8%)
NERVOUSNESS	8 (9.9%)	1 (1.5%)	9 (6.1%)
ALLERGIC REACTION	7 (8.6%)	2 (3.0%)	9 (6.1%)
INSOMNIA	4 (4.9%)	5 (7.6%)	9 (6.1%)
SOMNOLENCE	5 (6.2%)	3 (4.5%)	8 (5.4%)
ASTHENIA	3 (3.7%)	5 (7.6%)	8 (5.4%)
SINUSITIS	6 (7.4%)	1 (1.5%)	7 (4.8%)
DIARRHEA	5 (6.2%)	2 (3.0%)	7 (4.8%)
COUGH INCREASED	4 (4.9%)	2 (3.0%)	6 (4.1%)
HOSTILITY	4 (4.9%)	2 (3.0%)	6 (4.1%)
AGITATION	3 (3.7%)	3 (4.5%)	6 (4.1%)
ASTHMA	3 (3.7%)	3 (4.5%)	6 (4.1%)
BACK PAIN	3 (3.7%)	3 (4.5%)	6 (4.1%)
CONTACT DERMATITIS	4 (4.9%)	1 (1.5%)	5 (3.4%)
ALBUMINURIA	3 (3.7%)	2 (3.0%)	5 (3.4%)
DIZZINESS	3 (3.7%)	2 (3.0%)	5 (3.4%)
PAIN	3 (3.7%)	2 (3.0%)	5 (3.4%)
BRONCHITIS	2 (2.5%)	3 (4.5%)	5 (3.4%)
DECREASED APPETITE	2 (2.5%)	3 (4.5%)	5 (3.4%)
ACNE	3 (3.7%)	1 (1.5%)	4 (2.7%)
DEPRESSION	3 (3.7%)	1 (1.5%)	4 (2.7%)
OTITIS MEDIA	3 (3.7%)	1 (1.5%)	4 (2.7%)
LEUKOPENIA	2 (2.5%)	2 (3.0%)	4 (2.7%)
TOOTH CARIES	1 (1.2%)	3 (4.5%)	4 (2.7%)
CHEST PAIN	3 (3.7%)	0	3 (2.0%)
DRY MOUTH	3 (3.7%)	0	3 (2.0%)
HYPERKINESIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
ANXIETY	1 (1.2%)	2 (3.0%)	3 (2.0%)
HAEMATURIA	1 (1.2%)	2 (3.0%)	3 (2.0%)
HALLUCINATIONS	1 (1.2%)	2 (3.0%)	3 (2.0%)
INCREASED APPETITE	1 (1.2%)	2 (3.0%)	3 (2.0%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
PRURITUS	1 (1.2%)	2 (3.0%)	3 (2.0%)
RASH	1 (1.2%)	2 (3.0%)	3 (2.0%)
URINARY INCONTINENCE	1 (1.2%)	2 (3.0%)	3 (2.0%)
ARTHRALGIA	2 (2.5%)	0	2 (1.4%)
FACE EDEMA	2 (2.5%)	0	2 (1.4%)
MYALGIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
PNEUMONIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
CONCENTRATION IMPAIRED	0	2 (3.0%)	2 (1.4%)
EPISTAXIS	0	2 (3.0%)	2 (1.4%)
HYPESTHESIA	0	2 (3.0%)	2 (1.4%)
SYNCOPE	0	2 (3.0%)	2 (1.4%)
TREMOR	0	2 (3.0%)	2 (1.4%)
CONSTIPATION	1 (1.2%)	0	1 (0.7%)
NEUROSIS	1 (1.2%)	0	1 (0.7%)
VERTIGO	1 (1.2%)	0	1 (0.7%)
ABNORMAL VISION	0	1 (1.5%)	1 (0.7%)
GASTROENTERITIS	0	1 (1.5%)	1 (0.7%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
TOTAL	0	0	0

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
TOTAL	3 (9.1%)	0	3 (4.8%)
DYSMENORRHEA	3 (9.1%)	0	3 (4.8%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
TOTAL	40 (76.9%)	48 (75.0%)	88 (75.9%)
HEADACHE	19 (36.5%)	17 (26.6%)	36 (31.0%)
RESPIRATORY DISORDER	6 (11.5%)	13 (20.3%)	19 (16.4%)
INFECTION	8 (15.4%)	6 (9.4%)	14 (12.1%)
NERVOUSNESS	2 (3.8%)	12 (18.8%)	14 (12.1%)
NAUSEA	6 (11.5%)	7 (10.9%)	13 (11.2%)
ABDOMINAL PAIN	5 (9.6%)	8 (12.5%)	13 (11.2%)
TRAUMA	5 (9.6%)	8 (12.5%)	13 (11.2%)
HYPERKINESIA	6 (11.5%)	6 (9.4%)	12 (10.3%)
INSOMNIA	6 (11.5%)	6 (9.4%)	12 (10.3%)
PHARYNGITIS	6 (11.5%)	5 (7.8%)	11 (9.5%)
RHINITIS	5 (9.6%)	5 (7.8%)	10 (8.6%)
HOSTILITY	2 (3.8%)	7 (10.9%)	9 (7.8%)
ALLERGIC REACTION	4 (7.7%)	4 (6.3%)	8 (6.9%)
ASTHENIA	3 (5.8%)	4 (6.3%)	7 (6.0%)
SINUSITIS	5 (9.6%)	1 (1.6%)	6 (5.2%)
DIZZINESS	3 (5.8%)	3 (4.7%)	6 (5.2%)
FEVER	3 (5.8%)	3 (4.7%)	6 (5.2%)
OTITIS MEDIA	3 (5.8%)	3 (4.7%)	6 (5.2%)
ANXIETY	2 (3.8%)	4 (6.3%)	6 (5.2%)
DECREASED APPETITE	2 (3.8%)	4 (6.3%)	6 (5.2%)
ALBUMINURIA	5 (9.6%)	0	5 (4.3%)
DIARRHEA	4 (7.7%)	1 (1.6%)	5 (4.3%)
DYSPEPSIA	2 (3.8%)	3 (4.7%)	5 (4.3%)
SOMNOLENCE	2 (3.8%)	3 (4.7%)	5 (4.3%)
WEIGHT GAIN	2 (3.8%)	3 (4.7%)	5 (4.3%)
EMOTIONAL LABILITY	3 (5.8%)	1 (1.6%)	4 (3.4%)
NEUROSIS	3 (5.8%)	1 (1.6%)	4 (3.4%)
PAIN	3 (5.8%)	1 (1.6%)	4 (3.4%)
ACNE	2 (3.8%)	2 (3.1%)	4 (3.4%)
ASTHMA	2 (3.8%)	2 (3.1%)	4 (3.4%)
AGITATION	1 (1.9%)	3 (4.7%)	4 (3.4%)
VASODILATATION	0	4 (6.3%)	4 (3.4%)
ARTHRALGIA	2 (3.8%)	1 (1.6%)	3 (2.6%)
COUGH INCREASED	2 (3.8%)	1 (1.6%)	3 (2.6%)
OTITIS EXTERNA	2 (3.8%)	1 (1.6%)	3 (2.6%)
TOOTH DISORDER	2 (3.8%)	1 (1.6%)	3 (2.6%)
VERTIGO	1 (1.9%)	2 (3.1%)	3 (2.6%)
CONTACT DERMATITIS	0	3 (4.7%)	3 (2.6%)
RASH	0	3 (4.7%)	3 (2.6%)
CONCENTRATION IMPAIRED	2 (3.8%)	0	2 (1.7%)
BACK PAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
CONSTIPATION	1 (1.9%)	1 (1.6%)	2 (1.7%)
DEPRESSION	1 (1.9%)	1 (1.6%)	2 (1.7%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
DRY MOUTH	0	2 (3.1%)	2 (1.7%)
FLATULENCE	0	2 (3.1%)	2 (1.7%)
TREMOR	0	2 (3.1%)	2 (1.7%)
URINARY INCONTINENCE	0	2 (3.1%)	2 (1.7%)
BRONCHITIS	1 (1.9%)	0	1 (0.9%)
HAEMATURIA	1 (1.9%)	0	1 (0.9%)
MYALGIA	1 (1.9%)	0	1 (0.9%)
VOMITING	1 (1.9%)	0	1 (0.9%)
ABNORMAL VISION	0	1 (1.6%)	1 (0.9%)
EPISTAXIS	0	1 (1.6%)	1 (0.9%)
GASTROENTERITIS	0	1 (1.6%)	1 (0.9%)
PNEUMONIA	0	1 (1.6%)	1 (0.9%)
SYNCOPE	0	1 (1.6%)	1 (0.9%)
TOOTH CARIES	0	1 (1.6%)	1 (0.9%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
TOTAL	0	0	0

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
TOTAL	4 (14.3%)	1 (4.5%)	5 (10.0%)
DYSMENORRHEA	4 (14.3%)	1 (4.5%)	5 (10.0%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
TOTAL	106 (79.7%)	91 (70.0%)	197 (74.9%)
HEADACHE	39 (29.3%)	27 (20.8%)	66 (25.1%)
RESPIRATORY DISORDER	22 (16.5%)	26 (20.0%)	48 (18.3%)
TRAUMA	22 (16.5%)	14 (10.8%)	36 (13.7%)
INFECTION	16 (12.0%)	17 (13.1%)	33 (12.5%)
PHARYNGITIS	18 (13.5%)	10 (7.7%)	28 (10.6%)
ABDOMINAL PAIN	15 (11.3%)	12 (9.2%)	27 (10.3%)
NAUSEA	14 (10.5%)	11 (8.5%)	25 (9.5%)
NERVOUSNESS	10 (7.5%)	13 (10.0%)	23 (8.7%)
RHINITIS	13 (9.8%)	9 (6.9%)	22 (8.4%)
INSOMNIA	10 (7.5%)	11 (8.5%)	21 (8.0%)
VOMITING	13 (9.8%)	4 (3.1%)	17 (6.5%)
ALLERGIC REACTION	11 (8.3%)	6 (4.6%)	17 (6.5%)
FEVER	11 (8.3%)	6 (4.6%)	17 (6.5%)
DYSPEPSIA	9 (6.8%)	7 (5.4%)	16 (6.1%)
WEIGHT GAIN	7 (5.3%)	9 (6.9%)	16 (6.1%)
HYPERKINESIA	8 (6.0%)	7 (5.4%)	15 (5.7%)
ASTHENIA	6 (4.5%)	9 (6.9%)	15 (5.7%)
HOSTILITY	6 (4.5%)	9 (6.9%)	15 (5.7%)
EMOTIONAL LABILITY	10 (7.5%)	4 (3.1%)	14 (5.3%)
SINUSITIS	11 (8.3%)	2 (1.5%)	13 (4.9%)
SOMNOLENCE	7 (5.3%)	6 (4.6%)	13 (4.9%)
DIARRHEA	9 (6.8%)	3 (2.3%)	12 (4.6%)
DIZZINESS	6 (4.5%)	5 (3.8%)	11 (4.2%)
DECREASED APPETITE	4 (3.0%)	7 (5.4%)	11 (4.2%)
ALBUMINURIA	8 (6.0%)	2 (1.5%)	10 (3.8%)
OTITIS MEDIA	6 (4.5%)	4 (3.1%)	10 (3.8%)
ASTHMA	5 (3.8%)	5 (3.8%)	10 (3.8%)
AGITATION	4 (3.0%)	6 (4.6%)	10 (3.8%)
COUGH INCREASED	6 (4.5%)	3 (2.3%)	9 (3.4%)
PAIN	6 (4.5%)	3 (2.3%)	9 (3.4%)
ANXIETY	3 (2.3%)	6 (4.6%)	9 (3.4%)
ACNE	5 (3.8%)	3 (2.3%)	8 (3.0%)
BACK PAIN	4 (3.0%)	4 (3.1%)	8 (3.0%)
CONTACT DERMATITIS	4 (3.0%)	4 (3.1%)	8 (3.0%)
DEPRESSION	4 (3.0%)	2 (1.5%)	6 (2.3%)
BRONCHITIS	3 (2.3%)	3 (2.3%)	6 (2.3%)
RASH	1 (0.8%)	5 (3.8%)	6 (2.3%)
ARTHRALGIA	4 (3.0%)	1 (0.8%)	5 (1.9%)
NEUROSIS	4 (3.0%)	1 (0.8%)	5 (1.9%)
DRY MOUTH	3 (2.3%)	2 (1.5%)	5 (1.9%)
TOOTH CARIES	1 (0.8%)	4 (3.1%)	5 (1.9%)
URINARY INCONTINENCE	1 (0.8%)	4 (3.1%)	5 (1.9%)
CONCENTRATION IMPAIRED	2 (1.5%)	2 (1.5%)	4 (1.5%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
HAEMATURIA	2 (1.5%)	2 (1.5%)	4 (1.5%)
LEUKOPENIA	2 (1.5%)	2 (1.5%)	4 (1.5%)
VERTIGO	2 (1.5%)	2 (1.5%)	4 (1.5%)
TREMOR	0	4 (3.1%)	4 (1.5%)
VASODILATATION	0	4 (3.1%)	4 (1.5%)
CHEST PAIN	3 (2.3%)	0	3 (1.1%)
CONSTIPATION	2 (1.5%)	1 (0.8%)	3 (1.1%)
MYALGIA	2 (1.5%)	1 (0.8%)	3 (1.1%)
OTITIS EXTERNA	2 (1.5%)	1 (0.8%)	3 (1.1%)
TOOTH DISORDER	2 (1.5%)	1 (0.8%)	3 (1.1%)
HALLUCINATIONS	1 (0.8%)	2 (1.5%)	3 (1.1%)
INCREASED APPETITE	1 (0.8%)	2 (1.5%)	3 (1.1%)
PNEUMONIA	1 (0.8%)	2 (1.5%)	3 (1.1%)
PRURITUS	1 (0.8%)	2 (1.5%)	3 (1.1%)
EPISTAXIS	0	3 (2.3%)	3 (1.1%)
SYNCOPE	0	3 (2.3%)	3 (1.1%)
FACE EDEMA	2 (1.5%)	0	2 (0.8%)
ABNORMAL VISION	0	2 (1.5%)	2 (0.8%)
FLATULENCE	0	2 (1.5%)	2 (0.8%)
GASTROENTERITIS	0	2 (1.5%)	2 (0.8%)
HYPESTHESIA	0	2 (1.5%)	2 (0.8%)

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.1X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
TOTAL	7 (11.5%)	1 (2.0%)	8 (7.1%)
DYSMENORRHEA	7 (11.5%)	1 (2.0%)	8 (7.1%)

Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=13)	Total (N=22)
Body System	Preferred Term			
TOTAL	TOTAL	3 (33.3%)	5 (38.5%)	8 (36.4%)
Nervous System	TOTAL	2 (22.2%)	2 (15.4%)	4 (18.2%)
	DEPRESSION	2 (22.2%)	1 (7.7%)	3 (13.6%)
	HYSTERIA	0	1 (7.7%)	1 (4.5%)
Body as a Whole	TOTAL	1 (11.1%)	0	1 (4.5%)
	FEVER	1 (11.1%)	0	1 (4.5%)
Respiratory System	TOTAL	1 (11.1%)	0	1 (4.5%)
	RESPIRATORY DISORDER	1 (11.1%)	0	1 (4.5%)
Cardiovascular System	TOTAL	0	1 (7.7%)	1 (4.5%)
	SYNCOPE	0	1 (7.7%)	1 (4.5%)
Digestive System	TOTAL	0	1 (7.7%)	1 (4.5%)
	NAUSEA	0	1 (7.7%)	1 (4.5%)
Special Searches	TOTAL	0	1 (7.7%)	1 (4.5%)
	PUNCTURE SITE PAIN	0	1 (7.7%)	1 (4.5%)

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=3)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	3 (42.9%)	1 (12.5%)	4 (26.7%)
Body as a Whole	TOTAL	1 (14.3%)	1 (12.5%)	2 (13.3%)
	ABDOMINAL PAIN	1 (14.3%)	0	1 (6.7%)
	HEADACHE	1 (14.3%)	0	1 (6.7%)
	INFECTION	0	1 (12.5%)	1 (6.7%)
Nervous System	TOTAL	1 (14.3%)	0	1 (6.7%)
	NEUROSIS	1 (14.3%)	0	1 (6.7%)
Respiratory System	TOTAL	1 (14.3%)	0	1 (6.7%)
	SINUSITIS	1 (14.3%)	0	1 (6.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (12.5%)	1 (6.7%)
	WEIGHT GAIN	0	1 (12.5%)	1 (6.7%)

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=5)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=3)	Total (N=6)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=21)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	6 (37.5%)	6 (28.6%)	12 (32.4%)
Nervous System	TOTAL	3 (18.8%)	2 (9.5%)	5 (13.5%)
	DEPRESSION	2 (12.5%)	1 (4.8%)	3 (8.1%)
	NEUROSIS	1 (6.3%)	0	1 (2.7%)
	HYSTERIA	0	1 (4.8%)	1 (2.7%)
Body as a Whole	TOTAL	2 (12.5%)	1 (4.8%)	3 (8.1%)
	ABDOMINAL PAIN	1 (6.3%)	0	1 (2.7%)
	FEVER	1 (6.3%)	0	1 (2.7%)
	HEADACHE	1 (6.3%)	0	1 (2.7%)
	INFECTION	0	1 (4.8%)	1 (2.7%)
Respiratory System	TOTAL	2 (12.5%)	0	2 (5.4%)
	RESPIRATORY DISORDER	1 (6.3%)	0	1 (2.7%)
	SINUSITIS	1 (6.3%)	0	1 (2.7%)
Cardiovascular System	TOTAL	0	1 (4.8%)	1 (2.7%)
	SYNCOPE	0	1 (4.8%)	1 (2.7%)
Digestive System	TOTAL	0	1 (4.8%)	1 (2.7%)
	NAUSEA	0	1 (4.8%)	1 (2.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (4.8%)	1 (2.7%)
	WEIGHT GAIN	0	1 (4.8%)	1 (2.7%)
Special Searches	TOTAL	0	1 (4.8%)	1 (2.7%)
	PUNCTURE SITE PAIN	0	1 (4.8%)	1 (2.7%)

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=15)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=6)	Total (N=14)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=9)	Total (N=20)
Body System	Preferred Term			
TOTAL	TOTAL	3 (27.3%)	2 (22.2%)	5 (25.0%)
Hemic and Lymphatic System	TOTAL	1 (9.1%)	0	1 (5.0%)
	LEUKOPENIA	1 (9.1%)	0	1 (5.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (9.1%)	0	1 (5.0%)
	WEIGHT GAIN	1 (9.1%)	0	1 (5.0%)
Nervous System	TOTAL	1 (9.1%)	2 (22.2%)	3 (15.0%)
	HOSTILITY	1 (9.1%)	0	1 (5.0%)
	SOMNOLENCE	0	1 (11.1%)	1 (5.0%)
	WITHDRAWAL SYNDROME	0	1 (11.1%)	1 (5.0%)
Musculoskeletal System	TOTAL	0	1 (11.1%)	1 (5.0%)
	MYALGIA	0	1 (11.1%)	1 (5.0%)

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=2)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=6)	Total (N=10)
Body System	Preferred Term			
TOTAL	TOTAL	2 (50.0%)	2 (33.3%)	4 (40.0%)
Cardiovascular System	TOTAL	1 (25.0%)	0	1 (10.0%)
	BRADYCARDIA	1 (25.0%)	0	1 (10.0%)
Digestive System	TOTAL	1 (25.0%)	0	1 (10.0%)
	DYSPEPSIA	1 (25.0%)	0	1 (10.0%)
Body as a Whole	TOTAL	0	1 (16.7%)	1 (10.0%)
	HEADACHE	0	1 (16.7%)	1 (10.0%)
Nervous System	TOTAL	0	1 (16.7%)	1 (10.0%)
	ABNORMAL DREAMS	0	1 (16.7%)	1 (10.0%)
	INSOMNIA	0	1 (16.7%)	1 (10.0%)

Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=15)	Placebo (N=15)	Total (N=30)
Body System	Preferred Term			
TOTAL	TOTAL	5 (33.3%)	4 (26.7%)	9 (30.0%)
Cardiovascular System	TOTAL	1 (6.7%)	0	1 (3.3%)
	BRADYCARDIA	1 (6.7%)	0	1 (3.3%)
Digestive System	TOTAL	1 (6.7%)	0	1 (3.3%)
	DYSPEPSIA	1 (6.7%)	0	1 (3.3%)
Hemic and Lymphatic System	TOTAL	1 (6.7%)	0	1 (3.3%)
	LEUKOPENIA	1 (6.7%)	0	1 (3.3%)
Metabolic and Nutritional Disorders	TOTAL	1 (6.7%)	0	1 (3.3%)
	WEIGHT GAIN	1 (6.7%)	0	1 (3.3%)
Nervous System	TOTAL	1 (6.7%)	3 (20.0%)	4 (13.3%)
	HOSTILITY	1 (6.7%)	0	1 (3.3%)
	ABNORMAL DREAMS	0	1 (6.7%)	1 (3.3%)
	INSOMNIA	0	1 (6.7%)	1 (3.3%)
	SOMNOLENCE	0	1 (6.7%)	1 (3.3%)
	WITHDRAWAL SYNDROME	0	1 (6.7%)	1 (3.3%)
Body as a Whole	TOTAL	0	1 (6.7%)	1 (3.3%)
	HEADACHE	0	1 (6.7%)	1 (3.3%)
Musculoskeletal System	TOTAL	0	1 (6.7%)	1 (3.3%)
	MYALGIA	0	1 (6.7%)	1 (3.3%)

Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=12)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=3)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	6 (30.0%)	7 (31.8%)	13 (31.0%)
Nervous System	TOTAL	3 (15.0%)	4 (18.2%)	7 (16.7%)
	DEPRESSION	2 (10.0%)	1 (4.5%)	3 (7.1%)
	HOSTILITY	1 (5.0%)	0	1 (2.4%)
	HYSTERIA	0	1 (4.5%)	1 (2.4%)
	SOMNOLENCE	0	1 (4.5%)	1 (2.4%)
	WITHDRAWAL SYNDROME	0	1 (4.5%)	1 (2.4%)
Body as a Whole	TOTAL	1 (5.0%)	0	1 (2.4%)
	FEVER	1 (5.0%)	0	1 (2.4%)
Hemic and Lymphatic System	TOTAL	1 (5.0%)	0	1 (2.4%)
	LEUKOPENIA	1 (5.0%)	0	1 (2.4%)
Metabolic and Nutritional Disorders	TOTAL	1 (5.0%)	0	1 (2.4%)
	WEIGHT GAIN	1 (5.0%)	0	1 (2.4%)
Respiratory System	TOTAL	1 (5.0%)	0	1 (2.4%)
	RESPIRATORY DISORDER	1 (5.0%)	0	1 (2.4%)
Cardiovascular System	TOTAL	0	1 (4.5%)	1 (2.4%)
	SYNCOPE	0	1 (4.5%)	1 (2.4%)
Digestive System	TOTAL	0	1 (4.5%)	1 (2.4%)
	NAUSEA	0	1 (4.5%)	1 (2.4%)
Musculoskeletal System	TOTAL	0	1 (4.5%)	1 (2.4%)
	MYALGIA	0	1 (4.5%)	1 (2.4%)
Special Searches	TOTAL	0	1 (4.5%)	1 (2.4%)
	PUNCTURE SITE PAIN	0	1 (4.5%)	1 (2.4%)

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=5)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=14)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	5 (45.5%)	3 (21.4%)	8 (32.0%)
Body as a Whole	TOTAL	1 (9.1%)	2 (14.3%)	3 (12.0%)
	HEADACHE	1 (9.1%)	1 (7.1%)	2 (8.0%)
	ABDOMINAL PAIN	1 (9.1%)	0	1 (4.0%)
	INFECTION	0	1 (7.1%)	1 (4.0%)
Cardiovascular System	TOTAL	1 (9.1%)	0	1 (4.0%)
	BRADYCARDIA	1 (9.1%)	0	1 (4.0%)
Digestive System	TOTAL	1 (9.1%)	0	1 (4.0%)
	DYSPEPSIA	1 (9.1%)	0	1 (4.0%)
Nervous System	TOTAL	1 (9.1%)	1 (7.1%)	2 (8.0%)
	NEUROSIS	1 (9.1%)	0	1 (4.0%)
	ABNORMAL DREAMS	0	1 (7.1%)	1 (4.0%)
	INSOMNIA	0	1 (7.1%)	1 (4.0%)
Respiratory System	TOTAL	1 (9.1%)	0	1 (4.0%)
	SINUSITIS	1 (9.1%)	0	1 (4.0%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (7.1%)	1 (4.0%)
	WEIGHT GAIN	0	1 (7.1%)	1 (4.0%)

Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=10)	Total (N=17)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=4)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=31)	Placebo (N=36)	Total (N=67)
Body System	Preferred Term			
TOTAL	TOTAL	11 (35.5%)	10 (27.8%)	21 (31.3%)
Nervous System	TOTAL	4 (12.9%)	5 (13.9%)	9 (13.4%)
	DEPRESSION	2 (6.5%)	1 (2.8%)	3 (4.5%)
	HOSTILITY	1 (3.2%)	0	1 (1.5%)
	NEUROSIS	1 (3.2%)	0	1 (1.5%)
	ABNORMAL DREAMS	0	1 (2.8%)	1 (1.5%)
	HYSTERIA	0	1 (2.8%)	1 (1.5%)
	INSOMNIA	0	1 (2.8%)	1 (1.5%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.5%)
	WITHDRAWAL SYNDROME	0	1 (2.8%)	1 (1.5%)
Body as a Whole	TOTAL	2 (6.5%)	2 (5.6%)	4 (6.0%)
	HEADACHE	1 (3.2%)	1 (2.8%)	2 (3.0%)
	ABDOMINAL PAIN	1 (3.2%)	0	1 (1.5%)
	FEVER	1 (3.2%)	0	1 (1.5%)
	INFECTION	0	1 (2.8%)	1 (1.5%)
Respiratory System	TOTAL	2 (6.5%)	0	2 (3.0%)
	RESPIRATORY DISORDER	1 (3.2%)	0	1 (1.5%)
	SINUSITIS	1 (3.2%)	0	1 (1.5%)
Cardiovascular System	TOTAL	1 (3.2%)	1 (2.8%)	2 (3.0%)
	BRADYCARDIA	1 (3.2%)	0	1 (1.5%)
	SYNCOPE	0	1 (2.8%)	1 (1.5%)
Digestive System	TOTAL	1 (3.2%)	1 (2.8%)	2 (3.0%)
	DYSPEPSIA	1 (3.2%)	0	1 (1.5%)
	NAUSEA	0	1 (2.8%)	1 (1.5%)
Hemic and Lymphatic System	TOTAL	1 (3.2%)	0	1 (1.5%)
	LEUKOPENIA	1 (3.2%)	0	1 (1.5%)
Metabolic and Nutritional Disorders	TOTAL	1 (3.2%)	1 (2.8%)	2 (3.0%)
	WEIGHT GAIN	1 (3.2%)	1 (2.8%)	2 (3.0%)
Musculoskeletal System	TOTAL	0	1 (2.8%)	1 (1.5%)
	MYALGIA	0	1 (2.8%)	1 (1.5%)
Special Searches	TOTAL	0	1 (2.8%)	1 (1.5%)
	PUNCTURE SITE PAIN	0	1 (2.8%)	1 (1.5%)

Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=17)	Placebo (N=27)	Total (N=44)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=9)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=9)	Placebo (N=13)	Total (N=22)
Preferred Term			
TOTAL	3 (33.3%)	5 (38.5%)	8 (36.4%)
DEPRESSION	2 (22.2%)	1 (7.7%)	3 (13.6%)
FEVER	1 (11.1%)	0	1 (4.5%)
RESPIRATORY DISORDER	1 (11.1%)	0	1 (4.5%)
HYSTERIA	0	1 (7.7%)	1 (4.5%)
NAUSEA	0	1 (7.7%)	1 (4.5%)
PUNCTURE SITE PAIN	0	1 (7.7%)	1 (4.5%)
SYNCOPE	0	1 (7.7%)	1 (4.5%)

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=5)	Placebo (N=3)	Total (N=8)
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
Preferred Term			
TOTAL	3 (42.9%)	1 (12.5%)	4 (26.7%)
ABDOMINAL PAIN	1 (14.3%)	0	1 (6.7%)
HEADACHE	1 (14.3%)	0	1 (6.7%)
NEUROSIS	1 (14.3%)	0	1 (6.7%)
SINUSITIS	1 (14.3%)	0	1 (6.7%)
INFECTION	0	1 (12.5%)	1 (6.7%)
WEIGHT GAIN	0	1 (12.5%)	1 (6.7%)

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=4)	Placebo (N=5)	Total (N=9)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=3)	Placebo (N=3)	Total (N=6)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=16)	 Placebo (N=21)	 Total (N=37)
TOTAL	6 (37.5%)	6 (28.6%)	12 (32.4%)
DEPRESSION	2 (12.5%)	1 (4.8%)	3 (8.1%)
ABDOMINAL PAIN	1 (6.3%)	0	1 (2.7%)
FEVER	1 (6.3%)	0	1 (2.7%)
HEADACHE	1 (6.3%)	0	1 (2.7%)
NEUROSIS	1 (6.3%)	0	1 (2.7%)
RESPIRATORY DISORDER	1 (6.3%)	0	1 (2.7%)
SINUSITIS	1 (6.3%)	0	1 (2.7%)
HYSTERIA	0	1 (4.8%)	1 (2.7%)
INFECTION	0	1 (4.8%)	1 (2.7%)
NAUSEA	0	1 (4.8%)	1 (2.7%)
PUNCTURE SITE PAIN	0	1 (4.8%)	1 (2.7%)
SYNCOPE	0	1 (4.8%)	1 (2.7%)
WEIGHT GAIN	0	1 (4.8%)	1 (2.7%)

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=8)	Placebo (N=15)	Total (N=23)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=8)	Placebo (N=6)	Total (N=14)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=11)	Placebo (N=9)	Total (N=20)
Preferred Term			
TOTAL	3 (27.3%)	2 (22.2%)	5 (25.0%)
HOSTILITY	1 (9.1%)	0	1 (5.0%)
LEUKOPENIA	1 (9.1%)	0	1 (5.0%)
WEIGHT GAIN	1 (9.1%)	0	1 (5.0%)
MYALGIA	0	1 (11.1%)	1 (5.0%)
SOMNOLENCE	0	1 (11.1%)	1 (5.0%)
WITHDRAWAL SYNDROME	0	1 (11.1%)	1 (5.0%)

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=5)	Placebo (N=2)	Total (N=7)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=4)	 Placebo (N=6)	 Total (N=10)
TOTAL	2 (50.0%)	2 (33.3%)	4 (40.0%)
BRADYCARDIA	1 (25.0%)	0	1 (10.0%)
DYSPEPSIA	1 (25.0%)	0	1 (10.0%)
ABNORMAL DREAMS	0	1 (16.7%)	1 (10.0%)
HEADACHE	0	1 (16.7%)	1 (10.0%)
INSOMNIA	0	1 (16.7%)	1 (10.0%)

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=15)	 Placebo (N=15)	 Total (N=30)
TOTAL	5 (33.3%)	4 (26.7%)	9 (30.0%)
BRADYCARDIA	1 (6.7%)	0	1 (3.3%)
DYSPEPSIA	1 (6.7%)	0	1 (3.3%)
HOSTILITY	1 (6.7%)	0	1 (3.3%)
LEUKOPENIA	1 (6.7%)	0	1 (3.3%)
WEIGHT GAIN	1 (6.7%)	0	1 (3.3%)
ABNORMAL DREAMS	0	1 (6.7%)	1 (3.3%)
HEADACHE	0	1 (6.7%)	1 (3.3%)
INSOMNIA	0	1 (6.7%)	1 (3.3%)
MYALGIA	0	1 (6.7%)	1 (3.3%)
SOMNOLENCE	0	1 (6.7%)	1 (3.3%)
WITHDRAWAL SYNDROME	0	1 (6.7%)	1 (3.3%)

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=12)	Total (N=21)
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=6)	Placebo (N=3)	Total (N=9)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=20)	 Placebo (N=22)	 Total (N=42)
TOTAL	6 (30.0%)	7 (31.8%)	13 (31.0%)
DEPRESSION	2 (10.0%)	1 (4.5%)	3 (7.1%)
FEVER	1 (5.0%)	0	1 (2.4%)
HOSTILITY	1 (5.0%)	0	1 (2.4%)
LEUKOPENIA	1 (5.0%)	0	1 (2.4%)
RESPIRATORY DISORDER	1 (5.0%)	0	1 (2.4%)
WEIGHT GAIN	1 (5.0%)	0	1 (2.4%)
HYSTERIA	0	1 (4.5%)	1 (2.4%)
MYALGIA	0	1 (4.5%)	1 (2.4%)
NAUSEA	0	1 (4.5%)	1 (2.4%)
PUNCTURE SITE PAIN	0	1 (4.5%)	1 (2.4%)
SOMNOLENCE	0	1 (4.5%)	1 (2.4%)
SYNCOPE	0	1 (4.5%)	1 (2.4%)
WITHDRAWAL SYNDROME	0	1 (4.5%)	1 (2.4%)

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=10)	Placebo (N=5)	Total (N=15)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=11)	 Placebo (N=14)	 Total (N=25)
TOTAL	5 (45.5%)	3 (21.4%)	8 (32.0%)
HEADACHE	1 (9.1%)	1 (7.1%)	2 (8.0%)
ABDOMINAL PAIN	1 (9.1%)	0	1 (4.0%)
BRADYCARDIA	1 (9.1%)	0	1 (4.0%)
DYSPEPSIA	1 (9.1%)	0	1 (4.0%)
NEUROSIS	1 (9.1%)	0	1 (4.0%)
SINUSITIS	1 (9.1%)	0	1 (4.0%)
ABNORMAL DREAMS	0	1 (7.1%)	1 (4.0%)
INFECTION	0	1 (7.1%)	1 (4.0%)
INSOMNIA	0	1 (7.1%)	1 (4.0%)
WEIGHT GAIN	0	1 (7.1%)	1 (4.0%)

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=7)	Placebo (N=10)	Total (N=17)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=4)	Placebo (N=4)	Total (N=8)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=31)	Placebo (N=36)	Total (N=67)
TOTAL	11 (35.5%)	10 (27.8%)	21 (31.3%)
DEPRESSION	2 (6.5%)	1 (2.8%)	3 (4.5%)
HEADACHE	1 (3.2%)	1 (2.8%)	2 (3.0%)
WEIGHT GAIN	1 (3.2%)	1 (2.8%)	2 (3.0%)
ABDOMINAL PAIN	1 (3.2%)	0	1 (1.5%)
BRADYCARDIA	1 (3.2%)	0	1 (1.5%)
DYSPEPSIA	1 (3.2%)	0	1 (1.5%)
FEVER	1 (3.2%)	0	1 (1.5%)
HOSTILITY	1 (3.2%)	0	1 (1.5%)
LEUKOPENIA	1 (3.2%)	0	1 (1.5%)
NEUROSIS	1 (3.2%)	0	1 (1.5%)
RESPIRATORY DISORDER	1 (3.2%)	0	1 (1.5%)
SINUSITIS	1 (3.2%)	0	1 (1.5%)
ABNORMAL DREAMS	0	1 (2.8%)	1 (1.5%)
HYSTERIA	0	1 (2.8%)	1 (1.5%)
INFECTION	0	1 (2.8%)	1 (1.5%)
INSOMNIA	0	1 (2.8%)	1 (1.5%)
MYALGIA	0	1 (2.8%)	1 (1.5%)
NAUSEA	0	1 (2.8%)	1 (1.5%)
PUNCTURE SITE PAIN	0	1 (2.8%)	1 (1.5%)
SOMNOLENCE	0	1 (2.8%)	1 (1.5%)
SYNCOPE	0	1 (2.8%)	1 (1.5%)
WITHDRAWAL SYNDROME	0	1 (2.8%)	1 (1.5%)

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=17)	Placebo (N=27)	Total (N=44)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=14)	Placebo (N=9)	Total (N=23)
Preferred Term			
TOTAL	0	0	0

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
TOTAL	TOTAL	32 (82.1%)	25 (69.4%)	57 (76.0%)
Body as a Whole	TOTAL	22 (56.4%)	15 (41.7%)	37 (49.3%)
	TRAUMA	11 (28.2%)	4 (11.1%)	15 (20.0%)
	INFECTION	5 (12.8%)	9 (25.0%)	14 (18.7%)
	HEADACHE	9 (23.1%)	4 (11.1%)	13 (17.3%)
	ABDOMINAL PAIN	7 (17.9%)	3 (8.3%)	10 (13.3%)
	FEVER	6 (15.4%)	2 (5.6%)	8 (10.7%)
	ALLERGIC REACTION	3 (7.7%)	2 (5.6%)	5 (6.7%)
	PAIN	3 (7.7%)	1 (2.8%)	4 (5.3%)
	ASTHENIA	2 (5.1%)	2 (5.6%)	4 (5.3%)
	BACK PAIN	0	3 (8.3%)	3 (4.0%)
	FACE EDEMA	2 (5.1%)	0	2 (2.7%)
Respiratory System	TOTAL	20 (51.3%)	13 (36.1%)	33 (44.0%)
	RESPIRATORY DISORDER	10 (25.6%)	6 (16.7%)	16 (21.3%)
	PHARYNGITIS	8 (20.5%)	4 (11.1%)	12 (16.0%)
	RHINITIS	4 (10.3%)	3 (8.3%)	7 (9.3%)
	COUGH INCREASED	3 (7.7%)	1 (2.8%)	4 (5.3%)
	SINUSITIS	3 (7.7%)	1 (2.8%)	4 (5.3%)
	EPISTAXIS	0	2 (5.6%)	2 (2.7%)
	ASTHMA	0	1 (2.8%)	1 (1.3%)
	BRONCHITIS	0	1 (2.8%)	1 (1.3%)
	PNEUMONIA	0	1 (2.8%)	1 (1.3%)
	YAWN	0	1 (2.8%)	1 (1.3%)
Digestive System	TOTAL	15 (38.5%)	12 (33.3%)	27 (36.0%)
	VOMITING	7 (17.9%)	4 (11.1%)	11 (14.7%)
	DYSPEPSIA	4 (10.3%)	3 (8.3%)	7 (9.3%)
	NAUSEA	1 (2.6%)	3 (8.3%)	4 (5.3%)
	DIARRHEA	2 (5.1%)	1 (2.8%)	3 (4.0%)
	DRY MOUTH	2 (5.1%)	0	2 (2.7%)
	DECREASED APPETITE	1 (2.6%)	1 (2.8%)	2 (2.7%)
	TOOTH CARIES	0	2 (5.6%)	2 (2.7%)
	CONSTIPATION	1 (2.6%)	0	1 (1.3%)
	INCREASED APPETITE	1 (2.6%)	0	1 (1.3%)
	STOMATITIS	1 (2.6%)	0	1 (1.3%)
	GASTROENTERITIS	0	1 (2.8%)	1 (1.3%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (2.8%)	1 (1.3%)
Nervous System	TOTAL	14 (35.9%)	12 (33.3%)	26 (34.7%)
	NERVOUSNESS	5 (12.8%)	0	5 (6.7%)
	HOSTILITY	4 (10.3%)	1 (2.8%)	5 (6.7%)
	DEPRESSION	3 (7.7%)	1 (2.8%)	4 (5.3%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
Nervous System	INSOMNIA	1 (2.6%)	3 (8.3%)	4 (5.3%)
	HYPERKINESIA	2 (5.1%)	1 (2.8%)	3 (4.0%)
	AGITATION	1 (2.6%)	2 (5.6%)	3 (4.0%)
	HALLUCINATIONS	1 (2.6%)	1 (2.8%)	2 (2.7%)
	HYPESTHESIA	0	2 (5.6%)	2 (2.7%)
	CONVULSION	1 (2.6%)	0	1 (1.3%)
	EMOTIONAL LABILITY	1 (2.6%)	0	1 (1.3%)
	NEUROSIS	1 (2.6%)	0	1 (1.3%)
	VESTIBULAR DISORDER	1 (2.6%)	0	1 (1.3%)
	ANXIETY	0	1 (2.8%)	1 (1.3%)
	CONCENTRATION IMPAIRED	0	1 (2.8%)	1 (1.3%)
	DIZZINESS	0	1 (2.8%)	1 (1.3%)
	EUPHORIA	0	1 (2.8%)	1 (1.3%)
	HYSTERIA	0	1 (2.8%)	1 (1.3%)
	PARALYSIS	0	1 (2.8%)	1 (1.3%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.3%)
	TREMOR	0	1 (2.8%)	1 (1.3%)
Skin and Appendages	TOTAL	6 (15.4%)	4 (11.1%)	10 (13.3%)
	CONTACT DERMATITIS	2 (5.1%)	1 (2.8%)	3 (4.0%)
	RASH	1 (2.6%)	2 (5.6%)	3 (4.0%)
	ACNE	2 (5.1%)	0	2 (2.7%)
	HERPES ZOSTER	1 (2.6%)	0	1 (1.3%)
	MACULOPAPULAR RASH	0	1 (2.8%)	1 (1.3%)
	PRURITUS	0	1 (2.8%)	1 (1.3%)
Metabolic and Nutritional Disorders	TOTAL	5 (12.8%)	4 (11.1%)	9 (12.0%)
	WEIGHT GAIN	4 (10.3%)	3 (8.3%)	7 (9.3%)
	DEHYDRATION	1 (2.6%)	1 (2.8%)	2 (2.7%)
Musculoskeletal System	TOTAL	3 (7.7%)	1 (2.8%)	4 (5.3%)
	ARTHRALGIA	2 (5.1%)	0	2 (2.7%)
	TENDINOUS DISORDER	1 (2.6%)	0	1 (1.3%)
	ARTHROSIS	0	1 (2.8%)	1 (1.3%)
	MYALGIA	0	1 (2.8%)	1 (1.3%)
Special Senses	TOTAL	2 (5.1%)	2 (5.6%)	4 (5.3%)
	OTITIS MEDIA	2 (5.1%)	1 (2.8%)	3 (4.0%)
	ABNORMAL VISION	0	1 (2.8%)	1 (1.3%)
Urogenital System	TOTAL	2 (5.1%)	3 (8.3%)	5 (6.7%)
	URINARY INCONTINENCE	1 (2.6%)	2 (5.6%)	3 (4.0%)
	PYURIA	1 (2.6%)	0	1 (1.3%)

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
Urogenital System	ALBUMINURIA	0	1 (2.8%)	1 (1.3%)
	CYSTITIS	0	1 (2.8%)	1 (1.3%)
	HAEMATURIA	0	1 (2.8%)	1 (1.3%)
Hemic and Lymphatic System	TOTAL	1 (2.6%)	2 (5.6%)	3 (4.0%)
	LEUKOPENIA	1 (2.6%)	2 (5.6%)	3 (4.0%)
	ANEMIA	0	1 (2.8%)	1 (1.3%)
Cardiovascular System	TOTAL	0	3 (8.3%)	3 (4.0%)
	BUNDLE BRANCH BLOCK	0	1 (2.8%)	1 (1.3%)
	MIGRAINE	0	1 (2.8%)	1 (1.3%)
	SYNCOPE	0	1 (2.8%)	1 (1.3%)
Special Searches	TOTAL	0	1 (2.8%)	1 (1.3%)
	PUNCTURE SITE PAIN	0	1 (2.8%)	1 (1.3%)

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	22 (78.6%)	30 (83.3%)	52 (81.3%)
Body as a Whole	TOTAL	14 (50.0%)	18 (50.0%)	32 (50.0%)
	HEADACHE	9 (32.1%)	8 (22.2%)	17 (26.6%)
	TRAUMA	4 (14.3%)	4 (11.1%)	8 (12.5%)
	ABDOMINAL PAIN	3 (10.7%)	5 (13.9%)	8 (12.5%)
	INFECTION	3 (10.7%)	4 (11.1%)	7 (10.9%)
	FEVER	3 (10.7%)	1 (2.8%)	4 (6.3%)
	PAIN	2 (7.1%)	1 (2.8%)	3 (4.7%)
	ABSCESS	1 (3.6%)	0	1 (1.6%)
	BACK PAIN	1 (3.6%)	0	1 (1.6%)
	ALLERGIC REACTION	0	1 (2.8%)	1 (1.6%)
	SPINA BIFIDA	0	1 (2.8%)	1 (1.6%)
Digestive System	TOTAL	9 (32.1%)	6 (16.7%)	15 (23.4%)
	NAUSEA	5 (17.9%)	1 (2.8%)	6 (9.4%)
	DECREASED APPETITE	2 (7.1%)	2 (5.6%)	4 (6.3%)
	DIARRHEA	3 (10.7%)	0	3 (4.7%)
	DYSPEPSIA	2 (7.1%)	1 (2.8%)	3 (4.7%)
	GINGIVITIS	1 (3.6%)	1 (2.8%)	2 (3.1%)
	TOOTH DISORDER	1 (3.6%)	0	1 (1.6%)
	VOMITING	1 (3.6%)	0	1 (1.6%)
	FLATULENCE	0	1 (2.8%)	1 (1.6%)
	GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
	TOOTH CARIES	0	1 (2.8%)	1 (1.6%)
Nervous System	TOTAL	8 (28.6%)	22 (61.1%)	30 (46.9%)
	NERVOUSNESS	1 (3.6%)	9 (25.0%)	10 (15.6%)
	HYPERKINESIA	5 (17.9%)	4 (11.1%)	9 (14.1%)
	INSOMNIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
	HOSTILITY	1 (3.6%)	4 (11.1%)	5 (7.8%)
	ANXIETY	1 (3.6%)	3 (8.3%)	4 (6.3%)
	DIZZINESS	1 (3.6%)	2 (5.6%)	3 (4.7%)
	SOMNOLENCE	1 (3.6%)	2 (5.6%)	3 (4.7%)
	AGITATION	1 (3.6%)	1 (2.8%)	2 (3.1%)
	MYOCLONUS	1 (3.6%)	1 (2.8%)	2 (3.1%)
	VERTIGO	0	2 (5.6%)	2 (3.1%)
	CONCENTRATION IMPAIRED	1 (3.6%)	0	1 (1.6%)
	DEPRESSION	1 (3.6%)	0	1 (1.6%)
	EMOTIONAL LABILITY	1 (3.6%)	0	1 (1.6%)
	NEUROSIS	1 (3.6%)	0	1 (1.6%)
	DYSKINESIA	0	1 (2.8%)	1 (1.6%)
	LACK OF EMOTION	0	1 (2.8%)	1 (1.6%)
	MANIC REACTION	0	1 (2.8%)	1 (1.6%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Body System	Preferred Term			
Nervous System	PSYCHOSIS	0	1 (2.8%)	1 (1.6%)
	TREMOR	0	1 (2.8%)	1 (1.6%)
Respiratory System	TOTAL	8 (28.6%)	10 (27.8%)	18 (28.1%)
	RESPIRATORY DISORDER	2 (7.1%)	8 (22.2%)	10 (15.6%)
	PHARYNGITIS	5 (17.9%)	3 (8.3%)	8 (12.5%)
	RHINITIS	4 (14.3%)	4 (11.1%)	8 (12.5%)
	SINUSITIS	3 (10.7%)	1 (2.8%)	4 (6.3%)
	COUGH INCREASED	2 (7.1%)	1 (2.8%)	3 (4.7%)
	ASTHMA	1 (3.6%)	0	1 (1.6%)
Special Senses	TOTAL	5 (17.9%)	4 (11.1%)	9 (14.1%)
	OTITIS MEDIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
	OTITIS EXTERNA	2 (7.1%)	1 (2.8%)	3 (4.7%)
	EAR PAIN	1 (3.6%)	1 (2.8%)	2 (3.1%)
Hemic and Lymphatic System	TOTAL	2 (7.1%)	0	2 (3.1%)
	ANEMIA	1 (3.6%)	0	1 (1.6%)
	PURPURA	1 (3.6%)	0	1 (1.6%)
Skin and Appendages	TOTAL	2 (7.1%)	3 (8.3%)	5 (7.8%)
	CONTACT DERMATITIS	0	2 (5.6%)	2 (3.1%)
	RASH	0	2 (5.6%)	2 (3.1%)
	ACNE	1 (3.6%)	0	1 (1.6%)
	MACULOPAPULAR RASH	1 (3.6%)	0	1 (1.6%)
	FUNGAL DERMATITIS	0	1 (2.8%)	1 (1.6%)
	HERPES SIMPLEX	0	1 (2.8%)	1 (1.6%)
Urogenital System	TOTAL	2 (7.1%)	2 (5.6%)	4 (6.3%)
	ALBUMINURIA	2 (7.1%)	0	2 (3.1%)
	URINARY INCONTINENCE	0	2 (5.6%)	2 (3.1%)
	GLYCOSURIA	1 (3.6%)	0	1 (1.6%)
Cardiovascular System	TOTAL	1 (3.6%)	3 (8.3%)	4 (6.3%)
	VASODILATATION	0	3 (8.3%)	3 (4.7%)
	HAEMATOMA	1 (3.6%)	0	1 (1.6%)
Musculoskeletal System	TOTAL	1 (3.6%)	0	1 (1.6%)
	MYALGIA	1 (3.6%)	0	1 (1.6%)
Metabolic and Nutritional Disorders	TOTAL	0	3 (8.3%)	3 (4.7%)
	WEIGHT GAIN	0	3 (8.3%)	3 (4.7%)

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	1 (6.3%)	1 (7.7%)	2 (6.9%)
Urogenital System	TOTAL	1 (6.3%)	1 (7.7%)	2 (6.9%)
	DYSMENORRHEA	1 (6.3%)	1 (7.7%)	2 (6.9%)
	UTERUS DISORDERS	0	1 (7.7%)	1 (3.4%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
TOTAL	TOTAL	54 (80.6%)	55 (76.4%)	109 (78.4%)
Body as a Whole	TOTAL	36 (53.7%)	33 (45.8%)	69 (49.6%)
	HEADACHE	18 (26.9%)	12 (16.7%)	30 (21.6%)
	TRAUMA	15 (22.4%)	8 (11.1%)	23 (16.5%)
	INFECTION	8 (11.9%)	13 (18.1%)	21 (15.1%)
	ABDOMINAL PAIN	10 (14.9%)	8 (11.1%)	18 (12.9%)
	FEVER	9 (13.4%)	3 (4.2%)	12 (8.6%)
	PAIN	5 (7.5%)	2 (2.8%)	7 (5.0%)
	ALLERGIC REACTION	3 (4.5%)	3 (4.2%)	6 (4.3%)
	ASTHENIA	2 (3.0%)	2 (2.8%)	4 (2.9%)
	BACK PAIN	1 (1.5%)	3 (4.2%)	4 (2.9%)
	FACE EDEMA	2 (3.0%)	0	2 (1.4%)
	ABSCESS	1 (1.5%)	0	1 (0.7%)
	SPINA BIFIDA	0	1 (1.4%)	1 (0.7%)
Respiratory System	TOTAL	28 (41.8%)	23 (31.9%)	51 (36.7%)
	RESPIRATORY DISORDER	12 (17.9%)	14 (19.4%)	26 (18.7%)
	PHARYNGITIS	13 (19.4%)	7 (9.7%)	20 (14.4%)
	RHINITIS	8 (11.9%)	7 (9.7%)	15 (10.8%)
	SINUSITIS	6 (9.0%)	2 (2.8%)	8 (5.8%)
	COUGH INCREASED	5 (7.5%)	2 (2.8%)	7 (5.0%)
	ASTHMA	1 (1.5%)	1 (1.4%)	2 (1.4%)
	EPISTAXIS	0	2 (2.8%)	2 (1.4%)
	BRONCHITIS	0	1 (1.4%)	1 (0.7%)
	PNEUMONIA	0	1 (1.4%)	1 (0.7%)
	YAWN	0	1 (1.4%)	1 (0.7%)
Digestive System	TOTAL	24 (35.8%)	18 (25.0%)	42 (30.2%)
	VOMITING	8 (11.9%)	4 (5.6%)	12 (8.6%)
	DYSPEPSIA	6 (9.0%)	4 (5.6%)	10 (7.2%)
	NAUSEA	6 (9.0%)	4 (5.6%)	10 (7.2%)
	DIARRHEA	5 (7.5%)	1 (1.4%)	6 (4.3%)
	DECREASED APPETITE	3 (4.5%)	3 (4.2%)	6 (4.3%)
	TOOTH CARIES	0	3 (4.2%)	3 (2.2%)
	DRY MOUTH	2 (3.0%)	0	2 (1.4%)
	GINGIVITIS	1 (1.5%)	1 (1.4%)	2 (1.4%)
	GASTROENTERITIS	0	2 (2.8%)	2 (1.4%)
	CONSTIPATION	1 (1.5%)	0	1 (0.7%)
	INCREASED APPETITE	1 (1.5%)	0	1 (0.7%)
	STOMATITIS	1 (1.5%)	0	1 (0.7%)
	TOOTH DISORDER	1 (1.5%)	0	1 (0.7%)
	FLATULENCE	0	1 (1.4%)	1 (0.7%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.4%)	1 (0.7%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
Nervous System	TOTAL	22 (32.8%)	34 (47.2%)	56 (40.3%)
	NERVOUSNESS	6 (9.0%)	9 (12.5%)	15 (10.8%)
	HYPERKINESIA	7 (10.4%)	5 (6.9%)	12 (8.6%)
	HOSTILITY	5 (7.5%)	5 (6.9%)	10 (7.2%)
	INSOMNIA	4 (6.0%)	5 (6.9%)	9 (6.5%)
	DEPRESSION	4 (6.0%)	1 (1.4%)	5 (3.6%)
	AGITATION	2 (3.0%)	3 (4.2%)	5 (3.6%)
	ANXIETY	1 (1.5%)	4 (5.6%)	5 (3.6%)
	DIZZINESS	1 (1.5%)	3 (4.2%)	4 (2.9%)
	SOMNOLENCE	1 (1.5%)	3 (4.2%)	4 (2.9%)
	EMOTIONAL LABILITY	2 (3.0%)	0	2 (1.4%)
	NEUROSIS	2 (3.0%)	0	2 (1.4%)
	CONCENTRATION IMPAIRED	1 (1.5%)	1 (1.4%)	2 (1.4%)
	HALLUCINATIONS	1 (1.5%)	1 (1.4%)	2 (1.4%)
	MYOCLONUS	1 (1.5%)	1 (1.4%)	2 (1.4%)
	HYPESTHESIA	0	2 (2.8%)	2 (1.4%)
	TREMOR	0	2 (2.8%)	2 (1.4%)
	VERTIGO	0	2 (2.8%)	2 (1.4%)
	CONVULSION	1 (1.5%)	0	1 (0.7%)
	VESTIBULAR DISORDER	1 (1.5%)	0	1 (0.7%)
	DYSKINESIA	0	1 (1.4%)	1 (0.7%)
	EUPHORIA	0	1 (1.4%)	1 (0.7%)
	HYSTERIA	0	1 (1.4%)	1 (0.7%)
	LACK OF EMOTION	0	1 (1.4%)	1 (0.7%)
	MANIC REACTION	0	1 (1.4%)	1 (0.7%)
	PARALYSIS	0	1 (1.4%)	1 (0.7%)
	PSYCHOSIS	0	1 (1.4%)	1 (0.7%)
Skin and Appendages	TOTAL	8 (11.9%)	7 (9.7%)	15 (10.8%)
	CONTACT DERMATITIS	2 (3.0%)	3 (4.2%)	5 (3.6%)
	RASH	1 (1.5%)	4 (5.6%)	5 (3.6%)
	ACNE	3 (4.5%)	0	3 (2.2%)
	MACULOPAPULAR RASH	1 (1.5%)	1 (1.4%)	2 (1.4%)
	HERPES ZOSTER	1 (1.5%)	0	1 (0.7%)
	FUNGAL DERMATITIS	0	1 (1.4%)	1 (0.7%)
	HERPES SIMPLEX	0	1 (1.4%)	1 (0.7%)
	PRURITUS	0	1 (1.4%)	1 (0.7%)
Special Senses	TOTAL	7 (10.4%)	6 (8.3%)	13 (9.4%)
	OTITIS MEDIA	5 (7.5%)	3 (4.2%)	8 (5.8%)
	OTITIS EXTERNA	2 (3.0%)	1 (1.4%)	3 (2.2%)
	EAR PAIN	1 (1.5%)	1 (1.4%)	2 (1.4%)
	ABNORMAL VISION	0	1 (1.4%)	1 (0.7%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=67)	 Placebo (N=72)	 Total (N=139)
Metabolic and Nutritional Disorders	TOTAL	5 (7.5%)	7 (9.7%)	12 (8.6%)
	WEIGHT GAIN	4 (6.0%)	6 (8.3%)	10 (7.2%)
	DEHYDRATION	1 (1.5%)	1 (1.4%)	2 (1.4%)
Musculoskeletal System	TOTAL	4 (6.0%)	1 (1.4%)	5 (3.6%)
	ARTHRALGIA	2 (3.0%)	0	2 (1.4%)
	MYALGIA	1 (1.5%)	1 (1.4%)	2 (1.4%)
	TENDINOUS DISORDER	1 (1.5%)	0	1 (0.7%)
	ARTHROSIS	0	1 (1.4%)	1 (0.7%)
Urogenital System	TOTAL	4 (6.0%)	5 (6.9%)	9 (6.5%)
	URINARY INCONTINENCE	1 (1.5%)	4 (5.6%)	5 (3.6%)
	ALBUMINURIA	2 (3.0%)	1 (1.4%)	3 (2.2%)
	GLYCOSURIA	1 (1.5%)	0	1 (0.7%)
	PYURIA	1 (1.5%)	0	1 (0.7%)
	CYSTITIS	0	1 (1.4%)	1 (0.7%)
	HAEMATURIA	0	1 (1.4%)	1 (0.7%)
Hemic and Lymphatic System	TOTAL	3 (4.5%)	2 (2.8%)	5 (3.6%)
	LEUKOPENIA	1 (1.5%)	2 (2.8%)	3 (2.2%)
	ANEMIA	1 (1.5%)	1 (1.4%)	2 (1.4%)
	PURPURA	1 (1.5%)	0	1 (0.7%)
Cardiovascular System	TOTAL	1 (1.5%)	6 (8.3%)	7 (5.0%)
	VASODILATATION	0	3 (4.2%)	3 (2.2%)
	HAEMATOMA	1 (1.5%)	0	1 (0.7%)
	BUNDLE BRANCH BLOCK	0	1 (1.4%)	1 (0.7%)
	MIGRAINE	0	1 (1.4%)	1 (0.7%)
	SYNCOPE	0	1 (1.4%)	1 (0.7%)
Special Searches	TOTAL	0	1 (1.4%)	1 (0.7%)
	PUNCTURE SITE PAIN	0	1 (1.4%)	1 (0.7%)

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	1 (2.9%)	1 (3.7%)	2 (3.2%)
Urogenital System	TOTAL	1 (2.9%)	1 (3.7%)	2 (3.2%)
	DYSMENORRHEA	1 (2.9%)	1 (3.7%)	2 (3.2%)
	UTERUS DISORDERS	0	1 (3.7%)	1 (1.6%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Body System	Preferred Term			
TOTAL	TOTAL	34 (81.0%)	19 (63.3%)	53 (73.6%)
Body as a Whole	TOTAL	22 (52.4%)	9 (30.0%)	31 (43.1%)
	HEADACHE	11 (26.2%)	6 (20.0%)	17 (23.6%)
	TRAUMA	6 (14.3%)	2 (6.7%)	8 (11.1%)
	INFECTION	3 (7.1%)	2 (6.7%)	5 (6.9%)
	ALLERGIC REACTION	4 (9.5%)	0	4 (5.6%)
	ABDOMINAL PAIN	3 (7.1%)	1 (3.3%)	4 (5.6%)
	FEVER	3 (7.1%)	1 (3.3%)	4 (5.6%)
	ASTHENIA	1 (2.4%)	3 (10.0%)	4 (5.6%)
	BACK PAIN	3 (7.1%)	0	3 (4.2%)
	CHEST PAIN	3 (7.1%)	0	3 (4.2%)
	MALAISE	1 (2.4%)	0	1 (1.4%)
	PAIN	0	1 (3.3%)	1 (1.4%)
Nervous System	TOTAL	19 (45.2%)	11 (36.7%)	30 (41.7%)
	EMOTIONAL LABILITY	6 (14.3%)	3 (10.0%)	9 (12.5%)
	SOMNOLENCE	5 (11.9%)	3 (10.0%)	8 (11.1%)
	INSOMNIA	3 (7.1%)	2 (6.7%)	5 (6.9%)
	DIZZINESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
	NERVOUSNESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
	AGITATION	2 (4.8%)	1 (3.3%)	3 (4.2%)
	ANXIETY	1 (2.4%)	1 (3.3%)	2 (2.8%)
	HOSTILITY	1 (2.4%)	1 (3.3%)	2 (2.8%)
	WITHDRAWAL SYNDROME	0	2 (6.7%)	2 (2.8%)
	DEPRESSION	1 (2.4%)	0	1 (1.4%)
	LACK OF EMOTION	1 (2.4%)	0	1 (1.4%)
	PARESTHESIA	1 (2.4%)	0	1 (1.4%)
	VERTIGO	1 (2.4%)	0	1 (1.4%)
	CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.4%)
	HALLUCINATIONS	0	1 (3.3%)	1 (1.4%)
	LIBIDO DECREASED	0	1 (3.3%)	1 (1.4%)
	TREMOR	0	1 (3.3%)	1 (1.4%)
Respiratory System	TOTAL	16 (38.1%)	9 (30.0%)	25 (34.7%)
	RESPIRATORY DISORDER	7 (16.7%)	7 (23.3%)	14 (19.4%)
	PHARYNGITIS	4 (9.5%)	1 (3.3%)	5 (6.9%)
	RHINITIS	4 (9.5%)	1 (3.3%)	5 (6.9%)
	ASTHMA	3 (7.1%)	2 (6.7%)	5 (6.9%)
	BRONCHITIS	2 (4.8%)	2 (6.7%)	4 (5.6%)
	SINUSITIS	3 (7.1%)	0	3 (4.2%)
	COUGH INCREASED	1 (2.4%)	1 (3.3%)	2 (2.8%)
	DYSPNEA	1 (2.4%)	0	1 (1.4%)
	PNEUMONIA	1 (2.4%)	0	1 (1.4%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Body System	Preferred Term			
Digestive System	TOTAL	13 (31.0%)	7 (23.3%)	20 (27.8%)
	NAUSEA	7 (16.7%)	2 (6.7%)	9 (12.5%)
	VOMITING	5 (11.9%)	0	5 (6.9%)
	DIARRHEA	3 (7.1%)	1 (3.3%)	4 (5.6%)
	DYSPEPSIA	3 (7.1%)	1 (3.3%)	4 (5.6%)
	DECREASED APPETITE	1 (2.4%)	2 (6.7%)	3 (4.2%)
	TOOTH CARIES	1 (2.4%)	1 (3.3%)	2 (2.8%)
	INCREASED APPETITE	0	2 (6.7%)	2 (2.8%)
	DRY MOUTH	1 (2.4%)	0	1 (1.4%)
	GASTRITIS	1 (2.4%)	0	1 (1.4%)
	HEMATEMESIS	1 (2.4%)	0	1 (1.4%)
	GASTROINTESTINAL DISORDER	0	1 (3.3%)	1 (1.4%)
Skin and Appendages	TOTAL	5 (11.9%)	2 (6.7%)	7 (9.7%)
	CONTACT DERMATITIS	2 (4.8%)	0	2 (2.8%)
	ACNE	1 (2.4%)	1 (3.3%)	2 (2.8%)
	PRURITUS	1 (2.4%)	1 (3.3%)	2 (2.8%)
	FUNGAL DERMATITIS	1 (2.4%)	0	1 (1.4%)
	FURUNCULOSIS	1 (2.4%)	0	1 (1.4%)
Urogenital System	TOTAL	4 (9.5%)	1 (3.3%)	5 (6.9%)
	ALBUMINURIA	3 (7.1%)	1 (3.3%)	4 (5.6%)
	HAEMATURIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
	URINARY TRACT INFECTION	1 (2.4%)	0	1 (1.4%)
Hemic and Lymphatic System	TOTAL	3 (7.1%)	0	3 (4.2%)
	LEUKOPENIA	2 (4.8%)	0	2 (2.8%)
	LYMPHADENOPATHY	1 (2.4%)	0	1 (1.4%)
Metabolic and Nutritional Disorders	TOTAL	3 (7.1%)	3 (10.0%)	6 (8.3%)
	WEIGHT GAIN	2 (4.8%)	3 (10.0%)	5 (6.9%)
	WEIGHT LOSS	1 (2.4%)	0	1 (1.4%)
Musculoskeletal System	TOTAL	1 (2.4%)	1 (3.3%)	2 (2.8%)
	MYALGIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
Special Senses	TOTAL	1 (2.4%)	0	1 (1.4%)
	OTITIS MEDIA	1 (2.4%)	0	1 (1.4%)
Cardiovascular System	TOTAL	0	1 (3.3%)	1 (1.4%)
	SYNCOPE	0	1 (3.3%)	1 (1.4%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	3 (21.4%)	2 (13.3%)	5 (17.2%)
Urogenital System	TOTAL	3 (21.4%)	2 (13.3%)	5 (17.2%)
	DYSMENORRHEA	3 (21.4%)	0	3 (10.3%)
	FEMALE GENITAL DISORDERS	0	1 (6.7%)	1 (3.4%)
	MENSTRUAL DISORDER	0	1 (6.7%)	1 (3.4%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	18 (75.0%)	19 (67.9%)	37 (71.2%)
Body as a Whole	TOTAL	14 (58.3%)	15 (53.6%)	29 (55.8%)
	HEADACHE	10 (41.7%)	9 (32.1%)	19 (36.5%)
	INFECTION	5 (20.8%)	3 (10.7%)	8 (15.4%)
	ALLERGIC REACTION	4 (16.7%)	3 (10.7%)	7 (13.5%)
	ASTHENIA	3 (12.5%)	4 (14.3%)	7 (13.5%)
	ABDOMINAL PAIN	3 (12.5%)	3 (10.7%)	6 (11.5%)
	TRAUMA	1 (4.2%)	4 (14.3%)	5 (9.6%)
	FEVER	0	2 (7.1%)	2 (3.8%)
	ABNORMAL LABORATORY VALUE	1 (4.2%)	0	1 (1.9%)
	PAIN	1 (4.2%)	0	1 (1.9%)
	BACK PAIN	0	1 (3.6%)	1 (1.9%)
Nervous System	TOTAL	9 (37.5%)	10 (35.7%)	19 (36.5%)
	INSOMNIA	3 (12.5%)	5 (17.9%)	8 (15.4%)
	NEUROSIS	3 (12.5%)	1 (3.6%)	4 (7.7%)
	HOSTILITY	1 (4.2%)	3 (10.7%)	4 (7.7%)
	NERVOUSNESS	1 (4.2%)	3 (10.7%)	4 (7.7%)
	DIZZINESS	2 (8.3%)	1 (3.6%)	3 (5.8%)
	EMOTIONAL LABILITY	2 (8.3%)	1 (3.6%)	3 (5.8%)
	ABNORMAL DREAMS	1 (4.2%)	2 (7.1%)	3 (5.8%)
	HYPERKINESIA	1 (4.2%)	2 (7.1%)	3 (5.8%)
	ANXIETY	1 (4.2%)	1 (3.6%)	2 (3.8%)
	SOMNOLENCE	1 (4.2%)	1 (3.6%)	2 (3.8%)
	AGITATION	0	2 (7.1%)	2 (3.8%)
	CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.9%)
	MANIC REACTION	1 (4.2%)	0	1 (1.9%)
	VERTIGO	1 (4.2%)	0	1 (1.9%)
	DEPRESSION	0	1 (3.6%)	1 (1.9%)
	TREMOR	0	1 (3.6%)	1 (1.9%)
Respiratory System	TOTAL	9 (37.5%)	8 (28.6%)	17 (32.7%)
	RESPIRATORY DISORDER	4 (16.7%)	5 (17.9%)	9 (17.3%)
	SINUSITIS	3 (12.5%)	0	3 (5.8%)
	ASTHMA	1 (4.2%)	2 (7.1%)	3 (5.8%)
	PHARYNGITIS	1 (4.2%)	2 (7.1%)	3 (5.8%)
	RHINITIS	1 (4.2%)	1 (3.6%)	2 (3.8%)
	BRONCHITIS	1 (4.2%)	0	1 (1.9%)
	PLEURA DISORDER	1 (4.2%)	0	1 (1.9%)
	EPISTAXIS	0	1 (3.6%)	1 (1.9%)
	PNEUMONIA	0	1 (3.6%)	1 (1.9%)
Digestive System	TOTAL	4 (16.7%)	11 (39.3%)	15 (28.8%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
Digestive System	NAUSEA	1 (4.2%)	6 (21.4%)	7 (13.5%)
	DYSPEPSIA	1 (4.2%)	2 (7.1%)	3 (5.8%)
	CONSTIPATION	1 (4.2%)	1 (3.6%)	2 (3.8%)
	DIARRHEA	1 (4.2%)	1 (3.6%)	2 (3.8%)
	TOOTH DISORDER	1 (4.2%)	1 (3.6%)	2 (3.8%)
	DECREASED APPETITE	0	2 (7.1%)	2 (3.8%)
	DRY MOUTH	0	2 (7.1%)	2 (3.8%)
	FLATULENCE	0	1 (3.6%)	1 (1.9%)
	ULCERATIVE STOMATITIS	0	1 (3.6%)	1 (1.9%)
Urogenital System	TOTAL	4 (16.7%)	0	4 (7.7%)
	ALBUMINURIA	3 (12.5%)	0	3 (5.8%)
	DYSURIA	1 (4.2%)	0	1 (1.9%)
	HAEMATURIA	1 (4.2%)	0	1 (1.9%)
Musculoskeletal System	TOTAL	3 (12.5%)	1 (3.6%)	4 (7.7%)
	ARTHRALGIA	2 (8.3%)	1 (3.6%)	3 (5.8%)
	ARTHROSIS	1 (4.2%)	0	1 (1.9%)
Metabolic and Nutritional Disorders	TOTAL	2 (8.3%)	1 (3.6%)	3 (5.8%)
	WEIGHT GAIN	2 (8.3%)	0	2 (3.8%)
	WEIGHT LOSS	0	1 (3.6%)	1 (1.9%)
Special Senses	TOTAL	2 (8.3%)	3 (10.7%)	5 (9.6%)
	BLEPHARITIS	1 (4.2%)	0	1 (1.9%)
	EYE PAIN	1 (4.2%)	0	1 (1.9%)
	ABNORMAL VISION	0	1 (3.6%)	1 (1.9%)
	OTITIS MEDIA	0	1 (3.6%)	1 (1.9%)
	PHOTOPHOBIA	0	1 (3.6%)	1 (1.9%)
Cardiovascular System	TOTAL	1 (4.2%)	2 (7.1%)	3 (5.8%)
	BRADYCARDIA	1 (4.2%)	0	1 (1.9%)
	SYNCOPE	0	1 (3.6%)	1 (1.9%)
	VASODILATATION	0	1 (3.6%)	1 (1.9%)
Skin and Appendages	TOTAL	1 (4.2%)	4 (14.3%)	5 (9.6%)
	ACNE	1 (4.2%)	2 (7.1%)	3 (5.8%)
	CONTACT DERMATITIS	0	1 (3.6%)	1 (1.9%)
	RASH	0	1 (3.6%)	1 (1.9%)
	SWEATING	0	1 (3.6%)	1 (1.9%)
	URTICARIA	0	1 (3.6%)	1 (1.9%)
Hemic and Lymphatic System	TOTAL	0	2 (7.1%)	2 (3.8%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
Hemic and Lymphatic System	EOSINOPHILIA	0	1 (3.6%)	1 (1.9%)
	LEUKOCYTOSIS	0	1 (3.6%)	1 (1.9%)
	MONOCYTOSIS	0	1 (3.6%)	1 (1.9%)

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	3 (25.0%)	0	3 (14.3%)
Urogenital System	TOTAL	3 (25.0%)	0	3 (14.3%)
	DYSMENORRHEA	3 (25.0%)	0	3 (14.3%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
TOTAL	TOTAL	52 (78.8%)	38 (65.5%)	90 (72.6%)
Body as a Whole	TOTAL	36 (54.5%)	24 (41.4%)	60 (48.4%)
	HEADACHE	21 (31.8%)	15 (25.9%)	36 (29.0%)
	INFECTION	8 (12.1%)	5 (8.6%)	13 (10.5%)
	TRAUMA	7 (10.6%)	6 (10.3%)	13 (10.5%)
	ALLERGIC REACTION	8 (12.1%)	3 (5.2%)	11 (8.9%)
	ASTHENIA	4 (6.1%)	7 (12.1%)	11 (8.9%)
	ABDOMINAL PAIN	6 (9.1%)	4 (6.9%)	10 (8.1%)
	FEVER	3 (4.5%)	3 (5.2%)	6 (4.8%)
	BACK PAIN	3 (4.5%)	1 (1.7%)	4 (3.2%)
	CHEST PAIN	3 (4.5%)	0	3 (2.4%)
	PAIN	1 (1.5%)	1 (1.7%)	2 (1.6%)
	ABNORMAL LABORATORY VALUE	1 (1.5%)	0	1 (0.8%)
	MALAISE	1 (1.5%)	0	1 (0.8%)
Nervous System	TOTAL	28 (42.4%)	21 (36.2%)	49 (39.5%)
	INSOMNIA	6 (9.1%)	7 (12.1%)	13 (10.5%)
	EMOTIONAL LABILITY	8 (12.1%)	4 (6.9%)	12 (9.7%)
	SOMNOLENCE	6 (9.1%)	4 (6.9%)	10 (8.1%)
	NERVOUSNESS	4 (6.1%)	4 (6.9%)	8 (6.5%)
	DIZZINESS	5 (7.6%)	2 (3.4%)	7 (5.6%)
	HOSTILITY	2 (3.0%)	4 (6.9%)	6 (4.8%)
	AGITATION	2 (3.0%)	3 (5.2%)	5 (4.0%)
	NEUROSIS	3 (4.5%)	1 (1.7%)	4 (3.2%)
	ANXIETY	2 (3.0%)	2 (3.4%)	4 (3.2%)
	ABNORMAL DREAMS	1 (1.5%)	2 (3.4%)	3 (2.4%)
	HYPERKINESIA	1 (1.5%)	2 (3.4%)	3 (2.4%)
	VERTIGO	2 (3.0%)	0	2 (1.6%)
	CONCENTRATION IMPAIRED	1 (1.5%)	1 (1.7%)	2 (1.6%)
	DEPRESSION	1 (1.5%)	1 (1.7%)	2 (1.6%)
	TREMOR	0	2 (3.4%)	2 (1.6%)
	WITHDRAWAL SYNDROME	0	2 (3.4%)	2 (1.6%)
	LACK OF EMOTION	1 (1.5%)	0	1 (0.8%)
	MANIC REACTION	1 (1.5%)	0	1 (0.8%)
	PARESTHESIA	1 (1.5%)	0	1 (0.8%)
	HALLUCINATIONS	0	1 (1.7%)	1 (0.8%)
	LIBIDO DECREASED	0	1 (1.7%)	1 (0.8%)
Respiratory System	TOTAL	25 (37.9%)	17 (29.3%)	42 (33.9%)
	RESPIRATORY DISORDER	11 (16.7%)	12 (20.7%)	23 (18.5%)
	PHARYNGITIS	5 (7.6%)	3 (5.2%)	8 (6.5%)
	ASTHMA	4 (6.1%)	4 (6.9%)	8 (6.5%)
	RHINITIS	5 (7.6%)	2 (3.4%)	7 (5.6%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
Respiratory System	SINUSITIS	6 (9.1%)	0	6 (4.8%)
	BRONCHITIS	3 (4.5%)	2 (3.4%)	5 (4.0%)
	COUGH INCREASED	1 (1.5%)	1 (1.7%)	2 (1.6%)
	PNEUMONIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
	DYSPNEA	1 (1.5%)	0	1 (0.8%)
	PLEURA DISORDER	1 (1.5%)	0	1 (0.8%)
	EPISTAXIS	0	1 (1.7%)	1 (0.8%)
Digestive System	TOTAL	17 (25.8%)	18 (31.0%)	35 (28.2%)
	NAUSEA	8 (12.1%)	8 (13.8%)	16 (12.9%)
	DYSPEPSIA	4 (6.1%)	3 (5.2%)	7 (5.6%)
	DIARRHEA	4 (6.1%)	2 (3.4%)	6 (4.8%)
	VOMITING	5 (7.6%)	0	5 (4.0%)
	DECREASED APPETITE	1 (1.5%)	4 (6.9%)	5 (4.0%)
	DRY MOUTH	1 (1.5%)	2 (3.4%)	3 (2.4%)
	CONSTIPATION	1 (1.5%)	1 (1.7%)	2 (1.6%)
	TOOTH CARIES	1 (1.5%)	1 (1.7%)	2 (1.6%)
	TOOTH DISORDER	1 (1.5%)	1 (1.7%)	2 (1.6%)
	INCREASED APPETITE	0	2 (3.4%)	2 (1.6%)
	GASTRITIS	1 (1.5%)	0	1 (0.8%)
	HEMATEMESIS	1 (1.5%)	0	1 (0.8%)
	FLATULENCE	0	1 (1.7%)	1 (0.8%)
	GASTROINTESTINAL DISORDER	0	1 (1.7%)	1 (0.8%)
	ULCERATIVE STOMATITIS	0	1 (1.7%)	1 (0.8%)
Urogenital System	TOTAL	8 (12.1%)	1 (1.7%)	9 (7.3%)
	ALBUMINURIA	6 (9.1%)	1 (1.7%)	7 (5.6%)
	HAEMATURIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
	DYSURIA	1 (1.5%)	0	1 (0.8%)
	URINARY TRACT INFECTION	1 (1.5%)	0	1 (0.8%)
Skin and Appendages	TOTAL	6 (9.1%)	6 (10.3%)	12 (9.7%)
	ACNE	2 (3.0%)	3 (5.2%)	5 (4.0%)
	CONTACT DERMATITIS	2 (3.0%)	1 (1.7%)	3 (2.4%)
	PRURITUS	1 (1.5%)	1 (1.7%)	2 (1.6%)
	FUNGAL DERMATITIS	1 (1.5%)	0	1 (0.8%)
	FURUNCULOSIS	1 (1.5%)	0	1 (0.8%)
	RASH	0	1 (1.7%)	1 (0.8%)
	SWEATING	0	1 (1.7%)	1 (0.8%)
	URTICARIA	0	1 (1.7%)	1 (0.8%)
Metabolic and Nutritional Disorders	TOTAL	5 (7.6%)	4 (6.9%)	9 (7.3%)
	WEIGHT GAIN	4 (6.1%)	3 (5.2%)	7 (5.6%)

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	WEIGHT LOSS	1 (1.5%)	1 (1.7%)	2 (1.6%)
Musculoskeletal System	TOTAL	4 (6.1%)	2 (3.4%)	6 (4.8%)
	ARTHRALGIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
	MYALGIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
	ARTHROSIS	1 (1.5%)	0	1 (0.8%)
Hemic and Lymphatic System	TOTAL	3 (4.5%)	2 (3.4%)	5 (4.0%)
	LEUKOPENIA	2 (3.0%)	0	2 (1.6%)
	LYMPHADENOPATHY	1 (1.5%)	0	1 (0.8%)
	EOSINOPHILIA	0	1 (1.7%)	1 (0.8%)
	LEUKOCYTOSIS	0	1 (1.7%)	1 (0.8%)
	MONOCYTOSIS	0	1 (1.7%)	1 (0.8%)
Special Senses	TOTAL	3 (4.5%)	3 (5.2%)	6 (4.8%)
	OTITIS MEDIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
	BLEPHARITIS	1 (1.5%)	0	1 (0.8%)
	EYE PAIN	1 (1.5%)	0	1 (0.8%)
	ABNORMAL VISION	0	1 (1.7%)	1 (0.8%)
	PHOTOPHOBIA	0	1 (1.7%)	1 (0.8%)
Cardiovascular System	TOTAL	1 (1.5%)	3 (5.2%)	4 (3.2%)
	SYNCOPE	0	2 (3.4%)	2 (1.6%)
	BRADYCARDIA	1 (1.5%)	0	1 (0.8%)
	VASODILATATION	0	1 (1.7%)	1 (0.8%)

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	6 (23.1%)	2 (8.3%)	8 (16.0%)
Urogenital System	TOTAL	6 (23.1%)	2 (8.3%)	8 (16.0%)
	DYSMENORRHEA	6 (23.1%)	0	6 (12.0%)
	FEMALE GENITAL DISORDERS	0	1 (4.2%)	1 (2.0%)
	MENSTRUAL DISORDER	0	1 (4.2%)	1 (2.0%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	66 (81.5%)	44 (66.7%)	110 (74.8%)
Body as a Whole	TOTAL	44 (54.3%)	24 (36.4%)	68 (46.3%)
	HEADACHE	20 (24.7%)	10 (15.2%)	30 (20.4%)
	TRAUMA	17 (21.0%)	6 (9.1%)	23 (15.6%)
	INFECTION	8 (9.9%)	11 (16.7%)	19 (12.9%)
	ABDOMINAL PAIN	10 (12.3%)	4 (6.1%)	14 (9.5%)
	FEVER	9 (11.1%)	3 (4.5%)	12 (8.2%)
	ALLERGIC REACTION	7 (8.6%)	2 (3.0%)	9 (6.1%)
	ASTHENIA	3 (3.7%)	5 (7.6%)	8 (5.4%)
	BACK PAIN	3 (3.7%)	3 (4.5%)	6 (4.1%)
	PAIN	3 (3.7%)	2 (3.0%)	5 (3.4%)
	CHEST PAIN	3 (3.7%)	0	3 (2.0%)
	FACE EDEMA	2 (2.5%)	0	2 (1.4%)
	MALAISE	1 (1.2%)	0	1 (0.7%)
Respiratory System	TOTAL	36 (44.4%)	22 (33.3%)	58 (39.5%)
	RESPIRATORY DISORDER	17 (21.0%)	13 (19.7%)	30 (20.4%)
	PHARYNGITIS	12 (14.8%)	5 (7.6%)	17 (11.6%)
	RHINITIS	8 (9.9%)	4 (6.1%)	12 (8.2%)
	SINUSITIS	6 (7.4%)	1 (1.5%)	7 (4.8%)
	COUGH INCREASED	4 (4.9%)	2 (3.0%)	6 (4.1%)
	ASTHMA	3 (3.7%)	3 (4.5%)	6 (4.1%)
	BRONCHITIS	2 (2.5%)	3 (4.5%)	5 (3.4%)
	PNEUMONIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	EPISTAXIS	0	2 (3.0%)	2 (1.4%)
	DYSPNEA	1 (1.2%)	0	1 (0.7%)
	YAWN	0	1 (1.5%)	1 (0.7%)
Nervous System	TOTAL	33 (40.7%)	23 (34.8%)	56 (38.1%)
	EMOTIONAL LABILITY	7 (8.6%)	3 (4.5%)	10 (6.8%)
	NERVOUSNESS	8 (9.9%)	1 (1.5%)	9 (6.1%)
	SOMNOLENCE	5 (6.2%)	4 (6.1%)	9 (6.1%)
	INSOMNIA	4 (4.9%)	5 (7.6%)	9 (6.1%)
	HOSTILITY	5 (6.2%)	2 (3.0%)	7 (4.8%)
	AGITATION	3 (3.7%)	3 (4.5%)	6 (4.1%)
	DEPRESSION	4 (4.9%)	1 (1.5%)	5 (3.4%)
	DIZZINESS	3 (3.7%)	2 (3.0%)	5 (3.4%)
	HYPERKINESIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
	ANXIETY	1 (1.2%)	2 (3.0%)	3 (2.0%)
	HALLUCINATIONS	1 (1.2%)	2 (3.0%)	3 (2.0%)
	CONCENTRATION IMPAIRED	0	2 (3.0%)	2 (1.4%)
	HYPESTHESIA	0	2 (3.0%)	2 (1.4%)
	TREMOR	0	2 (3.0%)	2 (1.4%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
Nervous System	WITHDRAWAL SYNDROME	0	2 (3.0%)	2 (1.4%)
	CONVULSION	1 (1.2%)	0	1 (0.7%)
	LACK OF EMOTION	1 (1.2%)	0	1 (0.7%)
	NEUROSIS	1 (1.2%)	0	1 (0.7%)
	PARESTHESIA	1 (1.2%)	0	1 (0.7%)
	VERTIGO	1 (1.2%)	0	1 (0.7%)
	VESTIBULAR DISORDER	1 (1.2%)	0	1 (0.7%)
	EUPHORIA	0	1 (1.5%)	1 (0.7%)
	HYSTERIA	0	1 (1.5%)	1 (0.7%)
	LIBIDO DECREASED	0	1 (1.5%)	1 (0.7%)
	PARALYSIS	0	1 (1.5%)	1 (0.7%)
Digestive System	TOTAL	28 (34.6%)	19 (28.8%)	47 (32.0%)
	VOMITING	12 (14.8%)	4 (6.1%)	16 (10.9%)
	NAUSEA	8 (9.9%)	5 (7.6%)	13 (8.8%)
	DYSPEPSIA	7 (8.6%)	4 (6.1%)	11 (7.5%)
	DIARRHEA	5 (6.2%)	2 (3.0%)	7 (4.8%)
	DECREASED APPETITE	2 (2.5%)	3 (4.5%)	5 (3.4%)
	TOOTH CARIES	1 (1.2%)	3 (4.5%)	4 (2.7%)
	DRY MOUTH	3 (3.7%)	0	3 (2.0%)
	INCREASED APPETITE	1 (1.2%)	2 (3.0%)	3 (2.0%)
	CONSTIPATION	1 (1.2%)	0	1 (0.7%)
	GASTRITIS	1 (1.2%)	0	1 (0.7%)
	HEMATEMESIS	1 (1.2%)	0	1 (0.7%)
	STOMATITIS	1 (1.2%)	0	1 (0.7%)
	GASTROENTERITIS	0	1 (1.5%)	1 (0.7%)
	GASTROINTESTINAL DISORDER	0	1 (1.5%)	1 (0.7%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.7%)
Skin and Appendages	TOTAL	11 (13.6%)	6 (9.1%)	17 (11.6%)
	CONTACT DERMATITIS	4 (4.9%)	1 (1.5%)	5 (3.4%)
	ACNE	3 (3.7%)	1 (1.5%)	4 (2.7%)
	PRURITUS	1 (1.2%)	2 (3.0%)	3 (2.0%)
	RASH	1 (1.2%)	2 (3.0%)	3 (2.0%)
	FUNGAL DERMATITIS	1 (1.2%)	0	1 (0.7%)
	FURUNCULOSIS	1 (1.2%)	0	1 (0.7%)
	HERPES ZOSTER	1 (1.2%)	0	1 (0.7%)
	MACULOPAPULAR RASH	0	1 (1.5%)	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	8 (9.9%)	7 (10.6%)	15 (10.2%)
	WEIGHT GAIN	6 (7.4%)	6 (9.1%)	12 (8.2%)
	DEHYDRATION	1 (1.2%)	1 (1.5%)	2 (1.4%)
	WEIGHT LOSS	1 (1.2%)	0	1 (0.7%)

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
Urogenital System	TOTAL	6 (7.4%)	4 (6.1%)	10 (6.8%)
	ALBUMINURIA	3 (3.7%)	2 (3.0%)	5 (3.4%)
	HAEMATURIA	1 (1.2%)	2 (3.0%)	3 (2.0%)
	URINARY INCONTINENCE	1 (1.2%)	2 (3.0%)	3 (2.0%)
	PYURIA	1 (1.2%)	0	1 (0.7%)
	URINARY TRACT INFECTION	1 (1.2%)	0	1 (0.7%)
	CYSTITIS	0	1 (1.5%)	1 (0.7%)
Hemic and Lymphatic System	TOTAL	4 (4.9%)	2 (3.0%)	6 (4.1%)
	LEUKOPENIA	3 (3.7%)	2 (3.0%)	5 (3.4%)
	LYMPHADENOPATHY	1 (1.2%)	0	1 (0.7%)
	ANEMIA	0	1 (1.5%)	1 (0.7%)
Musculoskeletal System	TOTAL	4 (4.9%)	2 (3.0%)	6 (4.1%)
	MYALGIA	1 (1.2%)	2 (3.0%)	3 (2.0%)
	ARTHRALGIA	2 (2.5%)	0	2 (1.4%)
	TENDINOUS DISORDER	1 (1.2%)	0	1 (0.7%)
	ARTHROSIS	0	1 (1.5%)	1 (0.7%)
Special Senses	TOTAL	3 (3.7%)	2 (3.0%)	5 (3.4%)
	OTITIS MEDIA	3 (3.7%)	1 (1.5%)	4 (2.7%)
	ABNORMAL VISION	0	1 (1.5%)	1 (0.7%)
Cardiovascular System	TOTAL	0	4 (6.1%)	4 (2.7%)
	SYNCOPE	0	2 (3.0%)	2 (1.4%)
	BUNDLE BRANCH BLOCK	0	1 (1.5%)	1 (0.7%)
	MIGRAINE	0	1 (1.5%)	1 (0.7%)
Special Searches	TOTAL	0	1 (1.5%)	1 (0.7%)
	PUNCTURE SITE PAIN	0	1 (1.5%)	1 (0.7%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	3 (9.1%)	2 (6.9%)	5 (8.1%)
Urogenital System	TOTAL	3 (9.1%)	2 (6.9%)	5 (8.1%)
	DYSMENORRHEA	3 (9.1%)	0	3 (4.8%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.6%)
	MENSTRUAL DISORDER	0	1 (3.4%)	1 (1.6%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	40 (76.9%)	49 (76.6%)	89 (76.7%)
Body as a Whole	TOTAL	28 (53.8%)	33 (51.6%)	61 (52.6%)
	HEADACHE	19 (36.5%)	17 (26.6%)	36 (31.0%)
	INFECTION	8 (15.4%)	7 (10.9%)	15 (12.9%)
	ABDOMINAL PAIN	6 (11.5%)	8 (12.5%)	14 (12.1%)
	TRAUMA	5 (9.6%)	8 (12.5%)	13 (11.2%)
	ALLERGIC REACTION	4 (7.7%)	4 (6.3%)	8 (6.9%)
	ASTHENIA	3 (5.8%)	4 (6.3%)	7 (6.0%)
	FEVER	3 (5.8%)	3 (4.7%)	6 (5.2%)
	PAIN	3 (5.8%)	1 (1.6%)	4 (3.4%)
	BACK PAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
	ABNORMAL LABORATORY VALUE	1 (1.9%)	0	1 (0.9%)
	ABSCESS	1 (1.9%)	0	1 (0.9%)
	SPINA BIFIDA	0	1 (1.6%)	1 (0.9%)
Nervous System	TOTAL	17 (32.7%)	32 (50.0%)	49 (42.2%)
	NERVOUSNESS	2 (3.8%)	12 (18.8%)	14 (12.1%)
	INSOMNIA	6 (11.5%)	7 (10.9%)	13 (11.2%)
	HYPERKINESIA	6 (11.5%)	6 (9.4%)	12 (10.3%)
	HOSTILITY	2 (3.8%)	7 (10.9%)	9 (7.8%)
	DIZZINESS	3 (5.8%)	3 (4.7%)	6 (5.2%)
	ANXIETY	2 (3.8%)	4 (6.3%)	6 (5.2%)
	NEUROSIS	4 (7.7%)	1 (1.6%)	5 (4.3%)
	SOMNOLENCE	2 (3.8%)	3 (4.7%)	5 (4.3%)
	EMOTIONAL LABILITY	3 (5.8%)	1 (1.6%)	4 (3.4%)
	AGITATION	1 (1.9%)	3 (4.7%)	4 (3.4%)
	ABNORMAL DREAMS	1 (1.9%)	2 (3.1%)	3 (2.6%)
	VERTIGO	1 (1.9%)	2 (3.1%)	3 (2.6%)
	CONCENTRATION IMPAIRED	2 (3.8%)	0	2 (1.7%)
	DEPRESSION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	MANIC REACTION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	MYOCLONUS	1 (1.9%)	1 (1.6%)	2 (1.7%)
	TREMOR	0	2 (3.1%)	2 (1.7%)
	DYSKINESIA	0	1 (1.6%)	1 (0.9%)
	LACK OF EMOTION	0	1 (1.6%)	1 (0.9%)
	PSYCHOSIS	0	1 (1.6%)	1 (0.9%)
Respiratory System	TOTAL	17 (32.7%)	18 (28.1%)	35 (30.2%)
	RESPIRATORY DISORDER	6 (11.5%)	13 (20.3%)	19 (16.4%)
	PHARYNGITIS	6 (11.5%)	5 (7.8%)	11 (9.5%)
	RHINITIS	5 (9.6%)	5 (7.8%)	10 (8.6%)
	SINUSITIS	6 (11.5%)	1 (1.6%)	7 (6.0%)
	ASTHMA	2 (3.8%)	2 (3.1%)	4 (3.4%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
Respiratory System	COUGH INCREASED	2 (3.8%)	1 (1.6%)	3 (2.6%)
	BRONCHITIS	1 (1.9%)	0	1 (0.9%)
	PLEURA DISORDER	1 (1.9%)	0	1 (0.9%)
	EPISTAXIS	0	1 (1.6%)	1 (0.9%)
	PNEUMONIA	0	1 (1.6%)	1 (0.9%)
Digestive System	TOTAL	13 (25.0%)	17 (26.6%)	30 (25.9%)
	NAUSEA	6 (11.5%)	7 (10.9%)	13 (11.2%)
	DYSPEPSIA	3 (5.8%)	3 (4.7%)	6 (5.2%)
	DECREASED APPETITE	2 (3.8%)	4 (6.3%)	6 (5.2%)
	DIARRHEA	4 (7.7%)	1 (1.6%)	5 (4.3%)
	TOOTH DISORDER	2 (3.8%)	1 (1.6%)	3 (2.6%)
	CONSTIPATION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	GINGIVITIS	1 (1.9%)	1 (1.6%)	2 (1.7%)
	DRY MOUTH	0	2 (3.1%)	2 (1.7%)
	FLATULENCE	0	2 (3.1%)	2 (1.7%)
	VOMITING	1 (1.9%)	0	1 (0.9%)
	GASTROENTERITIS	0	1 (1.6%)	1 (0.9%)
	TOOTH CARIES	0	1 (1.6%)	1 (0.9%)
	ULCERATIVE STOMATITIS	0	1 (1.6%)	1 (0.9%)
Special Senses	TOTAL	7 (13.5%)	7 (10.9%)	14 (12.1%)
	OTITIS MEDIA	3 (5.8%)	3 (4.7%)	6 (5.2%)
	OTITIS EXTERNA	2 (3.8%)	1 (1.6%)	3 (2.6%)
	EAR PAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
	BLEPHARITIS	1 (1.9%)	0	1 (0.9%)
	EYE PAIN	1 (1.9%)	0	1 (0.9%)
	ABNORMAL VISION	0	1 (1.6%)	1 (0.9%)
	PHOTOPHOBIA	0	1 (1.6%)	1 (0.9%)
Urogenital System	TOTAL	6 (11.5%)	2 (3.1%)	8 (6.9%)
	ALBUMINURIA	5 (9.6%)	0	5 (4.3%)
	URINARY INCONTINENCE	0	2 (3.1%)	2 (1.7%)
	DYSURIA	1 (1.9%)	0	1 (0.9%)
	GLYCOSURIA	1 (1.9%)	0	1 (0.9%)
	HAEMATURIA	1 (1.9%)	0	1 (0.9%)
Musculoskeletal System	TOTAL	4 (7.7%)	1 (1.6%)	5 (4.3%)
	ARTHRALGIA	2 (3.8%)	1 (1.6%)	3 (2.6%)
	ARTHROSIS	1 (1.9%)	0	1 (0.9%)
	MYALGIA	1 (1.9%)	0	1 (0.9%)
Skin and Appendages	TOTAL	3 (5.8%)	7 (10.9%)	10 (8.6%)
	ACNE	2 (3.8%)	2 (3.1%)	4 (3.4%)

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
Skin and Appendages	CONTACT DERMATITIS	0	3 (4.7%)	3 (2.6%)
	RASH	0	3 (4.7%)	3 (2.6%)
	MACULOPAPULAR RASH	1 (1.9%)	0	1 (0.9%)
	FUNGAL DERMATITIS	0	1 (1.6%)	1 (0.9%)
	HERPES SIMPLEX	0	1 (1.6%)	1 (0.9%)
	SWEATING	0	1 (1.6%)	1 (0.9%)
	URTICARIA	0	1 (1.6%)	1 (0.9%)
Cardiovascular System	TOTAL	2 (3.8%)	5 (7.8%)	7 (6.0%)
	VASODILATATION	0	4 (6.3%)	4 (3.4%)
	BRADYCARDIA	1 (1.9%)	0	1 (0.9%)
	HAEMATOMA	1 (1.9%)	0	1 (0.9%)
	SYNCOPE	0	1 (1.6%)	1 (0.9%)
Hemic and Lymphatic System	TOTAL	2 (3.8%)	2 (3.1%)	4 (3.4%)
	ANEMIA	1 (1.9%)	0	1 (0.9%)
	PURPURA	1 (1.9%)	0	1 (0.9%)
	EOSINOPHILIA	0	1 (1.6%)	1 (0.9%)
	LEUKOCYTOSIS	0	1 (1.6%)	1 (0.9%)
	MONOCYTOSIS	0	1 (1.6%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	2 (3.8%)	4 (6.3%)	6 (5.2%)
	WEIGHT GAIN	2 (3.8%)	3 (4.7%)	5 (4.3%)
	WEIGHT LOSS	0	1 (1.6%)	1 (0.9%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	4 (14.3%)	1 (4.5%)	5 (10.0%)
Urogenital System	TOTAL	4 (14.3%)	1 (4.5%)	5 (10.0%)
	DYSMENORRHEA	4 (14.3%)	1 (4.5%)	5 (10.0%)
	UTERUS DISORDERS	0	1 (4.5%)	1 (2.0%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
TOTAL	TOTAL	106 (79.7%)	93 (71.5%)	199 (75.7%)
Body as a Whole	TOTAL	72 (54.1%)	57 (43.8%)	129 (49.0%)
	HEADACHE	39 (29.3%)	27 (20.8%)	66 (25.1%)
	TRAUMA	22 (16.5%)	14 (10.8%)	36 (13.7%)
	INFECTION	16 (12.0%)	18 (13.8%)	34 (12.9%)
	ABDOMINAL PAIN	16 (12.0%)	12 (9.2%)	28 (10.6%)
	FEVER	12 (9.0%)	6 (4.6%)	18 (6.8%)
	ALLERGIC REACTION	11 (8.3%)	6 (4.6%)	17 (6.5%)
	ASTHENIA	6 (4.5%)	9 (6.9%)	15 (5.7%)
	PAIN	6 (4.5%)	3 (2.3%)	9 (3.4%)
	BACK PAIN	4 (3.0%)	4 (3.1%)	8 (3.0%)
	CHEST PAIN	3 (2.3%)	0	3 (1.1%)
	FACE EDEMA	2 (1.5%)	0	2 (0.8%)
	ABNORMAL LABORATORY VALUE	1 (0.8%)	0	1 (0.4%)
	ABSCESS	1 (0.8%)	0	1 (0.4%)
	MALAISE	1 (0.8%)	0	1 (0.4%)
	SPINA BIFIDA	0	1 (0.8%)	1 (0.4%)
Respiratory System	TOTAL	53 (39.8%)	40 (30.8%)	93 (35.4%)
	RESPIRATORY DISORDER	23 (17.3%)	26 (20.0%)	49 (18.6%)
	PHARYNGITIS	18 (13.5%)	10 (7.7%)	28 (10.6%)
	RHINITIS	13 (9.8%)	9 (6.9%)	22 (8.4%)
	SINUSITIS	12 (9.0%)	2 (1.5%)	14 (5.3%)
	ASTHMA	5 (3.8%)	5 (3.8%)	10 (3.8%)
	COUGH INCREASED	6 (4.5%)	3 (2.3%)	9 (3.4%)
	BRONCHITIS	3 (2.3%)	3 (2.3%)	6 (2.3%)
	PNEUMONIA	1 (0.8%)	2 (1.5%)	3 (1.1%)
	EPISTAXIS	0	3 (2.3%)	3 (1.1%)
	DYSPNEA	1 (0.8%)	0	1 (0.4%)
	PLEURA DISORDER	1 (0.8%)	0	1 (0.4%)
	YAWN	0	1 (0.8%)	1 (0.4%)
Nervous System	TOTAL	50 (37.6%)	55 (42.3%)	105 (39.9%)
	NERVOUSNESS	10 (7.5%)	13 (10.0%)	23 (8.7%)
	INSOMNIA	10 (7.5%)	12 (9.2%)	22 (8.4%)
	HOSTILITY	7 (5.3%)	9 (6.9%)	16 (6.1%)
	HYPERKINESIA	8 (6.0%)	7 (5.4%)	15 (5.7%)
	EMOTIONAL LABILITY	10 (7.5%)	4 (3.1%)	14 (5.3%)
	SOMNOLENCE	7 (5.3%)	7 (5.4%)	14 (5.3%)
	DIZZINESS	6 (4.5%)	5 (3.8%)	11 (4.2%)
	AGITATION	4 (3.0%)	6 (4.6%)	10 (3.8%)
	ANXIETY	3 (2.3%)	6 (4.6%)	9 (3.4%)
	DEPRESSION	5 (3.8%)	2 (1.5%)	7 (2.7%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Nervous System	NEUROSIS	5 (3.8%)	1 (0.8%)	6 (2.3%)
	CONCENTRATION IMPAIRED	2 (1.5%)	2 (1.5%)	4 (1.5%)
	VERTIGO	2 (1.5%)	2 (1.5%)	4 (1.5%)
	TREMOR	0	4 (3.1%)	4 (1.5%)
	ABNORMAL DREAMS	1 (0.8%)	2 (1.5%)	3 (1.1%)
	HALLUCINATIONS	1 (0.8%)	2 (1.5%)	3 (1.1%)
	LACK OF EMOTION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	MANIC REACTION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	MYOCLONUS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	HYPESTHESIA	0	2 (1.5%)	2 (0.8%)
	WITHDRAWAL SYNDROME	0	2 (1.5%)	2 (0.8%)
	CONVULSION	1 (0.8%)	0	1 (0.4%)
	PARESTHESIA	1 (0.8%)	0	1 (0.4%)
	VESTIBULAR DISORDER	1 (0.8%)	0	1 (0.4%)
	DYSKINESIA	0	1 (0.8%)	1 (0.4%)
	EUPHORIA	0	1 (0.8%)	1 (0.4%)
	HYSTERIA	0	1 (0.8%)	1 (0.4%)
	LIBIDO DECREASED	0	1 (0.8%)	1 (0.4%)
	PARALYSIS	0	1 (0.8%)	1 (0.4%)
	PSYCHOSIS	0	1 (0.8%)	1 (0.4%)
Digestive System	TOTAL	41 (30.8%)	36 (27.7%)	77 (29.3%)
	NAUSEA	14 (10.5%)	12 (9.2%)	26 (9.9%)
	VOMITING	13 (9.8%)	4 (3.1%)	17 (6.5%)
	DYSPEPSIA	10 (7.5%)	7 (5.4%)	17 (6.5%)
	DIARRHEA	9 (6.8%)	3 (2.3%)	12 (4.6%)
	DECREASED APPETITE	4 (3.0%)	7 (5.4%)	11 (4.2%)
	DRY MOUTH	3 (2.3%)	2 (1.5%)	5 (1.9%)
	TOOTH CARIES	1 (0.8%)	4 (3.1%)	5 (1.9%)
	CONSTIPATION	2 (1.5%)	1 (0.8%)	3 (1.1%)
	TOOTH DISORDER	2 (1.5%)	1 (0.8%)	3 (1.1%)
	INCREASED APPETITE	1 (0.8%)	2 (1.5%)	3 (1.1%)
	GINGIVITIS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	FLATULENCE	0	2 (1.5%)	2 (0.8%)
	GASTROENTERITIS	0	2 (1.5%)	2 (0.8%)
	GASTRITIS	1 (0.8%)	0	1 (0.4%)
	HEMATEMESIS	1 (0.8%)	0	1 (0.4%)
	STOMATITIS	1 (0.8%)	0	1 (0.4%)
	GASTROINTESTINAL DISORDER	0	1 (0.8%)	1 (0.4%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (0.8%)	1 (0.4%)
	ULCERATIVE STOMATITIS	0	1 (0.8%)	1 (0.4%)
Skin and Appendages	TOTAL	14 (10.5%)	13 (10.0%)	27 (10.3%)
	ACNE	5 (3.8%)	3 (2.3%)	8 (3.0%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Skin and Appendages	CONTACT DERMATITIS	4 (3.0%)	4 (3.1%)	8 (3.0%)
	RASH	1 (0.8%)	5 (3.8%)	6 (2.3%)
	PRURITUS	1 (0.8%)	2 (1.5%)	3 (1.1%)
	FUNGAL DERMATITIS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	MACULOPAPULAR RASH	1 (0.8%)	1 (0.8%)	2 (0.8%)
	FURUNCULOSIS	1 (0.8%)	0	1 (0.4%)
	HERPES ZOSTER	1 (0.8%)	0	1 (0.4%)
	HERPES SIMPLEX	0	1 (0.8%)	1 (0.4%)
	SWEATING	0	1 (0.8%)	1 (0.4%)
	URTICARIA	0	1 (0.8%)	1 (0.4%)
Urogenital System	TOTAL	12 (9.0%)	6 (4.6%)	18 (6.8%)
	ALBUMINURIA	8 (6.0%)	2 (1.5%)	10 (3.8%)
	URINARY INCONTINENCE	1 (0.8%)	4 (3.1%)	5 (1.9%)
	HAEMATURIA	2 (1.5%)	2 (1.5%)	4 (1.5%)
	DYSURIA	1 (0.8%)	0	1 (0.4%)
	GLYCOSURIA	1 (0.8%)	0	1 (0.4%)
	PYURIA	1 (0.8%)	0	1 (0.4%)
	URINARY TRACT INFECTION	1 (0.8%)	0	1 (0.4%)
	CYSTITIS	0	1 (0.8%)	1 (0.4%)
Metabolic and Nutritional Disorders	TOTAL	10 (7.5%)	11 (8.5%)	21 (8.0%)
	WEIGHT GAIN	8 (6.0%)	9 (6.9%)	17 (6.5%)
	DEHYDRATION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	WEIGHT LOSS	1 (0.8%)	1 (0.8%)	2 (0.8%)
Special Senses	TOTAL	10 (7.5%)	9 (6.9%)	19 (7.2%)
	OTITIS MEDIA	6 (4.5%)	4 (3.1%)	10 (3.8%)
	OTITIS EXTERNA	2 (1.5%)	1 (0.8%)	3 (1.1%)
	EAR PAIN	1 (0.8%)	1 (0.8%)	2 (0.8%)
	ABNORMAL VISION	0	2 (1.5%)	2 (0.8%)
	BLEPHARITIS	1 (0.8%)	0	1 (0.4%)
	EYE PAIN	1 (0.8%)	0	1 (0.4%)
	PHOTOPHOBIA	0	1 (0.8%)	1 (0.4%)
Musculoskeletal System	TOTAL	8 (6.0%)	3 (2.3%)	11 (4.2%)
	ARTHRALGIA	4 (3.0%)	1 (0.8%)	5 (1.9%)
	MYALGIA	2 (1.5%)	2 (1.5%)	4 (1.5%)
	ARTHROSIS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	TENDINOUS DISORDER	1 (0.8%)	0	1 (0.4%)
Hemic and Lymphatic System	TOTAL	6 (4.5%)	4 (3.1%)	10 (3.8%)
	LEUKOPENIA	3 (2.3%)	2 (1.5%)	5 (1.9%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Hemic and Lymphatic System	ANEMIA	1 (0.8%)	1 (0.8%)	2 (0.8%)
	LYMPHADENOPATHY	1 (0.8%)	0	1 (0.4%)
	PURPURA	1 (0.8%)	0	1 (0.4%)
	EOSINOPHILIA	0	1 (0.8%)	1 (0.4%)
	LEUKOCYTOSIS	0	1 (0.8%)	1 (0.4%)
	MONOCYTOSIS	0	1 (0.8%)	1 (0.4%)
Cardiovascular System	TOTAL	2 (1.5%)	9 (6.9%)	11 (4.2%)
	VASODILATATION	0	4 (3.1%)	4 (1.5%)
	SYNCOPE	0	3 (2.3%)	3 (1.1%)
	BRADYCARDIA	1 (0.8%)	0	1 (0.4%)
	HAEMATOMA	1 (0.8%)	0	1 (0.4%)
	BUNDLE BRANCH BLOCK	0	1 (0.8%)	1 (0.4%)
	MIGRAINE	0	1 (0.8%)	1 (0.4%)
Special Searches	TOTAL	0	1 (0.8%)	1 (0.4%)
	PUNCTURE SITE PAIN	0	1 (0.8%)	1 (0.4%)

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	7 (11.5%)	3 (5.9%)	10 (8.9%)
Urogenital System	TOTAL	7 (11.5%)	3 (5.9%)	10 (8.9%)
	DYSMENORRHEA	7 (11.5%)	1 (2.0%)	8 (7.1%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (0.9%)
	MENSTRUAL DISORDER	0	1 (2.0%)	1 (0.9%)
	UTERUS DISORDERS	0	1 (2.0%)	1 (0.9%)

Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
TOTAL	32 (82.1%)	25 (69.4%)	57 (76.0%)
RESPIRATORY DISORDER	10 (25.6%)	6 (16.7%)	16 (21.3%)
TRAUMA	11 (28.2%)	4 (11.1%)	15 (20.0%)
INFECTION	5 (12.8%)	9 (25.0%)	14 (18.7%)
HEADACHE	9 (23.1%)	4 (11.1%)	13 (17.3%)
PHARYNGITIS	8 (20.5%)	4 (11.1%)	12 (16.0%)
VOMITING	7 (17.9%)	4 (11.1%)	11 (14.7%)
ABDOMINAL PAIN	7 (17.9%)	3 (8.3%)	10 (13.3%)
FEVER	6 (15.4%)	2 (5.6%)	8 (10.7%)
DYSPEPSIA	4 (10.3%)	3 (8.3%)	7 (9.3%)
RHINITIS	4 (10.3%)	3 (8.3%)	7 (9.3%)
WEIGHT GAIN	4 (10.3%)	3 (8.3%)	7 (9.3%)
NERVOUSNESS	5 (12.8%)	0	5 (6.7%)
HOSTILITY	4 (10.3%)	1 (2.8%)	5 (6.7%)
ALLERGIC REACTION	3 (7.7%)	2 (5.6%)	5 (6.7%)
COUGH INCREASED	3 (7.7%)	1 (2.8%)	4 (5.3%)
DEPRESSION	3 (7.7%)	1 (2.8%)	4 (5.3%)
PAIN	3 (7.7%)	1 (2.8%)	4 (5.3%)
SINUSITIS	3 (7.7%)	1 (2.8%)	4 (5.3%)
ASTHENIA	2 (5.1%)	2 (5.6%)	4 (5.3%)
INSOMNIA	1 (2.6%)	3 (8.3%)	4 (5.3%)
NAUSEA	1 (2.6%)	3 (8.3%)	4 (5.3%)
CONTACT DERMATITIS	2 (5.1%)	1 (2.8%)	3 (4.0%)
DIARRHEA	2 (5.1%)	1 (2.8%)	3 (4.0%)
HYPERKINESIA	2 (5.1%)	1 (2.8%)	3 (4.0%)
OTITIS MEDIA	2 (5.1%)	1 (2.8%)	3 (4.0%)
AGITATION	1 (2.6%)	2 (5.6%)	3 (4.0%)
LEUKOPENIA	1 (2.6%)	2 (5.6%)	3 (4.0%)
RASH	1 (2.6%)	2 (5.6%)	3 (4.0%)
URINARY INCONTINENCE	1 (2.6%)	2 (5.6%)	3 (4.0%)
BACK PAIN	0	3 (8.3%)	3 (4.0%)
ACNE	2 (5.1%)	0	2 (2.7%)
ARTHRALGIA	2 (5.1%)	0	2 (2.7%)
DRY MOUTH	2 (5.1%)	0	2 (2.7%)
FACE EDEMA	2 (5.1%)	0	2 (2.7%)
DECREASED APPETITE	1 (2.6%)	1 (2.8%)	2 (2.7%)
HALLUCINATIONS	1 (2.6%)	1 (2.8%)	2 (2.7%)
EPISTAXIS	0	2 (5.6%)	2 (2.7%)
HYPESTHESIA	0	2 (5.6%)	2 (2.7%)
TOOTH CARIES	0	2 (5.6%)	2 (2.7%)
CONSTIPATION	1 (2.6%)	0	1 (1.3%)
EMOTIONAL LABILITY	1 (2.6%)	0	1 (1.3%)
INCREASED APPETITE	1 (2.6%)	0	1 (1.3%)
NEUROSIS	1 (2.6%)	0	1 (1.3%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
ABNORMAL VISION	0	1 (2.8%)	1 (1.3%)
ALBUMINURIA	0	1 (2.8%)	1 (1.3%)
ANXIETY	0	1 (2.8%)	1 (1.3%)
ASTHMA	0	1 (2.8%)	1 (1.3%)
BRONCHITIS	0	1 (2.8%)	1 (1.3%)
CONCENTRATION IMPAIRED	0	1 (2.8%)	1 (1.3%)
DIZZINESS	0	1 (2.8%)	1 (1.3%)
GASTROENTERITIS	0	1 (2.8%)	1 (1.3%)
HAEMATURIA	0	1 (2.8%)	1 (1.3%)
MYALGIA	0	1 (2.8%)	1 (1.3%)
PNEUMONIA	0	1 (2.8%)	1 (1.3%)
PRURITUS	0	1 (2.8%)	1 (1.3%)
SOMNOLENCE	0	1 (2.8%)	1 (1.3%)
SYNCOPE	0	1 (2.8%)	1 (1.3%)
TREMOR	0	1 (2.8%)	1 (1.3%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Preferred Term			
TOTAL	22 (78.6%)	29 (80.6%)	51 (79.7%)
HEADACHE	9 (32.1%)	8 (22.2%)	17 (26.6%)
RESPIRATORY DISORDER	2 (7.1%)	8 (22.2%)	10 (15.6%)
NERVOUSNESS	1 (3.6%)	9 (25.0%)	10 (15.6%)
HYPERKINESIA	5 (17.9%)	4 (11.1%)	9 (14.1%)
PHARYNGITIS	5 (17.9%)	3 (8.3%)	8 (12.5%)
RHINITIS	4 (14.3%)	4 (11.1%)	8 (12.5%)
TRAUMA	4 (14.3%)	4 (11.1%)	8 (12.5%)
ABDOMINAL PAIN	3 (10.7%)	5 (13.9%)	8 (12.5%)
INFECTION	3 (10.7%)	4 (11.1%)	7 (10.9%)
NAUSEA	5 (17.9%)	1 (2.8%)	6 (9.4%)
INSOMNIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
OTITIS MEDIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
HOSTILITY	1 (3.6%)	4 (11.1%)	5 (7.8%)
FEVER	3 (10.7%)	1 (2.8%)	4 (6.3%)
SINUSITIS	3 (10.7%)	1 (2.8%)	4 (6.3%)
DECREASED APPETITE	2 (7.1%)	2 (5.6%)	4 (6.3%)
ANXIETY	1 (3.6%)	3 (8.3%)	4 (6.3%)
DIARRHEA	3 (10.7%)	0	3 (4.7%)
COUGH INCREASED	2 (7.1%)	1 (2.8%)	3 (4.7%)
DYSPEPSIA	2 (7.1%)	1 (2.8%)	3 (4.7%)
OTITIS EXTERNA	2 (7.1%)	1 (2.8%)	3 (4.7%)
PAIN	2 (7.1%)	1 (2.8%)	3 (4.7%)
DIZZINESS	1 (3.6%)	2 (5.6%)	3 (4.7%)
SOMNOLENCE	1 (3.6%)	2 (5.6%)	3 (4.7%)
VASODILATATION	0	3 (8.3%)	3 (4.7%)
WEIGHT GAIN	0	3 (8.3%)	3 (4.7%)
ALBUMINURIA	2 (7.1%)	0	2 (3.1%)
AGITATION	1 (3.6%)	1 (2.8%)	2 (3.1%)
CONTACT DERMATITIS	0	2 (5.6%)	2 (3.1%)
RASH	0	2 (5.6%)	2 (3.1%)
URINARY INCONTINENCE	0	2 (5.6%)	2 (3.1%)
VERTIGO	0	2 (5.6%)	2 (3.1%)
ACNE	1 (3.6%)	0	1 (1.6%)
ASTHMA	1 (3.6%)	0	1 (1.6%)
BACK PAIN	1 (3.6%)	0	1 (1.6%)
CONCENTRATION IMPAIRED	1 (3.6%)	0	1 (1.6%)
DEPRESSION	1 (3.6%)	0	1 (1.6%)
EMOTIONAL LABILITY	1 (3.6%)	0	1 (1.6%)
MYALGIA	1 (3.6%)	0	1 (1.6%)
NEUROSIS	1 (3.6%)	0	1 (1.6%)
TOOTH DISORDER	1 (3.6%)	0	1 (1.6%)
VOMITING	1 (3.6%)	0	1 (1.6%)
ALLERGIC REACTION	0	1 (2.8%)	1 (1.6%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
FLATULENCE	0	1 (2.8%)	1 (1.6%)
GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
TOOTH CARIES	0	1 (2.8%)	1 (1.6%)
TREMOR	0	1 (2.8%)	1 (1.6%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
TOTAL	1 (6.3%)	1 (7.7%)	2 (6.9%)
DYSMENORRHEA	1 (6.3%)	1 (7.7%)	2 (6.9%)

Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
TOTAL	54 (80.6%)	54 (75.0%)	108 (77.7%)
HEADACHE	18 (26.9%)	12 (16.7%)	30 (21.6%)
RESPIRATORY DISORDER	12 (17.9%)	14 (19.4%)	26 (18.7%)
TRAUMA	15 (22.4%)	8 (11.1%)	23 (16.5%)
INFECTION	8 (11.9%)	13 (18.1%)	21 (15.1%)
PHARYNGITIS	13 (19.4%)	7 (9.7%)	20 (14.4%)
ABDOMINAL PAIN	10 (14.9%)	8 (11.1%)	18 (12.9%)
RHINITIS	8 (11.9%)	7 (9.7%)	15 (10.8%)
NERVOUSNESS	6 (9.0%)	9 (12.5%)	15 (10.8%)
FEVER	9 (13.4%)	3 (4.2%)	12 (8.6%)
VOMITING	8 (11.9%)	4 (5.6%)	12 (8.6%)
HYPERKINESIA	7 (10.4%)	5 (6.9%)	12 (8.6%)
DYSPEPSIA	6 (9.0%)	4 (5.6%)	10 (7.2%)
NAUSEA	6 (9.0%)	4 (5.6%)	10 (7.2%)
HOSTILITY	5 (7.5%)	5 (6.9%)	10 (7.2%)
WEIGHT GAIN	4 (6.0%)	6 (8.3%)	10 (7.2%)
INSOMNIA	4 (6.0%)	5 (6.9%)	9 (6.5%)
SINUSITIS	6 (9.0%)	2 (2.8%)	8 (5.8%)
OTITIS MEDIA	5 (7.5%)	3 (4.2%)	8 (5.8%)
COUGH INCREASED	5 (7.5%)	2 (2.8%)	7 (5.0%)
PAIN	5 (7.5%)	2 (2.8%)	7 (5.0%)
DIARRHEA	5 (7.5%)	1 (1.4%)	6 (4.3%)
ALLERGIC REACTION	3 (4.5%)	3 (4.2%)	6 (4.3%)
DECREASED APPETITE	3 (4.5%)	3 (4.2%)	6 (4.3%)
DEPRESSION	4 (6.0%)	1 (1.4%)	5 (3.6%)
AGITATION	2 (3.0%)	3 (4.2%)	5 (3.6%)
CONTACT DERMATITIS	2 (3.0%)	3 (4.2%)	5 (3.6%)
ANXIETY	1 (1.5%)	4 (5.6%)	5 (3.6%)
RASH	1 (1.5%)	4 (5.6%)	5 (3.6%)
URINARY INCONTINENCE	1 (1.5%)	4 (5.6%)	5 (3.6%)
ASTHENIA	2 (3.0%)	2 (2.8%)	4 (2.9%)
BACK PAIN	1 (1.5%)	3 (4.2%)	4 (2.9%)
DIZZINESS	1 (1.5%)	3 (4.2%)	4 (2.9%)
SOMNOLENCE	1 (1.5%)	3 (4.2%)	4 (2.9%)
ACNE	3 (4.5%)	0	3 (2.2%)
ALBUMINURIA	2 (3.0%)	1 (1.4%)	3 (2.2%)
OTITIS EXTERNA	2 (3.0%)	1 (1.4%)	3 (2.2%)
LEUKOPENIA	1 (1.5%)	2 (2.8%)	3 (2.2%)
TOOTH CARIES	0	3 (4.2%)	3 (2.2%)
VASODILATATION	0	3 (4.2%)	3 (2.2%)
ARTHRALGIA	2 (3.0%)	0	2 (1.4%)
DRY MOUTH	2 (3.0%)	0	2 (1.4%)
EMOTIONAL LABILITY	2 (3.0%)	0	2 (1.4%)
FACE EDEMA	2 (3.0%)	0	2 (1.4%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Preferred Term			
NEUROSIS	2 (3.0%)	0	2 (1.4%)
ASTHMA	1 (1.5%)	1 (1.4%)	2 (1.4%)
CONCENTRATION IMPAIRED	1 (1.5%)	1 (1.4%)	2 (1.4%)
HALLUCINATIONS	1 (1.5%)	1 (1.4%)	2 (1.4%)
MYALGIA	1 (1.5%)	1 (1.4%)	2 (1.4%)
EPISTAXIS	0	2 (2.8%)	2 (1.4%)
GASTROENTERITIS	0	2 (2.8%)	2 (1.4%)
HYPESTHESIA	0	2 (2.8%)	2 (1.4%)
TREMOR	0	2 (2.8%)	2 (1.4%)
VERTIGO	0	2 (2.8%)	2 (1.4%)
CONSTIPATION	1 (1.5%)	0	1 (0.7%)
INCREASED APPETITE	1 (1.5%)	0	1 (0.7%)
TOOTH DISORDER	1 (1.5%)	0	1 (0.7%)
ABNORMAL VISION	0	1 (1.4%)	1 (0.7%)
BRONCHITIS	0	1 (1.4%)	1 (0.7%)
FLATULENCE	0	1 (1.4%)	1 (0.7%)
HAEMATURIA	0	1 (1.4%)	1 (0.7%)
PNEUMONIA	0	1 (1.4%)	1 (0.7%)
PRURITUS	0	1 (1.4%)	1 (0.7%)
SYNCOPE	0	1 (1.4%)	1 (0.7%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
Preferred Term			
TOTAL	1 (2.9%)	1 (3.7%)	2 (3.2%)
DYSMENORRHEA	1 (2.9%)	1 (3.7%)	2 (3.2%)

Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
TOTAL	34 (81.0%)	18 (60.0%)	52 (72.2%)
HEADACHE	11 (26.2%)	6 (20.0%)	17 (23.6%)
RESPIRATORY DISORDER	7 (16.7%)	7 (23.3%)	14 (19.4%)
NAUSEA	7 (16.7%)	2 (6.7%)	9 (12.5%)
EMOTIONAL LABILITY	6 (14.3%)	3 (10.0%)	9 (12.5%)
TRAUMA	6 (14.3%)	2 (6.7%)	8 (11.1%)
SOMNOLENCE	5 (11.9%)	3 (10.0%)	8 (11.1%)
VOMITING	5 (11.9%)	0	5 (6.9%)
PHARYNGITIS	4 (9.5%)	1 (3.3%)	5 (6.9%)
RHINITIS	4 (9.5%)	1 (3.3%)	5 (6.9%)
ASTHMA	3 (7.1%)	2 (6.7%)	5 (6.9%)
INFECTION	3 (7.1%)	2 (6.7%)	5 (6.9%)
INSOMNIA	3 (7.1%)	2 (6.7%)	5 (6.9%)
WEIGHT GAIN	2 (4.8%)	3 (10.0%)	5 (6.9%)
ALLERGIC REACTION	4 (9.5%)	0	4 (5.6%)
ABDOMINAL PAIN	3 (7.1%)	1 (3.3%)	4 (5.6%)
ALBUMINURIA	3 (7.1%)	1 (3.3%)	4 (5.6%)
DIARRHEA	3 (7.1%)	1 (3.3%)	4 (5.6%)
DIZZINESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
DYSPEPSIA	3 (7.1%)	1 (3.3%)	4 (5.6%)
FEVER	3 (7.1%)	1 (3.3%)	4 (5.6%)
NERVOUSNESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
BRONCHITIS	2 (4.8%)	2 (6.7%)	4 (5.6%)
ASTHENIA	1 (2.4%)	3 (10.0%)	4 (5.6%)
BACK PAIN	3 (7.1%)	0	3 (4.2%)
CHEST PAIN	3 (7.1%)	0	3 (4.2%)
SINUSITIS	3 (7.1%)	0	3 (4.2%)
AGITATION	2 (4.8%)	1 (3.3%)	3 (4.2%)
DECREASED APPETITE	1 (2.4%)	2 (6.7%)	3 (4.2%)
CONTACT DERMATITIS	2 (4.8%)	0	2 (2.8%)
LEUKOPENIA	2 (4.8%)	0	2 (2.8%)
ACNE	1 (2.4%)	1 (3.3%)	2 (2.8%)
ANXIETY	1 (2.4%)	1 (3.3%)	2 (2.8%)
COUGH INCREASED	1 (2.4%)	1 (3.3%)	2 (2.8%)
HAEMATURIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
HOSTILITY	1 (2.4%)	1 (3.3%)	2 (2.8%)
MYALGIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
PRURITUS	1 (2.4%)	1 (3.3%)	2 (2.8%)
TOOTH CARIES	1 (2.4%)	1 (3.3%)	2 (2.8%)
INCREASED APPETITE	0	2 (6.7%)	2 (2.8%)
WITHDRAWAL SYNDROME	0	2 (6.7%)	2 (2.8%)
DEPRESSION	1 (2.4%)	0	1 (1.4%)
DRY MOUTH	1 (2.4%)	0	1 (1.4%)
OTITIS MEDIA	1 (2.4%)	0	1 (1.4%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Preferred Term			
PNEUMONIA	1 (2.4%)	0	1 (1.4%)
VERTIGO	1 (2.4%)	0	1 (1.4%)
CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.4%)
HALLUCINATIONS	0	1 (3.3%)	1 (1.4%)
PAIN	0	1 (3.3%)	1 (1.4%)
SYNCOPE	0	1 (3.3%)	1 (1.4%)
TREMOR	0	1 (3.3%)	1 (1.4%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
Preferred Term			
TOTAL	3 (21.4%)	0	3 (10.3%)
DYSMENORRHEA	3 (21.4%)	0	3 (10.3%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
TOTAL	18 (75.0%)	19 (67.9%)	37 (71.2%)
HEADACHE	10 (41.7%)	9 (32.1%)	19 (36.5%)
RESPIRATORY DISORDER	4 (16.7%)	5 (17.9%)	9 (17.3%)
INFECTION	5 (20.8%)	3 (10.7%)	8 (15.4%)
INSOMNIA	3 (12.5%)	5 (17.9%)	8 (15.4%)
ALLERGIC REACTION	4 (16.7%)	3 (10.7%)	7 (13.5%)
ASTHENIA	3 (12.5%)	4 (14.3%)	7 (13.5%)
NAUSEA	1 (4.2%)	6 (21.4%)	7 (13.5%)
ABDOMINAL PAIN	3 (12.5%)	3 (10.7%)	6 (11.5%)
TRAUMA	1 (4.2%)	4 (14.3%)	5 (9.6%)
NEUROSIS	3 (12.5%)	1 (3.6%)	4 (7.7%)
HOSTILITY	1 (4.2%)	3 (10.7%)	4 (7.7%)
NERVOUSNESS	1 (4.2%)	3 (10.7%)	4 (7.7%)
ALBUMINURIA	3 (12.5%)	0	3 (5.8%)
SINUSITIS	3 (12.5%)	0	3 (5.8%)
ARTHRALGIA	2 (8.3%)	1 (3.6%)	3 (5.8%)
DIZZINESS	2 (8.3%)	1 (3.6%)	3 (5.8%)
EMOTIONAL LABILITY	2 (8.3%)	1 (3.6%)	3 (5.8%)
ABNORMAL DREAMS	1 (4.2%)	2 (7.1%)	3 (5.8%)
ACNE	1 (4.2%)	2 (7.1%)	3 (5.8%)
ASTHMA	1 (4.2%)	2 (7.1%)	3 (5.8%)
DYSPEPSIA	1 (4.2%)	2 (7.1%)	3 (5.8%)
HYPERKINESIA	1 (4.2%)	2 (7.1%)	3 (5.8%)
PHARYNGITIS	1 (4.2%)	2 (7.1%)	3 (5.8%)
WEIGHT GAIN	2 (8.3%)	0	2 (3.8%)
ANXIETY	1 (4.2%)	1 (3.6%)	2 (3.8%)
CONSTIPATION	1 (4.2%)	1 (3.6%)	2 (3.8%)
DIARRHEA	1 (4.2%)	1 (3.6%)	2 (3.8%)
RHINITIS	1 (4.2%)	1 (3.6%)	2 (3.8%)
SOMNOLENCE	1 (4.2%)	1 (3.6%)	2 (3.8%)
TOOTH DISORDER	1 (4.2%)	1 (3.6%)	2 (3.8%)
AGITATION	0	2 (7.1%)	2 (3.8%)
DECREASED APPETITE	0	2 (7.1%)	2 (3.8%)
DRY MOUTH	0	2 (7.1%)	2 (3.8%)
FEVER	0	2 (7.1%)	2 (3.8%)
BRONCHITIS	1 (4.2%)	0	1 (1.9%)
CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.9%)
HAEMATURIA	1 (4.2%)	0	1 (1.9%)
PAIN	1 (4.2%)	0	1 (1.9%)
VERTIGO	1 (4.2%)	0	1 (1.9%)
ABNORMAL VISION	0	1 (3.6%)	1 (1.9%)
BACK PAIN	0	1 (3.6%)	1 (1.9%)
CONTACT DERMATITIS	0	1 (3.6%)	1 (1.9%)
DEPRESSION	0	1 (3.6%)	1 (1.9%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Preferred Term			
EPISTAXIS	0	1 (3.6%)	1 (1.9%)
FLATULENCE	0	1 (3.6%)	1 (1.9%)
OTITIS MEDIA	0	1 (3.6%)	1 (1.9%)
PNEUMONIA	0	1 (3.6%)	1 (1.9%)
RASH	0	1 (3.6%)	1 (1.9%)
SYNCOPE	0	1 (3.6%)	1 (1.9%)
TREMOR	0	1 (3.6%)	1 (1.9%)
VASODILATATION	0	1 (3.6%)	1 (1.9%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
TOTAL	3 (25.0%)	0	3 (14.3%)
DYSMENORRHEA	3 (25.0%)	0	3 (14.3%)

Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
TOTAL	52 (78.8%)	37 (63.8%)	89 (71.8%)
HEADACHE	21 (31.8%)	15 (25.9%)	36 (29.0%)
RESPIRATORY DISORDER	11 (16.7%)	12 (20.7%)	23 (18.5%)
NAUSEA	8 (12.1%)	8 (13.8%)	16 (12.9%)
INFECTION	8 (12.1%)	5 (8.6%)	13 (10.5%)
TRAUMA	7 (10.6%)	6 (10.3%)	13 (10.5%)
INSOMNIA	6 (9.1%)	7 (12.1%)	13 (10.5%)
EMOTIONAL LABILITY	8 (12.1%)	4 (6.9%)	12 (9.7%)
ALLERGIC REACTION	8 (12.1%)	3 (5.2%)	11 (8.9%)
ASTHENIA	4 (6.1%)	7 (12.1%)	11 (8.9%)
ABDOMINAL PAIN	6 (9.1%)	4 (6.9%)	10 (8.1%)
SOMNOLENCE	6 (9.1%)	4 (6.9%)	10 (8.1%)
PHARYNGITIS	5 (7.6%)	3 (5.2%)	8 (6.5%)
ASTHMA	4 (6.1%)	4 (6.9%)	8 (6.5%)
NERVOUSNESS	4 (6.1%)	4 (6.9%)	8 (6.5%)
ALBUMINURIA	6 (9.1%)	1 (1.7%)	7 (5.6%)
DIZZINESS	5 (7.6%)	2 (3.4%)	7 (5.6%)
RHINITIS	5 (7.6%)	2 (3.4%)	7 (5.6%)
DYSPEPSIA	4 (6.1%)	3 (5.2%)	7 (5.6%)
WEIGHT GAIN	4 (6.1%)	3 (5.2%)	7 (5.6%)
SINUSITIS	6 (9.1%)	0	6 (4.8%)
DIARRHEA	4 (6.1%)	2 (3.4%)	6 (4.8%)
FEVER	3 (4.5%)	3 (5.2%)	6 (4.8%)
HOSTILITY	2 (3.0%)	4 (6.9%)	6 (4.8%)
VOMITING	5 (7.6%)	0	5 (4.0%)
BRONCHITIS	3 (4.5%)	2 (3.4%)	5 (4.0%)
ACNE	2 (3.0%)	3 (5.2%)	5 (4.0%)
AGITATION	2 (3.0%)	3 (5.2%)	5 (4.0%)
DECREASED APPETITE	1 (1.5%)	4 (6.9%)	5 (4.0%)
BACK PAIN	3 (4.5%)	1 (1.7%)	4 (3.2%)
NEUROSIS	3 (4.5%)	1 (1.7%)	4 (3.2%)
ANXIETY	2 (3.0%)	2 (3.4%)	4 (3.2%)
CHEST PAIN	3 (4.5%)	0	3 (2.4%)
ARTHRALGIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
CONTACT DERMATITIS	2 (3.0%)	1 (1.7%)	3 (2.4%)
HAEMATURIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
ABNORMAL DREAMS	1 (1.5%)	2 (3.4%)	3 (2.4%)
DRY MOUTH	1 (1.5%)	2 (3.4%)	3 (2.4%)
HYPERKINESIA	1 (1.5%)	2 (3.4%)	3 (2.4%)
LEUKOPENIA	2 (3.0%)	0	2 (1.6%)
VERTIGO	2 (3.0%)	0	2 (1.6%)
CONCENTRATION IMPAIRED	1 (1.5%)	1 (1.7%)	2 (1.6%)
CONSTIPATION	1 (1.5%)	1 (1.7%)	2 (1.6%)
COUGH INCREASED	1 (1.5%)	1 (1.7%)	2 (1.6%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
DEPRESSION	1 (1.5%)	1 (1.7%)	2 (1.6%)
MYALGIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
OTITIS MEDIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
PAIN	1 (1.5%)	1 (1.7%)	2 (1.6%)
PNEUMONIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
PRURITUS	1 (1.5%)	1 (1.7%)	2 (1.6%)
TOOTH CARIES	1 (1.5%)	1 (1.7%)	2 (1.6%)
TOOTH DISORDER	1 (1.5%)	1 (1.7%)	2 (1.6%)
INCREASED APPETITE	0	2 (3.4%)	2 (1.6%)
SYNCOPE	0	2 (3.4%)	2 (1.6%)
TREMOR	0	2 (3.4%)	2 (1.6%)
WITHDRAWAL SYNDROME	0	2 (3.4%)	2 (1.6%)
ABNORMAL VISION	0	1 (1.7%)	1 (0.8%)
EPISTAXIS	0	1 (1.7%)	1 (0.8%)
FLATULENCE	0	1 (1.7%)	1 (0.8%)
HALLUCINATIONS	0	1 (1.7%)	1 (0.8%)
RASH	0	1 (1.7%)	1 (0.8%)
VASODILATATION	0	1 (1.7%)	1 (0.8%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
TOTAL	0	0	0

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
TOTAL	6 (23.1%)	0	6 (12.0%)
DYSMENORRHEA	6 (23.1%)	0	6 (12.0%)

Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
TOTAL	66 (81.5%)	43 (65.2%)	109 (74.1%)
HEADACHE	20 (24.7%)	10 (15.2%)	30 (20.4%)
RESPIRATORY DISORDER	17 (21.0%)	13 (19.7%)	30 (20.4%)
TRAUMA	17 (21.0%)	6 (9.1%)	23 (15.6%)
INFECTION	8 (9.9%)	11 (16.7%)	19 (12.9%)
PHARYNGITIS	12 (14.8%)	5 (7.6%)	17 (11.6%)
VOMITING	12 (14.8%)	4 (6.1%)	16 (10.9%)
ABDOMINAL PAIN	10 (12.3%)	4 (6.1%)	14 (9.5%)
NAUSEA	8 (9.9%)	5 (7.6%)	13 (8.8%)
FEVER	9 (11.1%)	3 (4.5%)	12 (8.2%)
RHINITIS	8 (9.9%)	4 (6.1%)	12 (8.2%)
WEIGHT GAIN	6 (7.4%)	6 (9.1%)	12 (8.2%)
DYSPEPSIA	7 (8.6%)	4 (6.1%)	11 (7.5%)
EMOTIONAL LABILITY	7 (8.6%)	3 (4.5%)	10 (6.8%)
NERVOUSNESS	8 (9.9%)	1 (1.5%)	9 (6.1%)
ALLERGIC REACTION	7 (8.6%)	2 (3.0%)	9 (6.1%)
SOMNOLENCE	5 (6.2%)	4 (6.1%)	9 (6.1%)
INSOMNIA	4 (4.9%)	5 (7.6%)	9 (6.1%)
ASTHENIA	3 (3.7%)	5 (7.6%)	8 (5.4%)
SINUSITIS	6 (7.4%)	1 (1.5%)	7 (4.8%)
DIARRHEA	5 (6.2%)	2 (3.0%)	7 (4.8%)
HOSTILITY	5 (6.2%)	2 (3.0%)	7 (4.8%)
COUGH INCREASED	4 (4.9%)	2 (3.0%)	6 (4.1%)
AGITATION	3 (3.7%)	3 (4.5%)	6 (4.1%)
ASTHMA	3 (3.7%)	3 (4.5%)	6 (4.1%)
BACK PAIN	3 (3.7%)	3 (4.5%)	6 (4.1%)
CONTACT DERMATITIS	4 (4.9%)	1 (1.5%)	5 (3.4%)
DEPRESSION	4 (4.9%)	1 (1.5%)	5 (3.4%)
ALBUMINURIA	3 (3.7%)	2 (3.0%)	5 (3.4%)
DIZZINESS	3 (3.7%)	2 (3.0%)	5 (3.4%)
LEUKOPENIA	3 (3.7%)	2 (3.0%)	5 (3.4%)
PAIN	3 (3.7%)	2 (3.0%)	5 (3.4%)
BRONCHITIS	2 (2.5%)	3 (4.5%)	5 (3.4%)
DECREASED APPETITE	2 (2.5%)	3 (4.5%)	5 (3.4%)
ACNE	3 (3.7%)	1 (1.5%)	4 (2.7%)
OTITIS MEDIA	3 (3.7%)	1 (1.5%)	4 (2.7%)
TOOTH CARIES	1 (1.2%)	3 (4.5%)	4 (2.7%)
CHEST PAIN	3 (3.7%)	0	3 (2.0%)
DRY MOUTH	3 (3.7%)	0	3 (2.0%)
HYPERKINESIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
ANXIETY	1 (1.2%)	2 (3.0%)	3 (2.0%)
HAEMATURIA	1 (1.2%)	2 (3.0%)	3 (2.0%)
HALLUCINATIONS	1 (1.2%)	2 (3.0%)	3 (2.0%)
INCREASED APPETITE	1 (1.2%)	2 (3.0%)	3 (2.0%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
MYALGIA	1 (1.2%)	2 (3.0%)	3 (2.0%)
PRURITUS	1 (1.2%)	2 (3.0%)	3 (2.0%)
RASH	1 (1.2%)	2 (3.0%)	3 (2.0%)
URINARY INCONTINENCE	1 (1.2%)	2 (3.0%)	3 (2.0%)
ARTHRALGIA	2 (2.5%)	0	2 (1.4%)
FACE EDEMA	2 (2.5%)	0	2 (1.4%)
PNEUMONIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
CONCENTRATION IMPAIRED	0	2 (3.0%)	2 (1.4%)
EPISTAXIS	0	2 (3.0%)	2 (1.4%)
HYPESTHESIA	0	2 (3.0%)	2 (1.4%)
SYNCOPE	0	2 (3.0%)	2 (1.4%)
TREMOR	0	2 (3.0%)	2 (1.4%)
WITHDRAWAL SYNDROME	0	2 (3.0%)	2 (1.4%)
CONSTIPATION	1 (1.2%)	0	1 (0.7%)
NEUROSIS	1 (1.2%)	0	1 (0.7%)
VERTIGO	1 (1.2%)	0	1 (0.7%)
ABNORMAL VISION	0	1 (1.5%)	1 (0.7%)
GASTROENTERITIS	0	1 (1.5%)	1 (0.7%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
TOTAL	3 (9.1%)	0	3 (4.8%)
DYSMENORRHEA	3 (9.1%)	0	3 (4.8%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
TOTAL	40 (76.9%)	48 (75.0%)	88 (75.9%)
HEADACHE	19 (36.5%)	17 (26.6%)	36 (31.0%)
RESPIRATORY DISORDER	6 (11.5%)	13 (20.3%)	19 (16.4%)
INFECTION	8 (15.4%)	7 (10.9%)	15 (12.9%)
ABDOMINAL PAIN	6 (11.5%)	8 (12.5%)	14 (12.1%)
NERVOUSNESS	2 (3.8%)	12 (18.8%)	14 (12.1%)
INSOMNIA	6 (11.5%)	7 (10.9%)	13 (11.2%)
NAUSEA	6 (11.5%)	7 (10.9%)	13 (11.2%)
TRAUMA	5 (9.6%)	8 (12.5%)	13 (11.2%)
HYPERKINESIA	6 (11.5%)	6 (9.4%)	12 (10.3%)
PHARYNGITIS	6 (11.5%)	5 (7.8%)	11 (9.5%)
RHINITIS	5 (9.6%)	5 (7.8%)	10 (8.6%)
HOSTILITY	2 (3.8%)	7 (10.9%)	9 (7.8%)
ALLERGIC REACTION	4 (7.7%)	4 (6.3%)	8 (6.9%)
SINUSITIS	6 (11.5%)	1 (1.6%)	7 (6.0%)
ASTHENIA	3 (5.8%)	4 (6.3%)	7 (6.0%)
DIZZINESS	3 (5.8%)	3 (4.7%)	6 (5.2%)
DYSPEPSIA	3 (5.8%)	3 (4.7%)	6 (5.2%)
FEVER	3 (5.8%)	3 (4.7%)	6 (5.2%)
OTITIS MEDIA	3 (5.8%)	3 (4.7%)	6 (5.2%)
ANXIETY	2 (3.8%)	4 (6.3%)	6 (5.2%)
DECREASED APPETITE	2 (3.8%)	4 (6.3%)	6 (5.2%)
ALBUMINURIA	5 (9.6%)	0	5 (4.3%)
DIARRHEA	4 (7.7%)	1 (1.6%)	5 (4.3%)
NEUROSIS	4 (7.7%)	1 (1.6%)	5 (4.3%)
SOMNOLENCE	2 (3.8%)	3 (4.7%)	5 (4.3%)
WEIGHT GAIN	2 (3.8%)	3 (4.7%)	5 (4.3%)
EMOTIONAL LABILITY	3 (5.8%)	1 (1.6%)	4 (3.4%)
PAIN	3 (5.8%)	1 (1.6%)	4 (3.4%)
ACNE	2 (3.8%)	2 (3.1%)	4 (3.4%)
ASTHMA	2 (3.8%)	2 (3.1%)	4 (3.4%)
AGITATION	1 (1.9%)	3 (4.7%)	4 (3.4%)
VASODILATATION	0	4 (6.3%)	4 (3.4%)
ARTHRALGIA	2 (3.8%)	1 (1.6%)	3 (2.6%)
COUGH INCREASED	2 (3.8%)	1 (1.6%)	3 (2.6%)
OTITIS EXTERNA	2 (3.8%)	1 (1.6%)	3 (2.6%)
TOOTH DISORDER	2 (3.8%)	1 (1.6%)	3 (2.6%)
ABNORMAL DREAMS	1 (1.9%)	2 (3.1%)	3 (2.6%)
VERTIGO	1 (1.9%)	2 (3.1%)	3 (2.6%)
CONTACT DERMATITIS	0	3 (4.7%)	3 (2.6%)
RASH	0	3 (4.7%)	3 (2.6%)
CONCENTRATION IMPAIRED	2 (3.8%)	0	2 (1.7%)
BACK PAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
CONSTIPATION	1 (1.9%)	1 (1.6%)	2 (1.7%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
DEPRESSION	1 (1.9%)	1 (1.6%)	2 (1.7%)
DRY MOUTH	0	2 (3.1%)	2 (1.7%)
FLATULENCE	0	2 (3.1%)	2 (1.7%)
TREMOR	0	2 (3.1%)	2 (1.7%)
URINARY INCONTINENCE	0	2 (3.1%)	2 (1.7%)
BRONCHITIS	1 (1.9%)	0	1 (0.9%)
HAEMATURIA	1 (1.9%)	0	1 (0.9%)
MYALGIA	1 (1.9%)	0	1 (0.9%)
VOMITING	1 (1.9%)	0	1 (0.9%)
ABNORMAL VISION	0	1 (1.6%)	1 (0.9%)
EPISTAXIS	0	1 (1.6%)	1 (0.9%)
GASTROENTERITIS	0	1 (1.6%)	1 (0.9%)
PNEUMONIA	0	1 (1.6%)	1 (0.9%)
SYNCOPE	0	1 (1.6%)	1 (0.9%)
TOOTH CARIES	0	1 (1.6%)	1 (0.9%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
TOTAL	4 (14.3%)	1 (4.5%)	5 (10.0%)
DYSMENORRHEA	4 (14.3%)	1 (4.5%)	5 (10.0%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Preferred Term			
TOTAL	106 (79.7%)	91 (70.0%)	197 (74.9%)
HEADACHE	39 (29.3%)	27 (20.8%)	66 (25.1%)
RESPIRATORY DISORDER	23 (17.3%)	26 (20.0%)	49 (18.6%)
TRAUMA	22 (16.5%)	14 (10.8%)	36 (13.7%)
INFECTION	16 (12.0%)	18 (13.8%)	34 (12.9%)
PHARYNGITIS	18 (13.5%)	10 (7.7%)	28 (10.6%)
ABDOMINAL PAIN	16 (12.0%)	12 (9.2%)	28 (10.6%)
NAUSEA	14 (10.5%)	12 (9.2%)	26 (9.9%)
NERVOUSNESS	10 (7.5%)	13 (10.0%)	23 (8.7%)
RHINITIS	13 (9.8%)	9 (6.9%)	22 (8.4%)
INSOMNIA	10 (7.5%)	12 (9.2%)	22 (8.4%)
FEVER	12 (9.0%)	6 (4.6%)	18 (6.8%)
VOMITING	13 (9.8%)	4 (3.1%)	17 (6.5%)
ALLERGIC REACTION	11 (8.3%)	6 (4.6%)	17 (6.5%)
DYSPEPSIA	10 (7.5%)	7 (5.4%)	17 (6.5%)
WEIGHT GAIN	8 (6.0%)	9 (6.9%)	17 (6.5%)
HOSTILITY	7 (5.3%)	9 (6.9%)	16 (6.1%)
HYPERKINESIA	8 (6.0%)	7 (5.4%)	15 (5.7%)
ASTHENIA	6 (4.5%)	9 (6.9%)	15 (5.7%)
SINUSITIS	12 (9.0%)	2 (1.5%)	14 (5.3%)
EMOTIONAL LABILITY	10 (7.5%)	4 (3.1%)	14 (5.3%)
SOMNOLENCE	7 (5.3%)	7 (5.4%)	14 (5.3%)
DIARRHEA	9 (6.8%)	3 (2.3%)	12 (4.6%)
DIZZINESS	6 (4.5%)	5 (3.8%)	11 (4.2%)
DECREASED APPETITE	4 (3.0%)	7 (5.4%)	11 (4.2%)
ALBUMINURIA	8 (6.0%)	2 (1.5%)	10 (3.8%)
OTITIS MEDIA	6 (4.5%)	4 (3.1%)	10 (3.8%)
ASTHMA	5 (3.8%)	5 (3.8%)	10 (3.8%)
AGITATION	4 (3.0%)	6 (4.6%)	10 (3.8%)
COUGH INCREASED	6 (4.5%)	3 (2.3%)	9 (3.4%)
PAIN	6 (4.5%)	3 (2.3%)	9 (3.4%)
ANXIETY	3 (2.3%)	6 (4.6%)	9 (3.4%)
ACNE	5 (3.8%)	3 (2.3%)	8 (3.0%)
BACK PAIN	4 (3.0%)	4 (3.1%)	8 (3.0%)
CONTACT DERMATITIS	4 (3.0%)	4 (3.1%)	8 (3.0%)
DEPRESSION	5 (3.8%)	2 (1.5%)	7 (2.7%)
NEUROSIS	5 (3.8%)	1 (0.8%)	6 (2.3%)
BRONCHITIS	3 (2.3%)	3 (2.3%)	6 (2.3%)
RASH	1 (0.8%)	5 (3.8%)	6 (2.3%)
ARTHRALGIA	4 (3.0%)	1 (0.8%)	5 (1.9%)
DRY MOUTH	3 (2.3%)	2 (1.5%)	5 (1.9%)
LEUKOPENIA	3 (2.3%)	2 (1.5%)	5 (1.9%)
TOOTH CARIES	1 (0.8%)	4 (3.1%)	5 (1.9%)
URINARY INCONTINENCE	1 (0.8%)	4 (3.1%)	5 (1.9%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
CONCENTRATION IMPAIRED	2 (1.5%)	2 (1.5%)	4 (1.5%)
HAEMATURIA	2 (1.5%)	2 (1.5%)	4 (1.5%)
MYALGIA	2 (1.5%)	2 (1.5%)	4 (1.5%)
VERTIGO	2 (1.5%)	2 (1.5%)	4 (1.5%)
TREMOR	0	4 (3.1%)	4 (1.5%)
VASODILATATION	0	4 (3.1%)	4 (1.5%)
CHEST PAIN	3 (2.3%)	0	3 (1.1%)
CONSTIPATION	2 (1.5%)	1 (0.8%)	3 (1.1%)
OTITIS EXTERNA	2 (1.5%)	1 (0.8%)	3 (1.1%)
TOOTH DISORDER	2 (1.5%)	1 (0.8%)	3 (1.1%)
ABNORMAL DREAMS	1 (0.8%)	2 (1.5%)	3 (1.1%)
HALLUCINATIONS	1 (0.8%)	2 (1.5%)	3 (1.1%)
INCREASED APPETITE	1 (0.8%)	2 (1.5%)	3 (1.1%)
PNEUMONIA	1 (0.8%)	2 (1.5%)	3 (1.1%)
PRURITUS	1 (0.8%)	2 (1.5%)	3 (1.1%)
EPISTAXIS	0	3 (2.3%)	3 (1.1%)
SYNCOPE	0	3 (2.3%)	3 (1.1%)
FACE EDEMA	2 (1.5%)	0	2 (0.8%)
ABNORMAL VISION	0	2 (1.5%)	2 (0.8%)
FLATULENCE	0	2 (1.5%)	2 (0.8%)
GASTROENTERITIS	0	2 (1.5%)	2 (0.8%)
HYPESTHESIA	0	2 (1.5%)	2 (0.8%)
WITHDRAWAL SYNDROME	0	2 (1.5%)	2 (0.8%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
TOTAL	0	0	0

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase or Taper Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Preferred Term			
TOTAL	7 (11.5%)	1 (2.0%)	8 (7.1%)
DYSMENORRHEA	7 (11.5%)	1 (2.0%)	8 (7.1%)

Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=22)	Placebo (N=18)	Total (N=40)
Body System	Preferred Term			
TOTAL	TOTAL	8 (36.4%)	5 (27.8%)	13 (32.5%)
Body as a Whole	TOTAL	3 (13.6%)	1 (5.6%)	4 (10.0%)
	ABDOMINAL PAIN	3 (13.6%)	0	3 (7.5%)
	HEADACHE	2 (9.1%)	0	2 (5.0%)
	ALLERGIC REACTION	0	1 (5.6%)	1 (2.5%)
Digestive System	TOTAL	3 (13.6%)	2 (11.1%)	5 (12.5%)
	NAUSEA	1 (4.5%)	1 (5.6%)	2 (5.0%)
	INCREASED APPETITE	1 (4.5%)	0	1 (2.5%)
	TOOTH DISORDER	1 (4.5%)	0	1 (2.5%)
	VOMITING	1 (4.5%)	0	1 (2.5%)
	DIARRHEA	0	1 (5.6%)	1 (2.5%)
	FECAL INCONTINENCE	0	1 (5.6%)	1 (2.5%)
Nervous System	TOTAL	3 (13.6%)	2 (11.1%)	5 (12.5%)
	ANXIETY	1 (4.5%)	0	1 (2.5%)
	DEPRESSION	1 (4.5%)	0	1 (2.5%)
	INSOMNIA	1 (4.5%)	0	1 (2.5%)
	NERVOUSNESS	1 (4.5%)	0	1 (2.5%)
	WITHDRAWAL SYNDROME	1 (4.5%)	0	1 (2.5%)
	CONCENTRATION IMPAIRED	0	1 (5.6%)	1 (2.5%)
	HOSTILITY	0	1 (5.6%)	1 (2.5%)
Respiratory System	TOTAL	2 (9.1%)	2 (11.1%)	4 (10.0%)
	RESPIRATORY DISORDER	2 (9.1%)	2 (11.1%)	4 (10.0%)
Cardiovascular System	TOTAL	1 (4.5%)	0	1 (2.5%)
	MIGRAINE	1 (4.5%)	0	1 (2.5%)
Musculoskeletal System	TOTAL	1 (4.5%)	0	1 (2.5%)
	MYALGIA	1 (4.5%)	0	1 (2.5%)
Hemic and Lymphatic System	TOTAL	0	1 (5.6%)	1 (2.5%)
	LYMPHOCYTOSIS	0	1 (5.6%)	1 (2.5%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (5.6%)	1 (2.5%)
	SGOT INCREASED	0	1 (5.6%)	1 (2.5%)
Urogenital System	TOTAL	0	1 (5.6%)	1 (2.5%)
	URINARY INCONTINENCE	0	1 (5.6%)	1 (2.5%)

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=10)	Total (N=22)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=8)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=22)	Total (N=35)
Body System	Preferred Term			
TOTAL	TOTAL	5 (38.5%)	6 (27.3%)	11 (31.4%)
Body as a Whole	TOTAL	4 (30.8%)	4 (18.2%)	8 (22.9%)
	HEADACHE	2 (15.4%)	2 (9.1%)	4 (11.4%)
	FEVER	1 (7.7%)	1 (4.5%)	2 (5.7%)
	PAIN	1 (7.7%)	0	1 (2.9%)
	INFECTION	0	1 (4.5%)	1 (2.9%)
Digestive System	TOTAL	1 (7.7%)	0	1 (2.9%)
	TOOTH DISORDER	1 (7.7%)	0	1 (2.9%)
Nervous System	TOTAL	1 (7.7%)	0	1 (2.9%)
	NEUROSIS	1 (7.7%)	0	1 (2.9%)
Special Senses	TOTAL	1 (7.7%)	0	1 (2.9%)
	EAR PAIN	1 (7.7%)	0	1 (2.9%)
Respiratory System	TOTAL	0	1 (4.5%)	1 (2.9%)
	COUGH INCREASED	0	1 (4.5%)	1 (2.9%)
Skin and Appendages	TOTAL	0	1 (4.5%)	1 (2.9%)
	FUNGAL DERMATITIS	0	1 (4.5%)	1 (2.9%)

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=14)	Total (N=19)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=8)	Total (N=16)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=35)	Placebo (N=40)	Total (N=75)
Body System	Preferred Term			
TOTAL	TOTAL	13 (37.1%)	11 (27.5%)	24 (32.0%)
Body as a Whole	TOTAL	7 (20.0%)	5 (12.5%)	12 (16.0%)
	HEADACHE	4 (11.4%)	2 (5.0%)	6 (8.0%)
	ABDOMINAL PAIN	3 (8.6%)	0	3 (4.0%)
	FEVER	1 (2.9%)	1 (2.5%)	2 (2.7%)
	PAIN	1 (2.9%)	0	1 (1.3%)
	ALLERGIC REACTION	0	1 (2.5%)	1 (1.3%)
	INFECTION	0	1 (2.5%)	1 (1.3%)
Digestive System	TOTAL	4 (11.4%)	2 (5.0%)	6 (8.0%)
	TOOTH DISORDER	2 (5.7%)	0	2 (2.7%)
	NAUSEA	1 (2.9%)	1 (2.5%)	2 (2.7%)
	INCREASED APPETITE	1 (2.9%)	0	1 (1.3%)
	VOMITING	1 (2.9%)	0	1 (1.3%)
	DIARRHEA	0	1 (2.5%)	1 (1.3%)
	FECAL INCONTINENCE	0	1 (2.5%)	1 (1.3%)
Nervous System	TOTAL	4 (11.4%)	2 (5.0%)	6 (8.0%)
	ANXIETY	1 (2.9%)	0	1 (1.3%)
	DEPRESSION	1 (2.9%)	0	1 (1.3%)
	INSOMNIA	1 (2.9%)	0	1 (1.3%)
	NERVOUSNESS	1 (2.9%)	0	1 (1.3%)
	NEUROSIS	1 (2.9%)	0	1 (1.3%)
	WITHDRAWAL SYNDROME	1 (2.9%)	0	1 (1.3%)
	CONCENTRATION IMPAIRED	0	1 (2.5%)	1 (1.3%)
	HOSTILITY	0	1 (2.5%)	1 (1.3%)
Respiratory System	TOTAL	2 (5.7%)	3 (7.5%)	5 (6.7%)
	RESPIRATORY DISORDER	2 (5.7%)	2 (5.0%)	4 (5.3%)
	COUGH INCREASED	0	1 (2.5%)	1 (1.3%)
Cardiovascular System	TOTAL	1 (2.9%)	0	1 (1.3%)
	MIGRAINE	1 (2.9%)	0	1 (1.3%)
Musculoskeletal System	TOTAL	1 (2.9%)	0	1 (1.3%)
	MYALGIA	1 (2.9%)	0	1 (1.3%)
Special Senses	TOTAL	1 (2.9%)	0	1 (1.3%)
	EAR PAIN	1 (2.9%)	0	1 (1.3%)
Hemic and Lymphatic System	TOTAL	0	1 (2.5%)	1 (1.3%)
	LYMPHOCYTOSIS	0	1 (2.5%)	1 (1.3%)

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=35)	Placebo (N=40)	Total (N=75)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.5%)	1 (1.3%)
	SGOT INCREASED	0	1 (2.5%)	1 (1.3%)
Skin and Appendages	TOTAL	0	1 (2.5%)	1 (1.3%)
	FUNGAL DERMATITIS	0	1 (2.5%)	1 (1.3%)
Urogenital System	TOTAL	0	1 (2.5%)	1 (1.3%)
	URINARY INCONTINENCE	0	1 (2.5%)	1 (1.3%)

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=17)	Placebo (N=24)	Total (N=41)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=18)	Placebo (N=16)	Total (N=34)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=27)	Placebo (N=16)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	7 (25.9%)	2 (12.5%)	9 (20.9%)
Respiratory System	TOTAL	4 (14.8%)	1 (6.3%)	5 (11.6%)
	RESPIRATORY DISORDER	1 (3.7%)	1 (6.3%)	2 (4.7%)
	ASTHMA	1 (3.7%)	0	1 (2.3%)
	PHARYNGITIS	1 (3.7%)	0	1 (2.3%)
	SINUSITIS	1 (3.7%)	0	1 (2.3%)
Digestive System	TOTAL	2 (7.4%)	0	2 (4.7%)
	COLITIS	1 (3.7%)	0	1 (2.3%)
	DIARRHEA	1 (3.7%)	0	1 (2.3%)
	GASTROINTESTINAL DISORDER	1 (3.7%)	0	1 (2.3%)
Nervous System	TOTAL	1 (3.7%)	0	1 (2.3%)
	EMOTIONAL LABILITY	1 (3.7%)	0	1 (2.3%)
Urogenital System	TOTAL	1 (3.7%)	0	1 (2.3%)
	ALBUMINURIA	1 (3.7%)	0	1 (2.3%)
Body as a Whole	TOTAL	0	1 (6.3%)	1 (2.3%)
	INFECTION	0	1 (6.3%)	1 (2.3%)

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=17)	Placebo (N=8)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=8)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=11)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	5 (50.0%)	2 (18.2%)	7 (33.3%)
Respiratory System	TOTAL	3 (30.0%)	1 (9.1%)	4 (19.0%)
	RESPIRATORY DISORDER	1 (10.0%)	1 (9.1%)	2 (9.5%)
	COUGH INCREASED	1 (10.0%)	0	1 (4.8%)
	SINUSITIS	1 (10.0%)	0	1 (4.8%)
Nervous System	TOTAL	2 (20.0%)	0	2 (9.5%)
	CONCENTRATION IMPAIRED	1 (10.0%)	0	1 (4.8%)
	DIZZINESS	1 (10.0%)	0	1 (4.8%)
	PARESTHESIA	1 (10.0%)	0	1 (4.8%)
Body as a Whole	TOTAL	1 (10.0%)	0	1 (4.8%)
	HEADACHE	1 (10.0%)	0	1 (4.8%)
Digestive System	TOTAL	0	1 (9.1%)	1 (4.8%)
	DIARRHEA	0	1 (9.1%)	1 (4.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (9.1%)	1 (4.8%)
	NAUSEA	0	1 (9.1%)	1 (4.8%)
	VOMITING	0	1 (9.1%)	1 (4.8%)

Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=4)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=37)	Placebo (N=27)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	12 (32.4%)	4 (14.8%)	16 (25.0%)
Respiratory System	TOTAL	7 (18.9%)	2 (7.4%)	9 (14.1%)
	RESPIRATORY DISORDER	2 (5.4%)	2 (7.4%)	4 (6.3%)
	SINUSITIS	2 (5.4%)	0	2 (3.1%)
	ASTHMA	1 (2.7%)	0	1 (1.6%)
	COUGH INCREASED	1 (2.7%)	0	1 (1.6%)
	PHARYNGITIS	1 (2.7%)	0	1 (1.6%)
Nervous System	TOTAL	3 (8.1%)	0	3 (4.7%)
	CONCENTRATION IMPAIRED	1 (2.7%)	0	1 (1.6%)
	DIZZINESS	1 (2.7%)	0	1 (1.6%)
	EMOTIONAL LABILITY	1 (2.7%)	0	1 (1.6%)
	PARESTHESIA	1 (2.7%)	0	1 (1.6%)
Digestive System	TOTAL	2 (5.4%)	1 (3.7%)	3 (4.7%)
	DIARRHEA	1 (2.7%)	1 (3.7%)	2 (3.1%)
	COLITIS	1 (2.7%)	0	1 (1.6%)
	GASTROINTESTINAL DISORDER	1 (2.7%)	0	1 (1.6%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (3.7%)	1 (1.6%)
	NAUSEA	0	1 (3.7%)	1 (1.6%)
	VOMITING	0	1 (3.7%)	1 (1.6%)
Body as a Whole	TOTAL	1 (2.7%)	1 (3.7%)	2 (3.1%)
	HEADACHE	1 (2.7%)	0	1 (1.6%)
	INFECTION	0	1 (3.7%)	1 (1.6%)
Urogenital System	TOTAL	1 (2.7%)	0	1 (1.6%)
	ALBUMINURIA	1 (2.7%)	0	1 (1.6%)

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=15)	Total (N=38)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=12)	Total (N=26)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=34)	Total (N=83)
Body System	Preferred Term			
TOTAL	TOTAL	15 (30.6%)	7 (20.6%)	22 (26.5%)
Respiratory System	TOTAL	6 (12.2%)	3 (8.8%)	9 (10.8%)
	RESPIRATORY DISORDER	3 (6.1%)	3 (8.8%)	6 (7.2%)
	ASTHMA	1 (2.0%)	0	1 (1.2%)
	PHARYNGITIS	1 (2.0%)	0	1 (1.2%)
	SINUSITIS	1 (2.0%)	0	1 (1.2%)
Digestive System	TOTAL	5 (10.2%)	2 (5.9%)	7 (8.4%)
	DIARRHEA	1 (2.0%)	1 (2.9%)	2 (2.4%)
	NAUSEA	1 (2.0%)	1 (2.9%)	2 (2.4%)
	COLITIS	1 (2.0%)	0	1 (1.2%)
	GASTROINTESTINAL DISORDER	1 (2.0%)	0	1 (1.2%)
	INCREASED APPETITE	1 (2.0%)	0	1 (1.2%)
	TOOTH DISORDER	1 (2.0%)	0	1 (1.2%)
	VOMITING	1 (2.0%)	0	1 (1.2%)
	FECAL INCONTINENCE	0	1 (2.9%)	1 (1.2%)
Nervous System	TOTAL	4 (8.2%)	2 (5.9%)	6 (7.2%)
	ANXIETY	1 (2.0%)	0	1 (1.2%)
	DEPRESSION	1 (2.0%)	0	1 (1.2%)
	EMOTIONAL LABILITY	1 (2.0%)	0	1 (1.2%)
	INSOMNIA	1 (2.0%)	0	1 (1.2%)
	NERVOUSNESS	1 (2.0%)	0	1 (1.2%)
	WITHDRAWAL SYNDROME	1 (2.0%)	0	1 (1.2%)
	CONCENTRATION IMPAIRED	0	1 (2.9%)	1 (1.2%)
	HOSTILITY	0	1 (2.9%)	1 (1.2%)
Body as a Whole	TOTAL	3 (6.1%)	2 (5.9%)	5 (6.0%)
	ABDOMINAL PAIN	3 (6.1%)	0	3 (3.6%)
	HEADACHE	2 (4.1%)	0	2 (2.4%)
	ALLERGIC REACTION	0	1 (2.9%)	1 (1.2%)
	INFECTION	0	1 (2.9%)	1 (1.2%)
Cardiovascular System	TOTAL	1 (2.0%)	0	1 (1.2%)
	MIGRAINE	1 (2.0%)	0	1 (1.2%)
Musculoskeletal System	TOTAL	1 (2.0%)	0	1 (1.2%)
	MYALGIA	1 (2.0%)	0	1 (1.2%)
Urogenital System	TOTAL	1 (2.0%)	1 (2.9%)	2 (2.4%)
	ALBUMINURIA	1 (2.0%)	0	1 (1.2%)
	URINARY INCONTINENCE	0	1 (2.9%)	1 (1.2%)

Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=34)	Total (N=83)
Body System	Preferred Term			
Hemic and Lymphatic System	TOTAL	0	1 (2.9%)	1 (1.2%)
	LYMPHOCYTOSIS	0	1 (2.9%)	1 (1.2%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.9%)	1 (1.2%)
	SGOT INCREASED	0	1 (2.9%)	1 (1.2%)

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=29)	Placebo (N=18)	Total (N=47)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=16)	Total (N=36)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=33)	Total (N=56)
Body System	Preferred Term			
TOTAL	TOTAL	10 (43.5%)	8 (24.2%)	18 (32.1%)
Body as a Whole	TOTAL	5 (21.7%)	4 (12.1%)	9 (16.1%)
	HEADACHE	3 (13.0%)	2 (6.1%)	5 (8.9%)
	FEVER	1 (4.3%)	1 (3.0%)	2 (3.6%)
	PAIN	1 (4.3%)	0	1 (1.8%)
	INFECTION	0	1 (3.0%)	1 (1.8%)
Nervous System	TOTAL	3 (13.0%)	0	3 (5.4%)
	CONCENTRATION IMPAIRED	1 (4.3%)	0	1 (1.8%)
	DIZZINESS	1 (4.3%)	0	1 (1.8%)
	NEUROSIS	1 (4.3%)	0	1 (1.8%)
	PARESTHESIA	1 (4.3%)	0	1 (1.8%)
Respiratory System	TOTAL	3 (13.0%)	2 (6.1%)	5 (8.9%)
	COUGH INCREASED	1 (4.3%)	1 (3.0%)	2 (3.6%)
	RESPIRATORY DISORDER	1 (4.3%)	1 (3.0%)	2 (3.6%)
	SINUSITIS	1 (4.3%)	0	1 (1.8%)
Digestive System	TOTAL	1 (4.3%)	1 (3.0%)	2 (3.6%)
	TOOTH DISORDER	1 (4.3%)	0	1 (1.8%)
	DIARRHEA	0	1 (3.0%)	1 (1.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (3.0%)	1 (1.8%)
	NAUSEA	0	1 (3.0%)	1 (1.8%)
	VOMITING	0	1 (3.0%)	1 (1.8%)
Special Senses	TOTAL	1 (4.3%)	0	1 (1.8%)
	EAR PAIN	1 (4.3%)	0	1 (1.8%)
Skin and Appendages	TOTAL	0	1 (3.0%)	1 (1.8%)
	FUNGAL DERMATITIS	0	1 (3.0%)	1 (1.8%)

Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=21)	Total (N=32)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=12)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=67)	Total (N=139)
Body System	Preferred Term			
TOTAL	TOTAL	25 (34.7%)	15 (22.4%)	40 (28.8%)
Respiratory System	TOTAL	9 (12.5%)	5 (7.5%)	14 (10.1%)
	RESPIRATORY DISORDER	4 (5.6%)	4 (6.0%)	8 (5.8%)
	SINUSITIS	2 (2.8%)	0	2 (1.4%)
	COUGH INCREASED	1 (1.4%)	1 (1.5%)	2 (1.4%)
	ASTHMA	1 (1.4%)	0	1 (0.7%)
	PHARYNGITIS	1 (1.4%)	0	1 (0.7%)
Body as a Whole	TOTAL	8 (11.1%)	6 (9.0%)	14 (10.1%)
	HEADACHE	5 (6.9%)	2 (3.0%)	7 (5.0%)
	ABDOMINAL PAIN	3 (4.2%)	0	3 (2.2%)
	FEVER	1 (1.4%)	1 (1.5%)	2 (1.4%)
	INFECTION	0	2 (3.0%)	2 (1.4%)
	PAIN	1 (1.4%)	0	1 (0.7%)
	ALLERGIC REACTION	0	1 (1.5%)	1 (0.7%)
Nervous System	TOTAL	7 (9.7%)	2 (3.0%)	9 (6.5%)
	CONCENTRATION IMPAIRED	1 (1.4%)	1 (1.5%)	2 (1.4%)
	ANXIETY	1 (1.4%)	0	1 (0.7%)
	DEPRESSION	1 (1.4%)	0	1 (0.7%)
	DIZZINESS	1 (1.4%)	0	1 (0.7%)
	EMOTIONAL LABILITY	1 (1.4%)	0	1 (0.7%)
	INSOMNIA	1 (1.4%)	0	1 (0.7%)
	NERVOUSNESS	1 (1.4%)	0	1 (0.7%)
	NEUROSIS	1 (1.4%)	0	1 (0.7%)
	PARESTHESIA	1 (1.4%)	0	1 (0.7%)
	WITHDRAWAL SYNDROME	1 (1.4%)	0	1 (0.7%)
	HOSTILITY	0	1 (1.5%)	1 (0.7%)
Digestive System	TOTAL	6 (8.3%)	3 (4.5%)	9 (6.5%)
	DIARRHEA	1 (1.4%)	2 (3.0%)	3 (2.2%)
	NAUSEA	1 (1.4%)	2 (3.0%)	3 (2.2%)
	TOOTH DISORDER	2 (2.8%)	0	2 (1.4%)
	VOMITING	1 (1.4%)	1 (1.5%)	2 (1.4%)
	COLITIS	1 (1.4%)	0	1 (0.7%)
	GASTROINTESTINAL DISORDER	1 (1.4%)	0	1 (0.7%)
	INCREASED APPETITE	1 (1.4%)	0	1 (0.7%)
	FECAL INCONTINENCE	0	1 (1.5%)	1 (0.7%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.7%)
Cardiovascular System	TOTAL	1 (1.4%)	0	1 (0.7%)
	MIGRAINE	1 (1.4%)	0	1 (0.7%)

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=67)	Total (N=139)
Body System	Preferred Term			
Musculoskeletal System	TOTAL	1 (1.4%)	0	1 (0.7%)
	MYALGIA	1 (1.4%)	0	1 (0.7%)
Special Senses	TOTAL	1 (1.4%)	0	1 (0.7%)
	EAR PAIN	1 (1.4%)	0	1 (0.7%)
Urogenital System	TOTAL	1 (1.4%)	1 (1.5%)	2 (1.4%)
	ALBUMINURIA	1 (1.4%)	0	1 (0.7%)
	URINARY INCONTINENCE	0	1 (1.5%)	1 (0.7%)
Hemic and Lymphatic System	TOTAL	0	1 (1.5%)	1 (0.7%)
	LYMPHOCYTOSIS	0	1 (1.5%)	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.5%)	1 (0.7%)
	SGOT INCREASED	0	1 (1.5%)	1 (0.7%)
Skin and Appendages	TOTAL	0	1 (1.5%)	1 (0.7%)
	FUNGAL DERMATITIS	0	1 (1.5%)	1 (0.7%)

Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=40)	Placebo (N=39)	Total (N=79)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=32)	Placebo (N=28)	Total (N=60)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=22)	Placebo (N=18)	Total (N=40)
Preferred Term			
TOTAL	8 (36.4%)	5 (27.8%)	13 (32.5%)
RESPIRATORY DISORDER	2 (9.1%)	2 (11.1%)	4 (10.0%)
ABDOMINAL PAIN	3 (13.6%)	0	3 (7.5%)
HEADACHE	2 (9.1%)	0	2 (5.0%)
NAUSEA	1 (4.5%)	1 (5.6%)	2 (5.0%)
ANXIETY	1 (4.5%)	0	1 (2.5%)
DEPRESSION	1 (4.5%)	0	1 (2.5%)
INCREASED APPETITE	1 (4.5%)	0	1 (2.5%)
INSOMNIA	1 (4.5%)	0	1 (2.5%)
MIGRAINE	1 (4.5%)	0	1 (2.5%)
MYALGIA	1 (4.5%)	0	1 (2.5%)
NERVOUSNESS	1 (4.5%)	0	1 (2.5%)
TOOTH DISORDER	1 (4.5%)	0	1 (2.5%)
VOMITING	1 (4.5%)	0	1 (2.5%)
WITHDRAWAL SYNDROME	1 (4.5%)	0	1 (2.5%)
ALLERGIC REACTION	0	1 (5.6%)	1 (2.5%)
CONCENTRATION IMPAIRED	0	1 (5.6%)	1 (2.5%)
DIARRHEA	0	1 (5.6%)	1 (2.5%)
FECAL INCONTINENCE	0	1 (5.6%)	1 (2.5%)
HOSTILITY	0	1 (5.6%)	1 (2.5%)
LYMPHOCYTOSIS	0	1 (5.6%)	1 (2.5%)
SGOT INCREASED	0	1 (5.6%)	1 (2.5%)
URINARY INCONTINENCE	0	1 (5.6%)	1 (2.5%)

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=12)	Placebo (N=10)	Total (N=22)
TOTAL	0	0	0

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=10)	Placebo (N=8)	Total (N=18)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=13)	Placebo (N=22)	Total (N=35)
Preferred Term			
TOTAL	5 (38.5%)	6 (27.3%)	11 (31.4%)
HEADACHE	2 (15.4%)	2 (9.1%)	4 (11.4%)
FEVER	1 (7.7%)	1 (4.5%)	2 (5.7%)
EAR PAIN	1 (7.7%)	0	1 (2.9%)
NEUROSIS	1 (7.7%)	0	1 (2.9%)
PAIN	1 (7.7%)	0	1 (2.9%)
TOOTH DISORDER	1 (7.7%)	0	1 (2.9%)
COUGH INCREASED	0	1 (4.5%)	1 (2.9%)
FUNGAL DERMATITIS	0	1 (4.5%)	1 (2.9%)
INFECTION	0	1 (4.5%)	1 (2.9%)

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=5)	Placebo (N=14)	Total (N=19)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=8)	Placebo (N=8)	Total (N=16)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=35)	Placebo (N=40)	Total (N=75)
TOTAL	13 (37.1%)	11 (27.5%)	24 (32.0%)
HEADACHE	4 (11.4%)	2 (5.0%)	6 (8.0%)
RESPIRATORY DISORDER	2 (5.7%)	2 (5.0%)	4 (5.3%)
ABDOMINAL PAIN	3 (8.6%)	0	3 (4.0%)
TOOTH DISORDER	2 (5.7%)	0	2 (2.7%)
FEVER	1 (2.9%)	1 (2.5%)	2 (2.7%)
NAUSEA	1 (2.9%)	1 (2.5%)	2 (2.7%)
ANXIETY	1 (2.9%)	0	1 (1.3%)
DEPRESSION	1 (2.9%)	0	1 (1.3%)
EAR PAIN	1 (2.9%)	0	1 (1.3%)
INCREASED APPETITE	1 (2.9%)	0	1 (1.3%)
INSOMNIA	1 (2.9%)	0	1 (1.3%)
MIGRAINE	1 (2.9%)	0	1 (1.3%)
MYALGIA	1 (2.9%)	0	1 (1.3%)
NERVOUSNESS	1 (2.9%)	0	1 (1.3%)
NEUROSIS	1 (2.9%)	0	1 (1.3%)
PAIN	1 (2.9%)	0	1 (1.3%)
VOMITING	1 (2.9%)	0	1 (1.3%)
WITHDRAWAL SYNDROME	1 (2.9%)	0	1 (1.3%)
ALLERGIC REACTION	0	1 (2.5%)	1 (1.3%)
CONCENTRATION IMPAIRED	0	1 (2.5%)	1 (1.3%)
COUGH INCREASED	0	1 (2.5%)	1 (1.3%)
DIARRHEA	0	1 (2.5%)	1 (1.3%)
FECAL INCONTINENCE	0	1 (2.5%)	1 (1.3%)
FUNGAL DERMATITIS	0	1 (2.5%)	1 (1.3%)
HOSTILITY	0	1 (2.5%)	1 (1.3%)
INFECTION	0	1 (2.5%)	1 (1.3%)
LYMPHOCYTOSIS	0	1 (2.5%)	1 (1.3%)
SGOT INCREASED	0	1 (2.5%)	1 (1.3%)
URINARY INCONTINENCE	0	1 (2.5%)	1 (1.3%)

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=17)	Placebo (N=24)	Total (N=41)
TOTAL	0	0	0

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=18)	Placebo (N=16)	Total (N=34)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=27)	Placebo (N=16)	Total (N=43)
TOTAL	7 (25.9%)	2 (12.5%)	9 (20.9%)
RESPIRATORY DISORDER	1 (3.7%)	1 (6.3%)	2 (4.7%)
ALBUMINURIA	1 (3.7%)	0	1 (2.3%)
ASTHMA	1 (3.7%)	0	1 (2.3%)
COLITIS	1 (3.7%)	0	1 (2.3%)
DIARRHEA	1 (3.7%)	0	1 (2.3%)
EMOTIONAL LABILITY	1 (3.7%)	0	1 (2.3%)
GASTROINTESTINAL DISORDER	1 (3.7%)	0	1 (2.3%)
PHARYNGITIS	1 (3.7%)	0	1 (2.3%)
SINUSITIS	1 (3.7%)	0	1 (2.3%)
INFECTION	0	1 (6.3%)	1 (2.3%)

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=17)	Placebo (N=8)	Total (N=25)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=10)	Placebo (N=8)	Total (N=18)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=10)	Placebo (N=11)	Total (N=21)
Preferred Term			
TOTAL	5 (50.0%)	2 (18.2%)	7 (33.3%)
RESPIRATORY DISORDER	1 (10.0%)	1 (9.1%)	2 (9.5%)
CONCENTRATION IMPAIRED	1 (10.0%)	0	1 (4.8%)
COUGH INCREASED	1 (10.0%)	0	1 (4.8%)
DIZZINESS	1 (10.0%)	0	1 (4.8%)
HEADACHE	1 (10.0%)	0	1 (4.8%)
PARESTHESIA	1 (10.0%)	0	1 (4.8%)
SINUSITIS	1 (10.0%)	0	1 (4.8%)
DIARRHEA	0	1 (9.1%)	1 (4.8%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (9.1%)	1 (4.8%)
NAUSEA	0	1 (9.1%)	1 (4.8%)
VOMITING	0	1 (9.1%)	1 (4.8%)

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=4)	Placebo (N=4)	Total (N=8)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=37)	Placebo (N=27)	Total (N=64)
TOTAL	12 (32.4%)	4 (14.8%)	16 (25.0%)
RESPIRATORY DISORDER	2 (5.4%)	2 (7.4%)	4 (6.3%)
SINUSITIS	2 (5.4%)	0	2 (3.1%)
DIARRHEA	1 (2.7%)	1 (3.7%)	2 (3.1%)
ALBUMINURIA	1 (2.7%)	0	1 (1.6%)
ASTHMA	1 (2.7%)	0	1 (1.6%)
COLITIS	1 (2.7%)	0	1 (1.6%)
CONCENTRATION IMPAIRED	1 (2.7%)	0	1 (1.6%)
COUGH INCREASED	1 (2.7%)	0	1 (1.6%)
DIZZINESS	1 (2.7%)	0	1 (1.6%)
EMOTIONAL LABILITY	1 (2.7%)	0	1 (1.6%)
GASTROINTESTINAL DISORDER	1 (2.7%)	0	1 (1.6%)
HEADACHE	1 (2.7%)	0	1 (1.6%)
PARESTHESIA	1 (2.7%)	0	1 (1.6%)
PHARYNGITIS	1 (2.7%)	0	1 (1.6%)
INFECTION	0	1 (3.7%)	1 (1.6%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (3.7%)	1 (1.6%)
NAUSEA	0	1 (3.7%)	1 (1.6%)
VOMITING	0	1 (3.7%)	1 (1.6%)

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=23)	Placebo (N=15)	Total (N=38)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=14)	Placebo (N=12)	Total (N=26)
Preferred Term			
TOTAL	0	0	0

Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=49)	Placebo (N=34)	Total (N=83)
TOTAL	15 (30.6%)	7 (20.6%)	22 (26.5%)
RESPIRATORY DISORDER	3 (6.1%)	3 (8.8%)	6 (7.2%)
ABDOMINAL PAIN	3 (6.1%)	0	3 (3.6%)
HEADACHE	2 (4.1%)	0	2 (2.4%)
DIARRHEA	1 (2.0%)	1 (2.9%)	2 (2.4%)
NAUSEA	1 (2.0%)	1 (2.9%)	2 (2.4%)
ALBUMINURIA	1 (2.0%)	0	1 (1.2%)
ANXIETY	1 (2.0%)	0	1 (1.2%)
ASTHMA	1 (2.0%)	0	1 (1.2%)
COLITIS	1 (2.0%)	0	1 (1.2%)
DEPRESSION	1 (2.0%)	0	1 (1.2%)
EMOTIONAL LABILITY	1 (2.0%)	0	1 (1.2%)
GASTROINTESTINAL DISORDER	1 (2.0%)	0	1 (1.2%)
INCREASED APPETITE	1 (2.0%)	0	1 (1.2%)
INSOMNIA	1 (2.0%)	0	1 (1.2%)
MIGRAINE	1 (2.0%)	0	1 (1.2%)
MYALGIA	1 (2.0%)	0	1 (1.2%)
NERVOUSNESS	1 (2.0%)	0	1 (1.2%)
PHARYNGITIS	1 (2.0%)	0	1 (1.2%)
SINUSITIS	1 (2.0%)	0	1 (1.2%)
TOOTH DISORDER	1 (2.0%)	0	1 (1.2%)
VOMITING	1 (2.0%)	0	1 (1.2%)
WITHDRAWAL SYNDROME	1 (2.0%)	0	1 (1.2%)
ALLERGIC REACTION	0	1 (2.9%)	1 (1.2%)
CONCENTRATION IMPAIRED	0	1 (2.9%)	1 (1.2%)
FECAL INCONTINENCE	0	1 (2.9%)	1 (1.2%)
HOSTILITY	0	1 (2.9%)	1 (1.2%)
INFECTION	0	1 (2.9%)	1 (1.2%)
LYMPHOCYTOSIS	0	1 (2.9%)	1 (1.2%)
SGOT INCREASED	0	1 (2.9%)	1 (1.2%)
URINARY INCONTINENCE	0	1 (2.9%)	1 (1.2%)

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=29)	Placebo (N=18)	Total (N=47)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=20)	Placebo (N=16)	Total (N=36)
TOTAL	0	0	0

Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=23)	 Placebo (N=33)	 Total (N=56)
TOTAL	10 (43.5%)	8 (24.2%)	18 (32.1%)
HEADACHE	3 (13.0%)	2 (6.1%)	5 (8.9%)
COUGH INCREASED	1 (4.3%)	1 (3.0%)	2 (3.6%)
FEVER	1 (4.3%)	1 (3.0%)	2 (3.6%)
RESPIRATORY DISORDER	1 (4.3%)	1 (3.0%)	2 (3.6%)
CONCENTRATION IMPAIRED	1 (4.3%)	0	1 (1.8%)
DIZZINESS	1 (4.3%)	0	1 (1.8%)
EAR PAIN	1 (4.3%)	0	1 (1.8%)
NEUROSIS	1 (4.3%)	0	1 (1.8%)
PAIN	1 (4.3%)	0	1 (1.8%)
PARESTHESIA	1 (4.3%)	0	1 (1.8%)
SINUSITIS	1 (4.3%)	0	1 (1.8%)
TOOTH DISORDER	1 (4.3%)	0	1 (1.8%)
DIARRHEA	0	1 (3.0%)	1 (1.8%)
FUNGAL DERMATITIS	0	1 (3.0%)	1 (1.8%)
INFECTION	0	1 (3.0%)	1 (1.8%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (3.0%)	1 (1.8%)
NAUSEA	0	1 (3.0%)	1 (1.8%)
VOMITING	0	1 (3.0%)	1 (1.8%)

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=11)	Placebo (N=21)	Total (N=32)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=12)	Total (N=24)
Preferred Term			
TOTAL	0	0	0

Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=72)	Placebo (N=67)	Total (N=139)
TOTAL	25 (34.7%)	15 (22.4%)	40 (28.8%)
RESPIRATORY DISORDER	4 (5.6%)	4 (6.0%)	8 (5.8%)
HEADACHE	5 (6.9%)	2 (3.0%)	7 (5.0%)
ABDOMINAL PAIN	3 (4.2%)	0	3 (2.2%)
DIARRHEA	1 (1.4%)	2 (3.0%)	3 (2.2%)
NAUSEA	1 (1.4%)	2 (3.0%)	3 (2.2%)
SINUSITIS	2 (2.8%)	0	2 (1.4%)
TOOTH DISORDER	2 (2.8%)	0	2 (1.4%)
CONCENTRATION IMPAIRED	1 (1.4%)	1 (1.5%)	2 (1.4%)
COUGH INCREASED	1 (1.4%)	1 (1.5%)	2 (1.4%)
FEVER	1 (1.4%)	1 (1.5%)	2 (1.4%)
VOMITING	1 (1.4%)	1 (1.5%)	2 (1.4%)
INFECTION	0	2 (3.0%)	2 (1.4%)
ALBUMINURIA	1 (1.4%)	0	1 (0.7%)
ANXIETY	1 (1.4%)	0	1 (0.7%)
ASTHMA	1 (1.4%)	0	1 (0.7%)
COLITIS	1 (1.4%)	0	1 (0.7%)
DEPRESSION	1 (1.4%)	0	1 (0.7%)
DIZZINESS	1 (1.4%)	0	1 (0.7%)
EAR PAIN	1 (1.4%)	0	1 (0.7%)
EMOTIONAL LABILITY	1 (1.4%)	0	1 (0.7%)
GASTROINTESTINAL DISORDER	1 (1.4%)	0	1 (0.7%)
INCREASED APPETITE	1 (1.4%)	0	1 (0.7%)
INSOMNIA	1 (1.4%)	0	1 (0.7%)
MIGRAINE	1 (1.4%)	0	1 (0.7%)
MYALGIA	1 (1.4%)	0	1 (0.7%)
NERVOUSNESS	1 (1.4%)	0	1 (0.7%)
NEUROSIS	1 (1.4%)	0	1 (0.7%)
PAIN	1 (1.4%)	0	1 (0.7%)
PARESTHESIA	1 (1.4%)	0	1 (0.7%)
PHARYNGITIS	1 (1.4%)	0	1 (0.7%)
WITHDRAWAL SYNDROME	1 (1.4%)	0	1 (0.7%)
ALLERGIC REACTION	0	1 (1.5%)	1 (0.7%)
FECAL INCONTINENCE	0	1 (1.5%)	1 (0.7%)
FUNGAL DERMATITIS	0	1 (1.5%)	1 (0.7%)
HOSTILITY	0	1 (1.5%)	1 (0.7%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.7%)
LYMPHOCYTOSIS	0	1 (1.5%)	1 (0.7%)
SGOT INCREASED	0	1 (1.5%)	1 (0.7%)
URINARY INCONTINENCE	0	1 (1.5%)	1 (0.7%)

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=40)	Placebo (N=39)	Total (N=79)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=32)	Placebo (N=28)	Total (N=60)
TOTAL	0	0	0

Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=21)	Total (N=44)
Body System	Preferred Term			
TOTAL	TOTAL	9 (39.1%)	9 (42.9%)	18 (40.9%)
Body as a Whole	TOTAL	4 (17.4%)	1 (4.8%)	5 (11.4%)
	ABDOMINAL PAIN	3 (13.0%)	0	3 (6.8%)
	HEADACHE	2 (8.7%)	0	2 (4.5%)
	FEVER	1 (4.3%)	0	1 (2.3%)
	ALLERGIC REACTION	0	1 (4.8%)	1 (2.3%)
Nervous System	TOTAL	4 (17.4%)	4 (19.0%)	8 (18.2%)
	DEPRESSION	2 (8.7%)	1 (4.8%)	3 (6.8%)
	ANXIETY	1 (4.3%)	0	1 (2.3%)
	INSOMNIA	1 (4.3%)	0	1 (2.3%)
	NERVOUSNESS	1 (4.3%)	0	1 (2.3%)
	WITHDRAWAL SYNDROME	1 (4.3%)	0	1 (2.3%)
	CONCENTRATION IMPAIRED	0	1 (4.8%)	1 (2.3%)
	HOSTILITY	0	1 (4.8%)	1 (2.3%)
	HYSTERIA	0	1 (4.8%)	1 (2.3%)
Digestive System	TOTAL	3 (13.0%)	3 (14.3%)	6 (13.6%)
	NAUSEA	1 (4.3%)	2 (9.5%)	3 (6.8%)
	INCREASED APPETITE	1 (4.3%)	0	1 (2.3%)
	TOOTH DISORDER	1 (4.3%)	0	1 (2.3%)
	VOMITING	1 (4.3%)	0	1 (2.3%)
	DIARRHEA	0	1 (4.8%)	1 (2.3%)
	FECAL INCONTINENCE	0	1 (4.8%)	1 (2.3%)
Respiratory System	TOTAL	3 (13.0%)	2 (9.5%)	5 (11.4%)
	RESPIRATORY DISORDER	3 (13.0%)	2 (9.5%)	5 (11.4%)
Cardiovascular System	TOTAL	1 (4.3%)	1 (4.8%)	2 (4.5%)
	MIGRAINE	1 (4.3%)	0	1 (2.3%)
	SYNCOPE	0	1 (4.8%)	1 (2.3%)
Musculoskeletal System	TOTAL	1 (4.3%)	0	1 (2.3%)
	MYALGIA	1 (4.3%)	0	1 (2.3%)
Hemic and Lymphatic System	TOTAL	0	1 (4.8%)	1 (2.3%)
	LYMPHOCYTOSIS	0	1 (4.8%)	1 (2.3%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (4.8%)	1 (2.3%)
	SGOT INCREASED	0	1 (4.8%)	1 (2.3%)
Special Searches	TOTAL	0	1 (4.8%)	1 (2.3%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=21)	Total (N=44)
Body System	Preferred Term			
Special Searches	PUNCTURE SITE PAIN	0	1 (4.8%)	1 (2.3%)
Urogenital System	TOTAL	0	1 (4.8%)	1 (2.3%)
	URINARY INCONTINENCE	0	1 (4.8%)	1 (2.3%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=13)	Total (N=26)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=8)	Total (N=18)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=24)	Total (N=38)
Body System	Preferred Term			
TOTAL	TOTAL	7 (50.0%)	6 (25.0%)	13 (34.2%)
Body as a Whole	TOTAL	5 (35.7%)	5 (20.8%)	10 (26.3%)
	HEADACHE	3 (21.4%)	2 (8.3%)	5 (13.2%)
	FEVER	1 (7.1%)	1 (4.2%)	2 (5.3%)
	INFECTION	0	2 (8.3%)	2 (5.3%)
	ABDOMINAL PAIN	1 (7.1%)	0	1 (2.6%)
	PAIN	1 (7.1%)	0	1 (2.6%)
Nervous System	TOTAL	2 (14.3%)	0	2 (5.3%)
	NEUROSIS	2 (14.3%)	0	2 (5.3%)
Digestive System	TOTAL	1 (7.1%)	0	1 (2.6%)
	TOOTH DISORDER	1 (7.1%)	0	1 (2.6%)
Respiratory System	TOTAL	1 (7.1%)	1 (4.2%)	2 (5.3%)
	SINUSITIS	1 (7.1%)	0	1 (2.6%)
	COUGH INCREASED	0	1 (4.2%)	1 (2.6%)
Special Senses	TOTAL	1 (7.1%)	0	1 (2.6%)
	EAR PAIN	1 (7.1%)	0	1 (2.6%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (4.2%)	1 (2.6%)
	WEIGHT GAIN	0	1 (4.2%)	1 (2.6%)
Skin and Appendages	TOTAL	0	1 (4.2%)	1 (2.6%)
	FUNGAL DERMATITIS	0	1 (4.2%)	1 (2.6%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=15)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=9)	Total (N=17)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=37)	Placebo (N=45)	Total (N=82)
Body System	Preferred Term			
TOTAL	TOTAL	16 (43.2%)	15 (33.3%)	31 (37.8%)
Body as a Whole	TOTAL	9 (24.3%)	6 (13.3%)	15 (18.3%)
	HEADACHE	5 (13.5%)	2 (4.4%)	7 (8.5%)
	ABDOMINAL PAIN	4 (10.8%)	0	4 (4.9%)
	FEVER	2 (5.4%)	1 (2.2%)	3 (3.7%)
	INFECTION	0	2 (4.4%)	2 (2.4%)
	PAIN	1 (2.7%)	0	1 (1.2%)
	ALLERGIC REACTION	0	1 (2.2%)	1 (1.2%)
Nervous System	TOTAL	6 (16.2%)	4 (8.9%)	10 (12.2%)
	DEPRESSION	2 (5.4%)	1 (2.2%)	3 (3.7%)
	NEUROSIS	2 (5.4%)	0	2 (2.4%)
	ANXIETY	1 (2.7%)	0	1 (1.2%)
	INSOMNIA	1 (2.7%)	0	1 (1.2%)
	NERVOUSNESS	1 (2.7%)	0	1 (1.2%)
	WITHDRAWAL SYNDROME	1 (2.7%)	0	1 (1.2%)
	CONCENTRATION IMPAIRED	0	1 (2.2%)	1 (1.2%)
	HOSTILITY	0	1 (2.2%)	1 (1.2%)
	HYSTERIA	0	1 (2.2%)	1 (1.2%)
Digestive System	TOTAL	4 (10.8%)	3 (6.7%)	7 (8.5%)
	NAUSEA	1 (2.7%)	2 (4.4%)	3 (3.7%)
	TOOTH DISORDER	2 (5.4%)	0	2 (2.4%)
	INCREASED APPETITE	1 (2.7%)	0	1 (1.2%)
	VOMITING	1 (2.7%)	0	1 (1.2%)
	DIARRHEA	0	1 (2.2%)	1 (1.2%)
	FECAL INCONTINENCE	0	1 (2.2%)	1 (1.2%)
Respiratory System	TOTAL	4 (10.8%)	3 (6.7%)	7 (8.5%)
	RESPIRATORY DISORDER	3 (8.1%)	2 (4.4%)	5 (6.1%)
	SINUSITIS	1 (2.7%)	0	1 (1.2%)
	COUGH INCREASED	0	1 (2.2%)	1 (1.2%)
Cardiovascular System	TOTAL	1 (2.7%)	1 (2.2%)	2 (2.4%)
	MIGRAINE	1 (2.7%)	0	1 (1.2%)
	SYNCOPE	0	1 (2.2%)	1 (1.2%)
Musculoskeletal System	TOTAL	1 (2.7%)	0	1 (1.2%)
	MYALGIA	1 (2.7%)	0	1 (1.2%)
Special Senses	TOTAL	1 (2.7%)	0	1 (1.2%)
	EAR PAIN	1 (2.7%)	0	1 (1.2%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=37)	Placebo (N=45)	Total (N=82)
Body System	Preferred Term			
Hemic and Lymphatic System	TOTAL	0	1 (2.2%)	1 (1.2%)
	LYMPHOCYTOSIS	0	1 (2.2%)	1 (1.2%)
Metabolic and Nutritional Disorders	TOTAL	0	2 (4.4%)	2 (2.4%)
	SGOT INCREASED	0	1 (2.2%)	1 (1.2%)
	WEIGHT GAIN	0	1 (2.2%)	1 (1.2%)
Skin and Appendages	TOTAL	0	1 (2.2%)	1 (1.2%)
	FUNGAL DERMATITIS	0	1 (2.2%)	1 (1.2%)
Special Searches	TOTAL	0	1 (2.2%)	1 (1.2%)
	PUNCTURE SITE PAIN	0	1 (2.2%)	1 (1.2%)
Urogenital System	TOTAL	0	1 (2.2%)	1 (1.2%)
	URINARY INCONTINENCE	0	1 (2.2%)	1 (1.2%)

Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=28)	Total (N=47)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=18)	Placebo (N=17)	Total (N=35)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=29)	Placebo (N=19)	Total (N=48)
Body System	Preferred Term			
TOTAL	TOTAL	9 (31.0%)	3 (15.8%)	12 (25.0%)
Respiratory System	TOTAL	4 (13.8%)	1 (5.3%)	5 (10.4%)
	RESPIRATORY DISORDER	1 (3.4%)	1 (5.3%)	2 (4.2%)
	ASTHMA	1 (3.4%)	0	1 (2.1%)
	PHARYNGITIS	1 (3.4%)	0	1 (2.1%)
	SINUSITIS	1 (3.4%)	0	1 (2.1%)
Digestive System	TOTAL	2 (6.9%)	0	2 (4.2%)
	COLITIS	1 (3.4%)	0	1 (2.1%)
	DIARRHEA	1 (3.4%)	0	1 (2.1%)
	GASTROINTESTINAL DISORDER	1 (3.4%)	0	1 (2.1%)
Nervous System	TOTAL	2 (6.9%)	2 (10.5%)	4 (8.3%)
	EMOTIONAL LABILITY	1 (3.4%)	0	1 (2.1%)
	HOSTILITY	1 (3.4%)	0	1 (2.1%)
	SOMNOLENCE	0	1 (5.3%)	1 (2.1%)
	WITHDRAWAL SYNDROME	0	1 (5.3%)	1 (2.1%)
Hemic and Lymphatic System	TOTAL	1 (3.4%)	0	1 (2.1%)
	LEUKOPENIA	1 (3.4%)	0	1 (2.1%)
Metabolic and Nutritional Disorders	TOTAL	1 (3.4%)	0	1 (2.1%)
	WEIGHT GAIN	1 (3.4%)	0	1 (2.1%)
Urogenital System	TOTAL	1 (3.4%)	0	1 (2.1%)
	ALBUMINURIA	1 (3.4%)	0	1 (2.1%)
Body as a Whole	TOTAL	0	1 (5.3%)	1 (2.1%)
	INFECTION	0	1 (5.3%)	1 (2.1%)
Musculoskeletal System	TOTAL	0	1 (5.3%)	1 (2.1%)
	MYALGIA	0	1 (5.3%)	1 (2.1%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=18)	Placebo (N=11)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=8)	Total (N=19)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=14)	Total (N=26)
Body System	Preferred Term			
TOTAL	TOTAL	7 (58.3%)	4 (28.6%)	11 (42.3%)
Respiratory System	TOTAL	3 (25.0%)	1 (7.1%)	4 (15.4%)
	RESPIRATORY DISORDER	1 (8.3%)	1 (7.1%)	2 (7.7%)
	COUGH INCREASED	1 (8.3%)	0	1 (3.8%)
	SINUSITIS	1 (8.3%)	0	1 (3.8%)
Nervous System	TOTAL	2 (16.7%)	1 (7.1%)	3 (11.5%)
	CONCENTRATION IMPAIRED	1 (8.3%)	0	1 (3.8%)
	DIZZINESS	1 (8.3%)	0	1 (3.8%)
	PARESTHESIA	1 (8.3%)	0	1 (3.8%)
	ABNORMAL DREAMS	0	1 (7.1%)	1 (3.8%)
	INSOMNIA	0	1 (7.1%)	1 (3.8%)
Body as a Whole	TOTAL	1 (8.3%)	1 (7.1%)	2 (7.7%)
	HEADACHE	1 (8.3%)	1 (7.1%)	2 (7.7%)
Cardiovascular System	TOTAL	1 (8.3%)	0	1 (3.8%)
	BRADYCARDIA	1 (8.3%)	0	1 (3.8%)
Digestive System	TOTAL	1 (8.3%)	1 (7.1%)	2 (7.7%)
	DYSPEPSIA	1 (8.3%)	0	1 (3.8%)
	DIARRHEA	0	1 (7.1%)	1 (3.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (7.1%)	1 (3.8%)
	NAUSEA	0	1 (7.1%)	1 (3.8%)
	VOMITING	0	1 (7.1%)	1 (3.8%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=10)	Total (N=17)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=4)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=41)	Placebo (N=33)	Total (N=74)
Body System	Preferred Term			
TOTAL	TOTAL	16 (39.0%)	7 (21.2%)	23 (31.1%)
Respiratory System	TOTAL	7 (17.1%)	2 (6.1%)	9 (12.2%)
	RESPIRATORY DISORDER	2 (4.9%)	2 (6.1%)	4 (5.4%)
	SINUSITIS	2 (4.9%)	0	2 (2.7%)
	ASTHMA	1 (2.4%)	0	1 (1.4%)
	COUGH INCREASED	1 (2.4%)	0	1 (1.4%)
	PHARYNGITIS	1 (2.4%)	0	1 (1.4%)
Nervous System	TOTAL	4 (9.8%)	3 (9.1%)	7 (9.5%)
	CONCENTRATION IMPAIRED	1 (2.4%)	0	1 (1.4%)
	DIZZINESS	1 (2.4%)	0	1 (1.4%)
	EMOTIONAL LABILITY	1 (2.4%)	0	1 (1.4%)
	HOSTILITY	1 (2.4%)	0	1 (1.4%)
	PARESTHESIA	1 (2.4%)	0	1 (1.4%)
	ABNORMAL DREAMS	0	1 (3.0%)	1 (1.4%)
	INSOMNIA	0	1 (3.0%)	1 (1.4%)
	SOMNOLENCE	0	1 (3.0%)	1 (1.4%)
	WITHDRAWAL SYNDROME	0	1 (3.0%)	1 (1.4%)
Digestive System	TOTAL	3 (7.3%)	1 (3.0%)	4 (5.4%)
	DIARRHEA	1 (2.4%)	1 (3.0%)	2 (2.7%)
	COLITIS	1 (2.4%)	0	1 (1.4%)
	DYSPEPSIA	1 (2.4%)	0	1 (1.4%)
	GASTROINTESTINAL DISORDER	1 (2.4%)	0	1 (1.4%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (3.0%)	1 (1.4%)
	NAUSEA	0	1 (3.0%)	1 (1.4%)
	VOMITING	0	1 (3.0%)	1 (1.4%)
Body as a Whole	TOTAL	1 (2.4%)	2 (6.1%)	3 (4.1%)
	HEADACHE	1 (2.4%)	1 (3.0%)	2 (2.7%)
	INFECTION	0	1 (3.0%)	1 (1.4%)
Cardiovascular System	TOTAL	1 (2.4%)	0	1 (1.4%)
	BRADYCARDIA	1 (2.4%)	0	1 (1.4%)
Hemic and Lymphatic System	TOTAL	1 (2.4%)	0	1 (1.4%)
	LEUKOPENIA	1 (2.4%)	0	1 (1.4%)
Metabolic and Nutritional Disorders	TOTAL	1 (2.4%)	0	1 (1.4%)
	WEIGHT GAIN	1 (2.4%)	0	1 (1.4%)
Urogenital System	TOTAL	1 (2.4%)	0	1 (1.4%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=41)	Placebo (N=33)	Total (N=74)
Body System	Preferred Term			
Urogenital System	ALBUMINURIA	1 (2.4%)	0	1 (1.4%)
Musculoskeletal System	TOTAL	0	1 (3.0%)	1 (1.4%)
	MYALGIA	0	1 (3.0%)	1 (1.4%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=25)	Placebo (N=21)	Total (N=46)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=12)	Total (N=28)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=40)	Total (N=92)
Body System	Preferred Term			
TOTAL	TOTAL	18 (34.6%)	12 (30.0%)	30 (32.6%)
Respiratory System	TOTAL	7 (13.5%)	3 (7.5%)	10 (10.9%)
	RESPIRATORY DISORDER	4 (7.7%)	3 (7.5%)	7 (7.6%)
	ASTHMA	1 (1.9%)	0	1 (1.1%)
	PHARYNGITIS	1 (1.9%)	0	1 (1.1%)
	SINUSITIS	1 (1.9%)	0	1 (1.1%)
Nervous System	TOTAL	6 (11.5%)	6 (15.0%)	12 (13.0%)
	DEPRESSION	2 (3.8%)	1 (2.5%)	3 (3.3%)
	HOSTILITY	1 (1.9%)	1 (2.5%)	2 (2.2%)
	WITHDRAWAL SYNDROME	1 (1.9%)	1 (2.5%)	2 (2.2%)
	ANXIETY	1 (1.9%)	0	1 (1.1%)
	EMOTIONAL LABILITY	1 (1.9%)	0	1 (1.1%)
	INSOMNIA	1 (1.9%)	0	1 (1.1%)
	NERVOUSNESS	1 (1.9%)	0	1 (1.1%)
	CONCENTRATION IMPAIRED	0	1 (2.5%)	1 (1.1%)
	HYSTERIA	0	1 (2.5%)	1 (1.1%)
	SOMNOLENCE	0	1 (2.5%)	1 (1.1%)
Digestive System	TOTAL	5 (9.6%)	3 (7.5%)	8 (8.7%)
	NAUSEA	1 (1.9%)	2 (5.0%)	3 (3.3%)
	DIARRHEA	1 (1.9%)	1 (2.5%)	2 (2.2%)
	COLITIS	1 (1.9%)	0	1 (1.1%)
	GASTROINTESTINAL DISORDER	1 (1.9%)	0	1 (1.1%)
	INCREASED APPETITE	1 (1.9%)	0	1 (1.1%)
	TOOTH DISORDER	1 (1.9%)	0	1 (1.1%)
	VOMITING	1 (1.9%)	0	1 (1.1%)
	FECAL INCONTINENCE	0	1 (2.5%)	1 (1.1%)
Body as a Whole	TOTAL	4 (7.7%)	2 (5.0%)	6 (6.5%)
	ABDOMINAL PAIN	3 (5.8%)	0	3 (3.3%)
	HEADACHE	2 (3.8%)	0	2 (2.2%)
	FEVER	1 (1.9%)	0	1 (1.1%)
	ALLERGIC REACTION	0	1 (2.5%)	1 (1.1%)
	INFECTION	0	1 (2.5%)	1 (1.1%)
Cardiovascular System	TOTAL	1 (1.9%)	1 (2.5%)	2 (2.2%)
	MIGRAINE	1 (1.9%)	0	1 (1.1%)
	SYNCOPE	0	1 (2.5%)	1 (1.1%)
Hemic and Lymphatic System	TOTAL	1 (1.9%)	1 (2.5%)	2 (2.2%)
	LEUKOPENIA	1 (1.9%)	0	1 (1.1%)
	LYMPHOCYTOSIS	0	1 (2.5%)	1 (1.1%)

Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=40)	Total (N=92)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	TOTAL	1 (1.9%)	1 (2.5%)	2 (2.2%)
	WEIGHT GAIN	1 (1.9%)	0	1 (1.1%)
	SGOT INCREASED	0	1 (2.5%)	1 (1.1%)
Musculoskeletal System	TOTAL	1 (1.9%)	1 (2.5%)	2 (2.2%)
	MYALGIA	1 (1.9%)	1 (2.5%)	2 (2.2%)
Urogenital System	TOTAL	1 (1.9%)	1 (2.5%)	2 (2.2%)
	ALBUMINURIA	1 (1.9%)	0	1 (1.1%)
	URINARY INCONTINENCE	0	1 (2.5%)	1 (1.1%)
Special Searches	TOTAL	0	1 (2.5%)	1 (1.1%)
	PUNCTURE SITE PAIN	0	1 (2.5%)	1 (1.1%)

Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=31)	Placebo (N=24)	Total (N=55)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=21)	Placebo (N=16)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=26)	Placebo (N=38)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	14 (53.8%)	10 (26.3%)	24 (37.5%)
Body as a Whole	TOTAL	6 (23.1%)	6 (15.8%)	12 (18.8%)
	HEADACHE	4 (15.4%)	3 (7.9%)	7 (10.9%)
	FEVER	1 (3.8%)	1 (2.6%)	2 (3.1%)
	INFECTION	0	2 (5.3%)	2 (3.1%)
	ABDOMINAL PAIN	1 (3.8%)	0	1 (1.6%)
	PAIN	1 (3.8%)	0	1 (1.6%)
Nervous System	TOTAL	4 (15.4%)	1 (2.6%)	5 (7.8%)
	NEUROSIS	2 (7.7%)	0	2 (3.1%)
	CONCENTRATION IMPAIRED	1 (3.8%)	0	1 (1.6%)
	DIZZINESS	1 (3.8%)	0	1 (1.6%)
	PARESTHESIA	1 (3.8%)	0	1 (1.6%)
	ABNORMAL DREAMS	0	1 (2.6%)	1 (1.6%)
	INSOMNIA	0	1 (2.6%)	1 (1.6%)
Respiratory System	TOTAL	4 (15.4%)	2 (5.3%)	6 (9.4%)
	SINUSITIS	2 (7.7%)	0	2 (3.1%)
	COUGH INCREASED	1 (3.8%)	1 (2.6%)	2 (3.1%)
	RESPIRATORY DISORDER	1 (3.8%)	1 (2.6%)	2 (3.1%)
Digestive System	TOTAL	2 (7.7%)	1 (2.6%)	3 (4.7%)
	DYSPEPSIA	1 (3.8%)	0	1 (1.6%)
	TOOTH DISORDER	1 (3.8%)	0	1 (1.6%)
	DIARRHEA	0	1 (2.6%)	1 (1.6%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (2.6%)	1 (1.6%)
	NAUSEA	0	1 (2.6%)	1 (1.6%)
	VOMITING	0	1 (2.6%)	1 (1.6%)
Cardiovascular System	TOTAL	1 (3.8%)	0	1 (1.6%)
	BRADYCARDIA	1 (3.8%)	0	1 (1.6%)
Special Senses	TOTAL	1 (3.8%)	0	1 (1.6%)
	EAR PAIN	1 (3.8%)	0	1 (1.6%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.6%)	1 (1.6%)
	WEIGHT GAIN	0	1 (2.6%)	1 (1.6%)
Skin and Appendages	TOTAL	0	1 (2.6%)	1 (1.6%)
	FUNGAL DERMATITIS	0	1 (2.6%)	1 (1.6%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=25)	Total (N=38)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=13)	Placebo (N=13)	Total (N=26)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=78)	Placebo (N=78)	Total (N=156)
Body System	Preferred Term			
TOTAL	TOTAL	32 (41.0%)	22 (28.2%)	54 (34.6%)
Respiratory System	TOTAL	11 (14.1%)	5 (6.4%)	16 (10.3%)
	RESPIRATORY DISORDER	5 (6.4%)	4 (5.1%)	9 (5.8%)
	SINUSITIS	3 (3.8%)	0	3 (1.9%)
	COUGH INCREASED	1 (1.3%)	1 (1.3%)	2 (1.3%)
	ASTHMA	1 (1.3%)	0	1 (0.6%)
	PHARYNGITIS	1 (1.3%)	0	1 (0.6%)
Body as a Whole	TOTAL	10 (12.8%)	8 (10.3%)	18 (11.5%)
	HEADACHE	6 (7.7%)	3 (3.8%)	9 (5.8%)
	ABDOMINAL PAIN	4 (5.1%)	0	4 (2.6%)
	FEVER	2 (2.6%)	1 (1.3%)	3 (1.9%)
	INFECTION	0	3 (3.8%)	3 (1.9%)
	PAIN	1 (1.3%)	0	1 (0.6%)
	ALLERGIC REACTION	0	1 (1.3%)	1 (0.6%)
Nervous System	TOTAL	10 (12.8%)	7 (9.0%)	17 (10.9%)
	DEPRESSION	2 (2.6%)	1 (1.3%)	3 (1.9%)
	NEUROSIS	2 (2.6%)	0	2 (1.3%)
	CONCENTRATION IMPAIRED	1 (1.3%)	1 (1.3%)	2 (1.3%)
	HOSTILITY	1 (1.3%)	1 (1.3%)	2 (1.3%)
	INSOMNIA	1 (1.3%)	1 (1.3%)	2 (1.3%)
	WITHDRAWAL SYNDROME	1 (1.3%)	1 (1.3%)	2 (1.3%)
	ANXIETY	1 (1.3%)	0	1 (0.6%)
	DIZZINESS	1 (1.3%)	0	1 (0.6%)
	EMOTIONAL LABILITY	1 (1.3%)	0	1 (0.6%)
	NERVOUSNESS	1 (1.3%)	0	1 (0.6%)
	PARESTHESIA	1 (1.3%)	0	1 (0.6%)
	ABNORMAL DREAMS	0	1 (1.3%)	1 (0.6%)
	HYSTERIA	0	1 (1.3%)	1 (0.6%)
	SOMNOLENCE	0	1 (1.3%)	1 (0.6%)
Digestive System	TOTAL	7 (9.0%)	4 (5.1%)	11 (7.1%)
	NAUSEA	1 (1.3%)	3 (3.8%)	4 (2.6%)
	DIARRHEA	1 (1.3%)	2 (2.6%)	3 (1.9%)
	TOOTH DISORDER	2 (2.6%)	0	2 (1.3%)
	VOMITING	1 (1.3%)	1 (1.3%)	2 (1.3%)
	COLITIS	1 (1.3%)	0	1 (0.6%)
	DYSPEPSIA	1 (1.3%)	0	1 (0.6%)
	GASTROINTESTINAL DISORDER	1 (1.3%)	0	1 (0.6%)
	INCREASED APPETITE	1 (1.3%)	0	1 (0.6%)
	FECAL INCONTINENCE	0	1 (1.3%)	1 (0.6%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.3%)	1 (0.6%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=78)	Placebo (N=78)	Total (N=156)
Body System	Preferred Term			
Cardiovascular System	TOTAL	2 (2.6%)	1 (1.3%)	3 (1.9%)
	BRADYCARDIA	1 (1.3%)	0	1 (0.6%)
	MIGRAINE	1 (1.3%)	0	1 (0.6%)
	SYNCOPE	0	1 (1.3%)	1 (0.6%)
Hemic and Lymphatic System	TOTAL	1 (1.3%)	1 (1.3%)	2 (1.3%)
	LEUKOPENIA	1 (1.3%)	0	1 (0.6%)
	LYMPHOCYTOSIS	0	1 (1.3%)	1 (0.6%)
Metabolic and Nutritional Disorders	TOTAL	1 (1.3%)	2 (2.6%)	3 (1.9%)
	WEIGHT GAIN	1 (1.3%)	1 (1.3%)	2 (1.3%)
	SGOT INCREASED	0	1 (1.3%)	1 (0.6%)
Musculoskeletal System	TOTAL	1 (1.3%)	1 (1.3%)	2 (1.3%)
	MYALGIA	1 (1.3%)	1 (1.3%)	2 (1.3%)
Special Senses	TOTAL	1 (1.3%)	0	1 (0.6%)
	EAR PAIN	1 (1.3%)	0	1 (0.6%)
Urogenital System	TOTAL	1 (1.3%)	1 (1.3%)	2 (1.3%)
	ALBUMINURIA	1 (1.3%)	0	1 (0.6%)
	URINARY INCONTINENCE	0	1 (1.3%)	1 (0.6%)
Skin and Appendages	TOTAL	0	1 (1.3%)	1 (0.6%)
	FUNGAL DERMATITIS	0	1 (1.3%)	1 (0.6%)
Special Searches	TOTAL	0	1 (1.3%)	1 (0.6%)
	PUNCTURE SITE PAIN	0	1 (1.3%)	1 (0.6%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=44)	Placebo (N=49)	Total (N=93)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=34)	Placebo (N=29)	Total (N=63)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=23)	 Placebo (N=21)	 Total (N=44)
TOTAL	9 (39.1%)	9 (42.9%)	18 (40.9%)
RESPIRATORY DISORDER	3 (13.0%)	2 (9.5%)	5 (11.4%)
ABDOMINAL PAIN	3 (13.0%)	0	3 (6.8%)
DEPRESSION	2 (8.7%)	1 (4.8%)	3 (6.8%)
NAUSEA	1 (4.3%)	2 (9.5%)	3 (6.8%)
HEADACHE	2 (8.7%)	0	2 (4.5%)
ANXIETY	1 (4.3%)	0	1 (2.3%)
FEVER	1 (4.3%)	0	1 (2.3%)
INCREASED APPETITE	1 (4.3%)	0	1 (2.3%)
INSOMNIA	1 (4.3%)	0	1 (2.3%)
MIGRAINE	1 (4.3%)	0	1 (2.3%)
MYALGIA	1 (4.3%)	0	1 (2.3%)
NERVOUSNESS	1 (4.3%)	0	1 (2.3%)
TOOTH DISORDER	1 (4.3%)	0	1 (2.3%)
VOMITING	1 (4.3%)	0	1 (2.3%)
WITHDRAWAL SYNDROME	1 (4.3%)	0	1 (2.3%)
ALLERGIC REACTION	0	1 (4.8%)	1 (2.3%)
CONCENTRATION IMPAIRED	0	1 (4.8%)	1 (2.3%)
DIARRHEA	0	1 (4.8%)	1 (2.3%)
FECAL INCONTINENCE	0	1 (4.8%)	1 (2.3%)
HOSTILITY	0	1 (4.8%)	1 (2.3%)
HYSTERIA	0	1 (4.8%)	1 (2.3%)
LYMPHOCYTOSIS	0	1 (4.8%)	1 (2.3%)
PUNCTURE SITE PAIN	0	1 (4.8%)	1 (2.3%)
SGOT INCREASED	0	1 (4.8%)	1 (2.3%)
SYNCOPE	0	1 (4.8%)	1 (2.3%)
URINARY INCONTINENCE	0	1 (4.8%)	1 (2.3%)

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=13)	Placebo (N=13)	Total (N=26)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=10)	Placebo (N=8)	Total (N=18)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=14)	 Placebo (N=24)	 Total (N=38)
TOTAL	7 (50.0%)	6 (25.0%)	13 (34.2%)
HEADACHE	3 (21.4%)	2 (8.3%)	5 (13.2%)
NEUROSIS	2 (14.3%)	0	2 (5.3%)
FEVER	1 (7.1%)	1 (4.2%)	2 (5.3%)
INFECTION	0	2 (8.3%)	2 (5.3%)
ABDOMINAL PAIN	1 (7.1%)	0	1 (2.6%)
EAR PAIN	1 (7.1%)	0	1 (2.6%)
PAIN	1 (7.1%)	0	1 (2.6%)
SINUSITIS	1 (7.1%)	0	1 (2.6%)
TOOTH DISORDER	1 (7.1%)	0	1 (2.6%)
COUGH INCREASED	0	1 (4.2%)	1 (2.6%)
FUNGAL DERMATITIS	0	1 (4.2%)	1 (2.6%)
WEIGHT GAIN	0	1 (4.2%)	1 (2.6%)

BRL 29060 - 716

Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=6)	Placebo (N=15)	Total (N=21)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=8)	Placebo (N=9)	Total (N=17)
Preferred Term			
TOTAL	0	0	0

Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=37)	Placebo (N=45)	Total (N=82)
TOTAL	16 (43.2%)	15 (33.3%)	31 (37.8%)
HEADACHE	5 (13.5%)	2 (4.4%)	7 (8.5%)
RESPIRATORY DISORDER	3 (8.1%)	2 (4.4%)	5 (6.1%)
ABDOMINAL PAIN	4 (10.8%)	0	4 (4.9%)
DEPRESSION	2 (5.4%)	1 (2.2%)	3 (3.7%)
FEVER	2 (5.4%)	1 (2.2%)	3 (3.7%)
NAUSEA	1 (2.7%)	2 (4.4%)	3 (3.7%)
NEUROSIS	2 (5.4%)	0	2 (2.4%)
TOOTH DISORDER	2 (5.4%)	0	2 (2.4%)
INFECTION	0	2 (4.4%)	2 (2.4%)
ANXIETY	1 (2.7%)	0	1 (1.2%)
EAR PAIN	1 (2.7%)	0	1 (1.2%)
INCREASED APPETITE	1 (2.7%)	0	1 (1.2%)
INSOMNIA	1 (2.7%)	0	1 (1.2%)
MIGRAINE	1 (2.7%)	0	1 (1.2%)
MYALGIA	1 (2.7%)	0	1 (1.2%)
NERVOUSNESS	1 (2.7%)	0	1 (1.2%)
PAIN	1 (2.7%)	0	1 (1.2%)
SINUSITIS	1 (2.7%)	0	1 (1.2%)
VOMITING	1 (2.7%)	0	1 (1.2%)
WITHDRAWAL SYNDROME	1 (2.7%)	0	1 (1.2%)
ALLERGIC REACTION	0	1 (2.2%)	1 (1.2%)
CONCENTRATION IMPAIRED	0	1 (2.2%)	1 (1.2%)
COUGH INCREASED	0	1 (2.2%)	1 (1.2%)
DIARRHEA	0	1 (2.2%)	1 (1.2%)
FECAL INCONTINENCE	0	1 (2.2%)	1 (1.2%)
FUNGAL DERMATITIS	0	1 (2.2%)	1 (1.2%)
HOSTILITY	0	1 (2.2%)	1 (1.2%)
HYSTERIA	0	1 (2.2%)	1 (1.2%)
LYMPHOCYTOSIS	0	1 (2.2%)	1 (1.2%)
PUNCTURE SITE PAIN	0	1 (2.2%)	1 (1.2%)
SGOT INCREASED	0	1 (2.2%)	1 (1.2%)
SYNCOPE	0	1 (2.2%)	1 (1.2%)
URINARY INCONTINENCE	0	1 (2.2%)	1 (1.2%)
WEIGHT GAIN	0	1 (2.2%)	1 (1.2%)

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=19)	Placebo (N=28)	Total (N=47)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=18)	Placebo (N=17)	Total (N=35)
Preferred Term			
TOTAL	0	0	0

Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=29)	 Placebo (N=19)	 Total (N=48)
TOTAL	9 (31.0%)	3 (15.8%)	12 (25.0%)
RESPIRATORY DISORDER	1 (3.4%)	1 (5.3%)	2 (4.2%)
ALBUMINURIA	1 (3.4%)	0	1 (2.1%)
ASTHMA	1 (3.4%)	0	1 (2.1%)
COLITIS	1 (3.4%)	0	1 (2.1%)
DIARRHEA	1 (3.4%)	0	1 (2.1%)
EMOTIONAL LABILITY	1 (3.4%)	0	1 (2.1%)
GASTROINTESTINAL DISORDER	1 (3.4%)	0	1 (2.1%)
HOSTILITY	1 (3.4%)	0	1 (2.1%)
LEUKOPENIA	1 (3.4%)	0	1 (2.1%)
PHARYNGITIS	1 (3.4%)	0	1 (2.1%)
SINUSITIS	1 (3.4%)	0	1 (2.1%)
WEIGHT GAIN	1 (3.4%)	0	1 (2.1%)
INFECTION	0	1 (5.3%)	1 (2.1%)
MYALGIA	0	1 (5.3%)	1 (2.1%)
SOMNOLENCE	0	1 (5.3%)	1 (2.1%)
WITHDRAWAL SYNDROME	0	1 (5.3%)	1 (2.1%)

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=18)	Placebo (N=11)	Total (N=29)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=11)	Placebo (N=8)	Total (N=19)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=14)	Total (N=26)
Preferred Term			
TOTAL	7 (58.3%)	4 (28.6%)	11 (42.3%)
HEADACHE	1 (8.3%)	1 (7.1%)	2 (7.7%)
RESPIRATORY DISORDER	1 (8.3%)	1 (7.1%)	2 (7.7%)
BRADYCARDIA	1 (8.3%)	0	1 (3.8%)
CONCENTRATION IMPAIRED	1 (8.3%)	0	1 (3.8%)
COUGH INCREASED	1 (8.3%)	0	1 (3.8%)
DIZZINESS	1 (8.3%)	0	1 (3.8%)
DYSPEPSIA	1 (8.3%)	0	1 (3.8%)
PARESTHESIA	1 (8.3%)	0	1 (3.8%)
SINUSITIS	1 (8.3%)	0	1 (3.8%)
ABNORMAL DREAMS	0	1 (7.1%)	1 (3.8%)
DIARRHEA	0	1 (7.1%)	1 (3.8%)
INSOMNIA	0	1 (7.1%)	1 (3.8%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (7.1%)	1 (3.8%)
NAUSEA	0	1 (7.1%)	1 (3.8%)
VOMITING	0	1 (7.1%)	1 (3.8%)

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=7)	Placebo (N=10)	Total (N=17)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=5)	Placebo (N=4)	Total (N=9)
Preferred Term			
TOTAL	0	0	0

Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=41)	Placebo (N=33)	Total (N=74)
TOTAL	16 (39.0%)	7 (21.2%)	23 (31.1%)
RESPIRATORY DISORDER	2 (4.9%)	2 (6.1%)	4 (5.4%)
SINUSITIS	2 (4.9%)	0	2 (2.7%)
DIARRHEA	1 (2.4%)	1 (3.0%)	2 (2.7%)
HEADACHE	1 (2.4%)	1 (3.0%)	2 (2.7%)
ALBUMINURIA	1 (2.4%)	0	1 (1.4%)
ASTHMA	1 (2.4%)	0	1 (1.4%)
BRADYCARDIA	1 (2.4%)	0	1 (1.4%)
COLITIS	1 (2.4%)	0	1 (1.4%)
CONCENTRATION IMPAIRED	1 (2.4%)	0	1 (1.4%)
COUGH INCREASED	1 (2.4%)	0	1 (1.4%)
DIZZINESS	1 (2.4%)	0	1 (1.4%)
DYSPEPSIA	1 (2.4%)	0	1 (1.4%)
EMOTIONAL LABILITY	1 (2.4%)	0	1 (1.4%)
GASTROINTESTINAL DISORDER	1 (2.4%)	0	1 (1.4%)
HOSTILITY	1 (2.4%)	0	1 (1.4%)
LEUKOPENIA	1 (2.4%)	0	1 (1.4%)
PARESTHESIA	1 (2.4%)	0	1 (1.4%)
PHARYNGITIS	1 (2.4%)	0	1 (1.4%)
WEIGHT GAIN	1 (2.4%)	0	1 (1.4%)
ABNORMAL DREAMS	0	1 (3.0%)	1 (1.4%)
INFECTION	0	1 (3.0%)	1 (1.4%)
INSOMNIA	0	1 (3.0%)	1 (1.4%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (3.0%)	1 (1.4%)
MYALGIA	0	1 (3.0%)	1 (1.4%)
NAUSEA	0	1 (3.0%)	1 (1.4%)
SOMNOLENCE	0	1 (3.0%)	1 (1.4%)
VOMITING	0	1 (3.0%)	1 (1.4%)
WITHDRAWAL SYNDROME	0	1 (3.0%)	1 (1.4%)

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=25)	Placebo (N=21)	Total (N=46)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=16)	Placebo (N=12)	Total (N=28)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=52)	Placebo (N=40)	Total (N=92)
TOTAL	18 (34.6%)	12 (30.0%)	30 (32.6%)
RESPIRATORY DISORDER	4 (7.7%)	3 (7.5%)	7 (7.6%)
ABDOMINAL PAIN	3 (5.8%)	0	3 (3.3%)
DEPRESSION	2 (3.8%)	1 (2.5%)	3 (3.3%)
NAUSEA	1 (1.9%)	2 (5.0%)	3 (3.3%)
HEADACHE	2 (3.8%)	0	2 (2.2%)
DIARRHEA	1 (1.9%)	1 (2.5%)	2 (2.2%)
HOSTILITY	1 (1.9%)	1 (2.5%)	2 (2.2%)
MYALGIA	1 (1.9%)	1 (2.5%)	2 (2.2%)
WITHDRAWAL SYNDROME	1 (1.9%)	1 (2.5%)	2 (2.2%)
ALBUMINURIA	1 (1.9%)	0	1 (1.1%)
ANXIETY	1 (1.9%)	0	1 (1.1%)
ASTHMA	1 (1.9%)	0	1 (1.1%)
COLITIS	1 (1.9%)	0	1 (1.1%)
EMOTIONAL LABILITY	1 (1.9%)	0	1 (1.1%)
FEVER	1 (1.9%)	0	1 (1.1%)
GASTROINTESTINAL DISORDER	1 (1.9%)	0	1 (1.1%)
INCREASED APPETITE	1 (1.9%)	0	1 (1.1%)
INSOMNIA	1 (1.9%)	0	1 (1.1%)
LEUKOPENIA	1 (1.9%)	0	1 (1.1%)
MIGRAINE	1 (1.9%)	0	1 (1.1%)
NERVOUSNESS	1 (1.9%)	0	1 (1.1%)
PHARYNGITIS	1 (1.9%)	0	1 (1.1%)
SINUSITIS	1 (1.9%)	0	1 (1.1%)
TOOTH DISORDER	1 (1.9%)	0	1 (1.1%)
VOMITING	1 (1.9%)	0	1 (1.1%)
WEIGHT GAIN	1 (1.9%)	0	1 (1.1%)
ALLERGIC REACTION	0	1 (2.5%)	1 (1.1%)
CONCENTRATION IMPAIRED	0	1 (2.5%)	1 (1.1%)
FECAL INCONTINENCE	0	1 (2.5%)	1 (1.1%)
HYSTERIA	0	1 (2.5%)	1 (1.1%)
INFECTION	0	1 (2.5%)	1 (1.1%)
LYMPHOCYTOSIS	0	1 (2.5%)	1 (1.1%)
PUNCTURE SITE PAIN	0	1 (2.5%)	1 (1.1%)
SGOT INCREASED	0	1 (2.5%)	1 (1.1%)
SOMNOLENCE	0	1 (2.5%)	1 (1.1%)
SYNCOPE	0	1 (2.5%)	1 (1.1%)
URINARY INCONTINENCE	0	1 (2.5%)	1 (1.1%)

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=31)	Placebo (N=24)	Total (N=55)
TOTAL	0	0	0

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=21)	Placebo (N=16)	Total (N=37)
TOTAL	0	0	0

Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=26)	Placebo (N=38)	Total (N=64)
TOTAL	14 (53.8%)	10 (26.3%)	24 (37.5%)
HEADACHE	4 (15.4%)	3 (7.9%)	7 (10.9%)
NEUROSIS	2 (7.7%)	0	2 (3.1%)
SINUSITIS	2 (7.7%)	0	2 (3.1%)
COUGH INCREASED	1 (3.8%)	1 (2.6%)	2 (3.1%)
FEVER	1 (3.8%)	1 (2.6%)	2 (3.1%)
RESPIRATORY DISORDER	1 (3.8%)	1 (2.6%)	2 (3.1%)
INFECTION	0	2 (5.3%)	2 (3.1%)
ABDOMINAL PAIN	1 (3.8%)	0	1 (1.6%)
BRADYCARDIA	1 (3.8%)	0	1 (1.6%)
CONCENTRATION IMPAIRED	1 (3.8%)	0	1 (1.6%)
DIZZINESS	1 (3.8%)	0	1 (1.6%)
DYSPEPSIA	1 (3.8%)	0	1 (1.6%)
EAR PAIN	1 (3.8%)	0	1 (1.6%)
PAIN	1 (3.8%)	0	1 (1.6%)
PARESTHESIA	1 (3.8%)	0	1 (1.6%)
TOOTH DISORDER	1 (3.8%)	0	1 (1.6%)
ABNORMAL DREAMS	0	1 (2.6%)	1 (1.6%)
DIARRHEA	0	1 (2.6%)	1 (1.6%)
FUNGAL DERMATITIS	0	1 (2.6%)	1 (1.6%)
INSOMNIA	0	1 (2.6%)	1 (1.6%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (2.6%)	1 (1.6%)
NAUSEA	0	1 (2.6%)	1 (1.6%)
VOMITING	0	1 (2.6%)	1 (1.6%)
WEIGHT GAIN	0	1 (2.6%)	1 (1.6%)

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=13)	Placebo (N=25)	Total (N=38)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=13)	Placebo (N=13)	Total (N=26)
Preferred Term			
TOTAL	0	0	0

Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=78)	Placebo (N=78)	Total (N=156)
TOTAL	32 (41.0%)	22 (28.2%)	54 (34.6%)
HEADACHE	6 (7.7%)	3 (3.8%)	9 (5.8%)
RESPIRATORY DISORDER	5 (6.4%)	4 (5.1%)	9 (5.8%)
ABDOMINAL PAIN	4 (5.1%)	0	4 (2.6%)
NAUSEA	1 (1.3%)	3 (3.8%)	4 (2.6%)
SINUSITIS	3 (3.8%)	0	3 (1.9%)
DEPRESSION	2 (2.6%)	1 (1.3%)	3 (1.9%)
FEVER	2 (2.6%)	1 (1.3%)	3 (1.9%)
DIARRHEA	1 (1.3%)	2 (2.6%)	3 (1.9%)
INFECTION	0	3 (3.8%)	3 (1.9%)
NEUROSIS	2 (2.6%)	0	2 (1.3%)
TOOTH DISORDER	2 (2.6%)	0	2 (1.3%)
CONCENTRATION IMPAIRED	1 (1.3%)	1 (1.3%)	2 (1.3%)
COUGH INCREASED	1 (1.3%)	1 (1.3%)	2 (1.3%)
HOSTILITY	1 (1.3%)	1 (1.3%)	2 (1.3%)
INSOMNIA	1 (1.3%)	1 (1.3%)	2 (1.3%)
MYALGIA	1 (1.3%)	1 (1.3%)	2 (1.3%)
VOMITING	1 (1.3%)	1 (1.3%)	2 (1.3%)
WEIGHT GAIN	1 (1.3%)	1 (1.3%)	2 (1.3%)
WITHDRAWAL SYNDROME	1 (1.3%)	1 (1.3%)	2 (1.3%)
ALBUMINURIA	1 (1.3%)	0	1 (0.6%)
ANXIETY	1 (1.3%)	0	1 (0.6%)
ASTHMA	1 (1.3%)	0	1 (0.6%)
BRADYCARDIA	1 (1.3%)	0	1 (0.6%)
COLITIS	1 (1.3%)	0	1 (0.6%)
DIZZINESS	1 (1.3%)	0	1 (0.6%)
DYSPEPSIA	1 (1.3%)	0	1 (0.6%)
EAR PAIN	1 (1.3%)	0	1 (0.6%)
EMOTIONAL LABILITY	1 (1.3%)	0	1 (0.6%)
GASTROINTESTINAL DISORDER	1 (1.3%)	0	1 (0.6%)
INCREASED APPETITE	1 (1.3%)	0	1 (0.6%)
LEUKOPENIA	1 (1.3%)	0	1 (0.6%)
MIGRAINE	1 (1.3%)	0	1 (0.6%)
NERVOUSNESS	1 (1.3%)	0	1 (0.6%)
PAIN	1 (1.3%)	0	1 (0.6%)
PARESTHESIA	1 (1.3%)	0	1 (0.6%)
PHARYNGITIS	1 (1.3%)	0	1 (0.6%)
ABNORMAL DREAMS	0	1 (1.3%)	1 (0.6%)
ALLERGIC REACTION	0	1 (1.3%)	1 (0.6%)
FECAL INCONTINENCE	0	1 (1.3%)	1 (0.6%)
FUNGAL DERMATITIS	0	1 (1.3%)	1 (0.6%)
HYSTERIA	0	1 (1.3%)	1 (0.6%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.3%)	1 (0.6%)
LYMPHOCYTOSIS	0	1 (1.3%)	1 (0.6%)

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=78)	Placebo (N=78)	Total (N=156)
PUNCTURE SITE PAIN	0	1 (1.3%)	1 (0.6%)
SGOT INCREASED	0	1 (1.3%)	1 (0.6%)
SOMNOLENCE	0	1 (1.3%)	1 (0.6%)
SYNCOPE	0	1 (1.3%)	1 (0.6%)
URINARY INCONTINENCE	0	1 (1.3%)	1 (0.6%)

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=44)	Placebo (N=49)	Total (N=93)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.5.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=34)	Placebo (N=29)	Total (N=63)
Preferred Term			
TOTAL	0	0	0

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
TOTAL	TOTAL	32 (82.1%)	26 (72.2%)	58 (77.3%)
Body as a Whole	TOTAL	24 (61.5%)	15 (41.7%)	39 (52.0%)
	HEADACHE	11 (28.2%)	4 (11.1%)	15 (20.0%)
	TRAUMA	11 (28.2%)	4 (11.1%)	15 (20.0%)
	INFECTION	5 (12.8%)	9 (25.0%)	14 (18.7%)
	ABDOMINAL PAIN	10 (25.6%)	3 (8.3%)	13 (17.3%)
	FEVER	6 (15.4%)	2 (5.6%)	8 (10.7%)
	ALLERGIC REACTION	3 (7.7%)	2 (5.6%)	5 (6.7%)
	PAIN	3 (7.7%)	1 (2.8%)	4 (5.3%)
	ASTHENIA	2 (5.1%)	2 (5.6%)	4 (5.3%)
	BACK PAIN	0	3 (8.3%)	3 (4.0%)
	FACE EDEMA	2 (5.1%)	0	2 (2.7%)
Respiratory System	TOTAL	20 (51.3%)	13 (36.1%)	33 (44.0%)
	RESPIRATORY DISORDER	11 (28.2%)	6 (16.7%)	17 (22.7%)
	PHARYNGITIS	8 (20.5%)	4 (11.1%)	12 (16.0%)
	RHINITIS	4 (10.3%)	3 (8.3%)	7 (9.3%)
	COUGH INCREASED	3 (7.7%)	1 (2.8%)	4 (5.3%)
	SINUSITIS	3 (7.7%)	1 (2.8%)	4 (5.3%)
	EPISTAXIS	0	2 (5.6%)	2 (2.7%)
	ASTHMA	0	1 (2.8%)	1 (1.3%)
	BRONCHITIS	0	1 (2.8%)	1 (1.3%)
	PNEUMONIA	0	1 (2.8%)	1 (1.3%)
	YAWN	0	1 (2.8%)	1 (1.3%)
Digestive System	TOTAL	17 (43.6%)	14 (38.9%)	31 (41.3%)
	VOMITING	8 (20.5%)	4 (11.1%)	12 (16.0%)
	DYSPEPSIA	4 (10.3%)	3 (8.3%)	7 (9.3%)
	NAUSEA	2 (5.1%)	4 (11.1%)	6 (8.0%)
	DIARRHEA	2 (5.1%)	2 (5.6%)	4 (5.3%)
	DRY MOUTH	2 (5.1%)	0	2 (2.7%)
	INCREASED APPETITE	2 (5.1%)	0	2 (2.7%)
	DECREASED APPETITE	1 (2.6%)	1 (2.8%)	2 (2.7%)
	TOOTH CARIES	0	2 (5.6%)	2 (2.7%)
	CONSTIPATION	1 (2.6%)	0	1 (1.3%)
	STOMATITIS	1 (2.6%)	0	1 (1.3%)
	TOOTH DISORDER	1 (2.6%)	0	1 (1.3%)
	FECAL INCONTINENCE	0	1 (2.8%)	1 (1.3%)
	GASTROENTERITIS	0	1 (2.8%)	1 (1.3%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (2.8%)	1 (1.3%)
Nervous System	TOTAL	15 (38.5%)	13 (36.1%)	28 (37.3%)
	NERVOUSNESS	6 (15.4%)	0	6 (8.0%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
Nervous System	HOSTILITY	4 (10.3%)	2 (5.6%)	6 (8.0%)
	INSOMNIA	2 (5.1%)	3 (8.3%)	5 (6.7%)
	DEPRESSION	3 (7.7%)	1 (2.8%)	4 (5.3%)
	HYPERKINESIA	2 (5.1%)	1 (2.8%)	3 (4.0%)
	AGITATION	1 (2.6%)	2 (5.6%)	3 (4.0%)
	ANXIETY	1 (2.6%)	1 (2.8%)	2 (2.7%)
	HALLUCINATIONS	1 (2.6%)	1 (2.8%)	2 (2.7%)
	CONCENTRATION IMPAIRED	0	2 (5.6%)	2 (2.7%)
	HYPESTHESIA	0	2 (5.6%)	2 (2.7%)
	CONVULSION	1 (2.6%)	0	1 (1.3%)
	EMOTIONAL LABILITY	1 (2.6%)	0	1 (1.3%)
	NEUROSIS	1 (2.6%)	0	1 (1.3%)
	VESTIBULAR DISORDER	1 (2.6%)	0	1 (1.3%)
	WITHDRAWAL SYNDROME	1 (2.6%)	0	1 (1.3%)
	DIZZINESS	0	1 (2.8%)	1 (1.3%)
	EUPHORIA	0	1 (2.8%)	1 (1.3%)
	HYSTERIA	0	1 (2.8%)	1 (1.3%)
	PARALYSIS	0	1 (2.8%)	1 (1.3%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.3%)
	TREMOR	0	1 (2.8%)	1 (1.3%)
Skin and Appendages	TOTAL	6 (15.4%)	4 (11.1%)	10 (13.3%)
	CONTACT DERMATITIS	2 (5.1%)	1 (2.8%)	3 (4.0%)
	RASH	1 (2.6%)	2 (5.6%)	3 (4.0%)
	ACNE	2 (5.1%)	0	2 (2.7%)
	HERPES ZOSTER	1 (2.6%)	0	1 (1.3%)
	MACULOPAPULAR RASH	0	1 (2.8%)	1 (1.3%)
	PRURITUS	0	1 (2.8%)	1 (1.3%)
Metabolic and Nutritional Disorders	TOTAL	5 (12.8%)	5 (13.9%)	10 (13.3%)
	WEIGHT GAIN	4 (10.3%)	3 (8.3%)	7 (9.3%)
	DEHYDRATION	1 (2.6%)	1 (2.8%)	2 (2.7%)
	SGOT INCREASED	0	1 (2.8%)	1 (1.3%)
Musculoskeletal System	TOTAL	4 (10.3%)	1 (2.8%)	5 (6.7%)
	ARTHRALGIA	2 (5.1%)	0	2 (2.7%)
	MYALGIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
	TENDINOUS DISORDER	1 (2.6%)	0	1 (1.3%)
	ARTHROSIS	0	1 (2.8%)	1 (1.3%)
Special Senses	TOTAL	2 (5.1%)	2 (5.6%)	4 (5.3%)
	OTITIS MEDIA	2 (5.1%)	1 (2.8%)	3 (4.0%)
	ABNORMAL VISION	0	1 (2.8%)	1 (1.3%)

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
Urogenital System	TOTAL	2 (5.1%)	4 (11.1%)	6 (8.0%)
	URINARY INCONTINENCE	1 (2.6%)	3 (8.3%)	4 (5.3%)
	PYURIA	1 (2.6%)	0	1 (1.3%)
	ALBUMINURIA	0	1 (2.8%)	1 (1.3%)
	CYSTITIS	0	1 (2.8%)	1 (1.3%)
	HAEMATURIA	0	1 (2.8%)	1 (1.3%)
Cardiovascular System	TOTAL	1 (2.6%)	3 (8.3%)	4 (5.3%)
	MIGRAINE	1 (2.6%)	1 (2.8%)	2 (2.7%)
	BUNDLE BRANCH BLOCK	0	1 (2.8%)	1 (1.3%)
	SYNCOPE	0	1 (2.8%)	1 (1.3%)
Hemic and Lymphatic System	TOTAL	1 (2.6%)	2 (5.6%)	3 (4.0%)
	LEUKOPENIA	1 (2.6%)	2 (5.6%)	3 (4.0%)
	ANEMIA	0	1 (2.8%)	1 (1.3%)
	LYMPHOCYTOSIS	0	1 (2.8%)	1 (1.3%)
Special Searches	TOTAL	0	1 (2.8%)	1 (1.3%)
	PUNCTURE SITE PAIN	0	1 (2.8%)	1 (1.3%)

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	22 (78.6%)	31 (86.1%)	53 (82.8%)
Body as a Whole	TOTAL	15 (53.6%)	18 (50.0%)	33 (51.6%)
	HEADACHE	10 (35.7%)	9 (25.0%)	19 (29.7%)
	TRAUMA	4 (14.3%)	4 (11.1%)	8 (12.5%)
	ABDOMINAL PAIN	3 (10.7%)	5 (13.9%)	8 (12.5%)
	INFECTION	3 (10.7%)	5 (13.9%)	8 (12.5%)
	FEVER	4 (14.3%)	2 (5.6%)	6 (9.4%)
	PAIN	2 (7.1%)	1 (2.8%)	3 (4.7%)
	ABSCESS	1 (3.6%)	0	1 (1.6%)
	BACK PAIN	1 (3.6%)	0	1 (1.6%)
	ALLERGIC REACTION	0	1 (2.8%)	1 (1.6%)
	SPINA BIFIDA	0	1 (2.8%)	1 (1.6%)
Digestive System	TOTAL	9 (32.1%)	6 (16.7%)	15 (23.4%)
	NAUSEA	5 (17.9%)	1 (2.8%)	6 (9.4%)
	DECREASED APPETITE	2 (7.1%)	2 (5.6%)	4 (6.3%)
	DIARRHEA	3 (10.7%)	0	3 (4.7%)
	DYSPEPSIA	2 (7.1%)	1 (2.8%)	3 (4.7%)
	GINGIVITIS	1 (3.6%)	1 (2.8%)	2 (3.1%)
	TOOTH DISORDER	1 (3.6%)	0	1 (1.6%)
	VOMITING	1 (3.6%)	0	1 (1.6%)
	FLATULENCE	0	1 (2.8%)	1 (1.6%)
	GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
	TOOTH CARIES	0	1 (2.8%)	1 (1.6%)
Nervous System	TOTAL	9 (32.1%)	22 (61.1%)	31 (48.4%)
	NERVOUSNESS	1 (3.6%)	9 (25.0%)	10 (15.6%)
	HYPERKINESIA	5 (17.9%)	4 (11.1%)	9 (14.1%)
	INSOMNIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
	HOSTILITY	1 (3.6%)	4 (11.1%)	5 (7.8%)
	ANXIETY	1 (3.6%)	3 (8.3%)	4 (6.3%)
	DIZZINESS	1 (3.6%)	2 (5.6%)	3 (4.7%)
	SOMNOLENCE	1 (3.6%)	2 (5.6%)	3 (4.7%)
	NEUROSIS	2 (7.1%)	0	2 (3.1%)
	AGITATION	1 (3.6%)	1 (2.8%)	2 (3.1%)
	MYOCLONUS	1 (3.6%)	1 (2.8%)	2 (3.1%)
	VERTIGO	0	2 (5.6%)	2 (3.1%)
	CONCENTRATION IMPAIRED	1 (3.6%)	0	1 (1.6%)
	DEPRESSION	1 (3.6%)	0	1 (1.6%)
	EMOTIONAL LABILITY	1 (3.6%)	0	1 (1.6%)
	DYSKINESIA	0	1 (2.8%)	1 (1.6%)
	LACK OF EMOTION	0	1 (2.8%)	1 (1.6%)
	MANIC REACTION	0	1 (2.8%)	1 (1.6%)

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Body System	Preferred Term			
Nervous System	PSYCHOSIS	0	1 (2.8%)	1 (1.6%)
	TREMOR	0	1 (2.8%)	1 (1.6%)
Respiratory System	TOTAL	8 (28.6%)	10 (27.8%)	18 (28.1%)
	RESPIRATORY DISORDER	2 (7.1%)	8 (22.2%)	10 (15.6%)
	PHARYNGITIS	5 (17.9%)	3 (8.3%)	8 (12.5%)
	RHINITIS	4 (14.3%)	4 (11.1%)	8 (12.5%)
	SINUSITIS	3 (10.7%)	1 (2.8%)	4 (6.3%)
	COUGH INCREASED	2 (7.1%)	2 (5.6%)	4 (6.3%)
	ASTHMA	1 (3.6%)	0	1 (1.6%)
Special Senses	TOTAL	6 (21.4%)	4 (11.1%)	10 (15.6%)
	OTITIS MEDIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
	EAR PAIN	2 (7.1%)	1 (2.8%)	3 (4.7%)
	OTITIS EXTERNA	2 (7.1%)	1 (2.8%)	3 (4.7%)
Hemic and Lymphatic System	TOTAL	2 (7.1%)	0	2 (3.1%)
	ANEMIA	1 (3.6%)	0	1 (1.6%)
	PURPURA	1 (3.6%)	0	1 (1.6%)
Skin and Appendages	TOTAL	2 (7.1%)	4 (11.1%)	6 (9.4%)
	CONTACT DERMATITIS	0	2 (5.6%)	2 (3.1%)
	FUNGAL DERMATITIS	0	2 (5.6%)	2 (3.1%)
	RASH	0	2 (5.6%)	2 (3.1%)
	ACNE	1 (3.6%)	0	1 (1.6%)
	MACULOPAPULAR RASH	1 (3.6%)	0	1 (1.6%)
	HERPES SIMPLEX	0	1 (2.8%)	1 (1.6%)
Urogenital System	TOTAL	2 (7.1%)	2 (5.6%)	4 (6.3%)
	ALBUMINURIA	2 (7.1%)	0	2 (3.1%)
	URINARY INCONTINENCE	0	2 (5.6%)	2 (3.1%)
	GLYCOSURIA	1 (3.6%)	0	1 (1.6%)
Cardiovascular System	TOTAL	1 (3.6%)	3 (8.3%)	4 (6.3%)
	VASODILATATION	0	3 (8.3%)	3 (4.7%)
	HAEMATOMA	1 (3.6%)	0	1 (1.6%)
Musculoskeletal System	TOTAL	1 (3.6%)	0	1 (1.6%)
	MYALGIA	1 (3.6%)	0	1 (1.6%)
Metabolic and Nutritional Disorders	TOTAL	0	3 (8.3%)	3 (4.7%)
	WEIGHT GAIN	0	3 (8.3%)	3 (4.7%)

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
TOTAL	TOTAL	1 (6.3%)	1 (7.7%)	2 (6.9%)
Urogenital System	TOTAL	1 (6.3%)	1 (7.7%)	2 (6.9%)
	DYSMENORRHEA	1 (6.3%)	1 (7.7%)	2 (6.9%)
	UTERUS DISORDERS	0	1 (7.7%)	1 (3.4%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
TOTAL	TOTAL	54 (80.6%)	57 (79.2%)	111 (79.9%)
Body as a Whole	TOTAL	39 (58.2%)	33 (45.8%)	72 (51.8%)
	HEADACHE	21 (31.3%)	13 (18.1%)	34 (24.5%)
	TRAUMA	15 (22.4%)	8 (11.1%)	23 (16.5%)
	INFECTION	8 (11.9%)	14 (19.4%)	22 (15.8%)
	ABDOMINAL PAIN	13 (19.4%)	8 (11.1%)	21 (15.1%)
	FEVER	10 (14.9%)	4 (5.6%)	14 (10.1%)
	PAIN	5 (7.5%)	2 (2.8%)	7 (5.0%)
	ALLERGIC REACTION	3 (4.5%)	3 (4.2%)	6 (4.3%)
	ASTHENIA	2 (3.0%)	2 (2.8%)	4 (2.9%)
	BACK PAIN	1 (1.5%)	3 (4.2%)	4 (2.9%)
	FACE EDEMA	2 (3.0%)	0	2 (1.4%)
	ABSCESS	1 (1.5%)	0	1 (0.7%)
	SPINA BIFIDA	0	1 (1.4%)	1 (0.7%)
Respiratory System	TOTAL	28 (41.8%)	23 (31.9%)	51 (36.7%)
	RESPIRATORY DISORDER	13 (19.4%)	14 (19.4%)	27 (19.4%)
	PHARYNGITIS	13 (19.4%)	7 (9.7%)	20 (14.4%)
	RHINITIS	8 (11.9%)	7 (9.7%)	15 (10.8%)
	SINUSITIS	6 (9.0%)	2 (2.8%)	8 (5.8%)
	COUGH INCREASED	5 (7.5%)	3 (4.2%)	8 (5.8%)
	ASTHMA	1 (1.5%)	1 (1.4%)	2 (1.4%)
	EPISTAXIS	0	2 (2.8%)	2 (1.4%)
	BRONCHITIS	0	1 (1.4%)	1 (0.7%)
	PNEUMONIA	0	1 (1.4%)	1 (0.7%)
	YAWN	0	1 (1.4%)	1 (0.7%)
Digestive System	TOTAL	26 (38.8%)	20 (27.8%)	46 (33.1%)
	VOMITING	9 (13.4%)	4 (5.6%)	13 (9.4%)
	NAUSEA	7 (10.4%)	5 (6.9%)	12 (8.6%)
	DYSPEPSIA	6 (9.0%)	4 (5.6%)	10 (7.2%)
	DIARRHEA	5 (7.5%)	2 (2.8%)	7 (5.0%)
	DECREASED APPETITE	3 (4.5%)	3 (4.2%)	6 (4.3%)
	TOOTH CARIES	0	3 (4.2%)	3 (2.2%)
	DRY MOUTH	2 (3.0%)	0	2 (1.4%)
	INCREASED APPETITE	2 (3.0%)	0	2 (1.4%)
	TOOTH DISORDER	2 (3.0%)	0	2 (1.4%)
	GINGIVITIS	1 (1.5%)	1 (1.4%)	2 (1.4%)
	GASTROENTERITIS	0	2 (2.8%)	2 (1.4%)
	CONSTIPATION	1 (1.5%)	0	1 (0.7%)
	STOMATITIS	1 (1.5%)	0	1 (0.7%)
	FECAL INCONTINENCE	0	1 (1.4%)	1 (0.7%)
	FLATULENCE	0	1 (1.4%)	1 (0.7%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
Digestive System	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.4%)	1 (0.7%)
Nervous System	TOTAL	24 (35.8%)	35 (48.6%)	59 (42.4%)
	NERVOUSNESS	7 (10.4%)	9 (12.5%)	16 (11.5%)
	HYPERKINESIA	7 (10.4%)	5 (6.9%)	12 (8.6%)
	HOSTILITY	5 (7.5%)	6 (8.3%)	11 (7.9%)
	INSOMNIA	5 (7.5%)	5 (6.9%)	10 (7.2%)
	ANXIETY	2 (3.0%)	4 (5.6%)	6 (4.3%)
	DEPRESSION	4 (6.0%)	1 (1.4%)	5 (3.6%)
	AGITATION	2 (3.0%)	3 (4.2%)	5 (3.6%)
	DIZZINESS	1 (1.5%)	3 (4.2%)	4 (2.9%)
	SOMNOLENCE	1 (1.5%)	3 (4.2%)	4 (2.9%)
	NEUROSIS	3 (4.5%)	0	3 (2.2%)
	CONCENTRATION IMPAIRED	1 (1.5%)	2 (2.8%)	3 (2.2%)
	EMOTIONAL LABILITY	2 (3.0%)	0	2 (1.4%)
	HALLUCINATIONS	1 (1.5%)	1 (1.4%)	2 (1.4%)
	MYOCLONUS	1 (1.5%)	1 (1.4%)	2 (1.4%)
	HYPESTHESIA	0	2 (2.8%)	2 (1.4%)
	TREMOR	0	2 (2.8%)	2 (1.4%)
	VERTIGO	0	2 (2.8%)	2 (1.4%)
	CONVULSION	1 (1.5%)	0	1 (0.7%)
	VESTIBULAR DISORDER	1 (1.5%)	0	1 (0.7%)
	WITHDRAWAL SYNDROME	1 (1.5%)	0	1 (0.7%)
	DYSKINESIA	0	1 (1.4%)	1 (0.7%)
	EUPHORIA	0	1 (1.4%)	1 (0.7%)
	HYSTERIA	0	1 (1.4%)	1 (0.7%)
	LACK OF EMOTION	0	1 (1.4%)	1 (0.7%)
	MANIC REACTION	0	1 (1.4%)	1 (0.7%)
	PARALYSIS	0	1 (1.4%)	1 (0.7%)
	PSYCHOSIS	0	1 (1.4%)	1 (0.7%)
Skin and Appendages	TOTAL	8 (11.9%)	8 (11.1%)	16 (11.5%)
	CONTACT DERMATITIS	2 (3.0%)	3 (4.2%)	5 (3.6%)
	RASH	1 (1.5%)	4 (5.6%)	5 (3.6%)
	ACNE	3 (4.5%)	0	3 (2.2%)
	MACULOPAPULAR RASH	1 (1.5%)	1 (1.4%)	2 (1.4%)
	FUNGAL DERMATITIS	0	2 (2.8%)	2 (1.4%)
	HERPES ZOSTER	1 (1.5%)	0	1 (0.7%)
	HERPES SIMPLEX	0	1 (1.4%)	1 (0.7%)
	PRURITUS	0	1 (1.4%)	1 (0.7%)
Special Senses	TOTAL	8 (11.9%)	6 (8.3%)	14 (10.1%)
	OTITIS MEDIA	5 (7.5%)	3 (4.2%)	8 (5.8%)
	EAR PAIN	2 (3.0%)	1 (1.4%)	3 (2.2%)

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
Special Senses	OTITIS EXTERNA	2 (3.0%)	1 (1.4%)	3 (2.2%)
	ABNORMAL VISION	0	1 (1.4%)	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	5 (7.5%)	8 (11.1%)	13 (9.4%)
	WEIGHT GAIN	4 (6.0%)	6 (8.3%)	10 (7.2%)
	DEHYDRATION	1 (1.5%)	1 (1.4%)	2 (1.4%)
	SGOT INCREASED	0	1 (1.4%)	1 (0.7%)
Musculoskeletal System	TOTAL	5 (7.5%)	1 (1.4%)	6 (4.3%)
	MYALGIA	2 (3.0%)	1 (1.4%)	3 (2.2%)
	ARTHRALGIA	2 (3.0%)	0	2 (1.4%)
	TENDINOUS DISORDER	1 (1.5%)	0	1 (0.7%)
	ARTHROSIS	0	1 (1.4%)	1 (0.7%)
Urogenital System	TOTAL	4 (6.0%)	6 (8.3%)	10 (7.2%)
	URINARY INCONTINENCE	1 (1.5%)	5 (6.9%)	6 (4.3%)
	ALBUMINURIA	2 (3.0%)	1 (1.4%)	3 (2.2%)
	GLYCOSURIA	1 (1.5%)	0	1 (0.7%)
	PYURIA	1 (1.5%)	0	1 (0.7%)
	CYSTITIS	0	1 (1.4%)	1 (0.7%)
	HAEMATURIA	0	1 (1.4%)	1 (0.7%)
Hemic and Lymphatic System	TOTAL	3 (4.5%)	2 (2.8%)	5 (3.6%)
	LEUKOPENIA	1 (1.5%)	2 (2.8%)	3 (2.2%)
	ANEMIA	1 (1.5%)	1 (1.4%)	2 (1.4%)
	PURPURA	1 (1.5%)	0	1 (0.7%)
	LYMPHOCYTOSIS	0	1 (1.4%)	1 (0.7%)
Cardiovascular System	TOTAL	2 (3.0%)	6 (8.3%)	8 (5.8%)
	VASODILATATION	0	3 (4.2%)	3 (2.2%)
	MIGRAINE	1 (1.5%)	1 (1.4%)	2 (1.4%)
	HAEMATOMA	1 (1.5%)	0	1 (0.7%)
	BUNDLE BRANCH BLOCK	0	1 (1.4%)	1 (0.7%)
	SYNCOPE	0	1 (1.4%)	1 (0.7%)
Special Searches	TOTAL	0	1 (1.4%)	1 (0.7%)
	PUNCTURE SITE PAIN	0	1 (1.4%)	1 (0.7%)

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	1 (2.9%)	1 (3.7%)	2 (3.2%)
Urogenital System	TOTAL	1 (2.9%)	1 (3.7%)	2 (3.2%)
	DYSMENORRHEA	1 (2.9%)	1 (3.7%)	2 (3.2%)
	UTERUS DISORDERS	0	1 (3.7%)	1 (1.6%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Body System	Preferred Term			
TOTAL	TOTAL	34 (81.0%)	19 (63.3%)	53 (73.6%)
Body as a Whole	TOTAL	22 (52.4%)	10 (33.3%)	32 (44.4%)
	HEADACHE	11 (26.2%)	6 (20.0%)	17 (23.6%)
	TRAUMA	6 (14.3%)	2 (6.7%)	8 (11.1%)
	INFECTION	3 (7.1%)	3 (10.0%)	6 (8.3%)
	ALLERGIC REACTION	4 (9.5%)	0	4 (5.6%)
	ABDOMINAL PAIN	3 (7.1%)	1 (3.3%)	4 (5.6%)
	FEVER	3 (7.1%)	1 (3.3%)	4 (5.6%)
	ASTHENIA	1 (2.4%)	3 (10.0%)	4 (5.6%)
	BACK PAIN	3 (7.1%)	0	3 (4.2%)
	CHEST PAIN	3 (7.1%)	0	3 (4.2%)
	MALAISE	1 (2.4%)	0	1 (1.4%)
	PAIN	0	1 (3.3%)	1 (1.4%)
Nervous System	TOTAL	19 (45.2%)	11 (36.7%)	30 (41.7%)
	EMOTIONAL LABILITY	7 (16.7%)	3 (10.0%)	10 (13.9%)
	SOMNOLENCE	5 (11.9%)	3 (10.0%)	8 (11.1%)
	INSOMNIA	3 (7.1%)	2 (6.7%)	5 (6.9%)
	DIZZINESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
	NERVOUSNESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
	AGITATION	2 (4.8%)	1 (3.3%)	3 (4.2%)
	ANXIETY	1 (2.4%)	1 (3.3%)	2 (2.8%)
	HOSTILITY	1 (2.4%)	1 (3.3%)	2 (2.8%)
	WITHDRAWAL SYNDROME	0	2 (6.7%)	2 (2.8%)
	DEPRESSION	1 (2.4%)	0	1 (1.4%)
	LACK OF EMOTION	1 (2.4%)	0	1 (1.4%)
	PARESTHESIA	1 (2.4%)	0	1 (1.4%)
	VERTIGO	1 (2.4%)	0	1 (1.4%)
	CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.4%)
	HALLUCINATIONS	0	1 (3.3%)	1 (1.4%)
	LIBIDO DECREASED	0	1 (3.3%)	1 (1.4%)
	TREMOR	0	1 (3.3%)	1 (1.4%)
Respiratory System	TOTAL	18 (42.9%)	10 (33.3%)	28 (38.9%)
	RESPIRATORY DISORDER	8 (19.0%)	8 (26.7%)	16 (22.2%)
	PHARYNGITIS	5 (11.9%)	1 (3.3%)	6 (8.3%)
	ASTHMA	4 (9.5%)	2 (6.7%)	6 (8.3%)
	RHINITIS	4 (9.5%)	1 (3.3%)	5 (6.9%)
	SINUSITIS	4 (9.5%)	0	4 (5.6%)
	BRONCHITIS	2 (4.8%)	2 (6.7%)	4 (5.6%)
	COUGH INCREASED	1 (2.4%)	1 (3.3%)	2 (2.8%)
	DYSPNEA	1 (2.4%)	0	1 (1.4%)
	PNEUMONIA	1 (2.4%)	0	1 (1.4%)

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Body System	Preferred Term			
Digestive System	TOTAL	14 (33.3%)	7 (23.3%)	21 (29.2%)
	NAUSEA	7 (16.7%)	2 (6.7%)	9 (12.5%)
	VOMITING	5 (11.9%)	0	5 (6.9%)
	DIARRHEA	4 (9.5%)	1 (3.3%)	5 (6.9%)
	DYSPEPSIA	3 (7.1%)	1 (3.3%)	4 (5.6%)
	DECREASED APPETITE	1 (2.4%)	2 (6.7%)	3 (4.2%)
	GASTROINTESTINAL DISORDER	1 (2.4%)	1 (3.3%)	2 (2.8%)
	TOOTH CARIES	1 (2.4%)	1 (3.3%)	2 (2.8%)
	INCREASED APPETITE	0	2 (6.7%)	2 (2.8%)
	COLITIS	1 (2.4%)	0	1 (1.4%)
	DRY MOUTH	1 (2.4%)	0	1 (1.4%)
	GASTRITIS	1 (2.4%)	0	1 (1.4%)
	HEMATEMESIS	1 (2.4%)	0	1 (1.4%)
Skin and Appendages	TOTAL	5 (11.9%)	2 (6.7%)	7 (9.7%)
	CONTACT DERMATITIS	2 (4.8%)	0	2 (2.8%)
	ACNE	1 (2.4%)	1 (3.3%)	2 (2.8%)
	PRURITUS	1 (2.4%)	1 (3.3%)	2 (2.8%)
	FUNGAL DERMATITIS	1 (2.4%)	0	1 (1.4%)
	FURUNCULOSIS	1 (2.4%)	0	1 (1.4%)
Urogenital System	TOTAL	5 (11.9%)	1 (3.3%)	6 (8.3%)
	ALBUMINURIA	4 (9.5%)	1 (3.3%)	5 (6.9%)
	HAEMATURIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
	URINARY TRACT INFECTION	1 (2.4%)	0	1 (1.4%)
Hemic and Lymphatic System	TOTAL	3 (7.1%)	0	3 (4.2%)
	LEUKOPENIA	2 (4.8%)	0	2 (2.8%)
	LYMPHADENOPATHY	1 (2.4%)	0	1 (1.4%)
Metabolic and Nutritional Disorders	TOTAL	3 (7.1%)	3 (10.0%)	6 (8.3%)
	WEIGHT GAIN	2 (4.8%)	3 (10.0%)	5 (6.9%)
	WEIGHT LOSS	1 (2.4%)	0	1 (1.4%)
Musculoskeletal System	TOTAL	1 (2.4%)	1 (3.3%)	2 (2.8%)
	MYALGIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
Special Senses	TOTAL	1 (2.4%)	0	1 (1.4%)
	OTITIS MEDIA	1 (2.4%)	0	1 (1.4%)
Cardiovascular System	TOTAL	0	1 (3.3%)	1 (1.4%)
	SYNCOPE	0	1 (3.3%)	1 (1.4%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	3 (21.4%)	2 (13.3%)	5 (17.2%)
Urogenital System	TOTAL	3 (21.4%)	2 (13.3%)	5 (17.2%)
	DYSMENORRHEA	3 (21.4%)	0	3 (10.3%)
	FEMALE GENITAL DISORDERS	0	1 (6.7%)	1 (3.4%)
	MENSTRUAL DISORDER	0	1 (6.7%)	1 (3.4%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	19 (79.2%)	20 (71.4%)	39 (75.0%)
Body as a Whole	TOTAL	14 (58.3%)	15 (53.6%)	29 (55.8%)
	HEADACHE	10 (41.7%)	9 (32.1%)	19 (36.5%)
	INFECTION	5 (20.8%)	3 (10.7%)	8 (15.4%)
	ALLERGIC REACTION	4 (16.7%)	3 (10.7%)	7 (13.5%)
	ASTHENIA	3 (12.5%)	4 (14.3%)	7 (13.5%)
	ABDOMINAL PAIN	3 (12.5%)	3 (10.7%)	6 (11.5%)
	TRAUMA	1 (4.2%)	4 (14.3%)	5 (9.6%)
	FEVER	0	2 (7.1%)	2 (3.8%)
	ABNORMAL LABORATORY VALUE	1 (4.2%)	0	1 (1.9%)
	PAIN	1 (4.2%)	0	1 (1.9%)
	BACK PAIN	0	1 (3.6%)	1 (1.9%)
Nervous System	TOTAL	11 (45.8%)	10 (35.7%)	21 (40.4%)
	INSOMNIA	3 (12.5%)	5 (17.9%)	8 (15.4%)
	DIZZINESS	3 (12.5%)	1 (3.6%)	4 (7.7%)
	NEUROSIS	3 (12.5%)	1 (3.6%)	4 (7.7%)
	HOSTILITY	1 (4.2%)	3 (10.7%)	4 (7.7%)
	NERVOUSNESS	1 (4.2%)	3 (10.7%)	4 (7.7%)
	EMOTIONAL LABILITY	2 (8.3%)	1 (3.6%)	3 (5.8%)
	ABNORMAL DREAMS	1 (4.2%)	2 (7.1%)	3 (5.8%)
	HYPERKINESIA	1 (4.2%)	2 (7.1%)	3 (5.8%)
	CONCENTRATION IMPAIRED	2 (8.3%)	0	2 (3.8%)
	ANXIETY	1 (4.2%)	1 (3.6%)	2 (3.8%)
	SOMNOLENCE	1 (4.2%)	1 (3.6%)	2 (3.8%)
	AGITATION	0	2 (7.1%)	2 (3.8%)
	MANIC REACTION	1 (4.2%)	0	1 (1.9%)
	PARESTHESIA	1 (4.2%)	0	1 (1.9%)
	VERTIGO	1 (4.2%)	0	1 (1.9%)
	DEPRESSION	0	1 (3.6%)	1 (1.9%)
	TREMOR	0	1 (3.6%)	1 (1.9%)
Respiratory System	TOTAL	11 (45.8%)	9 (32.1%)	20 (38.5%)
	RESPIRATORY DISORDER	5 (20.8%)	6 (21.4%)	11 (21.2%)
	SINUSITIS	4 (16.7%)	0	4 (7.7%)
	ASTHMA	1 (4.2%)	2 (7.1%)	3 (5.8%)
	PHARYNGITIS	1 (4.2%)	2 (7.1%)	3 (5.8%)
	RHINITIS	1 (4.2%)	1 (3.6%)	2 (3.8%)
	BRONCHITIS	1 (4.2%)	0	1 (1.9%)
	COUGH INCREASED	1 (4.2%)	0	1 (1.9%)
	PLEURA DISORDER	1 (4.2%)	0	1 (1.9%)
	EPISTAXIS	0	1 (3.6%)	1 (1.9%)
	PNEUMONIA	0	1 (3.6%)	1 (1.9%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
Digestive System	TOTAL	4 (16.7%)	11 (39.3%)	15 (28.8%)
	NAUSEA	1 (4.2%)	6 (21.4%)	7 (13.5%)
	DIARRHEA	1 (4.2%)	2 (7.1%)	3 (5.8%)
	DYSPEPSIA	1 (4.2%)	2 (7.1%)	3 (5.8%)
	CONSTIPATION	1 (4.2%)	1 (3.6%)	2 (3.8%)
	TOOTH DISORDER	1 (4.2%)	1 (3.6%)	2 (3.8%)
	DECREASED APPETITE	0	2 (7.1%)	2 (3.8%)
	DRY MOUTH	0	2 (7.1%)	2 (3.8%)
	FLATULENCE	0	1 (3.6%)	1 (1.9%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (3.6%)	1 (1.9%)
	ULCERATIVE STOMATITIS	0	1 (3.6%)	1 (1.9%)
	VOMITING	0	1 (3.6%)	1 (1.9%)
Urogenital System	TOTAL	4 (16.7%)	0	4 (7.7%)
	ALBUMINURIA	3 (12.5%)	0	3 (5.8%)
	DYSURIA	1 (4.2%)	0	1 (1.9%)
	HAEMATURIA	1 (4.2%)	0	1 (1.9%)
Musculoskeletal System	TOTAL	3 (12.5%)	1 (3.6%)	4 (7.7%)
	ARTHRALGIA	2 (8.3%)	1 (3.6%)	3 (5.8%)
	ARTHROSIS	1 (4.2%)	0	1 (1.9%)
Metabolic and Nutritional Disorders	TOTAL	2 (8.3%)	1 (3.6%)	3 (5.8%)
	WEIGHT GAIN	2 (8.3%)	0	2 (3.8%)
	WEIGHT LOSS	0	1 (3.6%)	1 (1.9%)
Special Senses	TOTAL	2 (8.3%)	3 (10.7%)	5 (9.6%)
	BLEPHARITIS	1 (4.2%)	0	1 (1.9%)
	EYE PAIN	1 (4.2%)	0	1 (1.9%)
	ABNORMAL VISION	0	1 (3.6%)	1 (1.9%)
	OTITIS MEDIA	0	1 (3.6%)	1 (1.9%)
	PHOTOPHOBIA	0	1 (3.6%)	1 (1.9%)
Cardiovascular System	TOTAL	1 (4.2%)	2 (7.1%)	3 (5.8%)
	BRADYCARDIA	1 (4.2%)	0	1 (1.9%)
	SYNCOPE	0	1 (3.6%)	1 (1.9%)
	VASODILATATION	0	1 (3.6%)	1 (1.9%)
Skin and Appendages	TOTAL	1 (4.2%)	4 (14.3%)	5 (9.6%)
	ACNE	1 (4.2%)	2 (7.1%)	3 (5.8%)
	CONTACT DERMATITIS	0	1 (3.6%)	1 (1.9%)
	RASH	0	1 (3.6%)	1 (1.9%)
	SWEATING	0	1 (3.6%)	1 (1.9%)

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
Skin and Appendages	URTICARIA	0	1 (3.6%)	1 (1.9%)
Hemic and Lymphatic System	TOTAL	0	2 (7.1%)	2 (3.8%)
	EOSINOPHILIA	0	1 (3.6%)	1 (1.9%)
	LEUKOCYTOSIS	0	1 (3.6%)	1 (1.9%)
	MONOCYTOSIS	0	1 (3.6%)	1 (1.9%)

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	3 (25.0%)	0	3 (14.3%)
Urogenital System	TOTAL	3 (25.0%)	0	3 (14.3%)
	DYSMENORRHEA	3 (25.0%)	0	3 (14.3%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
TOTAL	TOTAL	53 (80.3%)	39 (67.2%)	92 (74.2%)
Body as a Whole	TOTAL	36 (54.5%)	25 (43.1%)	61 (49.2%)
	HEADACHE	21 (31.8%)	15 (25.9%)	36 (29.0%)
	INFECTION	8 (12.1%)	6 (10.3%)	14 (11.3%)
	TRAUMA	7 (10.6%)	6 (10.3%)	13 (10.5%)
	ALLERGIC REACTION	8 (12.1%)	3 (5.2%)	11 (8.9%)
	ASTHENIA	4 (6.1%)	7 (12.1%)	11 (8.9%)
	ABDOMINAL PAIN	6 (9.1%)	4 (6.9%)	10 (8.1%)
	FEVER	3 (4.5%)	3 (5.2%)	6 (4.8%)
	BACK PAIN	3 (4.5%)	1 (1.7%)	4 (3.2%)
	CHEST PAIN	3 (4.5%)	0	3 (2.4%)
	PAIN	1 (1.5%)	1 (1.7%)	2 (1.6%)
	ABNORMAL LABORATORY VALUE	1 (1.5%)	0	1 (0.8%)
	MALAISE	1 (1.5%)	0	1 (0.8%)
Nervous System	TOTAL	30 (45.5%)	21 (36.2%)	51 (41.1%)
	EMOTIONAL LABILITY	9 (13.6%)	4 (6.9%)	13 (10.5%)
	INSOMNIA	6 (9.1%)	7 (12.1%)	13 (10.5%)
	SOMNOLENCE	6 (9.1%)	4 (6.9%)	10 (8.1%)
	DIZZINESS	6 (9.1%)	2 (3.4%)	8 (6.5%)
	NERVOUSNESS	4 (6.1%)	4 (6.9%)	8 (6.5%)
	HOSTILITY	2 (3.0%)	4 (6.9%)	6 (4.8%)
	AGITATION	2 (3.0%)	3 (5.2%)	5 (4.0%)
	NEUROSIS	3 (4.5%)	1 (1.7%)	4 (3.2%)
	ANXIETY	2 (3.0%)	2 (3.4%)	4 (3.2%)
	CONCENTRATION IMPAIRED	2 (3.0%)	1 (1.7%)	3 (2.4%)
	ABNORMAL DREAMS	1 (1.5%)	2 (3.4%)	3 (2.4%)
	HYPERKINESIA	1 (1.5%)	2 (3.4%)	3 (2.4%)
	PARESTHESIA	2 (3.0%)	0	2 (1.6%)
	VERTIGO	2 (3.0%)	0	2 (1.6%)
	DEPRESSION	1 (1.5%)	1 (1.7%)	2 (1.6%)
	TREMOR	0	2 (3.4%)	2 (1.6%)
	WITHDRAWAL SYNDROME	0	2 (3.4%)	2 (1.6%)
	LACK OF EMOTION	1 (1.5%)	0	1 (0.8%)
	MANIC REACTION	1 (1.5%)	0	1 (0.8%)
	HALLUCINATIONS	0	1 (1.7%)	1 (0.8%)
	LIBIDO DECREASED	0	1 (1.7%)	1 (0.8%)
Respiratory System	TOTAL	29 (43.9%)	19 (32.8%)	48 (38.7%)
	RESPIRATORY DISORDER	13 (19.7%)	14 (24.1%)	27 (21.8%)
	PHARYNGITIS	6 (9.1%)	3 (5.2%)	9 (7.3%)
	ASTHMA	5 (7.6%)	4 (6.9%)	9 (7.3%)
	SINUSITIS	8 (12.1%)	0	8 (6.5%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
Respiratory System	RHINITIS	5 (7.6%)	2 (3.4%)	7 (5.6%)
	BRONCHITIS	3 (4.5%)	2 (3.4%)	5 (4.0%)
	COUGH INCREASED	2 (3.0%)	1 (1.7%)	3 (2.4%)
	PNEUMONIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
	DYSPNEA	1 (1.5%)	0	1 (0.8%)
	PLEURA DISORDER	1 (1.5%)	0	1 (0.8%)
	EPISTAXIS	0	1 (1.7%)	1 (0.8%)
Digestive System	TOTAL	18 (27.3%)	18 (31.0%)	36 (29.0%)
	NAUSEA	8 (12.1%)	8 (13.8%)	16 (12.9%)
	DIARRHEA	5 (7.6%)	3 (5.2%)	8 (6.5%)
	DYSPEPSIA	4 (6.1%)	3 (5.2%)	7 (5.6%)
	VOMITING	5 (7.6%)	1 (1.7%)	6 (4.8%)
	DECREASED APPETITE	1 (1.5%)	4 (6.9%)	5 (4.0%)
	DRY MOUTH	1 (1.5%)	2 (3.4%)	3 (2.4%)
	CONSTIPATION	1 (1.5%)	1 (1.7%)	2 (1.6%)
	GASTROINTESTINAL DISORDER	1 (1.5%)	1 (1.7%)	2 (1.6%)
	TOOTH CARIES	1 (1.5%)	1 (1.7%)	2 (1.6%)
	TOOTH DISORDER	1 (1.5%)	1 (1.7%)	2 (1.6%)
	INCREASED APPETITE	0	2 (3.4%)	2 (1.6%)
	COLITIS	1 (1.5%)	0	1 (0.8%)
	GASTRITIS	1 (1.5%)	0	1 (0.8%)
	HEMATEMESIS	1 (1.5%)	0	1 (0.8%)
	FLATULENCE	0	1 (1.7%)	1 (0.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.7%)	1 (0.8%)
	ULCERATIVE STOMATITIS	0	1 (1.7%)	1 (0.8%)
Urogenital System	TOTAL	9 (13.6%)	1 (1.7%)	10 (8.1%)
	ALBUMINURIA	7 (10.6%)	1 (1.7%)	8 (6.5%)
	HAEMATURIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
	DYSURIA	1 (1.5%)	0	1 (0.8%)
	URINARY TRACT INFECTION	1 (1.5%)	0	1 (0.8%)
Skin and Appendages	TOTAL	6 (9.1%)	6 (10.3%)	12 (9.7%)
	ACNE	2 (3.0%)	3 (5.2%)	5 (4.0%)
	CONTACT DERMATITIS	2 (3.0%)	1 (1.7%)	3 (2.4%)
	PRURITUS	1 (1.5%)	1 (1.7%)	2 (1.6%)
	FUNGAL DERMATITIS	1 (1.5%)	0	1 (0.8%)
	FURUNCULOSIS	1 (1.5%)	0	1 (0.8%)
	RASH	0	1 (1.7%)	1 (0.8%)
	SWEATING	0	1 (1.7%)	1 (0.8%)
	URTICARIA	0	1 (1.7%)	1 (0.8%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	TOTAL	5 (7.6%)	4 (6.9%)	9 (7.3%)
	WEIGHT GAIN	4 (6.1%)	3 (5.2%)	7 (5.6%)
	WEIGHT LOSS	1 (1.5%)	1 (1.7%)	2 (1.6%)
Musculoskeletal System	TOTAL	4 (6.1%)	2 (3.4%)	6 (4.8%)
	ARTHRALGIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
	MYALGIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
	ARTHROSIS	1 (1.5%)	0	1 (0.8%)
Hemic and Lymphatic System	TOTAL	3 (4.5%)	2 (3.4%)	5 (4.0%)
	LEUKOPENIA	2 (3.0%)	0	2 (1.6%)
	LYMPHADENOPATHY	1 (1.5%)	0	1 (0.8%)
	EOSINOPHILIA	0	1 (1.7%)	1 (0.8%)
	LEUKOCYTOSIS	0	1 (1.7%)	1 (0.8%)
	MONOCYTOSIS	0	1 (1.7%)	1 (0.8%)
Special Senses	TOTAL	3 (4.5%)	3 (5.2%)	6 (4.8%)
	OTITIS MEDIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
	BLEPHARITIS	1 (1.5%)	0	1 (0.8%)
	EYE PAIN	1 (1.5%)	0	1 (0.8%)
	ABNORMAL VISION	0	1 (1.7%)	1 (0.8%)
	PHOTOPHOBIA	0	1 (1.7%)	1 (0.8%)
Cardiovascular System	TOTAL	1 (1.5%)	3 (5.2%)	4 (3.2%)
	SYNCOPE	0	2 (3.4%)	2 (1.6%)
	BRADYCARDIA	1 (1.5%)	0	1 (0.8%)
	VASODILATATION	0	1 (1.7%)	1 (0.8%)

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	6 (23.1%)	2 (8.3%)	8 (16.0%)
Urogenital System	TOTAL	6 (23.1%)	2 (8.3%)	8 (16.0%)
	DYSMENORRHEA	6 (23.1%)	0	6 (12.0%)
	FEMALE GENITAL DISORDERS	0	1 (4.2%)	1 (2.0%)
	MENSTRUAL DISORDER	0	1 (4.2%)	1 (2.0%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	66 (81.5%)	45 (68.2%)	111 (75.5%)
Body as a Whole	TOTAL	46 (56.8%)	25 (37.9%)	71 (48.3%)
	HEADACHE	22 (27.2%)	10 (15.2%)	32 (21.8%)
	TRAUMA	17 (21.0%)	6 (9.1%)	23 (15.6%)
	INFECTION	8 (9.9%)	12 (18.2%)	20 (13.6%)
	ABDOMINAL PAIN	13 (16.0%)	4 (6.1%)	17 (11.6%)
	FEVER	9 (11.1%)	3 (4.5%)	12 (8.2%)
	ALLERGIC REACTION	7 (8.6%)	2 (3.0%)	9 (6.1%)
	ASTHENIA	3 (3.7%)	5 (7.6%)	8 (5.4%)
	BACK PAIN	3 (3.7%)	3 (4.5%)	6 (4.1%)
	PAIN	3 (3.7%)	2 (3.0%)	5 (3.4%)
	CHEST PAIN	3 (3.7%)	0	3 (2.0%)
	FACE EDEMA	2 (2.5%)	0	2 (1.4%)
	MALAISE	1 (1.2%)	0	1 (0.7%)
Respiratory System	TOTAL	38 (46.9%)	23 (34.8%)	61 (41.5%)
	RESPIRATORY DISORDER	19 (23.5%)	14 (21.2%)	33 (22.4%)
	PHARYNGITIS	13 (16.0%)	5 (7.6%)	18 (12.2%)
	RHINITIS	8 (9.9%)	4 (6.1%)	12 (8.2%)
	SINUSITIS	7 (8.6%)	1 (1.5%)	8 (5.4%)
	ASTHMA	4 (4.9%)	3 (4.5%)	7 (4.8%)
	COUGH INCREASED	4 (4.9%)	2 (3.0%)	6 (4.1%)
	BRONCHITIS	2 (2.5%)	3 (4.5%)	5 (3.4%)
	PNEUMONIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	EPISTAXIS	0	2 (3.0%)	2 (1.4%)
	DYSPNEA	1 (1.2%)	0	1 (0.7%)
	YAWN	0	1 (1.5%)	1 (0.7%)
Nervous System	TOTAL	34 (42.0%)	24 (36.4%)	58 (39.5%)
	EMOTIONAL LABILITY	8 (9.9%)	3 (4.5%)	11 (7.5%)
	NERVOUSNESS	9 (11.1%)	1 (1.5%)	10 (6.8%)
	INSOMNIA	5 (6.2%)	5 (7.6%)	10 (6.8%)
	SOMNOLENCE	5 (6.2%)	4 (6.1%)	9 (6.1%)
	HOSTILITY	5 (6.2%)	3 (4.5%)	8 (5.4%)
	AGITATION	3 (3.7%)	3 (4.5%)	6 (4.1%)
	DEPRESSION	4 (4.9%)	1 (1.5%)	5 (3.4%)
	DIZZINESS	3 (3.7%)	2 (3.0%)	5 (3.4%)
	ANXIETY	2 (2.5%)	2 (3.0%)	4 (2.7%)
	HYPERKINESIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
	HALLUCINATIONS	1 (1.2%)	2 (3.0%)	3 (2.0%)
	WITHDRAWAL SYNDROME	1 (1.2%)	2 (3.0%)	3 (2.0%)
	CONCENTRATION IMPAIRED	0	3 (4.5%)	3 (2.0%)
	HYPESTHESIA	0	2 (3.0%)	2 (1.4%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
Nervous System	TREMOR	0	2 (3.0%)	2 (1.4%)
	CONVULSION	1 (1.2%)	0	1 (0.7%)
	LACK OF EMOTION	1 (1.2%)	0	1 (0.7%)
	NEUROSIS	1 (1.2%)	0	1 (0.7%)
	PARESTHESIA	1 (1.2%)	0	1 (0.7%)
	VERTIGO	1 (1.2%)	0	1 (0.7%)
	VESTIBULAR DISORDER	1 (1.2%)	0	1 (0.7%)
	EUPHORIA	0	1 (1.5%)	1 (0.7%)
	HYSTERIA	0	1 (1.5%)	1 (0.7%)
	LIBIDO DECREASED	0	1 (1.5%)	1 (0.7%)
	PARALYSIS	0	1 (1.5%)	1 (0.7%)
Digestive System	TOTAL	31 (38.3%)	21 (31.8%)	52 (35.4%)
	VOMITING	13 (16.0%)	4 (6.1%)	17 (11.6%)
	NAUSEA	9 (11.1%)	6 (9.1%)	15 (10.2%)
	DYSPEPSIA	7 (8.6%)	4 (6.1%)	11 (7.5%)
	DIARRHEA	6 (7.4%)	3 (4.5%)	9 (6.1%)
	DECREASED APPETITE	2 (2.5%)	3 (4.5%)	5 (3.4%)
	INCREASED APPETITE	2 (2.5%)	2 (3.0%)	4 (2.7%)
	TOOTH CARIES	1 (1.2%)	3 (4.5%)	4 (2.7%)
	DRY MOUTH	3 (3.7%)	0	3 (2.0%)
	GASTROINTESTINAL DISORDER	1 (1.2%)	1 (1.5%)	2 (1.4%)
	COLITIS	1 (1.2%)	0	1 (0.7%)
	CONSTIPATION	1 (1.2%)	0	1 (0.7%)
	GASTRITIS	1 (1.2%)	0	1 (0.7%)
	HEMATEMESIS	1 (1.2%)	0	1 (0.7%)
	STOMATITIS	1 (1.2%)	0	1 (0.7%)
	TOOTH DISORDER	1 (1.2%)	0	1 (0.7%)
	FECAL INCONTINENCE	0	1 (1.5%)	1 (0.7%)
	GASTROENTERITIS	0	1 (1.5%)	1 (0.7%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.7%)
Skin and Appendages	TOTAL	11 (13.6%)	6 (9.1%)	17 (11.6%)
	CONTACT DERMATITIS	4 (4.9%)	1 (1.5%)	5 (3.4%)
	ACNE	3 (3.7%)	1 (1.5%)	4 (2.7%)
	PRURITUS	1 (1.2%)	2 (3.0%)	3 (2.0%)
	RASH	1 (1.2%)	2 (3.0%)	3 (2.0%)
	FUNGAL DERMATITIS	1 (1.2%)	0	1 (0.7%)
	FURUNCULOSIS	1 (1.2%)	0	1 (0.7%)
	HERPES ZOSTER	1 (1.2%)	0	1 (0.7%)
	MACULOPAPULAR RASH	0	1 (1.5%)	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	8 (9.9%)	8 (12.1%)	16 (10.9%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	WEIGHT GAIN	6 (7.4%)	6 (9.1%)	12 (8.2%)
	DEHYDRATION	1 (1.2%)	1 (1.5%)	2 (1.4%)
	WEIGHT LOSS	1 (1.2%)	0	1 (0.7%)
	SGOT INCREASED	0	1 (1.5%)	1 (0.7%)
Urogenital System	TOTAL	7 (8.6%)	5 (7.6%)	12 (8.2%)
	ALBUMINURIA	4 (4.9%)	2 (3.0%)	6 (4.1%)
	URINARY INCONTINENCE	1 (1.2%)	3 (4.5%)	4 (2.7%)
	HAEMATURIA	1 (1.2%)	2 (3.0%)	3 (2.0%)
	PYURIA	1 (1.2%)	0	1 (0.7%)
	URINARY TRACT INFECTION	1 (1.2%)	0	1 (0.7%)
	CYSTITIS	0	1 (1.5%)	1 (0.7%)
Musculoskeletal System	TOTAL	5 (6.2%)	2 (3.0%)	7 (4.8%)
	MYALGIA	2 (2.5%)	2 (3.0%)	4 (2.7%)
	ARTHRALGIA	2 (2.5%)	0	2 (1.4%)
	TENDINOUS DISORDER	1 (1.2%)	0	1 (0.7%)
	ARTHROSIS	0	1 (1.5%)	1 (0.7%)
Hemic and Lymphatic System	TOTAL	4 (4.9%)	2 (3.0%)	6 (4.1%)
	LEUKOPENIA	3 (3.7%)	2 (3.0%)	5 (3.4%)
	LYMPHADENOPATHY	1 (1.2%)	0	1 (0.7%)
	ANEMIA	0	1 (1.5%)	1 (0.7%)
	LYMPHOCYTOSIS	0	1 (1.5%)	1 (0.7%)
Special Senses	TOTAL	3 (3.7%)	2 (3.0%)	5 (3.4%)
	OTITIS MEDIA	3 (3.7%)	1 (1.5%)	4 (2.7%)
	ABNORMAL VISION	0	1 (1.5%)	1 (0.7%)
Cardiovascular System	TOTAL	1 (1.2%)	4 (6.1%)	5 (3.4%)
	MIGRAINE	1 (1.2%)	1 (1.5%)	2 (1.4%)
	SYNCOPE	0	2 (3.0%)	2 (1.4%)
	BUNDLE BRANCH BLOCK	0	1 (1.5%)	1 (0.7%)
Special Searches	TOTAL	0	1 (1.5%)	1 (0.7%)
	PUNCTURE SITE PAIN	0	1 (1.5%)	1 (0.7%)

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	3 (9.1%)	2 (6.9%)	5 (8.1%)
Urogenital System	TOTAL	3 (9.1%)	2 (6.9%)	5 (8.1%)
	DYSMENORRHEA	3 (9.1%)	0	3 (4.8%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.6%)
	MENSTRUAL DISORDER	0	1 (3.4%)	1 (1.6%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	41 (78.8%)	51 (79.7%)	92 (79.3%)
Body as a Whole	TOTAL	29 (55.8%)	33 (51.6%)	62 (53.4%)
	HEADACHE	20 (38.5%)	18 (28.1%)	38 (32.8%)
	INFECTION	8 (15.4%)	8 (12.5%)	16 (13.8%)
	ABDOMINAL PAIN	6 (11.5%)	8 (12.5%)	14 (12.1%)
	TRAUMA	5 (9.6%)	8 (12.5%)	13 (11.2%)
	ALLERGIC REACTION	4 (7.7%)	4 (6.3%)	8 (6.9%)
	FEVER	4 (7.7%)	4 (6.3%)	8 (6.9%)
	ASTHENIA	3 (5.8%)	4 (6.3%)	7 (6.0%)
	PAIN	3 (5.8%)	1 (1.6%)	4 (3.4%)
	BACK PAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
	ABNORMAL LABORATORY VALUE	1 (1.9%)	0	1 (0.9%)
	ABSCESS	1 (1.9%)	0	1 (0.9%)
	SPINA BIFIDA	0	1 (1.6%)	1 (0.9%)
Nervous System	TOTAL	20 (38.5%)	32 (50.0%)	52 (44.8%)
	NERVOUSNESS	2 (3.8%)	12 (18.8%)	14 (12.1%)
	INSOMNIA	6 (11.5%)	7 (10.9%)	13 (11.2%)
	HYPERKINESIA	6 (11.5%)	6 (9.4%)	12 (10.3%)
	HOSTILITY	2 (3.8%)	7 (10.9%)	9 (7.8%)
	DIZZINESS	4 (7.7%)	3 (4.7%)	7 (6.0%)
	NEUROSIS	5 (9.6%)	1 (1.6%)	6 (5.2%)
	ANXIETY	2 (3.8%)	4 (6.3%)	6 (5.2%)
	SOMNOLENCE	2 (3.8%)	3 (4.7%)	5 (4.3%)
	EMOTIONAL LABILITY	3 (5.8%)	1 (1.6%)	4 (3.4%)
	AGITATION	1 (1.9%)	3 (4.7%)	4 (3.4%)
	CONCENTRATION IMPAIRED	3 (5.8%)	0	3 (2.6%)
	ABNORMAL DREAMS	1 (1.9%)	2 (3.1%)	3 (2.6%)
	VERTIGO	1 (1.9%)	2 (3.1%)	3 (2.6%)
	DEPRESSION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	MANIC REACTION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	MYOCLONUS	1 (1.9%)	1 (1.6%)	2 (1.7%)
	TREMOR	0	2 (3.1%)	2 (1.7%)
	PARESTHESIA	1 (1.9%)	0	1 (0.9%)
	DYSKINESIA	0	1 (1.6%)	1 (0.9%)
	LACK OF EMOTION	0	1 (1.6%)	1 (0.9%)
	PSYCHOSIS	0	1 (1.6%)	1 (0.9%)
Respiratory System	TOTAL	19 (36.5%)	19 (29.7%)	38 (32.8%)
	RESPIRATORY DISORDER	7 (13.5%)	14 (21.9%)	21 (18.1%)
	PHARYNGITIS	6 (11.5%)	5 (7.8%)	11 (9.5%)
	RHINITIS	5 (9.6%)	5 (7.8%)	10 (8.6%)
	SINUSITIS	7 (13.5%)	1 (1.6%)	8 (6.9%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
Respiratory System	COUGH INCREASED	3 (5.8%)	2 (3.1%)	5 (4.3%)
	ASTHMA	2 (3.8%)	2 (3.1%)	4 (3.4%)
	BRONCHITIS	1 (1.9%)	0	1 (0.9%)
	PLEURA DISORDER	1 (1.9%)	0	1 (0.9%)
	EPISTAXIS	0	1 (1.6%)	1 (0.9%)
	PNEUMONIA	0	1 (1.6%)	1 (0.9%)
Digestive System	TOTAL	13 (25.0%)	17 (26.6%)	30 (25.9%)
	NAUSEA	6 (11.5%)	7 (10.9%)	13 (11.2%)
	DIARRHEA	4 (7.7%)	2 (3.1%)	6 (5.2%)
	DYSPEPSIA	3 (5.8%)	3 (4.7%)	6 (5.2%)
	DECREASED APPETITE	2 (3.8%)	4 (6.3%)	6 (5.2%)
	TOOTH DISORDER	2 (3.8%)	1 (1.6%)	3 (2.6%)
	CONSTIPATION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	GINGIVITIS	1 (1.9%)	1 (1.6%)	2 (1.7%)
	VOMITING	1 (1.9%)	1 (1.6%)	2 (1.7%)
	DRY MOUTH	0	2 (3.1%)	2 (1.7%)
	FLATULENCE	0	2 (3.1%)	2 (1.7%)
	GASTROENTERITIS	0	1 (1.6%)	1 (0.9%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.6%)	1 (0.9%)
	TOOTH CARIES	0	1 (1.6%)	1 (0.9%)
	ULCERATIVE STOMATITIS	0	1 (1.6%)	1 (0.9%)
Special Senses	TOTAL	8 (15.4%)	7 (10.9%)	15 (12.9%)
	OTITIS MEDIA	3 (5.8%)	3 (4.7%)	6 (5.2%)
	EAR PAIN	2 (3.8%)	1 (1.6%)	3 (2.6%)
	OTITIS EXTERNA	2 (3.8%)	1 (1.6%)	3 (2.6%)
	BLEPHARITIS	1 (1.9%)	0	1 (0.9%)
	EYE PAIN	1 (1.9%)	0	1 (0.9%)
	ABNORMAL VISION	0	1 (1.6%)	1 (0.9%)
	PHOTOPHOBIA	0	1 (1.6%)	1 (0.9%)
Urogenital System	TOTAL	6 (11.5%)	2 (3.1%)	8 (6.9%)
	ALBUMINURIA	5 (9.6%)	0	5 (4.3%)
	URINARY INCONTINENCE	0	2 (3.1%)	2 (1.7%)
	DYSURIA	1 (1.9%)	0	1 (0.9%)
	GLYCOSURIA	1 (1.9%)	0	1 (0.9%)
	HAEMATURIA	1 (1.9%)	0	1 (0.9%)
Musculoskeletal System	TOTAL	4 (7.7%)	1 (1.6%)	5 (4.3%)
	ARTHRALGIA	2 (3.8%)	1 (1.6%)	3 (2.6%)
	ARTHROSIS	1 (1.9%)	0	1 (0.9%)
	MYALGIA	1 (1.9%)	0	1 (0.9%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
Skin and Appendages	TOTAL	3 (5.8%)	8 (12.5%)	11 (9.5%)
	ACNE	2 (3.8%)	2 (3.1%)	4 (3.4%)
	CONTACT DERMATITIS	0	3 (4.7%)	3 (2.6%)
	RASH	0	3 (4.7%)	3 (2.6%)
	FUNGAL DERMATITIS	0	2 (3.1%)	2 (1.7%)
	MACULOPAPULAR RASH	1 (1.9%)	0	1 (0.9%)
	HERPES SIMPLEX	0	1 (1.6%)	1 (0.9%)
	SWEATING	0	1 (1.6%)	1 (0.9%)
	URTICARIA	0	1 (1.6%)	1 (0.9%)
Cardiovascular System	TOTAL	2 (3.8%)	5 (7.8%)	7 (6.0%)
	VASODILATATION	0	4 (6.3%)	4 (3.4%)
	BRADYCARDIA	1 (1.9%)	0	1 (0.9%)
	HAEMATOMA	1 (1.9%)	0	1 (0.9%)
	SYNCOPE	0	1 (1.6%)	1 (0.9%)
Hemic and Lymphatic System	TOTAL	2 (3.8%)	2 (3.1%)	4 (3.4%)
	ANEMIA	1 (1.9%)	0	1 (0.9%)
	PURPURA	1 (1.9%)	0	1 (0.9%)
	EOSINOPHILIA	0	1 (1.6%)	1 (0.9%)
	LEUKOCYTOSIS	0	1 (1.6%)	1 (0.9%)
	MONOCYTOSIS	0	1 (1.6%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	2 (3.8%)	4 (6.3%)	6 (5.2%)
	WEIGHT GAIN	2 (3.8%)	3 (4.7%)	5 (4.3%)
	WEIGHT LOSS	0	1 (1.6%)	1 (0.9%)

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	4 (14.3%)	1 (4.5%)	5 (10.0%)
Urogenital System	TOTAL	4 (14.3%)	1 (4.5%)	5 (10.0%)
	DYSMENORRHEA	4 (14.3%)	1 (4.5%)	5 (10.0%)
	UTERUS DISORDERS	0	1 (4.5%)	1 (2.0%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
TOTAL	TOTAL	107 (80.5%)	96 (73.8%)	203 (77.2%)
Body as a Whole	TOTAL	75 (56.4%)	58 (44.6%)	133 (50.6%)
	HEADACHE	42 (31.6%)	28 (21.5%)	70 (26.6%)
	TRAUMA	22 (16.5%)	14 (10.8%)	36 (13.7%)
	INFECTION	16 (12.0%)	20 (15.4%)	36 (13.7%)
	ABDOMINAL PAIN	19 (14.3%)	12 (9.2%)	31 (11.8%)
	FEVER	13 (9.8%)	7 (5.4%)	20 (7.6%)
	ALLERGIC REACTION	11 (8.3%)	6 (4.6%)	17 (6.5%)
	ASTHENIA	6 (4.5%)	9 (6.9%)	15 (5.7%)
	PAIN	6 (4.5%)	3 (2.3%)	9 (3.4%)
	BACK PAIN	4 (3.0%)	4 (3.1%)	8 (3.0%)
	CHEST PAIN	3 (2.3%)	0	3 (1.1%)
	FACE EDEMA	2 (1.5%)	0	2 (0.8%)
	ABNORMAL LABORATORY VALUE	1 (0.8%)	0	1 (0.4%)
	ABSCESS	1 (0.8%)	0	1 (0.4%)
	MALAISE	1 (0.8%)	0	1 (0.4%)
	SPINA BIFIDA	0	1 (0.8%)	1 (0.4%)
Respiratory System	TOTAL	57 (42.9%)	42 (32.3%)	99 (37.6%)
	RESPIRATORY DISORDER	26 (19.5%)	28 (21.5%)	54 (20.5%)
	PHARYNGITIS	19 (14.3%)	10 (7.7%)	29 (11.0%)
	RHINITIS	13 (9.8%)	9 (6.9%)	22 (8.4%)
	SINUSITIS	14 (10.5%)	2 (1.5%)	16 (6.1%)
	COUGH INCREASED	7 (5.3%)	4 (3.1%)	11 (4.2%)
	ASTHMA	6 (4.5%)	5 (3.8%)	11 (4.2%)
	BRONCHITIS	3 (2.3%)	3 (2.3%)	6 (2.3%)
	PNEUMONIA	1 (0.8%)	2 (1.5%)	3 (1.1%)
	EPISTAXIS	0	3 (2.3%)	3 (1.1%)
	DYSPNEA	1 (0.8%)	0	1 (0.4%)
	PLEURA DISORDER	1 (0.8%)	0	1 (0.4%)
	YAWN	0	1 (0.8%)	1 (0.4%)
Nervous System	TOTAL	54 (40.6%)	56 (43.1%)	110 (41.8%)
	NERVOUSNESS	11 (8.3%)	13 (10.0%)	24 (9.1%)
	INSOMNIA	11 (8.3%)	12 (9.2%)	23 (8.7%)
	HOSTILITY	7 (5.3%)	10 (7.7%)	17 (6.5%)
	EMOTIONAL LABILITY	11 (8.3%)	4 (3.1%)	15 (5.7%)
	HYPERKINESIA	8 (6.0%)	7 (5.4%)	15 (5.7%)
	SOMNOLENCE	7 (5.3%)	7 (5.4%)	14 (5.3%)
	DIZZINESS	7 (5.3%)	5 (3.8%)	12 (4.6%)
	AGITATION	4 (3.0%)	6 (4.6%)	10 (3.8%)
	ANXIETY	4 (3.0%)	6 (4.6%)	10 (3.8%)
	NEUROSIS	6 (4.5%)	1 (0.8%)	7 (2.7%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Nervous System	DEPRESSION	5 (3.8%)	2 (1.5%)	7 (2.7%)
	CONCENTRATION IMPAIRED	3 (2.3%)	3 (2.3%)	6 (2.3%)
	VERTIGO	2 (1.5%)	2 (1.5%)	4 (1.5%)
	TREMOR	0	4 (3.1%)	4 (1.5%)
	ABNORMAL DREAMS	1 (0.8%)	2 (1.5%)	3 (1.1%)
	HALLUCINATIONS	1 (0.8%)	2 (1.5%)	3 (1.1%)
	WITHDRAWAL SYNDROME	1 (0.8%)	2 (1.5%)	3 (1.1%)
	PARESTHESIA	2 (1.5%)	0	2 (0.8%)
	LACK OF EMOTION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	MANIC REACTION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	MYOCLONUS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	HYPESTHESIA	0	2 (1.5%)	2 (0.8%)
	CONVULSION	1 (0.8%)	0	1 (0.4%)
	VESTIBULAR DISORDER	1 (0.8%)	0	1 (0.4%)
	DYSKINESIA	0	1 (0.8%)	1 (0.4%)
	EUPHORIA	0	1 (0.8%)	1 (0.4%)
	HYSTERIA	0	1 (0.8%)	1 (0.4%)
	LIBIDO DECREASED	0	1 (0.8%)	1 (0.4%)
	PARALYSIS	0	1 (0.8%)	1 (0.4%)
	PSYCHOSIS	0	1 (0.8%)	1 (0.4%)
Digestive System	TOTAL	44 (33.1%)	38 (29.2%)	82 (31.2%)
	NAUSEA	15 (11.3%)	13 (10.0%)	28 (10.6%)
	VOMITING	14 (10.5%)	5 (3.8%)	19 (7.2%)
	DYSPEPSIA	10 (7.5%)	7 (5.4%)	17 (6.5%)
	DIARRHEA	10 (7.5%)	5 (3.8%)	15 (5.7%)
	DECREASED APPETITE	4 (3.0%)	7 (5.4%)	11 (4.2%)
	DRY MOUTH	3 (2.3%)	2 (1.5%)	5 (1.9%)
	TOOTH CARIES	1 (0.8%)	4 (3.1%)	5 (1.9%)
	TOOTH DISORDER	3 (2.3%)	1 (0.8%)	4 (1.5%)
	INCREASED APPETITE	2 (1.5%)	2 (1.5%)	4 (1.5%)
	CONSTIPATION	2 (1.5%)	1 (0.8%)	3 (1.1%)
	GASTROINTESTINAL DISORDER	1 (0.8%)	1 (0.8%)	2 (0.8%)
	GINGIVITIS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	FLATULENCE	0	2 (1.5%)	2 (0.8%)
	GASTROENTERITIS	0	2 (1.5%)	2 (0.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	2 (1.5%)	2 (0.8%)
	COLITIS	1 (0.8%)	0	1 (0.4%)
	GASTRITIS	1 (0.8%)	0	1 (0.4%)
	HEMATEMESIS	1 (0.8%)	0	1 (0.4%)
	STOMATITIS	1 (0.8%)	0	1 (0.4%)
	FECAL INCONTINENCE	0	1 (0.8%)	1 (0.4%)
	ULCERATIVE STOMATITIS	0	1 (0.8%)	1 (0.4%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Skin and Appendages	TOTAL	14 (10.5%)	14 (10.8%)	28 (10.6%)
	ACNE	5 (3.8%)	3 (2.3%)	8 (3.0%)
	CONTACT DERMATITIS	4 (3.0%)	4 (3.1%)	8 (3.0%)
	RASH	1 (0.8%)	5 (3.8%)	6 (2.3%)
	FUNGAL DERMATITIS	1 (0.8%)	2 (1.5%)	3 (1.1%)
	PRURITUS	1 (0.8%)	2 (1.5%)	3 (1.1%)
	MACULOPAPULAR RASH	1 (0.8%)	1 (0.8%)	2 (0.8%)
	FURUNCULOSIS	1 (0.8%)	0	1 (0.4%)
	HERPES ZOSTER	1 (0.8%)	0	1 (0.4%)
	HERPES SIMPLEX	0	1 (0.8%)	1 (0.4%)
	SWEATING	0	1 (0.8%)	1 (0.4%)
	URTICARIA	0	1 (0.8%)	1 (0.4%)
Urogenital System	TOTAL	13 (9.8%)	7 (5.4%)	20 (7.6%)
	ALBUMINURIA	9 (6.8%)	2 (1.5%)	11 (4.2%)
	URINARY INCONTINENCE	1 (0.8%)	5 (3.8%)	6 (2.3%)
	HAEMATURIA	2 (1.5%)	2 (1.5%)	4 (1.5%)
	DYSURIA	1 (0.8%)	0	1 (0.4%)
	GLYCOSURIA	1 (0.8%)	0	1 (0.4%)
	PYURIA	1 (0.8%)	0	1 (0.4%)
	URINARY TRACT INFECTION	1 (0.8%)	0	1 (0.4%)
	CYSTITIS	0	1 (0.8%)	1 (0.4%)
Special Senses	TOTAL	11 (8.3%)	9 (6.9%)	20 (7.6%)
	OTITIS MEDIA	6 (4.5%)	4 (3.1%)	10 (3.8%)
	EAR PAIN	2 (1.5%)	1 (0.8%)	3 (1.1%)
	OTITIS EXTERNA	2 (1.5%)	1 (0.8%)	3 (1.1%)
	ABNORMAL VISION	0	2 (1.5%)	2 (0.8%)
	BLEPHARITIS	1 (0.8%)	0	1 (0.4%)
	EYE PAIN	1 (0.8%)	0	1 (0.4%)
	PHOTOPHOBIA	0	1 (0.8%)	1 (0.4%)
Metabolic and Nutritional Disorders	TOTAL	10 (7.5%)	12 (9.2%)	22 (8.4%)
	WEIGHT GAIN	8 (6.0%)	9 (6.9%)	17 (6.5%)
	DEHYDRATION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	WEIGHT LOSS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	SGOT INCREASED	0	1 (0.8%)	1 (0.4%)
Musculoskeletal System	TOTAL	9 (6.8%)	3 (2.3%)	12 (4.6%)
	ARTHRALGIA	4 (3.0%)	1 (0.8%)	5 (1.9%)
	MYALGIA	3 (2.3%)	2 (1.5%)	5 (1.9%)
	ARTHROSIS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	TENDINOUS DISORDER	1 (0.8%)	0	1 (0.4%)

Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Hemic and Lymphatic System	TOTAL	6 (4.5%)	4 (3.1%)	10 (3.8%)
	LEUKOPENIA	3 (2.3%)	2 (1.5%)	5 (1.9%)
	ANEMIA	1 (0.8%)	1 (0.8%)	2 (0.8%)
	LYMPHADENOPATHY	1 (0.8%)	0	1 (0.4%)
	PURPURA	1 (0.8%)	0	1 (0.4%)
	EOSINOPHILIA	0	1 (0.8%)	1 (0.4%)
	LEUKOCYTOSIS	0	1 (0.8%)	1 (0.4%)
	LYMPHOCYTOSIS	0	1 (0.8%)	1 (0.4%)
	MONOCYTOSIS	0	1 (0.8%)	1 (0.4%)
Cardiovascular System	TOTAL	3 (2.3%)	9 (6.9%)	12 (4.6%)
	VASODILATATION	0	4 (3.1%)	4 (1.5%)
	SYNCOPE	0	3 (2.3%)	3 (1.1%)
	MIGRAINE	1 (0.8%)	1 (0.8%)	2 (0.8%)
	BRADYCARDIA	1 (0.8%)	0	1 (0.4%)
	HAEMATOMA	1 (0.8%)	0	1 (0.4%)
	BUNDLE BRANCH BLOCK	0	1 (0.8%)	1 (0.4%)
Special Searches	TOTAL	0	1 (0.8%)	1 (0.4%)
	PUNCTURE SITE PAIN	0	1 (0.8%)	1 (0.4%)

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.1.6

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase, Taper Phase or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	7 (11.5%)	3 (5.9%)	10 (8.9%)
Urogenital System	TOTAL	7 (11.5%)	3 (5.9%)	10 (8.9%)
	DYSMENORRHEA	7 (11.5%)	1 (2.0%)	8 (7.1%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (0.9%)
	MENSTRUAL DISORDER	0	1 (2.0%)	1 (0.9%)
	UTERUS DISORDERS	0	1 (2.0%)	1 (0.9%)

Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
TOTAL	32 (82.1%)	26 (72.2%)	58 (77.3%)
RESPIRATORY DISORDER	11 (28.2%)	6 (16.7%)	17 (22.7%)
HEADACHE	11 (28.2%)	4 (11.1%)	15 (20.0%)
TRAUMA	11 (28.2%)	4 (11.1%)	15 (20.0%)
INFECTION	5 (12.8%)	9 (25.0%)	14 (18.7%)
ABDOMINAL PAIN	10 (25.6%)	3 (8.3%)	13 (17.3%)
PHARYNGITIS	8 (20.5%)	4 (11.1%)	12 (16.0%)
VOMITING	8 (20.5%)	4 (11.1%)	12 (16.0%)
FEVER	6 (15.4%)	2 (5.6%)	8 (10.7%)
DYSPEPSIA	4 (10.3%)	3 (8.3%)	7 (9.3%)
RHINITIS	4 (10.3%)	3 (8.3%)	7 (9.3%)
WEIGHT GAIN	4 (10.3%)	3 (8.3%)	7 (9.3%)
NERVOUSNESS	6 (15.4%)	0	6 (8.0%)
HOSTILITY	4 (10.3%)	2 (5.6%)	6 (8.0%)
NAUSEA	2 (5.1%)	4 (11.1%)	6 (8.0%)
ALLERGIC REACTION	3 (7.7%)	2 (5.6%)	5 (6.7%)
INSOMNIA	2 (5.1%)	3 (8.3%)	5 (6.7%)
COUGH INCREASED	3 (7.7%)	1 (2.8%)	4 (5.3%)
DEPRESSION	3 (7.7%)	1 (2.8%)	4 (5.3%)
PAIN	3 (7.7%)	1 (2.8%)	4 (5.3%)
SINUSITIS	3 (7.7%)	1 (2.8%)	4 (5.3%)
ASTHENIA	2 (5.1%)	2 (5.6%)	4 (5.3%)
DIARRHEA	2 (5.1%)	2 (5.6%)	4 (5.3%)
URINARY INCONTINENCE	1 (2.6%)	3 (8.3%)	4 (5.3%)
CONTACT DERMATITIS	2 (5.1%)	1 (2.8%)	3 (4.0%)
HYPERKINESIA	2 (5.1%)	1 (2.8%)	3 (4.0%)
OTITIS MEDIA	2 (5.1%)	1 (2.8%)	3 (4.0%)
AGITATION	1 (2.6%)	2 (5.6%)	3 (4.0%)
LEUKOPENIA	1 (2.6%)	2 (5.6%)	3 (4.0%)
RASH	1 (2.6%)	2 (5.6%)	3 (4.0%)
BACK PAIN	0	3 (8.3%)	3 (4.0%)
ACNE	2 (5.1%)	0	2 (2.7%)
ARTHRALGIA	2 (5.1%)	0	2 (2.7%)
DRY MOUTH	2 (5.1%)	0	2 (2.7%)
FACE EDEMA	2 (5.1%)	0	2 (2.7%)
INCREASED APPETITE	2 (5.1%)	0	2 (2.7%)
ANXIETY	1 (2.6%)	1 (2.8%)	2 (2.7%)
DECREASED APPETITE	1 (2.6%)	1 (2.8%)	2 (2.7%)
HALLUCINATIONS	1 (2.6%)	1 (2.8%)	2 (2.7%)
MYALGIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
CONCENTRATION IMPAIRED	0	2 (5.6%)	2 (2.7%)
EPISTAXIS	0	2 (5.6%)	2 (2.7%)
HYPESTHESIA	0	2 (5.6%)	2 (2.7%)
TOOTH CARIES	0	2 (5.6%)	2 (2.7%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=39)	 Placebo (N=36)	 Total (N=75)
CONSTIPATION	1 (2.6%)	0	1 (1.3%)
EMOTIONAL LABILITY	1 (2.6%)	0	1 (1.3%)
NEUROSIS	1 (2.6%)	0	1 (1.3%)
TOOTH DISORDER	1 (2.6%)	0	1 (1.3%)
WITHDRAWAL SYNDROME	1 (2.6%)	0	1 (1.3%)
ABNORMAL VISION	0	1 (2.8%)	1 (1.3%)
ALBUMINURIA	0	1 (2.8%)	1 (1.3%)
ASTHMA	0	1 (2.8%)	1 (1.3%)
BRONCHITIS	0	1 (2.8%)	1 (1.3%)
DIZZINESS	0	1 (2.8%)	1 (1.3%)
GASTROENTERITIS	0	1 (2.8%)	1 (1.3%)
HAEMATURIA	0	1 (2.8%)	1 (1.3%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (2.8%)	1 (1.3%)
PNEUMONIA	0	1 (2.8%)	1 (1.3%)
PRURITUS	0	1 (2.8%)	1 (1.3%)
SOMNOLENCE	0	1 (2.8%)	1 (1.3%)
SYNCOPE	0	1 (2.8%)	1 (1.3%)
TREMOR	0	1 (2.8%)	1 (1.3%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
TOTAL	0	0	0

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
TOTAL	0	0	0

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
TOTAL	22 (78.6%)	30 (83.3%)	52 (81.3%)
HEADACHE	10 (35.7%)	9 (25.0%)	19 (29.7%)
RESPIRATORY DISORDER	2 (7.1%)	8 (22.2%)	10 (15.6%)
NERVOUSNESS	1 (3.6%)	9 (25.0%)	10 (15.6%)
HYPERKINESIA	5 (17.9%)	4 (11.1%)	9 (14.1%)
PHARYNGITIS	5 (17.9%)	3 (8.3%)	8 (12.5%)
RHINITIS	4 (14.3%)	4 (11.1%)	8 (12.5%)
TRAUMA	4 (14.3%)	4 (11.1%)	8 (12.5%)
ABDOMINAL PAIN	3 (10.7%)	5 (13.9%)	8 (12.5%)
INFECTION	3 (10.7%)	5 (13.9%)	8 (12.5%)
NAUSEA	5 (17.9%)	1 (2.8%)	6 (9.4%)
FEVER	4 (14.3%)	2 (5.6%)	6 (9.4%)
INSOMNIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
OTITIS MEDIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
HOSTILITY	1 (3.6%)	4 (11.1%)	5 (7.8%)
SINUSITIS	3 (10.7%)	1 (2.8%)	4 (6.3%)
COUGH INCREASED	2 (7.1%)	2 (5.6%)	4 (6.3%)
DECREASED APPETITE	2 (7.1%)	2 (5.6%)	4 (6.3%)
ANXIETY	1 (3.6%)	3 (8.3%)	4 (6.3%)
DIARRHEA	3 (10.7%)	0	3 (4.7%)
DYSPEPSIA	2 (7.1%)	1 (2.8%)	3 (4.7%)
EAR PAIN	2 (7.1%)	1 (2.8%)	3 (4.7%)
OTITIS EXTERNA	2 (7.1%)	1 (2.8%)	3 (4.7%)
PAIN	2 (7.1%)	1 (2.8%)	3 (4.7%)
DIZZINESS	1 (3.6%)	2 (5.6%)	3 (4.7%)
SOMNOLENCE	1 (3.6%)	2 (5.6%)	3 (4.7%)
VASODILATATION	0	3 (8.3%)	3 (4.7%)
WEIGHT GAIN	0	3 (8.3%)	3 (4.7%)
ALBUMINURIA	2 (7.1%)	0	2 (3.1%)
NEUROSIS	2 (7.1%)	0	2 (3.1%)
AGITATION	1 (3.6%)	1 (2.8%)	2 (3.1%)
CONTACT DERMATITIS	0	2 (5.6%)	2 (3.1%)
FUNGAL DERMATITIS	0	2 (5.6%)	2 (3.1%)
RASH	0	2 (5.6%)	2 (3.1%)
URINARY INCONTINENCE	0	2 (5.6%)	2 (3.1%)
VERTIGO	0	2 (5.6%)	2 (3.1%)
ACNE	1 (3.6%)	0	1 (1.6%)
ASTHMA	1 (3.6%)	0	1 (1.6%)
BACK PAIN	1 (3.6%)	0	1 (1.6%)
CONCENTRATION IMPAIRED	1 (3.6%)	0	1 (1.6%)
DEPRESSION	1 (3.6%)	0	1 (1.6%)
EMOTIONAL LABILITY	1 (3.6%)	0	1 (1.6%)
MYALGIA	1 (3.6%)	0	1 (1.6%)
TOOTH DISORDER	1 (3.6%)	0	1 (1.6%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
VOMITING	1 (3.6%)	0	1 (1.6%)
ALLERGIC REACTION	0	1 (2.8%)	1 (1.6%)
FLATULENCE	0	1 (2.8%)	1 (1.6%)
GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
TOOTH CARIES	0	1 (2.8%)	1 (1.6%)
TREMOR	0	1 (2.8%)	1 (1.6%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
TOTAL	0	0	0

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
TOTAL	1 (6.3%)	1 (7.7%)	2 (6.9%)
DYSMENORRHEA	1 (6.3%)	1 (7.7%)	2 (6.9%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
TOTAL	54 (80.6%)	56 (77.8%)	110 (79.1%)
HEADACHE	21 (31.3%)	13 (18.1%)	34 (24.5%)
RESPIRATORY DISORDER	13 (19.4%)	14 (19.4%)	27 (19.4%)
TRAUMA	15 (22.4%)	8 (11.1%)	23 (16.5%)
INFECTION	8 (11.9%)	14 (19.4%)	22 (15.8%)
ABDOMINAL PAIN	13 (19.4%)	8 (11.1%)	21 (15.1%)
PHARYNGITIS	13 (19.4%)	7 (9.7%)	20 (14.4%)
NERVOUSNESS	7 (10.4%)	9 (12.5%)	16 (11.5%)
RHINITIS	8 (11.9%)	7 (9.7%)	15 (10.8%)
FEVER	10 (14.9%)	4 (5.6%)	14 (10.1%)
VOMITING	9 (13.4%)	4 (5.6%)	13 (9.4%)
HYPERKINESIA	7 (10.4%)	5 (6.9%)	12 (8.6%)
NAUSEA	7 (10.4%)	5 (6.9%)	12 (8.6%)
HOSTILITY	5 (7.5%)	6 (8.3%)	11 (7.9%)
DYSPEPSIA	6 (9.0%)	4 (5.6%)	10 (7.2%)
INSOMNIA	5 (7.5%)	5 (6.9%)	10 (7.2%)
WEIGHT GAIN	4 (6.0%)	6 (8.3%)	10 (7.2%)
SINUSITIS	6 (9.0%)	2 (2.8%)	8 (5.8%)
COUGH INCREASED	5 (7.5%)	3 (4.2%)	8 (5.8%)
OTITIS MEDIA	5 (7.5%)	3 (4.2%)	8 (5.8%)
DIARRHEA	5 (7.5%)	2 (2.8%)	7 (5.0%)
PAIN	5 (7.5%)	2 (2.8%)	7 (5.0%)
ALLERGIC REACTION	3 (4.5%)	3 (4.2%)	6 (4.3%)
DECREASED APPETITE	3 (4.5%)	3 (4.2%)	6 (4.3%)
ANXIETY	2 (3.0%)	4 (5.6%)	6 (4.3%)
URINARY INCONTINENCE	1 (1.5%)	5 (6.9%)	6 (4.3%)
DEPRESSION	4 (6.0%)	1 (1.4%)	5 (3.6%)
AGITATION	2 (3.0%)	3 (4.2%)	5 (3.6%)
CONTACT DERMATITIS	2 (3.0%)	3 (4.2%)	5 (3.6%)
RASH	1 (1.5%)	4 (5.6%)	5 (3.6%)
ASTHENIA	2 (3.0%)	2 (2.8%)	4 (2.9%)
BACK PAIN	1 (1.5%)	3 (4.2%)	4 (2.9%)
DIZZINESS	1 (1.5%)	3 (4.2%)	4 (2.9%)
SOMNOLENCE	1 (1.5%)	3 (4.2%)	4 (2.9%)
ACNE	3 (4.5%)	0	3 (2.2%)
NEUROSIS	3 (4.5%)	0	3 (2.2%)
ALBUMINURIA	2 (3.0%)	1 (1.4%)	3 (2.2%)
EAR PAIN	2 (3.0%)	1 (1.4%)	3 (2.2%)
MYALGIA	2 (3.0%)	1 (1.4%)	3 (2.2%)
OTITIS EXTERNA	2 (3.0%)	1 (1.4%)	3 (2.2%)
CONCENTRATION IMPAIRED	1 (1.5%)	2 (2.8%)	3 (2.2%)
LEUKOPENIA	1 (1.5%)	2 (2.8%)	3 (2.2%)
TOOTH CARIES	0	3 (4.2%)	3 (2.2%)
VASODILATATION	0	3 (4.2%)	3 (2.2%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
ARTHRALGIA	2 (3.0%)	0	2 (1.4%)
DRY MOUTH	2 (3.0%)	0	2 (1.4%)
EMOTIONAL LABILITY	2 (3.0%)	0	2 (1.4%)
FACE EDEMA	2 (3.0%)	0	2 (1.4%)
INCREASED APPETITE	2 (3.0%)	0	2 (1.4%)
TOOTH DISORDER	2 (3.0%)	0	2 (1.4%)
ASTHMA	1 (1.5%)	1 (1.4%)	2 (1.4%)
HALLUCINATIONS	1 (1.5%)	1 (1.4%)	2 (1.4%)
EPISTAXIS	0	2 (2.8%)	2 (1.4%)
FUNGAL DERMATITIS	0	2 (2.8%)	2 (1.4%)
GASTROENTERITIS	0	2 (2.8%)	2 (1.4%)
HYPESTHESIA	0	2 (2.8%)	2 (1.4%)
TREMOR	0	2 (2.8%)	2 (1.4%)
VERTIGO	0	2 (2.8%)	2 (1.4%)
CONSTIPATION	1 (1.5%)	0	1 (0.7%)
WITHDRAWAL SYNDROME	1 (1.5%)	0	1 (0.7%)
ABNORMAL VISION	0	1 (1.4%)	1 (0.7%)
BRONCHITIS	0	1 (1.4%)	1 (0.7%)
FLATULENCE	0	1 (1.4%)	1 (0.7%)
HAEMATURIA	0	1 (1.4%)	1 (0.7%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.4%)	1 (0.7%)
PNEUMONIA	0	1 (1.4%)	1 (0.7%)
PRURITUS	0	1 (1.4%)	1 (0.7%)
SYNCOPE	0	1 (1.4%)	1 (0.7%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
TOTAL	0	0	0

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
TOTAL	1 (2.9%)	1 (3.7%)	2 (3.2%)
DYSMENORRHEA	1 (2.9%)	1 (3.7%)	2 (3.2%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
TOTAL	34 (81.0%)	18 (60.0%)	52 (72.2%)
HEADACHE	11 (26.2%)	6 (20.0%)	17 (23.6%)
RESPIRATORY DISORDER	8 (19.0%)	8 (26.7%)	16 (22.2%)
EMOTIONAL LABILITY	7 (16.7%)	3 (10.0%)	10 (13.9%)
NAUSEA	7 (16.7%)	2 (6.7%)	9 (12.5%)
TRAUMA	6 (14.3%)	2 (6.7%)	8 (11.1%)
SOMNOLENCE	5 (11.9%)	3 (10.0%)	8 (11.1%)
PHARYNGITIS	5 (11.9%)	1 (3.3%)	6 (8.3%)
ASTHMA	4 (9.5%)	2 (6.7%)	6 (8.3%)
INFECTION	3 (7.1%)	3 (10.0%)	6 (8.3%)
VOMITING	5 (11.9%)	0	5 (6.9%)
ALBUMINURIA	4 (9.5%)	1 (3.3%)	5 (6.9%)
DIARRHEA	4 (9.5%)	1 (3.3%)	5 (6.9%)
RHINITIS	4 (9.5%)	1 (3.3%)	5 (6.9%)
INSOMNIA	3 (7.1%)	2 (6.7%)	5 (6.9%)
WEIGHT GAIN	2 (4.8%)	3 (10.0%)	5 (6.9%)
ALLERGIC REACTION	4 (9.5%)	0	4 (5.6%)
SINUSITIS	4 (9.5%)	0	4 (5.6%)
ABDOMINAL PAIN	3 (7.1%)	1 (3.3%)	4 (5.6%)
DIZZINESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
DYSPEPSIA	3 (7.1%)	1 (3.3%)	4 (5.6%)
FEVER	3 (7.1%)	1 (3.3%)	4 (5.6%)
NERVOUSNESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
BRONCHITIS	2 (4.8%)	2 (6.7%)	4 (5.6%)
ASTHENIA	1 (2.4%)	3 (10.0%)	4 (5.6%)
BACK PAIN	3 (7.1%)	0	3 (4.2%)
CHEST PAIN	3 (7.1%)	0	3 (4.2%)
AGITATION	2 (4.8%)	1 (3.3%)	3 (4.2%)
DECREASED APPETITE	1 (2.4%)	2 (6.7%)	3 (4.2%)
CONTACT DERMATITIS	2 (4.8%)	0	2 (2.8%)
LEUKOPENIA	2 (4.8%)	0	2 (2.8%)
ACNE	1 (2.4%)	1 (3.3%)	2 (2.8%)
ANXIETY	1 (2.4%)	1 (3.3%)	2 (2.8%)
COUGH INCREASED	1 (2.4%)	1 (3.3%)	2 (2.8%)
HAEMATURIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
HOSTILITY	1 (2.4%)	1 (3.3%)	2 (2.8%)
MYALGIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
PRURITUS	1 (2.4%)	1 (3.3%)	2 (2.8%)
TOOTH CARIES	1 (2.4%)	1 (3.3%)	2 (2.8%)
INCREASED APPETITE	0	2 (6.7%)	2 (2.8%)
WITHDRAWAL SYNDROME	0	2 (6.7%)	2 (2.8%)
DEPRESSION	1 (2.4%)	0	1 (1.4%)
DRY MOUTH	1 (2.4%)	0	1 (1.4%)
FUNGAL DERMATITIS	1 (2.4%)	0	1 (1.4%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
OTITIS MEDIA	1 (2.4%)	0	1 (1.4%)
PARESTHESIA	1 (2.4%)	0	1 (1.4%)
PNEUMONIA	1 (2.4%)	0	1 (1.4%)
VERTIGO	1 (2.4%)	0	1 (1.4%)
CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.4%)
HALLUCINATIONS	0	1 (3.3%)	1 (1.4%)
PAIN	0	1 (3.3%)	1 (1.4%)
SYNCOPE	0	1 (3.3%)	1 (1.4%)
TREMOR	0	1 (3.3%)	1 (1.4%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
TOTAL	0	0	0

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
TOTAL	3 (21.4%)	0	3 (10.3%)
DYSMENORRHEA	3 (21.4%)	0	3 (10.3%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
TOTAL	19 (79.2%)	20 (71.4%)	39 (75.0%)
HEADACHE	10 (41.7%)	9 (32.1%)	19 (36.5%)
RESPIRATORY DISORDER	5 (20.8%)	6 (21.4%)	11 (21.2%)
INFECTION	5 (20.8%)	3 (10.7%)	8 (15.4%)
INSOMNIA	3 (12.5%)	5 (17.9%)	8 (15.4%)
ALLERGIC REACTION	4 (16.7%)	3 (10.7%)	7 (13.5%)
ASTHENIA	3 (12.5%)	4 (14.3%)	7 (13.5%)
NAUSEA	1 (4.2%)	6 (21.4%)	7 (13.5%)
ABDOMINAL PAIN	3 (12.5%)	3 (10.7%)	6 (11.5%)
TRAUMA	1 (4.2%)	4 (14.3%)	5 (9.6%)
SINUSITIS	4 (16.7%)	0	4 (7.7%)
DIZZINESS	3 (12.5%)	1 (3.6%)	4 (7.7%)
NEUROSIS	3 (12.5%)	1 (3.6%)	4 (7.7%)
HOSTILITY	1 (4.2%)	3 (10.7%)	4 (7.7%)
NERVOUSNESS	1 (4.2%)	3 (10.7%)	4 (7.7%)
ALBUMINURIA	3 (12.5%)	0	3 (5.8%)
ARTHRALGIA	2 (8.3%)	1 (3.6%)	3 (5.8%)
EMOTIONAL LABILITY	2 (8.3%)	1 (3.6%)	3 (5.8%)
ABNORMAL DREAMS	1 (4.2%)	2 (7.1%)	3 (5.8%)
ACNE	1 (4.2%)	2 (7.1%)	3 (5.8%)
ASTHMA	1 (4.2%)	2 (7.1%)	3 (5.8%)
DIARRHEA	1 (4.2%)	2 (7.1%)	3 (5.8%)
DYSPEPSIA	1 (4.2%)	2 (7.1%)	3 (5.8%)
HYPERKINESIA	1 (4.2%)	2 (7.1%)	3 (5.8%)
PHARYNGITIS	1 (4.2%)	2 (7.1%)	3 (5.8%)
CONCENTRATION IMPAIRED	2 (8.3%)	0	2 (3.8%)
WEIGHT GAIN	2 (8.3%)	0	2 (3.8%)
ANXIETY	1 (4.2%)	1 (3.6%)	2 (3.8%)
CONSTIPATION	1 (4.2%)	1 (3.6%)	2 (3.8%)
RHINITIS	1 (4.2%)	1 (3.6%)	2 (3.8%)
SOMNOLENCE	1 (4.2%)	1 (3.6%)	2 (3.8%)
TOOTH DISORDER	1 (4.2%)	1 (3.6%)	2 (3.8%)
AGITATION	0	2 (7.1%)	2 (3.8%)
DECREASED APPETITE	0	2 (7.1%)	2 (3.8%)
DRY MOUTH	0	2 (7.1%)	2 (3.8%)
FEVER	0	2 (7.1%)	2 (3.8%)
BRONCHITIS	1 (4.2%)	0	1 (1.9%)
COUGH INCREASED	1 (4.2%)	0	1 (1.9%)
HAEMATURIA	1 (4.2%)	0	1 (1.9%)
PAIN	1 (4.2%)	0	1 (1.9%)
PARESTHESIA	1 (4.2%)	0	1 (1.9%)
VERTIGO	1 (4.2%)	0	1 (1.9%)
ABNORMAL VISION	0	1 (3.6%)	1 (1.9%)
BACK PAIN	0	1 (3.6%)	1 (1.9%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Preferred Term			
CONTACT DERMATITIS	0	1 (3.6%)	1 (1.9%)
DEPRESSION	0	1 (3.6%)	1 (1.9%)
EPISTAXIS	0	1 (3.6%)	1 (1.9%)
FLATULENCE	0	1 (3.6%)	1 (1.9%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (3.6%)	1 (1.9%)
OTITIS MEDIA	0	1 (3.6%)	1 (1.9%)
PNEUMONIA	0	1 (3.6%)	1 (1.9%)
RASH	0	1 (3.6%)	1 (1.9%)
SYNCOPE	0	1 (3.6%)	1 (1.9%)
TREMOR	0	1 (3.6%)	1 (1.9%)
VASODILATATION	0	1 (3.6%)	1 (1.9%)
VOMITING	0	1 (3.6%)	1 (1.9%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
Preferred Term			
TOTAL	3 (25.0%)	0	3 (14.3%)
DYSMENORRHEA	3 (25.0%)	0	3 (14.3%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
TOTAL	53 (80.3%)	38 (65.5%)	91 (73.4%)
HEADACHE	21 (31.8%)	15 (25.9%)	36 (29.0%)
RESPIRATORY DISORDER	13 (19.7%)	14 (24.1%)	27 (21.8%)
NAUSEA	8 (12.1%)	8 (13.8%)	16 (12.9%)
INFECTION	8 (12.1%)	6 (10.3%)	14 (11.3%)
EMOTIONAL LABILITY	9 (13.6%)	4 (6.9%)	13 (10.5%)
TRAUMA	7 (10.6%)	6 (10.3%)	13 (10.5%)
INSOMNIA	6 (9.1%)	7 (12.1%)	13 (10.5%)
ALLERGIC REACTION	8 (12.1%)	3 (5.2%)	11 (8.9%)
ASTHENIA	4 (6.1%)	7 (12.1%)	11 (8.9%)
ABDOMINAL PAIN	6 (9.1%)	4 (6.9%)	10 (8.1%)
SOMNOLENCE	6 (9.1%)	4 (6.9%)	10 (8.1%)
PHARYNGITIS	6 (9.1%)	3 (5.2%)	9 (7.3%)
ASTHMA	5 (7.6%)	4 (6.9%)	9 (7.3%)
SINUSITIS	8 (12.1%)	0	8 (6.5%)
ALBUMINURIA	7 (10.6%)	1 (1.7%)	8 (6.5%)
DIZZINESS	6 (9.1%)	2 (3.4%)	8 (6.5%)
DIARRHEA	5 (7.6%)	3 (5.2%)	8 (6.5%)
NERVOUSNESS	4 (6.1%)	4 (6.9%)	8 (6.5%)
RHINITIS	5 (7.6%)	2 (3.4%)	7 (5.6%)
DYSPEPSIA	4 (6.1%)	3 (5.2%)	7 (5.6%)
WEIGHT GAIN	4 (6.1%)	3 (5.2%)	7 (5.6%)
VOMITING	5 (7.6%)	1 (1.7%)	6 (4.8%)
FEVER	3 (4.5%)	3 (5.2%)	6 (4.8%)
HOSTILITY	2 (3.0%)	4 (6.9%)	6 (4.8%)
BRONCHITIS	3 (4.5%)	2 (3.4%)	5 (4.0%)
ACNE	2 (3.0%)	3 (5.2%)	5 (4.0%)
AGITATION	2 (3.0%)	3 (5.2%)	5 (4.0%)
DECREASED APPETITE	1 (1.5%)	4 (6.9%)	5 (4.0%)
BACK PAIN	3 (4.5%)	1 (1.7%)	4 (3.2%)
NEUROSIS	3 (4.5%)	1 (1.7%)	4 (3.2%)
ANXIETY	2 (3.0%)	2 (3.4%)	4 (3.2%)
CHEST PAIN	3 (4.5%)	0	3 (2.4%)
ARTHRALGIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
CONCENTRATION IMPAIRED	2 (3.0%)	1 (1.7%)	3 (2.4%)
CONTACT DERMATITIS	2 (3.0%)	1 (1.7%)	3 (2.4%)
COUGH INCREASED	2 (3.0%)	1 (1.7%)	3 (2.4%)
HAEMATURIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
ABNORMAL DREAMS	1 (1.5%)	2 (3.4%)	3 (2.4%)
DRY MOUTH	1 (1.5%)	2 (3.4%)	3 (2.4%)
HYPERKINESIA	1 (1.5%)	2 (3.4%)	3 (2.4%)
LEUKOPENIA	2 (3.0%)	0	2 (1.6%)
PARESTHESIA	2 (3.0%)	0	2 (1.6%)
VERTIGO	2 (3.0%)	0	2 (1.6%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
CONSTIPATION	1 (1.5%)	1 (1.7%)	2 (1.6%)
DEPRESSION	1 (1.5%)	1 (1.7%)	2 (1.6%)
MYALGIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
OTITIS MEDIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
PAIN	1 (1.5%)	1 (1.7%)	2 (1.6%)
PNEUMONIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
PRURITUS	1 (1.5%)	1 (1.7%)	2 (1.6%)
TOOTH CARIES	1 (1.5%)	1 (1.7%)	2 (1.6%)
TOOTH DISORDER	1 (1.5%)	1 (1.7%)	2 (1.6%)
INCREASED APPETITE	0	2 (3.4%)	2 (1.6%)
SYNCOPE	0	2 (3.4%)	2 (1.6%)
TREMOR	0	2 (3.4%)	2 (1.6%)
WITHDRAWAL SYNDROME	0	2 (3.4%)	2 (1.6%)
FUNGAL DERMATITIS	1 (1.5%)	0	1 (0.8%)
ABNORMAL VISION	0	1 (1.7%)	1 (0.8%)
EPISTAXIS	0	1 (1.7%)	1 (0.8%)
FLATULENCE	0	1 (1.7%)	1 (0.8%)
HALLUCINATIONS	0	1 (1.7%)	1 (0.8%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.7%)	1 (0.8%)
RASH	0	1 (1.7%)	1 (0.8%)
VASODILATATION	0	1 (1.7%)	1 (0.8%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
TOTAL	6 (23.1%)	0	6 (12.0%)
DYSMENORRHEA	6 (23.1%)	0	6 (12.0%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
TOTAL	66 (81.5%)	44 (66.7%)	110 (74.8%)
RESPIRATORY DISORDER	19 (23.5%)	14 (21.2%)	33 (22.4%)
HEADACHE	22 (27.2%)	10 (15.2%)	32 (21.8%)
TRAUMA	17 (21.0%)	6 (9.1%)	23 (15.6%)
INFECTION	8 (9.9%)	12 (18.2%)	20 (13.6%)
PHARYNGITIS	13 (16.0%)	5 (7.6%)	18 (12.2%)
ABDOMINAL PAIN	13 (16.0%)	4 (6.1%)	17 (11.6%)
VOMITING	13 (16.0%)	4 (6.1%)	17 (11.6%)
NAUSEA	9 (11.1%)	6 (9.1%)	15 (10.2%)
FEVER	9 (11.1%)	3 (4.5%)	12 (8.2%)
RHINITIS	8 (9.9%)	4 (6.1%)	12 (8.2%)
WEIGHT GAIN	6 (7.4%)	6 (9.1%)	12 (8.2%)
EMOTIONAL LABILITY	8 (9.9%)	3 (4.5%)	11 (7.5%)
DYSPEPSIA	7 (8.6%)	4 (6.1%)	11 (7.5%)
NERVOUSNESS	9 (11.1%)	1 (1.5%)	10 (6.8%)
INSOMNIA	5 (6.2%)	5 (7.6%)	10 (6.8%)
ALLERGIC REACTION	7 (8.6%)	2 (3.0%)	9 (6.1%)
DIARRHEA	6 (7.4%)	3 (4.5%)	9 (6.1%)
SOMNOLENCE	5 (6.2%)	4 (6.1%)	9 (6.1%)
SINUSITIS	7 (8.6%)	1 (1.5%)	8 (5.4%)
HOSTILITY	5 (6.2%)	3 (4.5%)	8 (5.4%)
ASTHENIA	3 (3.7%)	5 (7.6%)	8 (5.4%)
ASTHMA	4 (4.9%)	3 (4.5%)	7 (4.8%)
ALBUMINURIA	4 (4.9%)	2 (3.0%)	6 (4.1%)
COUGH INCREASED	4 (4.9%)	2 (3.0%)	6 (4.1%)
AGITATION	3 (3.7%)	3 (4.5%)	6 (4.1%)
BACK PAIN	3 (3.7%)	3 (4.5%)	6 (4.1%)
CONTACT DERMATITIS	4 (4.9%)	1 (1.5%)	5 (3.4%)
DEPRESSION	4 (4.9%)	1 (1.5%)	5 (3.4%)
DIZZINESS	3 (3.7%)	2 (3.0%)	5 (3.4%)
LEUKOPENIA	3 (3.7%)	2 (3.0%)	5 (3.4%)
PAIN	3 (3.7%)	2 (3.0%)	5 (3.4%)
BRONCHITIS	2 (2.5%)	3 (4.5%)	5 (3.4%)
DECREASED APPETITE	2 (2.5%)	3 (4.5%)	5 (3.4%)
ACNE	3 (3.7%)	1 (1.5%)	4 (2.7%)
OTITIS MEDIA	3 (3.7%)	1 (1.5%)	4 (2.7%)
ANXIETY	2 (2.5%)	2 (3.0%)	4 (2.7%)
INCREASED APPETITE	2 (2.5%)	2 (3.0%)	4 (2.7%)
MYALGIA	2 (2.5%)	2 (3.0%)	4 (2.7%)
TOOTH CARIES	1 (1.2%)	3 (4.5%)	4 (2.7%)
URINARY INCONTINENCE	1 (1.2%)	3 (4.5%)	4 (2.7%)
CHEST PAIN	3 (3.7%)	0	3 (2.0%)
DRY MOUTH	3 (3.7%)	0	3 (2.0%)
HYPERKINESIA	2 (2.5%)	1 (1.5%)	3 (2.0%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
HAEMATURIA	1 (1.2%)	2 (3.0%)	3 (2.0%)
HALLUCINATIONS	1 (1.2%)	2 (3.0%)	3 (2.0%)
PRURITUS	1 (1.2%)	2 (3.0%)	3 (2.0%)
RASH	1 (1.2%)	2 (3.0%)	3 (2.0%)
WITHDRAWAL SYNDROME	1 (1.2%)	2 (3.0%)	3 (2.0%)
CONCENTRATION IMPAIRED	0	3 (4.5%)	3 (2.0%)
ARTHRALGIA	2 (2.5%)	0	2 (1.4%)
FACE EDEMA	2 (2.5%)	0	2 (1.4%)
PNEUMONIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
EPISTAXIS	0	2 (3.0%)	2 (1.4%)
HYPESTHESIA	0	2 (3.0%)	2 (1.4%)
SYNCOPE	0	2 (3.0%)	2 (1.4%)
TREMOR	0	2 (3.0%)	2 (1.4%)
CONSTIPATION	1 (1.2%)	0	1 (0.7%)
FUNGAL DERMATITIS	1 (1.2%)	0	1 (0.7%)
NEUROSIS	1 (1.2%)	0	1 (0.7%)
PARESTHESIA	1 (1.2%)	0	1 (0.7%)
TOOTH DISORDER	1 (1.2%)	0	1 (0.7%)
VERTIGO	1 (1.2%)	0	1 (0.7%)
ABNORMAL VISION	0	1 (1.5%)	1 (0.7%)
GASTROENTERITIS	0	1 (1.5%)	1 (0.7%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.7%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
TOTAL	3 (9.1%)	0	3 (4.8%)
DYSMENORRHEA	3 (9.1%)	0	3 (4.8%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
TOTAL	41 (78.8%)	50 (78.1%)	91 (78.4%)
HEADACHE	20 (38.5%)	18 (28.1%)	38 (32.8%)
RESPIRATORY DISORDER	7 (13.5%)	14 (21.9%)	21 (18.1%)
INFECTION	8 (15.4%)	8 (12.5%)	16 (13.8%)
ABDOMINAL PAIN	6 (11.5%)	8 (12.5%)	14 (12.1%)
NERVOUSNESS	2 (3.8%)	12 (18.8%)	14 (12.1%)
INSOMNIA	6 (11.5%)	7 (10.9%)	13 (11.2%)
NAUSEA	6 (11.5%)	7 (10.9%)	13 (11.2%)
TRAUMA	5 (9.6%)	8 (12.5%)	13 (11.2%)
HYPERKINESIA	6 (11.5%)	6 (9.4%)	12 (10.3%)
PHARYNGITIS	6 (11.5%)	5 (7.8%)	11 (9.5%)
RHINITIS	5 (9.6%)	5 (7.8%)	10 (8.6%)
HOSTILITY	2 (3.8%)	7 (10.9%)	9 (7.8%)
SINUSITIS	7 (13.5%)	1 (1.6%)	8 (6.9%)
ALLERGIC REACTION	4 (7.7%)	4 (6.3%)	8 (6.9%)
FEVER	4 (7.7%)	4 (6.3%)	8 (6.9%)
DIZZINESS	4 (7.7%)	3 (4.7%)	7 (6.0%)
ASTHENIA	3 (5.8%)	4 (6.3%)	7 (6.0%)
NEUROSIS	5 (9.6%)	1 (1.6%)	6 (5.2%)
DIARRHEA	4 (7.7%)	2 (3.1%)	6 (5.2%)
DYSPEPSIA	3 (5.8%)	3 (4.7%)	6 (5.2%)
OTITIS MEDIA	3 (5.8%)	3 (4.7%)	6 (5.2%)
ANXIETY	2 (3.8%)	4 (6.3%)	6 (5.2%)
DECREASED APPETITE	2 (3.8%)	4 (6.3%)	6 (5.2%)
ALBUMINURIA	5 (9.6%)	0	5 (4.3%)
COUGH INCREASED	3 (5.8%)	2 (3.1%)	5 (4.3%)
SOMNOLENCE	2 (3.8%)	3 (4.7%)	5 (4.3%)
WEIGHT GAIN	2 (3.8%)	3 (4.7%)	5 (4.3%)
EMOTIONAL LABILITY	3 (5.8%)	1 (1.6%)	4 (3.4%)
PAIN	3 (5.8%)	1 (1.6%)	4 (3.4%)
ACNE	2 (3.8%)	2 (3.1%)	4 (3.4%)
ASTHMA	2 (3.8%)	2 (3.1%)	4 (3.4%)
AGITATION	1 (1.9%)	3 (4.7%)	4 (3.4%)
VASODILATATION	0	4 (6.3%)	4 (3.4%)
CONCENTRATION IMPAIRED	3 (5.8%)	0	3 (2.6%)
ARTHRALGIA	2 (3.8%)	1 (1.6%)	3 (2.6%)
EAR PAIN	2 (3.8%)	1 (1.6%)	3 (2.6%)
OTITIS EXTERNA	2 (3.8%)	1 (1.6%)	3 (2.6%)
TOOTH DISORDER	2 (3.8%)	1 (1.6%)	3 (2.6%)
ABNORMAL DREAMS	1 (1.9%)	2 (3.1%)	3 (2.6%)
VERTIGO	1 (1.9%)	2 (3.1%)	3 (2.6%)
CONTACT DERMATITIS	0	3 (4.7%)	3 (2.6%)
RASH	0	3 (4.7%)	3 (2.6%)
BACK PAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)

Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
CONSTIPATION	1 (1.9%)	1 (1.6%)	2 (1.7%)
DEPRESSION	1 (1.9%)	1 (1.6%)	2 (1.7%)
VOMITING	1 (1.9%)	1 (1.6%)	2 (1.7%)
DRY MOUTH	0	2 (3.1%)	2 (1.7%)
FLATULENCE	0	2 (3.1%)	2 (1.7%)
FUNGAL DERMATITIS	0	2 (3.1%)	2 (1.7%)
TREMOR	0	2 (3.1%)	2 (1.7%)
URINARY INCONTINENCE	0	2 (3.1%)	2 (1.7%)
BRONCHITIS	1 (1.9%)	0	1 (0.9%)
HAEMATURIA	1 (1.9%)	0	1 (0.9%)
MYALGIA	1 (1.9%)	0	1 (0.9%)
PARESTHESIA	1 (1.9%)	0	1 (0.9%)
ABNORMAL VISION	0	1 (1.6%)	1 (0.9%)
EPISTAXIS	0	1 (1.6%)	1 (0.9%)
GASTROENTERITIS	0	1 (1.6%)	1 (0.9%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.6%)	1 (0.9%)
PNEUMONIA	0	1 (1.6%)	1 (0.9%)
SYNCOPE	0	1 (1.6%)	1 (0.9%)
TOOTH CARIES	0	1 (1.6%)	1 (0.9%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
TOTAL	0	0	0

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
TOTAL	4 (14.3%)	1 (4.5%)	5 (10.0%)
DYSMENORRHEA	4 (14.3%)	1 (4.5%)	5 (10.0%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
TOTAL	107 (80.5%)	94 (72.3%)	201 (76.4%)
HEADACHE	42 (31.6%)	28 (21.5%)	70 (26.6%)
RESPIRATORY DISORDER	26 (19.5%)	28 (21.5%)	54 (20.5%)
TRAUMA	22 (16.5%)	14 (10.8%)	36 (13.7%)
INFECTION	16 (12.0%)	20 (15.4%)	36 (13.7%)
ABDOMINAL PAIN	19 (14.3%)	12 (9.2%)	31 (11.8%)
PHARYNGITIS	19 (14.3%)	10 (7.7%)	29 (11.0%)
NAUSEA	15 (11.3%)	13 (10.0%)	28 (10.6%)
NERVOUSNESS	11 (8.3%)	13 (10.0%)	24 (9.1%)
INSOMNIA	11 (8.3%)	12 (9.2%)	23 (8.7%)
RHINITIS	13 (9.8%)	9 (6.9%)	22 (8.4%)
FEVER	13 (9.8%)	7 (5.4%)	20 (7.6%)
VOMITING	14 (10.5%)	5 (3.8%)	19 (7.2%)
ALLERGIC REACTION	11 (8.3%)	6 (4.6%)	17 (6.5%)
DYSPEPSIA	10 (7.5%)	7 (5.4%)	17 (6.5%)
WEIGHT GAIN	8 (6.0%)	9 (6.9%)	17 (6.5%)
HOSTILITY	7 (5.3%)	10 (7.7%)	17 (6.5%)
SINUSITIS	14 (10.5%)	2 (1.5%)	16 (6.1%)
EMOTIONAL LABILITY	11 (8.3%)	4 (3.1%)	15 (5.7%)
DIARRHEA	10 (7.5%)	5 (3.8%)	15 (5.7%)
HYPERKINESIA	8 (6.0%)	7 (5.4%)	15 (5.7%)
ASTHENIA	6 (4.5%)	9 (6.9%)	15 (5.7%)
SOMNOLENCE	7 (5.3%)	7 (5.4%)	14 (5.3%)
DIZZINESS	7 (5.3%)	5 (3.8%)	12 (4.6%)
ALBUMINURIA	9 (6.8%)	2 (1.5%)	11 (4.2%)
COUGH INCREASED	7 (5.3%)	4 (3.1%)	11 (4.2%)
ASTHMA	6 (4.5%)	5 (3.8%)	11 (4.2%)
DECREASED APPETITE	4 (3.0%)	7 (5.4%)	11 (4.2%)
OTITIS MEDIA	6 (4.5%)	4 (3.1%)	10 (3.8%)
AGITATION	4 (3.0%)	6 (4.6%)	10 (3.8%)
ANXIETY	4 (3.0%)	6 (4.6%)	10 (3.8%)
PAIN	6 (4.5%)	3 (2.3%)	9 (3.4%)
ACNE	5 (3.8%)	3 (2.3%)	8 (3.0%)
BACK PAIN	4 (3.0%)	4 (3.1%)	8 (3.0%)
CONTACT DERMATITIS	4 (3.0%)	4 (3.1%)	8 (3.0%)
NEUROSIS	6 (4.5%)	1 (0.8%)	7 (2.7%)
DEPRESSION	5 (3.8%)	2 (1.5%)	7 (2.7%)
BRONCHITIS	3 (2.3%)	3 (2.3%)	6 (2.3%)
CONCENTRATION IMPAIRED	3 (2.3%)	3 (2.3%)	6 (2.3%)
RASH	1 (0.8%)	5 (3.8%)	6 (2.3%)
URINARY INCONTINENCE	1 (0.8%)	5 (3.8%)	6 (2.3%)
ARTHRALGIA	4 (3.0%)	1 (0.8%)	5 (1.9%)
DRY MOUTH	3 (2.3%)	2 (1.5%)	5 (1.9%)
LEUKOPENIA	3 (2.3%)	2 (1.5%)	5 (1.9%)

Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=133)	 Placebo (N=130)	 Total (N=263)
MYALGIA	3 (2.3%)	2 (1.5%)	5 (1.9%)
TOOTH CARIES	1 (0.8%)	4 (3.1%)	5 (1.9%)
TOOTH DISORDER	3 (2.3%)	1 (0.8%)	4 (1.5%)
HAEMATURIA	2 (1.5%)	2 (1.5%)	4 (1.5%)
INCREASED APPETITE	2 (1.5%)	2 (1.5%)	4 (1.5%)
VERTIGO	2 (1.5%)	2 (1.5%)	4 (1.5%)
TREMOR	0	4 (3.1%)	4 (1.5%)
VASODILATATION	0	4 (3.1%)	4 (1.5%)
CHEST PAIN	3 (2.3%)	0	3 (1.1%)
CONSTIPATION	2 (1.5%)	1 (0.8%)	3 (1.1%)
EAR PAIN	2 (1.5%)	1 (0.8%)	3 (1.1%)
OTITIS EXTERNA	2 (1.5%)	1 (0.8%)	3 (1.1%)
ABNORMAL DREAMS	1 (0.8%)	2 (1.5%)	3 (1.1%)
FUNGAL DERMATITIS	1 (0.8%)	2 (1.5%)	3 (1.1%)
HALLUCINATIONS	1 (0.8%)	2 (1.5%)	3 (1.1%)
PNEUMONIA	1 (0.8%)	2 (1.5%)	3 (1.1%)
PRURITUS	1 (0.8%)	2 (1.5%)	3 (1.1%)
WITHDRAWAL SYNDROME	1 (0.8%)	2 (1.5%)	3 (1.1%)
EPISTAXIS	0	3 (2.3%)	3 (1.1%)
SYNCOPE	0	3 (2.3%)	3 (1.1%)
FACE EDEMA	2 (1.5%)	0	2 (0.8%)
PARESTHESIA	2 (1.5%)	0	2 (0.8%)
ABNORMAL VISION	0	2 (1.5%)	2 (0.8%)
FLATULENCE	0	2 (1.5%)	2 (0.8%)
GASTROENTERITIS	0	2 (1.5%)	2 (0.8%)
HYPESTHESIA	0	2 (1.5%)	2 (0.8%)
LIVER FUNCTION TESTS ABNORMAL	0	2 (1.5%)	2 (0.8%)

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
TOTAL	0	0	0

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Table 15.1.1.6.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase, Taper Phase or Follow-Up Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=61)	 Placebo (N=51)	 Total (N=112)
TOTAL	7 (11.5%)	1 (2.0%)	8 (7.1%)
DYSMENORRHEA	7 (11.5%)	1 (2.0%)	8 (7.1%)

Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=82)	Placebo (N=66)	Total (N=148)
Body System	Preferred Term			
TOTAL	TOTAL	6 (7.3%)	6 (9.1%)	12 (8.1%)
Nervous System	TOTAL	6 (7.3%)	4 (6.1%)	10 (6.8%)
	EMOTIONAL LABILITY	5 (6.1%)	1 (1.5%)	6 (4.1%)
	DEPRESSION	1 (1.2%)	1 (1.5%)	2 (1.4%)
	HOSTILITY	1 (1.2%)	1 (1.5%)	2 (1.4%)
	HALLUCINATIONS	0	1 (1.5%)	1 (0.7%)
	PARALYSIS	0	1 (1.5%)	1 (0.7%)
Body as a Whole	TOTAL	0	1 (1.5%)	1 (0.7%)
	TRAUMA	0	1 (1.5%)	1 (0.7%)
Respiratory System	TOTAL	0	1 (1.5%)	1 (0.7%)
	ASTHMA	0	1 (1.5%)	1 (0.7%)

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Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=37)	Total (N=86)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=53)	Placebo (N=64)	Total (N=117)
Body System	Preferred Term			
TOTAL	TOTAL	2 (3.8%)	1 (1.6%)	3 (2.6%)
Body as a Whole	TOTAL	2 (3.8%)	0	2 (1.7%)
	ABNORMAL LABORATORY VALUE	1 (1.9%)	0	1 (0.9%)
	ABSCESS	1 (1.9%)	0	1 (0.9%)
Nervous System	TOTAL	0	1 (1.6%)	1 (0.9%)
	PSYCHOSIS	0	1 (1.6%)	1 (0.9%)

Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=29)	Placebo (N=22)	Total (N=51)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=135)	Placebo (N=130)	Total (N=265)
Body System	Preferred Term			
TOTAL	TOTAL	8 (5.9%)	7 (5.4%)	15 (5.7%)
Nervous System	TOTAL	6 (4.4%)	5 (3.8%)	11 (4.2%)
	EMOTIONAL LABILITY	5 (3.7%)	1 (0.8%)	6 (2.3%)
	DEPRESSION	1 (0.7%)	1 (0.8%)	2 (0.8%)
	HOSTILITY	1 (0.7%)	1 (0.8%)	2 (0.8%)
	HALLUCINATIONS	0	1 (0.8%)	1 (0.4%)
	PARALYSIS	0	1 (0.8%)	1 (0.4%)
	PSYCHOSIS	0	1 (0.8%)	1 (0.4%)
Body as a Whole	TOTAL	2 (1.5%)	1 (0.8%)	3 (1.1%)
	ABNORMAL LABORATORY VALUE	1 (0.7%)	0	1 (0.4%)
	ABSCESS	1 (0.7%)	0	1 (0.4%)
	TRAUMA	0	1 (0.8%)	1 (0.4%)
Respiratory System	TOTAL	0	1 (0.8%)	1 (0.4%)
	ASTHMA	0	1 (0.8%)	1 (0.4%)

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Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=73)	Placebo (N=79)	Total (N=152)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Open-label Treatment, Taper or Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
All Patients
Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=62)	Placebo (N=51)	Total (N=113)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
TOTAL	TOTAL	27 (69.2%)	22 (61.1%)	49 (65.3%)
Respiratory System	TOTAL	16 (41.0%)	11 (30.6%)	27 (36.0%)
	PHARYNGITIS	6 (15.4%)	4 (11.1%)	10 (13.3%)
	RESPIRATORY DISORDER	5 (12.8%)	3 (8.3%)	8 (10.7%)
	RHINITIS	2 (5.1%)	3 (8.3%)	5 (6.7%)
	SINUSITIS	3 (7.7%)	0	3 (4.0%)
	COUGH INCREASED	2 (5.1%)	1 (2.8%)	3 (4.0%)
	EPISTAXIS	0	2 (5.6%)	2 (2.7%)
	YAWN	0	1 (2.8%)	1 (1.3%)
Body as a Whole	TOTAL	15 (38.5%)	13 (36.1%)	28 (37.3%)
	HEADACHE	8 (20.5%)	3 (8.3%)	11 (14.7%)
	TRAUMA	7 (17.9%)	1 (2.8%)	8 (10.7%)
	ABDOMINAL PAIN	4 (10.3%)	2 (5.6%)	6 (8.0%)
	INFECTION	1 (2.6%)	5 (13.9%)	6 (8.0%)
	ASTHENIA	1 (2.6%)	2 (5.6%)	3 (4.0%)
	FEVER	1 (2.6%)	2 (5.6%)	3 (4.0%)
	BACK PAIN	0	3 (8.3%)	3 (4.0%)
	PAIN	2 (5.1%)	0	2 (2.7%)
	ALLERGIC REACTION	1 (2.6%)	1 (2.8%)	2 (2.7%)
	FACE EDEMA	1 (2.6%)	0	1 (1.3%)
Digestive System	TOTAL	8 (20.5%)	9 (25.0%)	17 (22.7%)
	DYSPEPSIA	4 (10.3%)	3 (8.3%)	7 (9.3%)
	DRY MOUTH	2 (5.1%)	0	2 (2.7%)
	DECREASED APPETITE	1 (2.6%)	1 (2.8%)	2 (2.7%)
	NAUSEA	1 (2.6%)	1 (2.8%)	2 (2.7%)
	VOMITING	0	2 (5.6%)	2 (2.7%)
	INCREASED APPETITE	1 (2.6%)	0	1 (1.3%)
	DIARRHEA	0	1 (2.8%)	1 (1.3%)
	GASTROENTERITIS	0	1 (2.8%)	1 (1.3%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (2.8%)	1 (1.3%)
	TOOTH CARIES	0	1 (2.8%)	1 (1.3%)
Nervous System	TOTAL	5 (12.8%)	5 (13.9%)	10 (13.3%)
	INSOMNIA	1 (2.6%)	3 (8.3%)	4 (5.3%)
	DEPRESSION	1 (2.6%)	1 (2.8%)	2 (2.7%)
	HYPERKINESIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
	AGITATION	1 (2.6%)	0	1 (1.3%)
	HALLUCINATIONS	1 (2.6%)	0	1 (1.3%)
	NERVOUSNESS	1 (2.6%)	0	1 (1.3%)
	NEUROSIS	1 (2.6%)	0	1 (1.3%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
Nervous System	ANXIETY	0	1 (2.8%)	1 (1.3%)
	DIZZINESS	0	1 (2.8%)	1 (1.3%)
	HYPESTHESIA	0	1 (2.8%)	1 (1.3%)
Skin and Appendages	TOTAL	4 (10.3%)	2 (5.6%)	6 (8.0%)
	ACNE	2 (5.1%)	0	2 (2.7%)
	RASH	1 (2.6%)	1 (2.8%)	2 (2.7%)
	CONTACT DERMATITIS	1 (2.6%)	0	1 (1.3%)
	MACULOPAPULAR RASH	0	1 (2.8%)	1 (1.3%)
	PRURITUS	0	1 (2.8%)	1 (1.3%)
Metabolic and Nutritional Disorders	TOTAL	2 (5.1%)	2 (5.6%)	4 (5.3%)
	WEIGHT GAIN	2 (5.1%)	2 (5.6%)	4 (5.3%)
Musculoskeletal System	TOTAL	2 (5.1%)	0	2 (2.7%)
	ARTHRALGIA	2 (5.1%)	0	2 (2.7%)
Urogenital System	TOTAL	2 (5.1%)	3 (8.3%)	5 (6.7%)
	URINARY INCONTINENCE	1 (2.6%)	1 (2.8%)	2 (2.7%)
	PYURIA	1 (2.6%)	0	1 (1.3%)
	ALBUMINURIA	0	1 (2.8%)	1 (1.3%)
	CYSTITIS	0	1 (2.8%)	1 (1.3%)
	HAEMATURIA	0	1 (2.8%)	1 (1.3%)
Hemic and Lymphatic System	TOTAL	1 (2.6%)	1 (2.8%)	2 (2.7%)
	LEUKOPENIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
	ANEMIA	0	1 (2.8%)	1 (1.3%)
Special Senses	TOTAL	1 (2.6%)	1 (2.8%)	2 (2.7%)
	OTITIS MEDIA	1 (2.6%)	0	1 (1.3%)
	ABNORMAL VISION	0	1 (2.8%)	1 (1.3%)
Cardiovascular System	TOTAL	0	1 (2.8%)	1 (1.3%)
	BUNDLE BRANCH BLOCK	0	1 (2.8%)	1 (1.3%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
TOTAL	TOTAL	27 (69.2%)	19 (52.8%)	46 (61.3%)
Body as a Whole	TOTAL	15 (38.5%)	10 (27.8%)	25 (33.3%)
	INFECTION	4 (10.3%)	5 (13.9%)	9 (12.0%)
	TRAUMA	5 (12.8%)	2 (5.6%)	7 (9.3%)
	ABDOMINAL PAIN	4 (10.3%)	1 (2.8%)	5 (6.7%)
	FEVER	4 (10.3%)	1 (2.8%)	5 (6.7%)
	HEADACHE	3 (7.7%)	1 (2.8%)	4 (5.3%)
	ALLERGIC REACTION	2 (5.1%)	1 (2.8%)	3 (4.0%)
	PAIN	1 (2.6%)	1 (2.8%)	2 (2.7%)
	ASTHENIA	1 (2.6%)	0	1 (1.3%)
	FACE EDEMA	1 (2.6%)	0	1 (1.3%)
Nervous System	TOTAL	10 (25.6%)	7 (19.4%)	17 (22.7%)
	NERVOUSNESS	4 (10.3%)	0	4 (5.3%)
	HOSTILITY	3 (7.7%)	0	3 (4.0%)
	AGITATION	1 (2.6%)	2 (5.6%)	3 (4.0%)
	CONVULSION	1 (2.6%)	0	1 (1.3%)
	DEPRESSION	1 (2.6%)	0	1 (1.3%)
	HYPERKINESIA	1 (2.6%)	0	1 (1.3%)
	VESTIBULAR DISORDER	1 (2.6%)	0	1 (1.3%)
	CONCENTRATION IMPAIRED	0	1 (2.8%)	1 (1.3%)
	HALLUCINATIONS	0	1 (2.8%)	1 (1.3%)
	HYPESTHESIA	0	1 (2.8%)	1 (1.3%)
	INSOMNIA	0	1 (2.8%)	1 (1.3%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.3%)
	TREMOR	0	1 (2.8%)	1 (1.3%)
Digestive System	TOTAL	9 (23.1%)	4 (11.1%)	13 (17.3%)
	VOMITING	7 (17.9%)	2 (5.6%)	9 (12.0%)
	DIARRHEA	2 (5.1%)	0	2 (2.7%)
	CONSTIPATION	1 (2.6%)	0	1 (1.3%)
	STOMATITIS	1 (2.6%)	0	1 (1.3%)
	NAUSEA	0	1 (2.8%)	1 (1.3%)
	TOOTH CARIES	0	1 (2.8%)	1 (1.3%)
Respiratory System	TOTAL	9 (23.1%)	7 (19.4%)	16 (21.3%)
	RESPIRATORY DISORDER	5 (12.8%)	4 (11.1%)	9 (12.0%)
	PHARYNGITIS	2 (5.1%)	0	2 (2.7%)
	RHINITIS	2 (5.1%)	0	2 (2.7%)
	SINUSITIS	1 (2.6%)	1 (2.8%)	2 (2.7%)
	COUGH INCREASED	1 (2.6%)	0	1 (1.3%)
	BRONCHITIS	0	1 (2.8%)	1 (1.3%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
Respiratory System	PNEUMONIA	0	1 (2.8%)	1 (1.3%)
Metabolic and Nutritional Disorders	TOTAL	3 (7.7%)	2 (5.6%)	5 (6.7%)
	WEIGHT GAIN	2 (5.1%)	1 (2.8%)	3 (4.0%)
	DEHYDRATION	1 (2.6%)	1 (2.8%)	2 (2.7%)
Skin and Appendages	TOTAL	3 (7.7%)	1 (2.8%)	4 (5.3%)
	CONTACT DERMATITIS	1 (2.6%)	1 (2.8%)	2 (2.7%)
	ACNE	1 (2.6%)	0	1 (1.3%)
	HERPES ZOSTER	1 (2.6%)	0	1 (1.3%)
Special Senses	TOTAL	2 (5.1%)	0	2 (2.7%)
	OTITIS MEDIA	2 (5.1%)	0	2 (2.7%)
Musculoskeletal System	TOTAL	1 (2.6%)	1 (2.8%)	2 (2.7%)
	TENDINOUS DISORDER	1 (2.6%)	0	1 (1.3%)
	ARTHROSIS	0	1 (2.8%)	1 (1.3%)
	MYALGIA	0	1 (2.8%)	1 (1.3%)
Urogenital System	TOTAL	1 (2.6%)	0	1 (1.3%)
	URINARY INCONTINENCE	1 (2.6%)	0	1 (1.3%)
Cardiovascular System	TOTAL	0	2 (5.6%)	2 (2.7%)
	MIGRAINE	0	1 (2.8%)	1 (1.3%)
	SYNCOPE	0	1 (2.8%)	1 (1.3%)
Hemic and Lymphatic System	TOTAL	0	1 (2.8%)	1 (1.3%)
	LEUKOPENIA	0	1 (2.8%)	1 (1.3%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
TOTAL	TOTAL	3 (7.7%)	7 (19.4%)	10 (13.3%)
Nervous System	TOTAL	3 (7.7%)	3 (8.3%)	6 (8.0%)
	HOSTILITY	2 (5.1%)	1 (2.8%)	3 (4.0%)
	DEPRESSION	1 (2.6%)	0	1 (1.3%)
	EMOTIONAL LABILITY	1 (2.6%)	0	1 (1.3%)
	AGITATION	0	1 (2.8%)	1 (1.3%)
	EUPHORIA	0	1 (2.8%)	1 (1.3%)
	PARALYSIS	0	1 (2.8%)	1 (1.3%)
Body as a Whole	TOTAL	0	1 (2.8%)	1 (1.3%)
	TRAUMA	0	1 (2.8%)	1 (1.3%)
Cardiovascular System	TOTAL	0	1 (2.8%)	1 (1.3%)
	MIGRAINE	0	1 (2.8%)	1 (1.3%)
Respiratory System	TOTAL	0	1 (2.8%)	1 (1.3%)
	ASTHMA	0	1 (2.8%)	1 (1.3%)
Skin and Appendages	TOTAL	0	1 (2.8%)	1 (1.3%)
	RASH	0	1 (2.8%)	1 (1.3%)
Special Senses	TOTAL	0	1 (2.8%)	1 (1.3%)
	OTITIS MEDIA	0	1 (2.8%)	1 (1.3%)
Urogenital System	TOTAL	0	1 (2.8%)	1 (1.3%)
	URINARY INCONTINENCE	0	1 (2.8%)	1 (1.3%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	19 (67.9%)	23 (63.9%)	42 (65.6%)
Body as a Whole	TOTAL	9 (32.1%)	14 (38.9%)	23 (35.9%)
	HEADACHE	6 (21.4%)	6 (16.7%)	12 (18.8%)
	ABDOMINAL PAIN	1 (3.6%)	5 (13.9%)	6 (9.4%)
	TRAUMA	2 (7.1%)	3 (8.3%)	5 (7.8%)
	FEVER	2 (7.1%)	1 (2.8%)	3 (4.7%)
	PAIN	2 (7.1%)	1 (2.8%)	3 (4.7%)
	BACK PAIN	1 (3.6%)	0	1 (1.6%)
	ALLERGIC REACTION	0	1 (2.8%)	1 (1.6%)
	INFECTION	0	1 (2.8%)	1 (1.6%)
	SPINA BIFIDA	0	1 (2.8%)	1 (1.6%)
Digestive System	TOTAL	8 (28.6%)	5 (13.9%)	13 (20.3%)
	NAUSEA	5 (17.9%)	0	5 (7.8%)
	DECREASED APPETITE	2 (7.1%)	2 (5.6%)	4 (6.3%)
	DIARRHEA	3 (10.7%)	0	3 (4.7%)
	DYSPEPSIA	2 (7.1%)	0	2 (3.1%)
	VOMITING	1 (3.6%)	0	1 (1.6%)
	FLATULENCE	0	1 (2.8%)	1 (1.6%)
	GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
	TOOTH CARIES	0	1 (2.8%)	1 (1.6%)
Respiratory System	TOTAL	7 (25.0%)	9 (25.0%)	16 (25.0%)
	RHINITIS	4 (14.3%)	4 (11.1%)	8 (12.5%)
	RESPIRATORY DISORDER	1 (3.6%)	6 (16.7%)	7 (10.9%)
	PHARYNGITIS	3 (10.7%)	3 (8.3%)	6 (9.4%)
	COUGH INCREASED	2 (7.1%)	0	2 (3.1%)
	SINUSITIS	1 (3.6%)	1 (2.8%)	2 (3.1%)
	ASTHMA	1 (3.6%)	0	1 (1.6%)
Nervous System	TOTAL	5 (17.9%)	13 (36.1%)	18 (28.1%)
	NERVOUSNESS	1 (3.6%)	5 (13.9%)	6 (9.4%)
	INSOMNIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
	HYPERKINESIA	3 (10.7%)	0	3 (4.7%)
	AGITATION	1 (3.6%)	1 (2.8%)	2 (3.1%)
	DIZZINESS	1 (3.6%)	1 (2.8%)	2 (3.1%)
	HOSTILITY	1 (3.6%)	1 (2.8%)	2 (3.1%)
	MYOCLONUS	1 (3.6%)	1 (2.8%)	2 (3.1%)
	VERTIGO	0	2 (5.6%)	2 (3.1%)
	ANXIETY	1 (3.6%)	0	1 (1.6%)
	CONCENTRATION IMPAIRED	1 (3.6%)	0	1 (1.6%)
	DYSKINESIA	0	1 (2.8%)	1 (1.6%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Body System	Preferred Term			
Nervous System	SOMNOLENCE	0	1 (2.8%)	1 (1.6%)
	TREMOR	0	1 (2.8%)	1 (1.6%)
Urogenital System	TOTAL	2 (7.1%)	1 (2.8%)	3 (4.7%)
	ALBUMINURIA	2 (7.1%)	0	2 (3.1%)
	GLYCOSURIA	1 (3.6%)	0	1 (1.6%)
	URINARY INCONTINENCE	0	1 (2.8%)	1 (1.6%)
Cardiovascular System	TOTAL	1 (3.6%)	3 (8.3%)	4 (6.3%)
	VASODILATATION	0	3 (8.3%)	3 (4.7%)
	HAEMATOMA	1 (3.6%)	0	1 (1.6%)
Hemic and Lymphatic System	TOTAL	1 (3.6%)	0	1 (1.6%)
	ANEMIA	1 (3.6%)	0	1 (1.6%)
Musculoskeletal System	TOTAL	1 (3.6%)	0	1 (1.6%)
	MYALGIA	1 (3.6%)	0	1 (1.6%)
Skin and Appendages	TOTAL	1 (3.6%)	2 (5.6%)	3 (4.7%)
	RASH	0	2 (5.6%)	2 (3.1%)
	MACULOPAPULAR RASH	1 (3.6%)	0	1 (1.6%)
	CONTACT DERMATITIS	0	1 (2.8%)	1 (1.6%)
	HERPES SIMPLEX	0	1 (2.8%)	1 (1.6%)
Special Senses	TOTAL	1 (3.6%)	3 (8.3%)	4 (6.3%)
	OTITIS EXTERNA	1 (3.6%)	1 (2.8%)	2 (3.1%)
	EAR PAIN	0	1 (2.8%)	1 (1.6%)
	OTITIS MEDIA	0	1 (2.8%)	1 (1.6%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.8%)	1 (1.6%)
	WEIGHT GAIN	0	1 (2.8%)	1 (1.6%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	15 (53.6%)	23 (63.9%)	38 (59.4%)
Body as a Whole	TOTAL	9 (32.1%)	7 (19.4%)	16 (25.0%)
	HEADACHE	5 (17.9%)	2 (5.6%)	7 (10.9%)
	INFECTION	2 (7.1%)	3 (8.3%)	5 (7.8%)
	TRAUMA	3 (10.7%)	0	3 (4.7%)
	ABDOMINAL PAIN	1 (3.6%)	1 (2.8%)	2 (3.1%)
	PAIN	1 (3.6%)	1 (2.8%)	2 (3.1%)
	FEVER	1 (3.6%)	0	1 (1.6%)
Nervous System	TOTAL	5 (17.9%)	16 (44.4%)	21 (32.8%)
	HYPERKINESIA	3 (10.7%)	3 (8.3%)	6 (9.4%)
	NERVOUSNESS	0	6 (16.7%)	6 (9.4%)
	ANXIETY	0	3 (8.3%)	3 (4.7%)
	HOSTILITY	0	3 (8.3%)	3 (4.7%)
	SOMNOLENCE	1 (3.6%)	1 (2.8%)	2 (3.1%)
	DEPRESSION	1 (3.6%)	0	1 (1.6%)
	EMOTIONAL LABILITY	1 (3.6%)	0	1 (1.6%)
	AGITATION	0	1 (2.8%)	1 (1.6%)
	DIZZINESS	0	1 (2.8%)	1 (1.6%)
	LACK OF EMOTION	0	1 (2.8%)	1 (1.6%)
	MANIC REACTION	0	1 (2.8%)	1 (1.6%)
	PSYCHOSIS	0	1 (2.8%)	1 (1.6%)
Respiratory System	TOTAL	4 (14.3%)	3 (8.3%)	7 (10.9%)
	PHARYNGITIS	3 (10.7%)	1 (2.8%)	4 (6.3%)
	RESPIRATORY DISORDER	2 (7.1%)	2 (5.6%)	4 (6.3%)
	COUGH INCREASED	1 (3.6%)	1 (2.8%)	2 (3.1%)
	SINUSITIS	1 (3.6%)	0	1 (1.6%)
	RHINITIS	0	1 (2.8%)	1 (1.6%)
Special Senses	TOTAL	4 (14.3%)	1 (2.8%)	5 (7.8%)
	OTITIS MEDIA	3 (10.7%)	1 (2.8%)	4 (6.3%)
	EAR PAIN	1 (3.6%)	0	1 (1.6%)
	OTITIS EXTERNA	1 (3.6%)	0	1 (1.6%)
Digestive System	TOTAL	1 (3.6%)	2 (5.6%)	3 (4.7%)
	GINGIVITIS	1 (3.6%)	1 (2.8%)	2 (3.1%)
	TOOTH DISORDER	1 (3.6%)	0	1 (1.6%)
	DYSPEPSIA	0	1 (2.8%)	1 (1.6%)
	NAUSEA	0	1 (2.8%)	1 (1.6%)
Hemic and Lymphatic System	TOTAL	1 (3.6%)	0	1 (1.6%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Body System	Preferred Term			
Hemic and Lymphatic System	PURPURA	1 (3.6%)	0	1 (1.6%)
Skin and Appendages	TOTAL	1 (3.6%)	2 (5.6%)	3 (4.7%)
	ACNE	1 (3.6%)	0	1 (1.6%)
	CONTACT DERMATITIS	0	1 (2.8%)	1 (1.6%)
	FUNGAL DERMATITIS	0	1 (2.8%)	1 (1.6%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.8%)	1 (1.6%)
	WEIGHT GAIN	0	1 (2.8%)	1 (1.6%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	2 (7.1%)	5 (13.9%)	7 (10.9%)
Body as a Whole	TOTAL	2 (7.1%)	1 (2.8%)	3 (4.7%)
	ABSCESS	1 (3.6%)	0	1 (1.6%)
	INFECTION	1 (3.6%)	0	1 (1.6%)
	TRAUMA	0	1 (2.8%)	1 (1.6%)
Respiratory System	TOTAL	1 (3.6%)	0	1 (1.6%)
	PHARYNGITIS	1 (3.6%)	0	1 (1.6%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.8%)	1 (1.6%)
	WEIGHT GAIN	0	1 (2.8%)	1 (1.6%)
Nervous System	TOTAL	0	3 (8.3%)	3 (4.7%)
	HOSTILITY	0	1 (2.8%)	1 (1.6%)
	HYPERKINESIA	0	1 (2.8%)	1 (1.6%)
	NERVOUSNESS	0	1 (2.8%)	1 (1.6%)
Urogenital System	TOTAL	0	1 (2.8%)	1 (1.6%)
	URINARY INCONTINENCE	0	1 (2.8%)	1 (1.6%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (7.7%)	1 (3.4%)
Urogenital System	TOTAL	0	1 (7.7%)	1 (3.4%)
	DYSMENORRHEA	0	1 (7.7%)	1 (3.4%)
	UTERUS DISORDERS	0	1 (7.7%)	1 (3.4%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	1 (6.3%)	0	1 (3.4%)
Urogenital System	TOTAL	1 (6.3%)	0	1 (3.4%)
	DYSMENORRHEA	1 (6.3%)	0	1 (3.4%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
TOTAL	TOTAL	46 (68.7%)	45 (62.5%)	91 (65.5%)
Body as a Whole	TOTAL	24 (35.8%)	27 (37.5%)	51 (36.7%)
	HEADACHE	14 (20.9%)	9 (12.5%)	23 (16.5%)
	TRAUMA	9 (13.4%)	4 (5.6%)	13 (9.4%)
	ABDOMINAL PAIN	5 (7.5%)	7 (9.7%)	12 (8.6%)
	INFECTION	1 (1.5%)	6 (8.3%)	7 (5.0%)
	FEVER	3 (4.5%)	3 (4.2%)	6 (4.3%)
	PAIN	4 (6.0%)	1 (1.4%)	5 (3.6%)
	BACK PAIN	1 (1.5%)	3 (4.2%)	4 (2.9%)
	ALLERGIC REACTION	1 (1.5%)	2 (2.8%)	3 (2.2%)
	ASTHENIA	1 (1.5%)	2 (2.8%)	3 (2.2%)
	FACE EDEMA	1 (1.5%)	0	1 (0.7%)
	SPINA BIFIDA	0	1 (1.4%)	1 (0.7%)
Respiratory System	TOTAL	23 (34.3%)	20 (27.8%)	43 (30.9%)
	PHARYNGITIS	9 (13.4%)	7 (9.7%)	16 (11.5%)
	RESPIRATORY DISORDER	6 (9.0%)	9 (12.5%)	15 (10.8%)
	RHINITIS	6 (9.0%)	7 (9.7%)	13 (9.4%)
	COUGH INCREASED	4 (6.0%)	1 (1.4%)	5 (3.6%)
	SINUSITIS	4 (6.0%)	1 (1.4%)	5 (3.6%)
	EPISTAXIS	0	2 (2.8%)	2 (1.4%)
	ASTHMA	1 (1.5%)	0	1 (0.7%)
	YAWN	0	1 (1.4%)	1 (0.7%)
Digestive System	TOTAL	16 (23.9%)	14 (19.4%)	30 (21.6%)
	DYSPEPSIA	6 (9.0%)	3 (4.2%)	9 (6.5%)
	NAUSEA	6 (9.0%)	1 (1.4%)	7 (5.0%)
	DECREASED APPETITE	3 (4.5%)	3 (4.2%)	6 (4.3%)
	DIARRHEA	3 (4.5%)	1 (1.4%)	4 (2.9%)
	VOMITING	1 (1.5%)	2 (2.8%)	3 (2.2%)
	DRY MOUTH	2 (3.0%)	0	2 (1.4%)
	GASTROENTERITIS	0	2 (2.8%)	2 (1.4%)
	TOOTH CARIES	0	2 (2.8%)	2 (1.4%)
	INCREASED APPETITE	1 (1.5%)	0	1 (0.7%)
	FLATULENCE	0	1 (1.4%)	1 (0.7%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.4%)	1 (0.7%)
Nervous System	TOTAL	10 (14.9%)	18 (25.0%)	28 (20.1%)
	INSOMNIA	4 (6.0%)	5 (6.9%)	9 (6.5%)
	NERVOUSNESS	2 (3.0%)	5 (6.9%)	7 (5.0%)
	HYPERKINESIA	4 (6.0%)	1 (1.4%)	5 (3.6%)
	AGITATION	2 (3.0%)	1 (1.4%)	3 (2.2%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Nervous System	DIZZINESS	1 (1.5%)	2 (2.8%)	3 (2.2%)
	ANXIETY	1 (1.5%)	1 (1.4%)	2 (1.4%)
	DEPRESSION	1 (1.5%)	1 (1.4%)	2 (1.4%)
	HOSTILITY	1 (1.5%)	1 (1.4%)	2 (1.4%)
	MYOCLONUS	1 (1.5%)	1 (1.4%)	2 (1.4%)
	VERTIGO	0	2 (2.8%)	2 (1.4%)
	CONCENTRATION IMPAIRED	1 (1.5%)	0	1 (0.7%)
	HALLUCINATIONS	1 (1.5%)	0	1 (0.7%)
	NEUROSIS	1 (1.5%)	0	1 (0.7%)
	DYSKINESIA	0	1 (1.4%)	1 (0.7%)
	HYPESTHESIA	0	1 (1.4%)	1 (0.7%)
	SOMNOLENCE	0	1 (1.4%)	1 (0.7%)
	TREMOR	0	1 (1.4%)	1 (0.7%)
Skin and Appendages	TOTAL	5 (7.5%)	4 (5.6%)	9 (6.5%)
	RASH	1 (1.5%)	3 (4.2%)	4 (2.9%)
	ACNE	2 (3.0%)	0	2 (1.4%)
	CONTACT DERMATITIS	1 (1.5%)	1 (1.4%)	2 (1.4%)
	MACULOPAPULAR RASH	1 (1.5%)	1 (1.4%)	2 (1.4%)
	HERPES SIMPLEX	0	1 (1.4%)	1 (0.7%)
	PRURITUS	0	1 (1.4%)	1 (0.7%)
Urogenital System	TOTAL	4 (6.0%)	4 (5.6%)	8 (5.8%)
	ALBUMINURIA	2 (3.0%)	1 (1.4%)	3 (2.2%)
	URINARY INCONTINENCE	1 (1.5%)	2 (2.8%)	3 (2.2%)
	GLYCOSURIA	1 (1.5%)	0	1 (0.7%)
	PYURIA	1 (1.5%)	0	1 (0.7%)
	CYSTITIS	0	1 (1.4%)	1 (0.7%)
	HAEMATURIA	0	1 (1.4%)	1 (0.7%)
Musculoskeletal System	TOTAL	3 (4.5%)	0	3 (2.2%)
	ARTHRALGIA	2 (3.0%)	0	2 (1.4%)
	MYALGIA	1 (1.5%)	0	1 (0.7%)
Hemic and Lymphatic System	TOTAL	2 (3.0%)	1 (1.4%)	3 (2.2%)
	ANEMIA	1 (1.5%)	1 (1.4%)	2 (1.4%)
	LEUKOPENIA	1 (1.5%)	1 (1.4%)	2 (1.4%)
Metabolic and Nutritional Disorders	TOTAL	2 (3.0%)	3 (4.2%)	5 (3.6%)
	WEIGHT GAIN	2 (3.0%)	3 (4.2%)	5 (3.6%)
Special Senses	TOTAL	2 (3.0%)	4 (5.6%)	6 (4.3%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
Special Senses	OTITIS EXTERNA	1 (1.5%)	1 (1.4%)	2 (1.4%)
	OTITIS MEDIA	1 (1.5%)	1 (1.4%)	2 (1.4%)
	ABNORMAL VISION	0	1 (1.4%)	1 (0.7%)
	EAR PAIN	0	1 (1.4%)	1 (0.7%)
Cardiovascular System	TOTAL	1 (1.5%)	4 (5.6%)	5 (3.6%)
	VASODILATATION	0	3 (4.2%)	3 (2.2%)
	HAEMATOMA	1 (1.5%)	0	1 (0.7%)
	BUNDLE BRANCH BLOCK	0	1 (1.4%)	1 (0.7%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
TOTAL	TOTAL	42 (62.7%)	42 (58.3%)	84 (60.4%)
Body as a Whole	TOTAL	24 (35.8%)	17 (23.6%)	41 (29.5%)
	INFECTION	6 (9.0%)	8 (11.1%)	14 (10.1%)
	HEADACHE	8 (11.9%)	3 (4.2%)	11 (7.9%)
	TRAUMA	8 (11.9%)	2 (2.8%)	10 (7.2%)
	ABDOMINAL PAIN	5 (7.5%)	2 (2.8%)	7 (5.0%)
	FEVER	5 (7.5%)	1 (1.4%)	6 (4.3%)
	PAIN	2 (3.0%)	2 (2.8%)	4 (2.9%)
	ALLERGIC REACTION	2 (3.0%)	1 (1.4%)	3 (2.2%)
	ASTHENIA	1 (1.5%)	0	1 (0.7%)
	FACE EDEMA	1 (1.5%)	0	1 (0.7%)
Nervous System	TOTAL	15 (22.4%)	23 (31.9%)	38 (27.3%)
	NERVOUSNESS	4 (6.0%)	6 (8.3%)	10 (7.2%)
	HYPERKINESIA	4 (6.0%)	3 (4.2%)	7 (5.0%)
	HOSTILITY	3 (4.5%)	3 (4.2%)	6 (4.3%)
	AGITATION	1 (1.5%)	3 (4.2%)	4 (2.9%)
	SOMNOLENCE	1 (1.5%)	2 (2.8%)	3 (2.2%)
	ANXIETY	0	3 (4.2%)	3 (2.2%)
	DEPRESSION	2 (3.0%)	0	2 (1.4%)
	CONVULSION	1 (1.5%)	0	1 (0.7%)
	EMOTIONAL LABILITY	1 (1.5%)	0	1 (0.7%)
	VESTIBULAR DISORDER	1 (1.5%)	0	1 (0.7%)
	CONCENTRATION IMPAIRED	0	1 (1.4%)	1 (0.7%)
	DIZZINESS	0	1 (1.4%)	1 (0.7%)
	HALLUCINATIONS	0	1 (1.4%)	1 (0.7%)
	HYPESTHESIA	0	1 (1.4%)	1 (0.7%)
	INSOMNIA	0	1 (1.4%)	1 (0.7%)
	LACK OF EMOTION	0	1 (1.4%)	1 (0.7%)
	MANIC REACTION	0	1 (1.4%)	1 (0.7%)
	PSYCHOSIS	0	1 (1.4%)	1 (0.7%)
	TREMOR	0	1 (1.4%)	1 (0.7%)
Respiratory System	TOTAL	13 (19.4%)	10 (13.9%)	23 (16.5%)
	RESPIRATORY DISORDER	7 (10.4%)	6 (8.3%)	13 (9.4%)
	PHARYNGITIS	5 (7.5%)	1 (1.4%)	6 (4.3%)
	COUGH INCREASED	2 (3.0%)	1 (1.4%)	3 (2.2%)
	RHINITIS	2 (3.0%)	1 (1.4%)	3 (2.2%)
	SINUSITIS	2 (3.0%)	1 (1.4%)	3 (2.2%)
	BRONCHITIS	0	1 (1.4%)	1 (0.7%)
	PNEUMONIA	0	1 (1.4%)	1 (0.7%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
Digestive System	TOTAL	10 (14.9%)	6 (8.3%)	16 (11.5%)
	VOMITING	7 (10.4%)	2 (2.8%)	9 (6.5%)
	DIARRHEA	2 (3.0%)	0	2 (1.4%)
	GINGIVITIS	1 (1.5%)	1 (1.4%)	2 (1.4%)
	NAUSEA	0	2 (2.8%)	2 (1.4%)
	CONSTIPATION	1 (1.5%)	0	1 (0.7%)
	STOMATITIS	1 (1.5%)	0	1 (0.7%)
	TOOTH DISORDER	1 (1.5%)	0	1 (0.7%)
	DYSPEPSIA	0	1 (1.4%)	1 (0.7%)
	TOOTH CARIES	0	1 (1.4%)	1 (0.7%)
Special Senses	TOTAL	6 (9.0%)	1 (1.4%)	7 (5.0%)
	OTITIS MEDIA	5 (7.5%)	1 (1.4%)	6 (4.3%)
	EAR PAIN	1 (1.5%)	0	1 (0.7%)
	OTITIS EXTERNA	1 (1.5%)	0	1 (0.7%)
Skin and Appendages	TOTAL	4 (6.0%)	3 (4.2%)	7 (5.0%)
	CONTACT DERMATITIS	1 (1.5%)	2 (2.8%)	3 (2.2%)
	ACNE	2 (3.0%)	0	2 (1.4%)
	HERPES ZOSTER	1 (1.5%)	0	1 (0.7%)
	FUNGAL DERMATITIS	0	1 (1.4%)	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	3 (4.5%)	3 (4.2%)	6 (4.3%)
	WEIGHT GAIN	2 (3.0%)	2 (2.8%)	4 (2.9%)
	DEHYDRATION	1 (1.5%)	1 (1.4%)	2 (1.4%)
Hemic and Lymphatic System	TOTAL	1 (1.5%)	1 (1.4%)	2 (1.4%)
	PURPURA	1 (1.5%)	0	1 (0.7%)
	LEUKOPENIA	0	1 (1.4%)	1 (0.7%)
Musculoskeletal System	TOTAL	1 (1.5%)	1 (1.4%)	2 (1.4%)
	TENDINOUS DISORDER	1 (1.5%)	0	1 (0.7%)
	ARTHROSIS	0	1 (1.4%)	1 (0.7%)
	MYALGIA	0	1 (1.4%)	1 (0.7%)
Urogenital System	TOTAL	1 (1.5%)	0	1 (0.7%)
	URINARY INCONTINENCE	1 (1.5%)	0	1 (0.7%)
Cardiovascular System	TOTAL	0	2 (2.8%)	2 (1.4%)
	MIGRAINE	0	1 (1.4%)	1 (0.7%)
	SYNCOPE	0	1 (1.4%)	1 (0.7%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
TOTAL	TOTAL	5 (7.5%)	12 (16.7%)	17 (12.2%)
Nervous System	TOTAL	3 (4.5%)	6 (8.3%)	9 (6.5%)
	HOSTILITY	2 (3.0%)	2 (2.8%)	4 (2.9%)
	DEPRESSION	1 (1.5%)	0	1 (0.7%)
	EMOTIONAL LABILITY	1 (1.5%)	0	1 (0.7%)
	AGITATION	0	1 (1.4%)	1 (0.7%)
	EUPHORIA	0	1 (1.4%)	1 (0.7%)
	HYPERKINESIA	0	1 (1.4%)	1 (0.7%)
	NERVOUSNESS	0	1 (1.4%)	1 (0.7%)
	PARALYSIS	0	1 (1.4%)	1 (0.7%)
Body as a Whole	TOTAL	2 (3.0%)	2 (2.8%)	4 (2.9%)
	TRAUMA	0	2 (2.8%)	2 (1.4%)
	ABSCESS	1 (1.5%)	0	1 (0.7%)
	INFECTION	1 (1.5%)	0	1 (0.7%)
Respiratory System	TOTAL	1 (1.5%)	1 (1.4%)	2 (1.4%)
	PHARYNGITIS	1 (1.5%)	0	1 (0.7%)
	ASTHMA	0	1 (1.4%)	1 (0.7%)
Cardiovascular System	TOTAL	0	1 (1.4%)	1 (0.7%)
	MIGRAINE	0	1 (1.4%)	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.4%)	1 (0.7%)
	WEIGHT GAIN	0	1 (1.4%)	1 (0.7%)
Skin and Appendages	TOTAL	0	1 (1.4%)	1 (0.7%)
	RASH	0	1 (1.4%)	1 (0.7%)
Special Senses	TOTAL	0	1 (1.4%)	1 (0.7%)
	OTITIS MEDIA	0	1 (1.4%)	1 (0.7%)
Urogenital System	TOTAL	0	2 (2.8%)	2 (1.4%)
	URINARY INCONTINENCE	0	2 (2.8%)	2 (1.4%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (3.7%)	1 (1.6%)
Urogenital System	TOTAL	0	1 (3.7%)	1 (1.6%)
	DYSMENORRHEA	0	1 (3.7%)	1 (1.6%)
	UTERUS DISORDERS	0	1 (3.7%)	1 (1.6%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	1 (2.9%)	0	1 (1.6%)
Urogenital System	TOTAL	1 (2.9%)	0	1 (1.6%)
	DYSMENORRHEA	1 (2.9%)	0	1 (1.6%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Body System	Preferred Term			
TOTAL	TOTAL	26 (61.9%)	18 (60.0%)	44 (61.1%)
Body as a Whole	TOTAL	15 (35.7%)	7 (23.3%)	22 (30.6%)
	HEADACHE	7 (16.7%)	5 (16.7%)	12 (16.7%)
	ALLERGIC REACTION	4 (9.5%)	0	4 (5.6%)
	ABDOMINAL PAIN	3 (7.1%)	0	3 (4.2%)
	CHEST PAIN	3 (7.1%)	0	3 (4.2%)
	FEVER	3 (7.1%)	0	3 (4.2%)
	TRAUMA	1 (2.4%)	2 (6.7%)	3 (4.2%)
	ASTHENIA	0	2 (6.7%)	2 (2.8%)
	BACK PAIN	1 (2.4%)	0	1 (1.4%)
	MALAISE	1 (2.4%)	0	1 (1.4%)
	INFECTION	0	1 (3.3%)	1 (1.4%)
	PAIN	0	1 (3.3%)	1 (1.4%)
Nervous System	TOTAL	14 (33.3%)	6 (20.0%)	20 (27.8%)
	SOMNOLENCE	4 (9.5%)	0	4 (5.6%)
	DIZZINESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
	NERVOUSNESS	3 (7.1%)	0	3 (4.2%)
	INSOMNIA	1 (2.4%)	2 (6.7%)	3 (4.2%)
	EMOTIONAL LABILITY	1 (2.4%)	1 (3.3%)	2 (2.8%)
	PARESTHESIA	1 (2.4%)	0	1 (1.4%)
	VERTIGO	1 (2.4%)	0	1 (1.4%)
	AGITATION	0	1 (3.3%)	1 (1.4%)
	CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.4%)
	LIBIDO DECREASED	0	1 (3.3%)	1 (1.4%)
	TREMOR	0	1 (3.3%)	1 (1.4%)
Respiratory System	TOTAL	13 (31.0%)	8 (26.7%)	21 (29.2%)
	RESPIRATORY DISORDER	5 (11.9%)	7 (23.3%)	12 (16.7%)
	PHARYNGITIS	3 (7.1%)	1 (3.3%)	4 (5.6%)
	RHINITIS	3 (7.1%)	1 (3.3%)	4 (5.6%)
	ASTHMA	1 (2.4%)	2 (6.7%)	3 (4.2%)
	SINUSITIS	2 (4.8%)	0	2 (2.8%)
	COUGH INCREASED	1 (2.4%)	1 (3.3%)	2 (2.8%)
	DYSPNEA	1 (2.4%)	0	1 (1.4%)
Digestive System	TOTAL	10 (23.8%)	6 (20.0%)	16 (22.2%)
	NAUSEA	5 (11.9%)	2 (6.7%)	7 (9.7%)
	VOMITING	3 (7.1%)	0	3 (4.2%)
	DIARRHEA	2 (4.8%)	1 (3.3%)	3 (4.2%)
	DYSPEPSIA	2 (4.8%)	1 (3.3%)	3 (4.2%)
	DECREASED APPETITE	1 (2.4%)	2 (6.7%)	3 (4.2%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Body System	Preferred Term			
Digestive System	INCREASED APPETITE	0	2 (6.7%)	2 (2.8%)
	DRY MOUTH	1 (2.4%)	0	1 (1.4%)
	GASTRITIS	1 (2.4%)	0	1 (1.4%)
	TOOTH CARIES	1 (2.4%)	0	1 (1.4%)
	GASTROINTESTINAL DISORDER	0	1 (3.3%)	1 (1.4%)
Skin and Appendages	TOTAL	3 (7.1%)	1 (3.3%)	4 (5.6%)
	PRURITUS	1 (2.4%)	1 (3.3%)	2 (2.8%)
	CONTACT DERMATITIS	1 (2.4%)	0	1 (1.4%)
	FUNGAL DERMATITIS	1 (2.4%)	0	1 (1.4%)
Urogenital System	TOTAL	3 (7.1%)	1 (3.3%)	4 (5.6%)
	ALBUMINURIA	3 (7.1%)	1 (3.3%)	4 (5.6%)
	HAEMATURIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
Hemic and Lymphatic System	TOTAL	2 (4.8%)	0	2 (2.8%)
	LEUKOPENIA	1 (2.4%)	0	1 (1.4%)
	LYMPHADENOPATHY	1 (2.4%)	0	1 (1.4%)
Special Senses	TOTAL	1 (2.4%)	0	1 (1.4%)
	OTITIS MEDIA	1 (2.4%)	0	1 (1.4%)
Cardiovascular System	TOTAL	0	1 (3.3%)	1 (1.4%)
	SYNCOPE	0	1 (3.3%)	1 (1.4%)
Metabolic and Nutritional Disorders	TOTAL	0	3 (10.0%)	3 (4.2%)
	WEIGHT GAIN	0	3 (10.0%)	3 (4.2%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Body System	Preferred Term			
TOTAL	TOTAL	27 (64.3%)	9 (30.0%)	36 (50.0%)
Body as a Whole	TOTAL	15 (35.7%)	4 (13.3%)	19 (26.4%)
	HEADACHE	6 (14.3%)	1 (3.3%)	7 (9.7%)
	TRAUMA	5 (11.9%)	1 (3.3%)	6 (8.3%)
	INFECTION	2 (4.8%)	1 (3.3%)	3 (4.2%)
	BACK PAIN	2 (4.8%)	0	2 (2.8%)
	ABDOMINAL PAIN	1 (2.4%)	1 (3.3%)	2 (2.8%)
	ASTHENIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
	CHEST PAIN	1 (2.4%)	0	1 (1.4%)
	FEVER	0	1 (3.3%)	1 (1.4%)
Respiratory System	TOTAL	9 (21.4%)	3 (10.0%)	12 (16.7%)
	RESPIRATORY DISORDER	4 (9.5%)	1 (3.3%)	5 (6.9%)
	BRONCHITIS	2 (4.8%)	2 (6.7%)	4 (5.6%)
	ASTHMA	2 (4.8%)	0	2 (2.8%)
	PHARYNGITIS	1 (2.4%)	0	1 (1.4%)
	PNEUMONIA	1 (2.4%)	0	1 (1.4%)
	RHINITIS	1 (2.4%)	0	1 (1.4%)
	SINUSITIS	1 (2.4%)	0	1 (1.4%)
Nervous System	TOTAL	6 (14.3%)	5 (16.7%)	11 (15.3%)
	EMOTIONAL LABILITY	2 (4.8%)	2 (6.7%)	4 (5.6%)
	SOMNOLENCE	1 (2.4%)	2 (6.7%)	3 (4.2%)
	INSOMNIA	2 (4.8%)	0	2 (2.8%)
	AGITATION	1 (2.4%)	1 (3.3%)	2 (2.8%)
	ANXIETY	1 (2.4%)	0	1 (1.4%)
	DEPRESSION	1 (2.4%)	0	1 (1.4%)
	HOSTILITY	0	1 (3.3%)	1 (1.4%)
	NERVOUSNESS	0	1 (3.3%)	1 (1.4%)
	WITHDRAWAL SYNDROME	0	1 (3.3%)	1 (1.4%)
Digestive System	TOTAL	4 (9.5%)	1 (3.3%)	5 (6.9%)
	NAUSEA	2 (4.8%)	0	2 (2.8%)
	VOMITING	2 (4.8%)	0	2 (2.8%)
	DYSPEPSIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
	DIARRHEA	1 (2.4%)	0	1 (1.4%)
	HEMATEMESIS	1 (2.4%)	0	1 (1.4%)
Skin and Appendages	TOTAL	3 (7.1%)	1 (3.3%)	4 (5.6%)
	ACNE	1 (2.4%)	1 (3.3%)	2 (2.8%)
	CONTACT DERMATITIS	1 (2.4%)	0	1 (1.4%)
	FURUNCULOSIS	1 (2.4%)	0	1 (1.4%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	TOTAL	2 (4.8%)	0	2 (2.8%)
	WEIGHT GAIN	1 (2.4%)	0	1 (1.4%)
	WEIGHT LOSS	1 (2.4%)	0	1 (1.4%)
Musculoskeletal System	TOTAL	1 (2.4%)	0	1 (1.4%)
	MYALGIA	1 (2.4%)	0	1 (1.4%)
Urogenital System	TOTAL	1 (2.4%)	0	1 (1.4%)
	URINARY TRACT INFECTION	1 (2.4%)	0	1 (1.4%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Body System	Preferred Term			
TOTAL	TOTAL	6 (14.3%)	4 (13.3%)	10 (13.9%)
Body as a Whole	TOTAL	3 (7.1%)	0	3 (4.2%)
	BACK PAIN	1 (2.4%)	0	1 (1.4%)
	INFECTION	1 (2.4%)	0	1 (1.4%)
	TRAUMA	1 (2.4%)	0	1 (1.4%)
Nervous System	TOTAL	3 (7.1%)	3 (10.0%)	6 (8.3%)
	EMOTIONAL LABILITY	3 (7.1%)	1 (3.3%)	4 (5.6%)
	AGITATION	1 (2.4%)	0	1 (1.4%)
	LACK OF EMOTION	1 (2.4%)	0	1 (1.4%)
	ANXIETY	0	1 (3.3%)	1 (1.4%)
	HALLUCINATIONS	0	1 (3.3%)	1 (1.4%)
Digestive System	TOTAL	0	1 (3.3%)	1 (1.4%)
	TOOTH CARIES	0	1 (3.3%)	1 (1.4%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	1 (7.1%)	2 (13.3%)	3 (10.3%)
Urogenital System	TOTAL	1 (7.1%)	2 (13.3%)	3 (10.3%)
	DYSMENORRHEA	1 (7.1%)	0	1 (3.4%)
	FEMALE GENITAL DISORDERS	0	1 (6.7%)	1 (3.4%)
	MENSTRUAL DISORDER	0	1 (6.7%)	1 (3.4%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	2 (14.3%)	0	2 (6.9%)
Urogenital System	TOTAL	2 (14.3%)	0	2 (6.9%)
	DYSMENORRHEA	2 (14.3%)	0	2 (6.9%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	16 (66.7%)	16 (57.1%)	32 (61.5%)
Body as a Whole	TOTAL	13 (54.2%)	9 (32.1%)	22 (42.3%)
	HEADACHE	7 (29.2%)	7 (25.0%)	14 (26.9%)
	ALLERGIC REACTION	3 (12.5%)	2 (7.1%)	5 (9.6%)
	INFECTION	3 (12.5%)	1 (3.6%)	4 (7.7%)
	ASTHENIA	2 (8.3%)	2 (7.1%)	4 (7.7%)
	TRAUMA	1 (4.2%)	2 (7.1%)	3 (5.8%)
	ABDOMINAL PAIN	2 (8.3%)	0	2 (3.8%)
	ABNORMAL LABORATORY VALUE	1 (4.2%)	0	1 (1.9%)
	PAIN	1 (4.2%)	0	1 (1.9%)
	FEVER	0	1 (3.6%)	1 (1.9%)
Nervous System	TOTAL	5 (20.8%)	4 (14.3%)	9 (17.3%)
	INSOMNIA	2 (8.3%)	1 (3.6%)	3 (5.8%)
	NEUROSIS	2 (8.3%)	1 (3.6%)	3 (5.8%)
	ABNORMAL DREAMS	1 (4.2%)	0	1 (1.9%)
	DIZZINESS	1 (4.2%)	0	1 (1.9%)
	EMOTIONAL LABILITY	1 (4.2%)	0	1 (1.9%)
	AGITATION	0	1 (3.6%)	1 (1.9%)
	HOSTILITY	0	1 (3.6%)	1 (1.9%)
	HYPERKINESIA	0	1 (3.6%)	1 (1.9%)
	NERVOUSNESS	0	1 (3.6%)	1 (1.9%)
	SOMNOLENCE	0	1 (3.6%)	1 (1.9%)
	TREMOR	0	1 (3.6%)	1 (1.9%)
Respiratory System	TOTAL	5 (20.8%)	4 (14.3%)	9 (17.3%)
	RESPIRATORY DISORDER	2 (8.3%)	2 (7.1%)	4 (7.7%)
	SINUSITIS	2 (8.3%)	0	2 (3.8%)
	RHINITIS	1 (4.2%)	1 (3.6%)	2 (3.8%)
	PHARYNGITIS	1 (4.2%)	0	1 (1.9%)
	PLEURA DISORDER	1 (4.2%)	0	1 (1.9%)
	ASTHMA	0	1 (3.6%)	1 (1.9%)
	EPISTAXIS	0	1 (3.6%)	1 (1.9%)
Urogenital System	TOTAL	4 (16.7%)	0	4 (7.7%)
	ALBUMINURIA	3 (12.5%)	0	3 (5.8%)
	DYSURIA	1 (4.2%)	0	1 (1.9%)
	HAEMATURIA	1 (4.2%)	0	1 (1.9%)
Musculoskeletal System	TOTAL	2 (8.3%)	1 (3.6%)	3 (5.8%)
	ARTHRALGIA	1 (4.2%)	1 (3.6%)	2 (3.8%)
	ARTHROSIS	1 (4.2%)	0	1 (1.9%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
Special Senses	TOTAL	2 (8.3%)	2 (7.1%)	4 (7.7%)
	BLEPHARITIS	1 (4.2%)	0	1 (1.9%)
	EYE PAIN	1 (4.2%)	0	1 (1.9%)
	ABNORMAL VISION	0	1 (3.6%)	1 (1.9%)
	PHOTOPHOBIA	0	1 (3.6%)	1 (1.9%)
Digestive System	TOTAL	1 (4.2%)	6 (21.4%)	7 (13.5%)
	NAUSEA	1 (4.2%)	3 (10.7%)	4 (7.7%)
	DECREASED APPETITE	0	2 (7.1%)	2 (3.8%)
	DRY MOUTH	0	2 (7.1%)	2 (3.8%)
	CONSTIPATION	0	1 (3.6%)	1 (1.9%)
	FLATULENCE	0	1 (3.6%)	1 (1.9%)
	ULCERATIVE STOMATITIS	0	1 (3.6%)	1 (1.9%)
Metabolic and Nutritional Disorders	TOTAL	1 (4.2%)	0	1 (1.9%)
	WEIGHT GAIN	1 (4.2%)	0	1 (1.9%)
Cardiovascular System	TOTAL	0	1 (3.6%)	1 (1.9%)
	VASODILATATION	0	1 (3.6%)	1 (1.9%)
Hemic and Lymphatic System	TOTAL	0	1 (3.6%)	1 (1.9%)
	LEUKOCYTOSIS	0	1 (3.6%)	1 (1.9%)
Skin and Appendages	TOTAL	0	4 (14.3%)	4 (7.7%)
	ACNE	0	2 (7.1%)	2 (3.8%)
	CONTACT DERMATITIS	0	1 (3.6%)	1 (1.9%)
	RASH	0	1 (3.6%)	1 (1.9%)
	SWEATING	0	1 (3.6%)	1 (1.9%)
	URTICARIA	0	1 (3.6%)	1 (1.9%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	14 (58.3%)	16 (57.1%)	30 (57.7%)
Body as a Whole	TOTAL	8 (33.3%)	9 (32.1%)	17 (32.7%)
	HEADACHE	4 (16.7%)	4 (14.3%)	8 (15.4%)
	ASTHENIA	2 (8.3%)	2 (7.1%)	4 (7.7%)
	INFECTION	2 (8.3%)	1 (3.6%)	3 (5.8%)
	ABDOMINAL PAIN	1 (4.2%)	2 (7.1%)	3 (5.8%)
	ALLERGIC REACTION	1 (4.2%)	1 (3.6%)	2 (3.8%)
	TRAUMA	0	2 (7.1%)	2 (3.8%)
	BACK PAIN	0	1 (3.6%)	1 (1.9%)
	FEVER	0	1 (3.6%)	1 (1.9%)
Nervous System	TOTAL	6 (25.0%)	8 (28.6%)	14 (26.9%)
	INSOMNIA	1 (4.2%)	3 (10.7%)	4 (7.7%)
	HOSTILITY	1 (4.2%)	2 (7.1%)	3 (5.8%)
	NERVOUSNESS	1 (4.2%)	2 (7.1%)	3 (5.8%)
	ANXIETY	1 (4.2%)	1 (3.6%)	2 (3.8%)
	DIZZINESS	1 (4.2%)	1 (3.6%)	2 (3.8%)
	EMOTIONAL LABILITY	1 (4.2%)	1 (3.6%)	2 (3.8%)
	HYPERKINESIA	1 (4.2%)	1 (3.6%)	2 (3.8%)
	CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.9%)
	MANIC REACTION	1 (4.2%)	0	1 (1.9%)
	VERTIGO	1 (4.2%)	0	1 (1.9%)
	ABNORMAL DREAMS	0	1 (3.6%)	1 (1.9%)
	AGITATION	0	1 (3.6%)	1 (1.9%)
	DEPRESSION	0	1 (3.6%)	1 (1.9%)
Respiratory System	TOTAL	4 (16.7%)	6 (21.4%)	10 (19.2%)
	RESPIRATORY DISORDER	2 (8.3%)	4 (14.3%)	6 (11.5%)
	ASTHMA	1 (4.2%)	2 (7.1%)	3 (5.8%)
	PHARYNGITIS	0	2 (7.1%)	2 (3.8%)
	BRONCHITIS	1 (4.2%)	0	1 (1.9%)
	SINUSITIS	1 (4.2%)	0	1 (1.9%)
	PNEUMONIA	0	1 (3.6%)	1 (1.9%)
Digestive System	TOTAL	3 (12.5%)	5 (17.9%)	8 (15.4%)
	DIARRHEA	1 (4.2%)	1 (3.6%)	2 (3.8%)
	TOOTH DISORDER	1 (4.2%)	1 (3.6%)	2 (3.8%)
	DYSPEPSIA	0	2 (7.1%)	2 (3.8%)
	NAUSEA	0	2 (7.1%)	2 (3.8%)
	CONSTIPATION	1 (4.2%)	0	1 (1.9%)
	DECREASED APPETITE	0	1 (3.6%)	1 (1.9%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	TOTAL	1 (4.2%)	1 (3.6%)	2 (3.8%)
	WEIGHT GAIN	1 (4.2%)	0	1 (1.9%)
	WEIGHT LOSS	0	1 (3.6%)	1 (1.9%)
Musculoskeletal System	TOTAL	1 (4.2%)	0	1 (1.9%)
	ARTHRALGIA	1 (4.2%)	0	1 (1.9%)
Skin and Appendages	TOTAL	1 (4.2%)	0	1 (1.9%)
	ACNE	1 (4.2%)	0	1 (1.9%)
Hemic and Lymphatic System	TOTAL	0	1 (3.6%)	1 (1.9%)
	EOSINOPHILIA	0	1 (3.6%)	1 (1.9%)
	MONOCYTOSIS	0	1 (3.6%)	1 (1.9%)
Special Senses	TOTAL	0	1 (3.6%)	1 (1.9%)
	OTITIS MEDIA	0	1 (3.6%)	1 (1.9%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	2 (8.3%)	2 (7.1%)	4 (7.7%)
Nervous System	TOTAL	2 (8.3%)	1 (3.6%)	3 (5.8%)
	NEUROSIS	1 (4.2%)	0	1 (1.9%)
	SOMNOLENCE	1 (4.2%)	0	1 (1.9%)
	HOSTILITY	0	1 (3.6%)	1 (1.9%)
Body as a Whole	TOTAL	0	1 (3.6%)	1 (1.9%)
	ABDOMINAL PAIN	0	1 (3.6%)	1 (1.9%)
	INFECTION	0	1 (3.6%)	1 (1.9%)
Cardiovascular System	TOTAL	0	1 (3.6%)	1 (1.9%)
	SYNCOPE	0	1 (3.6%)	1 (1.9%)
Digestive System	TOTAL	0	1 (3.6%)	1 (1.9%)
	NAUSEA	0	1 (3.6%)	1 (1.9%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	3 (25.0%)	0	3 (14.3%)
Urogenital System	TOTAL	3 (25.0%)	0	3 (14.3%)
	DYSMENORRHEA	3 (25.0%)	0	3 (14.3%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
TOTAL	TOTAL	42 (63.6%)	34 (58.6%)	76 (61.3%)
Body as a Whole	TOTAL	28 (42.4%)	16 (27.6%)	44 (35.5%)
	HEADACHE	14 (21.2%)	12 (20.7%)	26 (21.0%)
	ALLERGIC REACTION	7 (10.6%)	2 (3.4%)	9 (7.3%)
	ASTHENIA	2 (3.0%)	4 (6.9%)	6 (4.8%)
	TRAUMA	2 (3.0%)	4 (6.9%)	6 (4.8%)
	ABDOMINAL PAIN	5 (7.6%)	0	5 (4.0%)
	INFECTION	3 (4.5%)	2 (3.4%)	5 (4.0%)
	FEVER	3 (4.5%)	1 (1.7%)	4 (3.2%)
	CHEST PAIN	3 (4.5%)	0	3 (2.4%)
	PAIN	1 (1.5%)	1 (1.7%)	2 (1.6%)
	ABNORMAL LABORATORY VALUE	1 (1.5%)	0	1 (0.8%)
	BACK PAIN	1 (1.5%)	0	1 (0.8%)
	MALAISE	1 (1.5%)	0	1 (0.8%)
Nervous System	TOTAL	19 (28.8%)	10 (17.2%)	29 (23.4%)
	INSOMNIA	3 (4.5%)	3 (5.2%)	6 (4.8%)
	DIZZINESS	4 (6.1%)	1 (1.7%)	5 (4.0%)
	SOMNOLENCE	4 (6.1%)	1 (1.7%)	5 (4.0%)
	NERVOUSNESS	3 (4.5%)	1 (1.7%)	4 (3.2%)
	EMOTIONAL LABILITY	2 (3.0%)	1 (1.7%)	3 (2.4%)
	NEUROSIS	2 (3.0%)	1 (1.7%)	3 (2.4%)
	AGITATION	0	2 (3.4%)	2 (1.6%)
	TREMOR	0	2 (3.4%)	2 (1.6%)
	ABNORMAL DREAMS	1 (1.5%)	0	1 (0.8%)
	PARESTHESIA	1 (1.5%)	0	1 (0.8%)
	VERTIGO	1 (1.5%)	0	1 (0.8%)
	CONCENTRATION IMPAIRED	0	1 (1.7%)	1 (0.8%)
	HOSTILITY	0	1 (1.7%)	1 (0.8%)
	HYPERKINESIA	0	1 (1.7%)	1 (0.8%)
	LIBIDO DECREASED	0	1 (1.7%)	1 (0.8%)
Respiratory System	TOTAL	18 (27.3%)	12 (20.7%)	30 (24.2%)
	RESPIRATORY DISORDER	7 (10.6%)	9 (15.5%)	16 (12.9%)
	RHINITIS	4 (6.1%)	2 (3.4%)	6 (4.8%)
	PHARYNGITIS	4 (6.1%)	1 (1.7%)	5 (4.0%)
	SINUSITIS	4 (6.1%)	0	4 (3.2%)
	ASTHMA	1 (1.5%)	3 (5.2%)	4 (3.2%)
	COUGH INCREASED	1 (1.5%)	1 (1.7%)	2 (1.6%)
	DYSPNEA	1 (1.5%)	0	1 (0.8%)
	PLEURA DISORDER	1 (1.5%)	0	1 (0.8%)
	EPISTAXIS	0	1 (1.7%)	1 (0.8%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
Digestive System	TOTAL	11 (16.7%)	12 (20.7%)	23 (18.5%)
	NAUSEA	6 (9.1%)	5 (8.6%)	11 (8.9%)
	DECREASED APPETITE	1 (1.5%)	4 (6.9%)	5 (4.0%)
	VOMITING	3 (4.5%)	0	3 (2.4%)
	DIARRHEA	2 (3.0%)	1 (1.7%)	3 (2.4%)
	DYSPEPSIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
	DRY MOUTH	1 (1.5%)	2 (3.4%)	3 (2.4%)
	INCREASED APPETITE	0	2 (3.4%)	2 (1.6%)
	GASTRITIS	1 (1.5%)	0	1 (0.8%)
	TOOTH CARIES	1 (1.5%)	0	1 (0.8%)
	CONSTIPATION	0	1 (1.7%)	1 (0.8%)
	FLATULENCE	0	1 (1.7%)	1 (0.8%)
	GASTROINTESTINAL DISORDER	0	1 (1.7%)	1 (0.8%)
	ULCERATIVE STOMATITIS	0	1 (1.7%)	1 (0.8%)
Urogenital System	TOTAL	7 (10.6%)	1 (1.7%)	8 (6.5%)
	ALBUMINURIA	6 (9.1%)	1 (1.7%)	7 (5.6%)
	HAEMATURIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
	DYSURIA	1 (1.5%)	0	1 (0.8%)
Skin and Appendages	TOTAL	3 (4.5%)	5 (8.6%)	8 (6.5%)
	CONTACT DERMATITIS	1 (1.5%)	1 (1.7%)	2 (1.6%)
	PRURITUS	1 (1.5%)	1 (1.7%)	2 (1.6%)
	ACNE	0	2 (3.4%)	2 (1.6%)
	FUNGAL DERMATITIS	1 (1.5%)	0	1 (0.8%)
	RASH	0	1 (1.7%)	1 (0.8%)
	SWEATING	0	1 (1.7%)	1 (0.8%)
	URTICARIA	0	1 (1.7%)	1 (0.8%)
Special Senses	TOTAL	3 (4.5%)	2 (3.4%)	5 (4.0%)
	BLEPHARITIS	1 (1.5%)	0	1 (0.8%)
	EYE PAIN	1 (1.5%)	0	1 (0.8%)
	OTITIS MEDIA	1 (1.5%)	0	1 (0.8%)
	ABNORMAL VISION	0	1 (1.7%)	1 (0.8%)
	PHOTOPHOBIA	0	1 (1.7%)	1 (0.8%)
Hemic and Lymphatic System	TOTAL	2 (3.0%)	1 (1.7%)	3 (2.4%)
	LEUKOPENIA	1 (1.5%)	0	1 (0.8%)
	LYMPHADENOPATHY	1 (1.5%)	0	1 (0.8%)
	LEUKOCYTOSIS	0	1 (1.7%)	1 (0.8%)
Musculoskeletal System	TOTAL	2 (3.0%)	1 (1.7%)	3 (2.4%)
	ARTHRALGIA	1 (1.5%)	1 (1.7%)	2 (1.6%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
Musculoskeletal System	ARTHROSIS	1 (1.5%)	0	1 (0.8%)
Metabolic and Nutritional Disorders	TOTAL	1 (1.5%)	3 (5.2%)	4 (3.2%)
	WEIGHT GAIN	1 (1.5%)	3 (5.2%)	4 (3.2%)
Cardiovascular System	TOTAL	0	2 (3.4%)	2 (1.6%)
	SYNCOPE	0	1 (1.7%)	1 (0.8%)
	VASODILATATION	0	1 (1.7%)	1 (0.8%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
TOTAL	TOTAL	41 (62.1%)	25 (43.1%)	66 (53.2%)
Body as a Whole	TOTAL	23 (34.8%)	13 (22.4%)	36 (29.0%)
	HEADACHE	10 (15.2%)	5 (8.6%)	15 (12.1%)
	TRAUMA	5 (7.6%)	3 (5.2%)	8 (6.5%)
	INFECTION	4 (6.1%)	2 (3.4%)	6 (4.8%)
	ASTHENIA	3 (4.5%)	3 (5.2%)	6 (4.8%)
	ABDOMINAL PAIN	2 (3.0%)	3 (5.2%)	5 (4.0%)
	BACK PAIN	2 (3.0%)	1 (1.7%)	3 (2.4%)
	ALLERGIC REACTION	1 (1.5%)	1 (1.7%)	2 (1.6%)
	FEVER	0	2 (3.4%)	2 (1.6%)
	CHEST PAIN	1 (1.5%)	0	1 (0.8%)
Respiratory System	TOTAL	13 (19.7%)	9 (15.5%)	22 (17.7%)
	RESPIRATORY DISORDER	6 (9.1%)	5 (8.6%)	11 (8.9%)
	ASTHMA	3 (4.5%)	2 (3.4%)	5 (4.0%)
	BRONCHITIS	3 (4.5%)	2 (3.4%)	5 (4.0%)
	PHARYNGITIS	1 (1.5%)	2 (3.4%)	3 (2.4%)
	SINUSITIS	2 (3.0%)	0	2 (1.6%)
	PNEUMONIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
	RHINITIS	1 (1.5%)	0	1 (0.8%)
Nervous System	TOTAL	12 (18.2%)	13 (22.4%)	25 (20.2%)
	EMOTIONAL LABILITY	3 (4.5%)	3 (5.2%)	6 (4.8%)
	INSOMNIA	3 (4.5%)	3 (5.2%)	6 (4.8%)
	HOSTILITY	1 (1.5%)	3 (5.2%)	4 (3.2%)
	NERVOUSNESS	1 (1.5%)	3 (5.2%)	4 (3.2%)
	ANXIETY	2 (3.0%)	1 (1.7%)	3 (2.4%)
	AGITATION	1 (1.5%)	2 (3.4%)	3 (2.4%)
	SOMNOLENCE	1 (1.5%)	2 (3.4%)	3 (2.4%)
	DEPRESSION	1 (1.5%)	1 (1.7%)	2 (1.6%)
	DIZZINESS	1 (1.5%)	1 (1.7%)	2 (1.6%)
	HYPERKINESIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
	CONCENTRATION IMPAIRED	1 (1.5%)	0	1 (0.8%)
	MANIC REACTION	1 (1.5%)	0	1 (0.8%)
	VERTIGO	1 (1.5%)	0	1 (0.8%)
	ABNORMAL DREAMS	0	1 (1.7%)	1 (0.8%)
	WITHDRAWAL SYNDROME	0	1 (1.7%)	1 (0.8%)
Digestive System	TOTAL	7 (10.6%)	6 (10.3%)	13 (10.5%)
	NAUSEA	2 (3.0%)	2 (3.4%)	4 (3.2%)
	DYSPEPSIA	1 (1.5%)	3 (5.2%)	4 (3.2%)
	DIARRHEA	2 (3.0%)	1 (1.7%)	3 (2.4%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
Digestive System	VOMITING	2 (3.0%)	0	2 (1.6%)
	TOOTH DISORDER	1 (1.5%)	1 (1.7%)	2 (1.6%)
	CONSTIPATION	1 (1.5%)	0	1 (0.8%)
	HEMATEMESIS	1 (1.5%)	0	1 (0.8%)
	DECREASED APPETITE	0	1 (1.7%)	1 (0.8%)
Skin and Appendages	TOTAL	4 (6.1%)	1 (1.7%)	5 (4.0%)
	ACNE	2 (3.0%)	1 (1.7%)	3 (2.4%)
	CONTACT DERMATITIS	1 (1.5%)	0	1 (0.8%)
	FURUNCULOSIS	1 (1.5%)	0	1 (0.8%)
Metabolic and Nutritional Disorders	TOTAL	3 (4.5%)	1 (1.7%)	4 (3.2%)
	WEIGHT GAIN	2 (3.0%)	0	2 (1.6%)
	WEIGHT LOSS	1 (1.5%)	1 (1.7%)	2 (1.6%)
Musculoskeletal System	TOTAL	2 (3.0%)	0	2 (1.6%)
	ARTHRALGIA	1 (1.5%)	0	1 (0.8%)
	MYALGIA	1 (1.5%)	0	1 (0.8%)
Urogenital System	TOTAL	1 (1.5%)	0	1 (0.8%)
	URINARY TRACT INFECTION	1 (1.5%)	0	1 (0.8%)
Hemic and Lymphatic System	TOTAL	0	1 (1.7%)	1 (0.8%)
	EOSINOPHILIA	0	1 (1.7%)	1 (0.8%)
	MONOCYTOSIS	0	1 (1.7%)	1 (0.8%)
Special Senses	TOTAL	0	1 (1.7%)	1 (0.8%)
	OTITIS MEDIA	0	1 (1.7%)	1 (0.8%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
TOTAL	TOTAL	8 (12.1%)	6 (10.3%)	14 (11.3%)
Nervous System	TOTAL	5 (7.6%)	4 (6.9%)	9 (7.3%)
	EMOTIONAL LABILITY	3 (4.5%)	1 (1.7%)	4 (3.2%)
	AGITATION	1 (1.5%)	0	1 (0.8%)
	LACK OF EMOTION	1 (1.5%)	0	1 (0.8%)
	NEUROSIS	1 (1.5%)	0	1 (0.8%)
	SOMNOLENCE	1 (1.5%)	0	1 (0.8%)
	ANXIETY	0	1 (1.7%)	1 (0.8%)
	HALLUCINATIONS	0	1 (1.7%)	1 (0.8%)
	HOSTILITY	0	1 (1.7%)	1 (0.8%)
Body as a Whole	TOTAL	3 (4.5%)	1 (1.7%)	4 (3.2%)
	INFECTION	1 (1.5%)	1 (1.7%)	2 (1.6%)
	BACK PAIN	1 (1.5%)	0	1 (0.8%)
	TRAUMA	1 (1.5%)	0	1 (0.8%)
	ABDOMINAL PAIN	0	1 (1.7%)	1 (0.8%)
Cardiovascular System	TOTAL	0	1 (1.7%)	1 (0.8%)
	SYNCOPE	0	1 (1.7%)	1 (0.8%)
Digestive System	TOTAL	0	2 (3.4%)	2 (1.6%)
	NAUSEA	0	1 (1.7%)	1 (0.8%)
	TOOTH CARIES	0	1 (1.7%)	1 (0.8%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	1 (3.8%)	2 (8.3%)	3 (6.0%)
Urogenital System	TOTAL	1 (3.8%)	2 (8.3%)	3 (6.0%)
	DYSMENORRHEA	1 (3.8%)	0	1 (2.0%)
	FEMALE GENITAL DISORDERS	0	1 (4.2%)	1 (2.0%)
	MENSTRUAL DISORDER	0	1 (4.2%)	1 (2.0%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	5 (19.2%)	0	5 (10.0%)
Urogenital System	TOTAL	5 (19.2%)	0	5 (10.0%)
	DYSMENORRHEA	5 (19.2%)	0	5 (10.0%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	53 (65.4%)	40 (60.6%)	93 (63.3%)
Body as a Whole	TOTAL	30 (37.0%)	20 (30.3%)	50 (34.0%)
	HEADACHE	15 (18.5%)	8 (12.1%)	23 (15.6%)
	TRAUMA	8 (9.9%)	3 (4.5%)	11 (7.5%)
	ABDOMINAL PAIN	7 (8.6%)	2 (3.0%)	9 (6.1%)
	INFECTION	1 (1.2%)	6 (9.1%)	7 (4.8%)
	ALLERGIC REACTION	5 (6.2%)	1 (1.5%)	6 (4.1%)
	FEVER	4 (4.9%)	2 (3.0%)	6 (4.1%)
	ASTHENIA	1 (1.2%)	4 (6.1%)	5 (3.4%)
	BACK PAIN	1 (1.2%)	3 (4.5%)	4 (2.7%)
	CHEST PAIN	3 (3.7%)	0	3 (2.0%)
	PAIN	2 (2.5%)	1 (1.5%)	3 (2.0%)
	FACE EDEMA	1 (1.2%)	0	1 (0.7%)
	MALAISE	1 (1.2%)	0	1 (0.7%)
Respiratory System	TOTAL	29 (35.8%)	19 (28.8%)	48 (32.7%)
	RESPIRATORY DISORDER	10 (12.3%)	10 (15.2%)	20 (13.6%)
	PHARYNGITIS	9 (11.1%)	5 (7.6%)	14 (9.5%)
	RHINITIS	5 (6.2%)	4 (6.1%)	9 (6.1%)
	SINUSITIS	5 (6.2%)	0	5 (3.4%)
	COUGH INCREASED	3 (3.7%)	2 (3.0%)	5 (3.4%)
	ASTHMA	1 (1.2%)	2 (3.0%)	3 (2.0%)
	EPISTAXIS	0	2 (3.0%)	2 (1.4%)
	DYSPNEA	1 (1.2%)	0	1 (0.7%)
	YAWN	0	1 (1.5%)	1 (0.7%)
Nervous System	TOTAL	19 (23.5%)	11 (16.7%)	30 (20.4%)
	INSOMNIA	2 (2.5%)	5 (7.6%)	7 (4.8%)
	DIZZINESS	3 (3.7%)	2 (3.0%)	5 (3.4%)
	NERVOUSNESS	4 (4.9%)	0	4 (2.7%)
	SOMNOLENCE	4 (4.9%)	0	4 (2.7%)
	AGITATION	1 (1.2%)	1 (1.5%)	2 (1.4%)
	DEPRESSION	1 (1.2%)	1 (1.5%)	2 (1.4%)
	EMOTIONAL LABILITY	1 (1.2%)	1 (1.5%)	2 (1.4%)
	HYPERKINESIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	HALLUCINATIONS	1 (1.2%)	0	1 (0.7%)
	NEUROSIS	1 (1.2%)	0	1 (0.7%)
	PARESTHESIA	1 (1.2%)	0	1 (0.7%)
	VERTIGO	1 (1.2%)	0	1 (0.7%)
	ANXIETY	0	1 (1.5%)	1 (0.7%)
	CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.7%)
	HYPESTHESIA	0	1 (1.5%)	1 (0.7%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Nervous System	LIBIDO DECREASED	0	1 (1.5%)	1 (0.7%)
	TREMOR	0	1 (1.5%)	1 (0.7%)
Digestive System	TOTAL	18 (22.2%)	15 (22.7%)	33 (22.4%)
	DYSPEPSIA	6 (7.4%)	4 (6.1%)	10 (6.8%)
	NAUSEA	6 (7.4%)	3 (4.5%)	9 (6.1%)
	VOMITING	3 (3.7%)	2 (3.0%)	5 (3.4%)
	DECREASED APPETITE	2 (2.5%)	3 (4.5%)	5 (3.4%)
	DIARRHEA	2 (2.5%)	2 (3.0%)	4 (2.7%)
	DRY MOUTH	3 (3.7%)	0	3 (2.0%)
	INCREASED APPETITE	1 (1.2%)	2 (3.0%)	3 (2.0%)
	TOOTH CARIES	1 (1.2%)	1 (1.5%)	2 (1.4%)
	GASTRITIS	1 (1.2%)	0	1 (0.7%)
	GASTROENTERITIS	0	1 (1.5%)	1 (0.7%)
	GASTROINTESTINAL DISORDER	0	1 (1.5%)	1 (0.7%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.7%)
Skin and Appendages	TOTAL	7 (8.6%)	3 (4.5%)	10 (6.8%)
	PRURITUS	1 (1.2%)	2 (3.0%)	3 (2.0%)
	ACNE	2 (2.5%)	0	2 (1.4%)
	CONTACT DERMATITIS	2 (2.5%)	0	2 (1.4%)
	RASH	1 (1.2%)	1 (1.5%)	2 (1.4%)
	FUNGAL DERMATITIS	1 (1.2%)	0	1 (0.7%)
	MACULOPAPULAR RASH	0	1 (1.5%)	1 (0.7%)
Urogenital System	TOTAL	5 (6.2%)	4 (6.1%)	9 (6.1%)
	ALBUMINURIA	3 (3.7%)	2 (3.0%)	5 (3.4%)
	HAEMATURIA	1 (1.2%)	2 (3.0%)	3 (2.0%)
	URINARY INCONTINENCE	1 (1.2%)	1 (1.5%)	2 (1.4%)
	PYURIA	1 (1.2%)	0	1 (0.7%)
	CYSTITIS	0	1 (1.5%)	1 (0.7%)
Hemic and Lymphatic System	TOTAL	3 (3.7%)	1 (1.5%)	4 (2.7%)
	LEUKOPENIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
	LYMPHADENOPATHY	1 (1.2%)	0	1 (0.7%)
	ANEMIA	0	1 (1.5%)	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	2 (2.5%)	5 (7.6%)	7 (4.8%)
	WEIGHT GAIN	2 (2.5%)	5 (7.6%)	7 (4.8%)
Musculoskeletal System	TOTAL	2 (2.5%)	0	2 (1.4%)
	ARTHRALGIA	2 (2.5%)	0	2 (1.4%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
Special Senses	TOTAL	2 (2.5%)	1 (1.5%)	3 (2.0%)
	OTITIS MEDIA	2 (2.5%)	0	2 (1.4%)
	ABNORMAL VISION	0	1 (1.5%)	1 (0.7%)
Cardiovascular System	TOTAL	0	2 (3.0%)	2 (1.4%)
	BUNDLE BRANCH BLOCK	0	1 (1.5%)	1 (0.7%)
	SYNCOPE	0	1 (1.5%)	1 (0.7%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	54 (66.7%)	28 (42.4%)	82 (55.8%)
Body as a Whole	TOTAL	30 (37.0%)	14 (21.2%)	44 (29.9%)
	TRAUMA	10 (12.3%)	3 (4.5%)	13 (8.8%)
	INFECTION	6 (7.4%)	6 (9.1%)	12 (8.2%)
	HEADACHE	9 (11.1%)	2 (3.0%)	11 (7.5%)
	ABDOMINAL PAIN	5 (6.2%)	2 (3.0%)	7 (4.8%)
	FEVER	4 (4.9%)	2 (3.0%)	6 (4.1%)
	ALLERGIC REACTION	2 (2.5%)	1 (1.5%)	3 (2.0%)
	ASTHENIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
	BACK PAIN	2 (2.5%)	0	2 (1.4%)
	PAIN	1 (1.2%)	1 (1.5%)	2 (1.4%)
	CHEST PAIN	1 (1.2%)	0	1 (0.7%)
	FACE EDEMA	1 (1.2%)	0	1 (0.7%)
Respiratory System	TOTAL	18 (22.2%)	10 (15.2%)	28 (19.0%)
	RESPIRATORY DISORDER	9 (11.1%)	5 (7.6%)	14 (9.5%)
	BRONCHITIS	2 (2.5%)	3 (4.5%)	5 (3.4%)
	PHARYNGITIS	3 (3.7%)	0	3 (2.0%)
	RHINITIS	3 (3.7%)	0	3 (2.0%)
	SINUSITIS	2 (2.5%)	1 (1.5%)	3 (2.0%)
	ASTHMA	2 (2.5%)	0	2 (1.4%)
	PNEUMONIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	COUGH INCREASED	1 (1.2%)	0	1 (0.7%)
Nervous System	TOTAL	16 (19.8%)	12 (18.2%)	28 (19.0%)
	NERVOUSNESS	4 (4.9%)	1 (1.5%)	5 (3.4%)
	AGITATION	2 (2.5%)	3 (4.5%)	5 (3.4%)
	HOSTILITY	3 (3.7%)	1 (1.5%)	4 (2.7%)
	EMOTIONAL LABILITY	2 (2.5%)	2 (3.0%)	4 (2.7%)
	SOMNOLENCE	1 (1.2%)	3 (4.5%)	4 (2.7%)
	INSOMNIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
	DEPRESSION	2 (2.5%)	0	2 (1.4%)
	ANXIETY	1 (1.2%)	0	1 (0.7%)
	CONVULSION	1 (1.2%)	0	1 (0.7%)
	HYPERKINESIA	1 (1.2%)	0	1 (0.7%)
	VESTIBULAR DISORDER	1 (1.2%)	0	1 (0.7%)
	CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.7%)
	HALLUCINATIONS	0	1 (1.5%)	1 (0.7%)
	HYPESTHESIA	0	1 (1.5%)	1 (0.7%)
	TREMOR	0	1 (1.5%)	1 (0.7%)
	WITHDRAWAL SYNDROME	0	1 (1.5%)	1 (0.7%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
Digestive System	TOTAL	13 (16.0%)	5 (7.6%)	18 (12.2%)
	VOMITING	9 (11.1%)	2 (3.0%)	11 (7.5%)
	DIARRHEA	3 (3.7%)	0	3 (2.0%)
	NAUSEA	2 (2.5%)	1 (1.5%)	3 (2.0%)
	DYSPEPSIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	CONSTIPATION	1 (1.2%)	0	1 (0.7%)
	HEMATEMESIS	1 (1.2%)	0	1 (0.7%)
	STOMATITIS	1 (1.2%)	0	1 (0.7%)
	TOOTH CARIES	0	1 (1.5%)	1 (0.7%)
Skin and Appendages	TOTAL	6 (7.4%)	2 (3.0%)	8 (5.4%)
	ACNE	2 (2.5%)	1 (1.5%)	3 (2.0%)
	CONTACT DERMATITIS	2 (2.5%)	1 (1.5%)	3 (2.0%)
	FURUNCULOSIS	1 (1.2%)	0	1 (0.7%)
	HERPES ZOSTER	1 (1.2%)	0	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	5 (6.2%)	2 (3.0%)	7 (4.8%)
	WEIGHT GAIN	3 (3.7%)	1 (1.5%)	4 (2.7%)
	DEHYDRATION	1 (1.2%)	1 (1.5%)	2 (1.4%)
	WEIGHT LOSS	1 (1.2%)	0	1 (0.7%)
Musculoskeletal System	TOTAL	2 (2.5%)	1 (1.5%)	3 (2.0%)
	MYALGIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	TENDINOUS DISORDER	1 (1.2%)	0	1 (0.7%)
	ARTHROSIS	0	1 (1.5%)	1 (0.7%)
Special Senses	TOTAL	2 (2.5%)	0	2 (1.4%)
	OTITIS MEDIA	2 (2.5%)	0	2 (1.4%)
Urogenital System	TOTAL	2 (2.5%)	0	2 (1.4%)
	URINARY INCONTINENCE	1 (1.2%)	0	1 (0.7%)
	URINARY TRACT INFECTION	1 (1.2%)	0	1 (0.7%)
Cardiovascular System	TOTAL	0	2 (3.0%)	2 (1.4%)
	MIGRAINE	0	1 (1.5%)	1 (0.7%)
	SYNCOPE	0	1 (1.5%)	1 (0.7%)
Hemic and Lymphatic System	TOTAL	0	1 (1.5%)	1 (0.7%)
	LEUKOPENIA	0	1 (1.5%)	1 (0.7%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	9 (11.1%)	11 (16.7%)	20 (13.6%)
Nervous System	TOTAL	6 (7.4%)	6 (9.1%)	12 (8.2%)
	EMOTIONAL LABILITY	4 (4.9%)	1 (1.5%)	5 (3.4%)
	HOSTILITY	2 (2.5%)	1 (1.5%)	3 (2.0%)
	AGITATION	1 (1.2%)	1 (1.5%)	2 (1.4%)
	DEPRESSION	1 (1.2%)	0	1 (0.7%)
	LACK OF EMOTION	1 (1.2%)	0	1 (0.7%)
	ANXIETY	0	1 (1.5%)	1 (0.7%)
	EUPHORIA	0	1 (1.5%)	1 (0.7%)
	HALLUCINATIONS	0	1 (1.5%)	1 (0.7%)
	PARALYSIS	0	1 (1.5%)	1 (0.7%)
Body as a Whole	TOTAL	3 (3.7%)	1 (1.5%)	4 (2.7%)
	TRAUMA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	BACK PAIN	1 (1.2%)	0	1 (0.7%)
	INFECTION	1 (1.2%)	0	1 (0.7%)
Cardiovascular System	TOTAL	0	1 (1.5%)	1 (0.7%)
	MIGRAINE	0	1 (1.5%)	1 (0.7%)
Digestive System	TOTAL	0	1 (1.5%)	1 (0.7%)
	TOOTH CARIES	0	1 (1.5%)	1 (0.7%)
Respiratory System	TOTAL	0	1 (1.5%)	1 (0.7%)
	ASTHMA	0	1 (1.5%)	1 (0.7%)
Skin and Appendages	TOTAL	0	1 (1.5%)	1 (0.7%)
	RASH	0	1 (1.5%)	1 (0.7%)
Special Senses	TOTAL	0	1 (1.5%)	1 (0.7%)
	OTITIS MEDIA	0	1 (1.5%)	1 (0.7%)
Urogenital System	TOTAL	0	1 (1.5%)	1 (0.7%)
	URINARY INCONTINENCE	0	1 (1.5%)	1 (0.7%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	1 (3.0%)	2 (6.9%)	3 (4.8%)
Urogenital System	TOTAL	1 (3.0%)	2 (6.9%)	3 (4.8%)
	DYSMENORRHEA	1 (3.0%)	0	1 (1.6%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.6%)
	MENSTRUAL DISORDER	0	1 (3.4%)	1 (1.6%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	2 (6.1%)	0	2 (3.2%)
Urogenital System	TOTAL	2 (6.1%)	0	2 (3.2%)
	DYSMENORRHEA	2 (6.1%)	0	2 (3.2%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	35 (67.3%)	39 (60.9%)	74 (63.8%)
Body as a Whole	TOTAL	22 (42.3%)	23 (35.9%)	45 (38.8%)
	HEADACHE	13 (25.0%)	13 (20.3%)	26 (22.4%)
	ABDOMINAL PAIN	3 (5.8%)	5 (7.8%)	8 (6.9%)
	TRAUMA	3 (5.8%)	5 (7.8%)	8 (6.9%)
	ALLERGIC REACTION	3 (5.8%)	3 (4.7%)	6 (5.2%)
	INFECTION	3 (5.8%)	2 (3.1%)	5 (4.3%)
	PAIN	3 (5.8%)	1 (1.6%)	4 (3.4%)
	ASTHENIA	2 (3.8%)	2 (3.1%)	4 (3.4%)
	FEVER	2 (3.8%)	2 (3.1%)	4 (3.4%)
	ABNORMAL LABORATORY VALUE	1 (1.9%)	0	1 (0.9%)
	BACK PAIN	1 (1.9%)	0	1 (0.9%)
	SPINA BIFIDA	0	1 (1.6%)	1 (0.9%)
Respiratory System	TOTAL	12 (23.1%)	13 (20.3%)	25 (21.6%)
	RESPIRATORY DISORDER	3 (5.8%)	8 (12.5%)	11 (9.5%)
	RHINITIS	5 (9.6%)	5 (7.8%)	10 (8.6%)
	PHARYNGITIS	4 (7.7%)	3 (4.7%)	7 (6.0%)
	SINUSITIS	3 (5.8%)	1 (1.6%)	4 (3.4%)
	COUGH INCREASED	2 (3.8%)	0	2 (1.7%)
	ASTHMA	1 (1.9%)	1 (1.6%)	2 (1.7%)
	PLEURA DISORDER	1 (1.9%)	0	1 (0.9%)
	EPISTAXIS	0	1 (1.6%)	1 (0.9%)
Nervous System	TOTAL	10 (19.2%)	17 (26.6%)	27 (23.3%)
	INSOMNIA	5 (9.6%)	3 (4.7%)	8 (6.9%)
	NERVOUSNESS	1 (1.9%)	6 (9.4%)	7 (6.0%)
	HYPERKINESIA	3 (5.8%)	1 (1.6%)	4 (3.4%)
	DIZZINESS	2 (3.8%)	1 (1.6%)	3 (2.6%)
	NEUROSIS	2 (3.8%)	1 (1.6%)	3 (2.6%)
	AGITATION	1 (1.9%)	2 (3.1%)	3 (2.6%)
	HOSTILITY	1 (1.9%)	2 (3.1%)	3 (2.6%)
	MYOCLONUS	1 (1.9%)	1 (1.6%)	2 (1.7%)
	SOMNOLENCE	0	2 (3.1%)	2 (1.7%)
	TREMOR	0	2 (3.1%)	2 (1.7%)
	VERTIGO	0	2 (3.1%)	2 (1.7%)
	ABNORMAL DREAMS	1 (1.9%)	0	1 (0.9%)
	ANXIETY	1 (1.9%)	0	1 (0.9%)
	CONCENTRATION IMPAIRED	1 (1.9%)	0	1 (0.9%)
	EMOTIONAL LABILITY	1 (1.9%)	0	1 (0.9%)
	DYSKINESIA	0	1 (1.6%)	1 (0.9%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
Digestive System	TOTAL	9 (17.3%)	11 (17.2%)	20 (17.2%)
	NAUSEA	6 (11.5%)	3 (4.7%)	9 (7.8%)
	DECREASED APPETITE	2 (3.8%)	4 (6.3%)	6 (5.2%)
	DIARRHEA	3 (5.8%)	0	3 (2.6%)
	DYSPEPSIA	2 (3.8%)	0	2 (1.7%)
	DRY MOUTH	0	2 (3.1%)	2 (1.7%)
	FLATULENCE	0	2 (3.1%)	2 (1.7%)
	VOMITING	1 (1.9%)	0	1 (0.9%)
	CONSTIPATION	0	1 (1.6%)	1 (0.9%)
	GASTROENTERITIS	0	1 (1.6%)	1 (0.9%)
	TOOTH CARIES	0	1 (1.6%)	1 (0.9%)
	ULCERATIVE STOMATITIS	0	1 (1.6%)	1 (0.9%)
Urogenital System	TOTAL	6 (11.5%)	1 (1.6%)	7 (6.0%)
	ALBUMINURIA	5 (9.6%)	0	5 (4.3%)
	DYSURIA	1 (1.9%)	0	1 (0.9%)
	GLYCOSURIA	1 (1.9%)	0	1 (0.9%)
	HAEMATURIA	1 (1.9%)	0	1 (0.9%)
	URINARY INCONTINENCE	0	1 (1.6%)	1 (0.9%)
Musculoskeletal System	TOTAL	3 (5.8%)	1 (1.6%)	4 (3.4%)
	ARTHRALGIA	1 (1.9%)	1 (1.6%)	2 (1.7%)
	ARTHROSIS	1 (1.9%)	0	1 (0.9%)
	MYALGIA	1 (1.9%)	0	1 (0.9%)
Special Senses	TOTAL	3 (5.8%)	5 (7.8%)	8 (6.9%)
	OTITIS EXTERNA	1 (1.9%)	1 (1.6%)	2 (1.7%)
	BLEPHARITIS	1 (1.9%)	0	1 (0.9%)
	EYE PAIN	1 (1.9%)	0	1 (0.9%)
	ABNORMAL VISION	0	1 (1.6%)	1 (0.9%)
	EAR PAIN	0	1 (1.6%)	1 (0.9%)
	OTITIS MEDIA	0	1 (1.6%)	1 (0.9%)
	PHOTOPHOBIA	0	1 (1.6%)	1 (0.9%)
Cardiovascular System	TOTAL	1 (1.9%)	4 (6.3%)	5 (4.3%)
	VASODILATATION	0	4 (6.3%)	4 (3.4%)
	HAEMATOMA	1 (1.9%)	0	1 (0.9%)
Hemic and Lymphatic System	TOTAL	1 (1.9%)	1 (1.6%)	2 (1.7%)
	ANEMIA	1 (1.9%)	0	1 (0.9%)
	LEUKOCYTOSIS	0	1 (1.6%)	1 (0.9%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	TOTAL	1 (1.9%)	1 (1.6%)	2 (1.7%)
	WEIGHT GAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
Skin and Appendages	TOTAL	1 (1.9%)	6 (9.4%)	7 (6.0%)
	RASH	0	3 (4.7%)	3 (2.6%)
	ACNE	0	2 (3.1%)	2 (1.7%)
	CONTACT DERMATITIS	0	2 (3.1%)	2 (1.7%)
	MACULOPAPULAR RASH	1 (1.9%)	0	1 (0.9%)
	HERPES SIMPLEX	0	1 (1.6%)	1 (0.9%)
	SWEATING	0	1 (1.6%)	1 (0.9%)
	URTICARIA	0	1 (1.6%)	1 (0.9%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	29 (55.8%)	39 (60.9%)	68 (58.6%)
Body as a Whole	TOTAL	17 (32.7%)	16 (25.0%)	33 (28.4%)
	HEADACHE	9 (17.3%)	6 (9.4%)	15 (12.9%)
	INFECTION	4 (7.7%)	4 (6.3%)	8 (6.9%)
	TRAUMA	3 (5.8%)	2 (3.1%)	5 (4.3%)
	ABDOMINAL PAIN	2 (3.8%)	3 (4.7%)	5 (4.3%)
	ASTHENIA	2 (3.8%)	2 (3.1%)	4 (3.4%)
	ALLERGIC REACTION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	FEVER	1 (1.9%)	1 (1.6%)	2 (1.7%)
	PAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
	BACK PAIN	0	1 (1.6%)	1 (0.9%)
Nervous System	TOTAL	11 (21.2%)	24 (37.5%)	35 (30.2%)
	NERVOUSNESS	1 (1.9%)	8 (12.5%)	9 (7.8%)
	HYPERKINESIA	4 (7.7%)	4 (6.3%)	8 (6.9%)
	HOSTILITY	1 (1.9%)	5 (7.8%)	6 (5.2%)
	ANXIETY	1 (1.9%)	4 (6.3%)	5 (4.3%)
	INSOMNIA	1 (1.9%)	3 (4.7%)	4 (3.4%)
	EMOTIONAL LABILITY	2 (3.8%)	1 (1.6%)	3 (2.6%)
	DIZZINESS	1 (1.9%)	2 (3.1%)	3 (2.6%)
	DEPRESSION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	MANIC REACTION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	SOMNOLENCE	1 (1.9%)	1 (1.6%)	2 (1.7%)
	AGITATION	0	2 (3.1%)	2 (1.7%)
	CONCENTRATION IMPAIRED	1 (1.9%)	0	1 (0.9%)
	VERTIGO	1 (1.9%)	0	1 (0.9%)
	ABNORMAL DREAMS	0	1 (1.6%)	1 (0.9%)
	LACK OF EMOTION	0	1 (1.6%)	1 (0.9%)
	PSYCHOSIS	0	1 (1.6%)	1 (0.9%)
Respiratory System	TOTAL	8 (15.4%)	9 (14.1%)	17 (14.7%)
	RESPIRATORY DISORDER	4 (7.7%)	6 (9.4%)	10 (8.6%)
	PHARYNGITIS	3 (5.8%)	3 (4.7%)	6 (5.2%)
	ASTHMA	1 (1.9%)	2 (3.1%)	3 (2.6%)
	SINUSITIS	2 (3.8%)	0	2 (1.7%)
	COUGH INCREASED	1 (1.9%)	1 (1.6%)	2 (1.7%)
	BRONCHITIS	1 (1.9%)	0	1 (0.9%)
	PNEUMONIA	0	1 (1.6%)	1 (0.9%)
	RHINITIS	0	1 (1.6%)	1 (0.9%)
Digestive System	TOTAL	4 (7.7%)	7 (10.9%)	11 (9.5%)
	TOOTH DISORDER	2 (3.8%)	1 (1.6%)	3 (2.6%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
Digestive System	DYSPEPSIA	0	3 (4.7%)	3 (2.6%)
	NAUSEA	0	3 (4.7%)	3 (2.6%)
	DIARRHEA	1 (1.9%)	1 (1.6%)	2 (1.7%)
	GINGIVITIS	1 (1.9%)	1 (1.6%)	2 (1.7%)
	CONSTIPATION	1 (1.9%)	0	1 (0.9%)
	DECREASED APPETITE	0	1 (1.6%)	1 (0.9%)
Special Senses	TOTAL	4 (7.7%)	2 (3.1%)	6 (5.2%)
	OTITIS MEDIA	3 (5.8%)	2 (3.1%)	5 (4.3%)
	EAR PAIN	1 (1.9%)	0	1 (0.9%)
	OTITIS EXTERNA	1 (1.9%)	0	1 (0.9%)
Skin and Appendages	TOTAL	2 (3.8%)	2 (3.1%)	4 (3.4%)
	ACNE	2 (3.8%)	0	2 (1.7%)
	CONTACT DERMATITIS	0	1 (1.6%)	1 (0.9%)
	FUNGAL DERMATITIS	0	1 (1.6%)	1 (0.9%)
Hemic and Lymphatic System	TOTAL	1 (1.9%)	1 (1.6%)	2 (1.7%)
	PURPURA	1 (1.9%)	0	1 (0.9%)
	EOSINOPHILIA	0	1 (1.6%)	1 (0.9%)
	MONOCYTOSIS	0	1 (1.6%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	1 (1.9%)	2 (3.1%)	3 (2.6%)
	WEIGHT GAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
	WEIGHT LOSS	0	1 (1.6%)	1 (0.9%)
Musculoskeletal System	TOTAL	1 (1.9%)	0	1 (0.9%)
	ARTHRALGIA	1 (1.9%)	0	1 (0.9%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	4 (7.7%)	7 (10.9%)	11 (9.5%)
Body as a Whole	TOTAL	2 (3.8%)	2 (3.1%)	4 (3.4%)
	INFECTION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	ABSCESS	1 (1.9%)	0	1 (0.9%)
	ABDOMINAL PAIN	0	1 (1.6%)	1 (0.9%)
	TRAUMA	0	1 (1.6%)	1 (0.9%)
Nervous System	TOTAL	2 (3.8%)	4 (6.3%)	6 (5.2%)
	HOSTILITY	0	2 (3.1%)	2 (1.7%)
	NEUROSIS	1 (1.9%)	0	1 (0.9%)
	SOMNOLENCE	1 (1.9%)	0	1 (0.9%)
	HYPERKINESIA	0	1 (1.6%)	1 (0.9%)
	NERVOUSNESS	0	1 (1.6%)	1 (0.9%)
Respiratory System	TOTAL	1 (1.9%)	0	1 (0.9%)
	PHARYNGITIS	1 (1.9%)	0	1 (0.9%)
Cardiovascular System	TOTAL	0	1 (1.6%)	1 (0.9%)
	SYNCOPE	0	1 (1.6%)	1 (0.9%)
Digestive System	TOTAL	0	1 (1.6%)	1 (0.9%)
	NAUSEA	0	1 (1.6%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.6%)	1 (0.9%)
	WEIGHT GAIN	0	1 (1.6%)	1 (0.9%)
Urogenital System	TOTAL	0	1 (1.6%)	1 (0.9%)
	URINARY INCONTINENCE	0	1 (1.6%)	1 (0.9%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (4.5%)	1 (2.0%)
Urogenital System	TOTAL	0	1 (4.5%)	1 (2.0%)
	DYSMENORRHEA	0	1 (4.5%)	1 (2.0%)
	UTERUS DISORDERS	0	1 (4.5%)	1 (2.0%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	4 (14.3%)	0	4 (8.0%)
Urogenital System	TOTAL	4 (14.3%)	0	4 (8.0%)
	DYSMENORRHEA	4 (14.3%)	0	4 (8.0%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
TOTAL	TOTAL	88 (66.2%)	79 (60.8%)	167 (63.5%)
Body as a Whole	TOTAL	52 (39.1%)	43 (33.1%)	95 (36.1%)
	HEADACHE	28 (21.1%)	21 (16.2%)	49 (18.6%)
	TRAUMA	11 (8.3%)	8 (6.2%)	19 (7.2%)
	ABDOMINAL PAIN	10 (7.5%)	7 (5.4%)	17 (6.5%)
	ALLERGIC REACTION	8 (6.0%)	4 (3.1%)	12 (4.6%)
	INFECTION	4 (3.0%)	8 (6.2%)	12 (4.6%)
	FEVER	6 (4.5%)	4 (3.1%)	10 (3.8%)
	ASTHENIA	3 (2.3%)	6 (4.6%)	9 (3.4%)
	PAIN	5 (3.8%)	2 (1.5%)	7 (2.7%)
	BACK PAIN	2 (1.5%)	3 (2.3%)	5 (1.9%)
	CHEST PAIN	3 (2.3%)	0	3 (1.1%)
	ABNORMAL LABORATORY VALUE	1 (0.8%)	0	1 (0.4%)
	FACE EDEMA	1 (0.8%)	0	1 (0.4%)
	MALAISE	1 (0.8%)	0	1 (0.4%)
	SPINA BIFIDA	0	1 (0.8%)	1 (0.4%)
Respiratory System	TOTAL	41 (30.8%)	32 (24.6%)	73 (27.8%)
	RESPIRATORY DISORDER	13 (9.8%)	18 (13.8%)	31 (11.8%)
	PHARYNGITIS	13 (9.8%)	8 (6.2%)	21 (8.0%)
	RHINITIS	10 (7.5%)	9 (6.9%)	19 (7.2%)
	SINUSITIS	8 (6.0%)	1 (0.8%)	9 (3.4%)
	COUGH INCREASED	5 (3.8%)	2 (1.5%)	7 (2.7%)
	ASTHMA	2 (1.5%)	3 (2.3%)	5 (1.9%)
	EPISTAXIS	0	3 (2.3%)	3 (1.1%)
	DYSPNEA	1 (0.8%)	0	1 (0.4%)
	PLEURA DISORDER	1 (0.8%)	0	1 (0.4%)
	YAWN	0	1 (0.8%)	1 (0.4%)
Nervous System	TOTAL	29 (21.8%)	28 (21.5%)	57 (21.7%)
	INSOMNIA	7 (5.3%)	8 (6.2%)	15 (5.7%)
	NERVOUSNESS	5 (3.8%)	6 (4.6%)	11 (4.2%)
	DIZZINESS	5 (3.8%)	3 (2.3%)	8 (3.0%)
	HYPERKINESIA	4 (3.0%)	2 (1.5%)	6 (2.3%)
	SOMNOLENCE	4 (3.0%)	2 (1.5%)	6 (2.3%)
	AGITATION	2 (1.5%)	3 (2.3%)	5 (1.9%)
	NEUROSIS	3 (2.3%)	1 (0.8%)	4 (1.5%)
	EMOTIONAL LABILITY	2 (1.5%)	1 (0.8%)	3 (1.1%)
	HOSTILITY	1 (0.8%)	2 (1.5%)	3 (1.1%)
	VERTIGO	1 (0.8%)	2 (1.5%)	3 (1.1%)
	TREMOR	0	3 (2.3%)	3 (1.1%)
	ANXIETY	1 (0.8%)	1 (0.8%)	2 (0.8%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Nervous System	CONCENTRATION IMPAIRED	1 (0.8%)	1 (0.8%)	2 (0.8%)
	DEPRESSION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	MYOCLONUS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	ABNORMAL DREAMS	1 (0.8%)	0	1 (0.4%)
	HALLUCINATIONS	1 (0.8%)	0	1 (0.4%)
	PARESTHESIA	1 (0.8%)	0	1 (0.4%)
	DYSKINESIA	0	1 (0.8%)	1 (0.4%)
	HYPESTHESIA	0	1 (0.8%)	1 (0.4%)
	LIBIDO DECREASED	0	1 (0.8%)	1 (0.4%)
Digestive System	TOTAL	27 (20.3%)	26 (20.0%)	53 (20.2%)
	NAUSEA	12 (9.0%)	6 (4.6%)	18 (6.8%)
	DYSPEPSIA	8 (6.0%)	4 (3.1%)	12 (4.6%)
	DECREASED APPETITE	4 (3.0%)	7 (5.4%)	11 (4.2%)
	DIARRHEA	5 (3.8%)	2 (1.5%)	7 (2.7%)
	VOMITING	4 (3.0%)	2 (1.5%)	6 (2.3%)
	DRY MOUTH	3 (2.3%)	2 (1.5%)	5 (1.9%)
	INCREASED APPETITE	1 (0.8%)	2 (1.5%)	3 (1.1%)
	TOOTH CARIES	1 (0.8%)	2 (1.5%)	3 (1.1%)
	FLATULENCE	0	2 (1.5%)	2 (0.8%)
	GASTROENTERITIS	0	2 (1.5%)	2 (0.8%)
	GASTRITIS	1 (0.8%)	0	1 (0.4%)
	CONSTIPATION	0	1 (0.8%)	1 (0.4%)
	GASTROINTESTINAL DISORDER	0	1 (0.8%)	1 (0.4%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (0.8%)	1 (0.4%)
	ULCERATIVE STOMATITIS	0	1 (0.8%)	1 (0.4%)
Urogenital System	TOTAL	11 (8.3%)	5 (3.8%)	16 (6.1%)
	ALBUMINURIA	8 (6.0%)	2 (1.5%)	10 (3.8%)
	HAEMATURIA	2 (1.5%)	2 (1.5%)	4 (1.5%)
	URINARY INCONTINENCE	1 (0.8%)	2 (1.5%)	3 (1.1%)
	DYSURIA	1 (0.8%)	0	1 (0.4%)
	GLYCOSURIA	1 (0.8%)	0	1 (0.4%)
	PYURIA	1 (0.8%)	0	1 (0.4%)
	CYSTITIS	0	1 (0.8%)	1 (0.4%)
Skin and Appendages	TOTAL	8 (6.0%)	9 (6.9%)	17 (6.5%)
	RASH	1 (0.8%)	4 (3.1%)	5 (1.9%)
	ACNE	2 (1.5%)	2 (1.5%)	4 (1.5%)
	CONTACT DERMATITIS	2 (1.5%)	2 (1.5%)	4 (1.5%)
	PRURITUS	1 (0.8%)	2 (1.5%)	3 (1.1%)
	MACULOPAPULAR RASH	1 (0.8%)	1 (0.8%)	2 (0.8%)
	FUNGAL DERMATITIS	1 (0.8%)	0	1 (0.4%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Skin and Appendages	HERPES SIMPLEX	0	1 (0.8%)	1 (0.4%)
	SWEATING	0	1 (0.8%)	1 (0.4%)
	URTICARIA	0	1 (0.8%)	1 (0.4%)
Musculoskeletal System	TOTAL	5 (3.8%)	1 (0.8%)	6 (2.3%)
	ARTHRALGIA	3 (2.3%)	1 (0.8%)	4 (1.5%)
	ARTHROSIS	1 (0.8%)	0	1 (0.4%)
	MYALGIA	1 (0.8%)	0	1 (0.4%)
Special Senses	TOTAL	5 (3.8%)	6 (4.6%)	11 (4.2%)
	OTITIS MEDIA	2 (1.5%)	1 (0.8%)	3 (1.1%)
	OTITIS EXTERNA	1 (0.8%)	1 (0.8%)	2 (0.8%)
	ABNORMAL VISION	0	2 (1.5%)	2 (0.8%)
	BLEPHARITIS	1 (0.8%)	0	1 (0.4%)
	EYE PAIN	1 (0.8%)	0	1 (0.4%)
	EAR PAIN	0	1 (0.8%)	1 (0.4%)
	PHOTOPHOBIA	0	1 (0.8%)	1 (0.4%)
Hemic and Lymphatic System	TOTAL	4 (3.0%)	2 (1.5%)	6 (2.3%)
	LEUKOPENIA	2 (1.5%)	1 (0.8%)	3 (1.1%)
	ANEMIA	1 (0.8%)	1 (0.8%)	2 (0.8%)
	LYMPHADENOPATHY	1 (0.8%)	0	1 (0.4%)
	LEUKOCYTOSIS	0	1 (0.8%)	1 (0.4%)
Metabolic and Nutritional Disorders	TOTAL	3 (2.3%)	6 (4.6%)	9 (3.4%)
	WEIGHT GAIN	3 (2.3%)	6 (4.6%)	9 (3.4%)
Cardiovascular System	TOTAL	1 (0.8%)	6 (4.6%)	7 (2.7%)
	VASODILATATION	0	4 (3.1%)	4 (1.5%)
	HAEMATOMA	1 (0.8%)	0	1 (0.4%)
	BUNDLE BRANCH BLOCK	0	1 (0.8%)	1 (0.4%)
	SYNCOPE	0	1 (0.8%)	1 (0.4%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
TOTAL	TOTAL	83 (62.4%)	67 (51.5%)	150 (57.0%)
Body as a Whole	TOTAL	47 (35.3%)	30 (23.1%)	77 (29.3%)
	HEADACHE	18 (13.5%)	8 (6.2%)	26 (9.9%)
	INFECTION	10 (7.5%)	10 (7.7%)	20 (7.6%)
	TRAUMA	13 (9.8%)	5 (3.8%)	18 (6.8%)
	ABDOMINAL PAIN	7 (5.3%)	5 (3.8%)	12 (4.6%)
	FEVER	5 (3.8%)	3 (2.3%)	8 (3.0%)
	ASTHENIA	4 (3.0%)	3 (2.3%)	7 (2.7%)
	ALLERGIC REACTION	3 (2.3%)	2 (1.5%)	5 (1.9%)
	PAIN	2 (1.5%)	2 (1.5%)	4 (1.5%)
	BACK PAIN	2 (1.5%)	1 (0.8%)	3 (1.1%)
	CHEST PAIN	1 (0.8%)	0	1 (0.4%)
	FACE EDEMA	1 (0.8%)	0	1 (0.4%)
Nervous System	TOTAL	27 (20.3%)	36 (27.7%)	63 (24.0%)
	NERVOUSNESS	5 (3.8%)	9 (6.9%)	14 (5.3%)
	HOSTILITY	4 (3.0%)	6 (4.6%)	10 (3.8%)
	HYPERKINESIA	5 (3.8%)	4 (3.1%)	9 (3.4%)
	EMOTIONAL LABILITY	4 (3.0%)	3 (2.3%)	7 (2.7%)
	INSOMNIA	3 (2.3%)	4 (3.1%)	7 (2.7%)
	AGITATION	2 (1.5%)	5 (3.8%)	7 (2.7%)
	ANXIETY	2 (1.5%)	4 (3.1%)	6 (2.3%)
	SOMNOLENCE	2 (1.5%)	4 (3.1%)	6 (2.3%)
	DEPRESSION	3 (2.3%)	1 (0.8%)	4 (1.5%)
	DIZZINESS	1 (0.8%)	2 (1.5%)	3 (1.1%)
	CONCENTRATION IMPAIRED	1 (0.8%)	1 (0.8%)	2 (0.8%)
	MANIC REACTION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	CONVULSION	1 (0.8%)	0	1 (0.4%)
	VERTIGO	1 (0.8%)	0	1 (0.4%)
	VESTIBULAR DISORDER	1 (0.8%)	0	1 (0.4%)
	ABNORMAL DREAMS	0	1 (0.8%)	1 (0.4%)
	HALLUCINATIONS	0	1 (0.8%)	1 (0.4%)
	HYPESTHESIA	0	1 (0.8%)	1 (0.4%)
	LACK OF EMOTION	0	1 (0.8%)	1 (0.4%)
	PSYCHOSIS	0	1 (0.8%)	1 (0.4%)
	TREMOR	0	1 (0.8%)	1 (0.4%)
	WITHDRAWAL SYNDROME	0	1 (0.8%)	1 (0.4%)
Respiratory System	TOTAL	26 (19.5%)	19 (14.6%)	45 (17.1%)
	RESPIRATORY DISORDER	13 (9.8%)	11 (8.5%)	24 (9.1%)
	PHARYNGITIS	6 (4.5%)	3 (2.3%)	9 (3.4%)
	BRONCHITIS	3 (2.3%)	3 (2.3%)	6 (2.3%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Respiratory System	SINUSITIS	4 (3.0%)	1 (0.8%)	5 (1.9%)
	ASTHMA	3 (2.3%)	2 (1.5%)	5 (1.9%)
	RHINITIS	3 (2.3%)	1 (0.8%)	4 (1.5%)
	COUGH INCREASED	2 (1.5%)	1 (0.8%)	3 (1.1%)
	PNEUMONIA	1 (0.8%)	2 (1.5%)	3 (1.1%)
Digestive System	TOTAL	17 (12.8%)	12 (9.2%)	29 (11.0%)
	VOMITING	9 (6.8%)	2 (1.5%)	11 (4.2%)
	NAUSEA	2 (1.5%)	4 (3.1%)	6 (2.3%)
	DIARRHEA	4 (3.0%)	1 (0.8%)	5 (1.9%)
	DYSPEPSIA	1 (0.8%)	4 (3.1%)	5 (1.9%)
	TOOTH DISORDER	2 (1.5%)	1 (0.8%)	3 (1.1%)
	CONSTIPATION	2 (1.5%)	0	2 (0.8%)
	GINGIVITIS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	HEMATEMESIS	1 (0.8%)	0	1 (0.4%)
	STOMATITIS	1 (0.8%)	0	1 (0.4%)
	DECREASED APPETITE	0	1 (0.8%)	1 (0.4%)
	TOOTH CARIES	0	1 (0.8%)	1 (0.4%)
Skin and Appendages	TOTAL	8 (6.0%)	4 (3.1%)	12 (4.6%)
	ACNE	4 (3.0%)	1 (0.8%)	5 (1.9%)
	CONTACT DERMATITIS	2 (1.5%)	2 (1.5%)	4 (1.5%)
	FURUNCULOSIS	1 (0.8%)	0	1 (0.4%)
	HERPES ZOSTER	1 (0.8%)	0	1 (0.4%)
	FUNGAL DERMATITIS	0	1 (0.8%)	1 (0.4%)
Metabolic and Nutritional Disorders	TOTAL	6 (4.5%)	4 (3.1%)	10 (3.8%)
	WEIGHT GAIN	4 (3.0%)	2 (1.5%)	6 (2.3%)
	DEHYDRATION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	WEIGHT LOSS	1 (0.8%)	1 (0.8%)	2 (0.8%)
Special Senses	TOTAL	6 (4.5%)	2 (1.5%)	8 (3.0%)
	OTITIS MEDIA	5 (3.8%)	2 (1.5%)	7 (2.7%)
	EAR PAIN	1 (0.8%)	0	1 (0.4%)
	OTITIS EXTERNA	1 (0.8%)	0	1 (0.4%)
Musculoskeletal System	TOTAL	3 (2.3%)	1 (0.8%)	4 (1.5%)
	MYALGIA	1 (0.8%)	1 (0.8%)	2 (0.8%)
	ARTHRALGIA	1 (0.8%)	0	1 (0.4%)
	TENDINOUS DISORDER	1 (0.8%)	0	1 (0.4%)
	ARTHROSIS	0	1 (0.8%)	1 (0.4%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Urogenital System	TOTAL	2 (1.5%)	0	2 (0.8%)
	URINARY INCONTINENCE	1 (0.8%)	0	1 (0.4%)
	URINARY TRACT INFECTION	1 (0.8%)	0	1 (0.4%)
Hemic and Lymphatic System	TOTAL	1 (0.8%)	2 (1.5%)	3 (1.1%)
	PURPURA	1 (0.8%)	0	1 (0.4%)
	EOSINOPHILIA	0	1 (0.8%)	1 (0.4%)
	LEUKOPENIA	0	1 (0.8%)	1 (0.4%)
	MONOCYTOSIS	0	1 (0.8%)	1 (0.4%)
Cardiovascular System	TOTAL	0	2 (1.5%)	2 (0.8%)
	MIGRAINE	0	1 (0.8%)	1 (0.4%)
	SYNCOPE	0	1 (0.8%)	1 (0.4%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
TOTAL	TOTAL	13 (9.8%)	18 (13.8%)	31 (11.8%)
Nervous System	TOTAL	8 (6.0%)	10 (7.7%)	18 (6.8%)
	EMOTIONAL LABILITY	4 (3.0%)	1 (0.8%)	5 (1.9%)
	HOSTILITY	2 (1.5%)	3 (2.3%)	5 (1.9%)
	AGITATION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	DEPRESSION	1 (0.8%)	0	1 (0.4%)
	LACK OF EMOTION	1 (0.8%)	0	1 (0.4%)
	NEUROSIS	1 (0.8%)	0	1 (0.4%)
	SOMNOLENCE	1 (0.8%)	0	1 (0.4%)
	ANXIETY	0	1 (0.8%)	1 (0.4%)
	EUPHORIA	0	1 (0.8%)	1 (0.4%)
	HALLUCINATIONS	0	1 (0.8%)	1 (0.4%)
	HYPERKINESIA	0	1 (0.8%)	1 (0.4%)
	NERVOUSNESS	0	1 (0.8%)	1 (0.4%)
	PARALYSIS	0	1 (0.8%)	1 (0.4%)
Body as a Whole	TOTAL	5 (3.8%)	3 (2.3%)	8 (3.0%)
	INFECTION	2 (1.5%)	1 (0.8%)	3 (1.1%)
	TRAUMA	1 (0.8%)	2 (1.5%)	3 (1.1%)
	ABSCESS	1 (0.8%)	0	1 (0.4%)
	BACK PAIN	1 (0.8%)	0	1 (0.4%)
	ABDOMINAL PAIN	0	1 (0.8%)	1 (0.4%)
Respiratory System	TOTAL	1 (0.8%)	1 (0.8%)	2 (0.8%)
	PHARYNGITIS	1 (0.8%)	0	1 (0.4%)
	ASTHMA	0	1 (0.8%)	1 (0.4%)
Cardiovascular System	TOTAL	0	2 (1.5%)	2 (0.8%)
	MIGRAINE	0	1 (0.8%)	1 (0.4%)
	SYNCOPE	0	1 (0.8%)	1 (0.4%)
Digestive System	TOTAL	0	2 (1.5%)	2 (0.8%)
	NAUSEA	0	1 (0.8%)	1 (0.4%)
	TOOTH CARIES	0	1 (0.8%)	1 (0.4%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (0.8%)	1 (0.4%)
	WEIGHT GAIN	0	1 (0.8%)	1 (0.4%)
Skin and Appendages	TOTAL	0	1 (0.8%)	1 (0.4%)
	RASH	0	1 (0.8%)	1 (0.4%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Special Senses	TOTAL	0	1 (0.8%)	1 (0.4%)
	OTITIS MEDIA	0	1 (0.8%)	1 (0.4%)
Urogenital System	TOTAL	0	2 (1.5%)	2 (0.8%)
	URINARY INCONTINENCE	0	2 (1.5%)	2 (0.8%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	1 (1.6%)	3 (5.9%)	4 (3.6%)
Urogenital System	TOTAL	1 (1.6%)	3 (5.9%)	4 (3.6%)
	DYSMENORRHEA	1 (1.6%)	1 (2.0%)	2 (1.8%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (0.9%)
	MENSTRUAL DISORDER	0	1 (2.0%)	1 (0.9%)
	UTERUS DISORDERS	0	1 (2.0%)	1 (0.9%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	6 (9.8%)	0	6 (5.4%)
Urogenital System	TOTAL	6 (9.8%)	0	6 (5.4%)
	DYSMENORRHEA	6 (9.8%)	0	6 (5.4%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
TOTAL	27 (69.2%)	21 (58.3%)	48 (64.0%)
HEADACHE	8 (20.5%)	3 (8.3%)	11 (14.7%)
PHARYNGITIS	6 (15.4%)	4 (11.1%)	10 (13.3%)
TRAUMA	7 (17.9%)	1 (2.8%)	8 (10.7%)
RESPIRATORY DISORDER	5 (12.8%)	3 (8.3%)	8 (10.7%)
DYSPEPSIA	4 (10.3%)	3 (8.3%)	7 (9.3%)
ABDOMINAL PAIN	4 (10.3%)	2 (5.6%)	6 (8.0%)
INFECTION	1 (2.6%)	5 (13.9%)	6 (8.0%)
RHINITIS	2 (5.1%)	3 (8.3%)	5 (6.7%)
WEIGHT GAIN	2 (5.1%)	2 (5.6%)	4 (5.3%)
INSOMNIA	1 (2.6%)	3 (8.3%)	4 (5.3%)
SINUSITIS	3 (7.7%)	0	3 (4.0%)
COUGH INCREASED	2 (5.1%)	1 (2.8%)	3 (4.0%)
ASTHENIA	1 (2.6%)	2 (5.6%)	3 (4.0%)
FEVER	1 (2.6%)	2 (5.6%)	3 (4.0%)
BACK PAIN	0	3 (8.3%)	3 (4.0%)
ACNE	2 (5.1%)	0	2 (2.7%)
ARTHRALGIA	2 (5.1%)	0	2 (2.7%)
DRY MOUTH	2 (5.1%)	0	2 (2.7%)
PAIN	2 (5.1%)	0	2 (2.7%)
ALLERGIC REACTION	1 (2.6%)	1 (2.8%)	2 (2.7%)
DECREASED APPETITE	1 (2.6%)	1 (2.8%)	2 (2.7%)
DEPRESSION	1 (2.6%)	1 (2.8%)	2 (2.7%)
HYPERKINESIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
LEUKOPENIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
NAUSEA	1 (2.6%)	1 (2.8%)	2 (2.7%)
RASH	1 (2.6%)	1 (2.8%)	2 (2.7%)
URINARY INCONTINENCE	1 (2.6%)	1 (2.8%)	2 (2.7%)
EPISTAXIS	0	2 (5.6%)	2 (2.7%)
VOMITING	0	2 (5.6%)	2 (2.7%)
AGITATION	1 (2.6%)	0	1 (1.3%)
CONTACT DERMATITIS	1 (2.6%)	0	1 (1.3%)
FACE EDEMA	1 (2.6%)	0	1 (1.3%)
HALLUCINATIONS	1 (2.6%)	0	1 (1.3%)
INCREASED APPETITE	1 (2.6%)	0	1 (1.3%)
NERVOUSNESS	1 (2.6%)	0	1 (1.3%)
NEUROSIS	1 (2.6%)	0	1 (1.3%)
OTITIS MEDIA	1 (2.6%)	0	1 (1.3%)
ABNORMAL VISION	0	1 (2.8%)	1 (1.3%)
ALBUMINURIA	0	1 (2.8%)	1 (1.3%)
ANXIETY	0	1 (2.8%)	1 (1.3%)
DIARRHEA	0	1 (2.8%)	1 (1.3%)
DIZZINESS	0	1 (2.8%)	1 (1.3%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
GASTROENTERITIS	0	1 (2.8%)	1 (1.3%)
HAEMATURIA	0	1 (2.8%)	1 (1.3%)
HYPESTHESIA	0	1 (2.8%)	1 (1.3%)
PRURITUS	0	1 (2.8%)	1 (1.3%)
TOOTH CARIES	0	1 (2.8%)	1 (1.3%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
TOTAL	25 (64.1%)	19 (52.8%)	44 (58.7%)
VOMITING	7 (17.9%)	2 (5.6%)	9 (12.0%)
RESPIRATORY DISORDER	5 (12.8%)	4 (11.1%)	9 (12.0%)
INFECTION	4 (10.3%)	5 (13.9%)	9 (12.0%)
TRAUMA	5 (12.8%)	2 (5.6%)	7 (9.3%)
ABDOMINAL PAIN	4 (10.3%)	1 (2.8%)	5 (6.7%)
FEVER	4 (10.3%)	1 (2.8%)	5 (6.7%)
NERVOUSNESS	4 (10.3%)	0	4 (5.3%)
HEADACHE	3 (7.7%)	1 (2.8%)	4 (5.3%)
HOSTILITY	3 (7.7%)	0	3 (4.0%)
ALLERGIC REACTION	2 (5.1%)	1 (2.8%)	3 (4.0%)
WEIGHT GAIN	2 (5.1%)	1 (2.8%)	3 (4.0%)
AGITATION	1 (2.6%)	2 (5.6%)	3 (4.0%)
DIARRHEA	2 (5.1%)	0	2 (2.7%)
OTITIS MEDIA	2 (5.1%)	0	2 (2.7%)
PHARYNGITIS	2 (5.1%)	0	2 (2.7%)
RHINITIS	2 (5.1%)	0	2 (2.7%)
CONTACT DERMATITIS	1 (2.6%)	1 (2.8%)	2 (2.7%)
PAIN	1 (2.6%)	1 (2.8%)	2 (2.7%)
SINUSITIS	1 (2.6%)	1 (2.8%)	2 (2.7%)
ACNE	1 (2.6%)	0	1 (1.3%)
ASTHENIA	1 (2.6%)	0	1 (1.3%)
CONSTIPATION	1 (2.6%)	0	1 (1.3%)
COUGH INCREASED	1 (2.6%)	0	1 (1.3%)
DEPRESSION	1 (2.6%)	0	1 (1.3%)
FACE EDEMA	1 (2.6%)	0	1 (1.3%)
HYPERKINESIA	1 (2.6%)	0	1 (1.3%)
URINARY INCONTINENCE	1 (2.6%)	0	1 (1.3%)
BRONCHITIS	0	1 (2.8%)	1 (1.3%)
CONCENTRATION IMPAIRED	0	1 (2.8%)	1 (1.3%)
HALLUCINATIONS	0	1 (2.8%)	1 (1.3%)
HYPESTHESIA	0	1 (2.8%)	1 (1.3%)
INSOMNIA	0	1 (2.8%)	1 (1.3%)
LEUKOPENIA	0	1 (2.8%)	1 (1.3%)
MYALGIA	0	1 (2.8%)	1 (1.3%)
NAUSEA	0	1 (2.8%)	1 (1.3%)
PNEUMONIA	0	1 (2.8%)	1 (1.3%)
SOMNOLENCE	0	1 (2.8%)	1 (1.3%)
SYNCOPE	0	1 (2.8%)	1 (1.3%)
TOOTH CARIES	0	1 (2.8%)	1 (1.3%)
TREMOR	0	1 (2.8%)	1 (1.3%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Preferred Term			
TOTAL	3 (7.7%)	6 (16.7%)	9 (12.0%)
HOSTILITY	2 (5.1%)	1 (2.8%)	3 (4.0%)
DEPRESSION	1 (2.6%)	0	1 (1.3%)
EMOTIONAL LABILITY	1 (2.6%)	0	1 (1.3%)
AGITATION	0	1 (2.8%)	1 (1.3%)
ASTHMA	0	1 (2.8%)	1 (1.3%)
OTITIS MEDIA	0	1 (2.8%)	1 (1.3%)
RASH	0	1 (2.8%)	1 (1.3%)
TRAUMA	0	1 (2.8%)	1 (1.3%)
URINARY INCONTINENCE	0	1 (2.8%)	1 (1.3%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
TOTAL	18 (64.3%)	22 (61.1%)	40 (62.5%)
HEADACHE	6 (21.4%)	6 (16.7%)	12 (18.8%)
RHINITIS	4 (14.3%)	4 (11.1%)	8 (12.5%)
RESPIRATORY DISORDER	1 (3.6%)	6 (16.7%)	7 (10.9%)
PHARYNGITIS	3 (10.7%)	3 (8.3%)	6 (9.4%)
ABDOMINAL PAIN	1 (3.6%)	5 (13.9%)	6 (9.4%)
NERVOUSNESS	1 (3.6%)	5 (13.9%)	6 (9.4%)
NAUSEA	5 (17.9%)	0	5 (7.8%)
INSOMNIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
TRAUMA	2 (7.1%)	3 (8.3%)	5 (7.8%)
DECREASED APPETITE	2 (7.1%)	2 (5.6%)	4 (6.3%)
DIARRHEA	3 (10.7%)	0	3 (4.7%)
HYPERKINESIA	3 (10.7%)	0	3 (4.7%)
FEVER	2 (7.1%)	1 (2.8%)	3 (4.7%)
PAIN	2 (7.1%)	1 (2.8%)	3 (4.7%)
VASODILATATION	0	3 (8.3%)	3 (4.7%)
ALBUMINURIA	2 (7.1%)	0	2 (3.1%)
COUGH INCREASED	2 (7.1%)	0	2 (3.1%)
DYSPEPSIA	2 (7.1%)	0	2 (3.1%)
AGITATION	1 (3.6%)	1 (2.8%)	2 (3.1%)
DIZZINESS	1 (3.6%)	1 (2.8%)	2 (3.1%)
HOSTILITY	1 (3.6%)	1 (2.8%)	2 (3.1%)
OTITIS EXTERNA	1 (3.6%)	1 (2.8%)	2 (3.1%)
SINUSITIS	1 (3.6%)	1 (2.8%)	2 (3.1%)
RASH	0	2 (5.6%)	2 (3.1%)
VERTIGO	0	2 (5.6%)	2 (3.1%)
ANXIETY	1 (3.6%)	0	1 (1.6%)
ASTHMA	1 (3.6%)	0	1 (1.6%)
BACK PAIN	1 (3.6%)	0	1 (1.6%)
CONCENTRATION IMPAIRED	1 (3.6%)	0	1 (1.6%)
MYALGIA	1 (3.6%)	0	1 (1.6%)
VOMITING	1 (3.6%)	0	1 (1.6%)
ALLERGIC REACTION	0	1 (2.8%)	1 (1.6%)
CONTACT DERMATITIS	0	1 (2.8%)	1 (1.6%)
FLATULENCE	0	1 (2.8%)	1 (1.6%)
GASTROENTERITIS	0	1 (2.8%)	1 (1.6%)
INFECTION	0	1 (2.8%)	1 (1.6%)
OTITIS MEDIA	0	1 (2.8%)	1 (1.6%)
SOMNOLENCE	0	1 (2.8%)	1 (1.6%)
TOOTH CARIES	0	1 (2.8%)	1 (1.6%)
TREMOR	0	1 (2.8%)	1 (1.6%)
URINARY INCONTINENCE	0	1 (2.8%)	1 (1.6%)
WEIGHT GAIN	0	1 (2.8%)	1 (1.6%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Preferred Term			
TOTAL	15 (53.6%)	21 (58.3%)	36 (56.3%)
HEADACHE	5 (17.9%)	2 (5.6%)	7 (10.9%)
HYPERKINESIA	3 (10.7%)	3 (8.3%)	6 (9.4%)
NERVOUSNESS	0	6 (16.7%)	6 (9.4%)
INFECTION	2 (7.1%)	3 (8.3%)	5 (7.8%)
OTITIS MEDIA	3 (10.7%)	1 (2.8%)	4 (6.3%)
PHARYNGITIS	3 (10.7%)	1 (2.8%)	4 (6.3%)
RESPIRATORY DISORDER	2 (7.1%)	2 (5.6%)	4 (6.3%)
TRAUMA	3 (10.7%)	0	3 (4.7%)
ANXIETY	0	3 (8.3%)	3 (4.7%)
HOSTILITY	0	3 (8.3%)	3 (4.7%)
ABDOMINAL PAIN	1 (3.6%)	1 (2.8%)	2 (3.1%)
COUGH INCREASED	1 (3.6%)	1 (2.8%)	2 (3.1%)
PAIN	1 (3.6%)	1 (2.8%)	2 (3.1%)
SOMNOLENCE	1 (3.6%)	1 (2.8%)	2 (3.1%)
ACNE	1 (3.6%)	0	1 (1.6%)
DEPRESSION	1 (3.6%)	0	1 (1.6%)
EMOTIONAL LABILITY	1 (3.6%)	0	1 (1.6%)
FEVER	1 (3.6%)	0	1 (1.6%)
OTITIS EXTERNA	1 (3.6%)	0	1 (1.6%)
SINUSITIS	1 (3.6%)	0	1 (1.6%)
TOOTH DISORDER	1 (3.6%)	0	1 (1.6%)
AGITATION	0	1 (2.8%)	1 (1.6%)
CONTACT DERMATITIS	0	1 (2.8%)	1 (1.6%)
DIZZINESS	0	1 (2.8%)	1 (1.6%)
DYSPEPSIA	0	1 (2.8%)	1 (1.6%)
NAUSEA	0	1 (2.8%)	1 (1.6%)
RHINITIS	0	1 (2.8%)	1 (1.6%)
WEIGHT GAIN	0	1 (2.8%)	1 (1.6%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
TOTAL	2 (7.1%)	5 (13.9%)	7 (10.9%)
INFECTION	1 (3.6%)	0	1 (1.6%)
PHARYNGITIS	1 (3.6%)	0	1 (1.6%)
HOSTILITY	0	1 (2.8%)	1 (1.6%)
HYPERKINESIA	0	1 (2.8%)	1 (1.6%)
NERVOUSNESS	0	1 (2.8%)	1 (1.6%)
TRAUMA	0	1 (2.8%)	1 (1.6%)
URINARY INCONTINENCE	0	1 (2.8%)	1 (1.6%)
WEIGHT GAIN	0	1 (2.8%)	1 (1.6%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=16)	 Placebo (N=13)	 Total (N=29)
TOTAL	0	1 (7.7%)	1 (3.4%)
DYSMENORRHEA	0	1 (7.7%)	1 (3.4%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
Preferred Term			
TOTAL	1 (6.3%)	0	1 (3.4%)
DYSMENORRHEA	1 (6.3%)	0	1 (3.4%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Preferred Term			
TOTAL	45 (67.2%)	43 (59.7%)	88 (63.3%)
HEADACHE	14 (20.9%)	9 (12.5%)	23 (16.5%)
PHARYNGITIS	9 (13.4%)	7 (9.7%)	16 (11.5%)
RESPIRATORY DISORDER	6 (9.0%)	9 (12.5%)	15 (10.8%)
TRAUMA	9 (13.4%)	4 (5.6%)	13 (9.4%)
RHINITIS	6 (9.0%)	7 (9.7%)	13 (9.4%)
ABDOMINAL PAIN	5 (7.5%)	7 (9.7%)	12 (8.6%)
DYSPEPSIA	6 (9.0%)	3 (4.2%)	9 (6.5%)
INSOMNIA	4 (6.0%)	5 (6.9%)	9 (6.5%)
NAUSEA	6 (9.0%)	1 (1.4%)	7 (5.0%)
NERVOUSNESS	2 (3.0%)	5 (6.9%)	7 (5.0%)
INFECTION	1 (1.5%)	6 (8.3%)	7 (5.0%)
DECREASED APPETITE	3 (4.5%)	3 (4.2%)	6 (4.3%)
FEVER	3 (4.5%)	3 (4.2%)	6 (4.3%)
COUGH INCREASED	4 (6.0%)	1 (1.4%)	5 (3.6%)
HYPERKINESIA	4 (6.0%)	1 (1.4%)	5 (3.6%)
PAIN	4 (6.0%)	1 (1.4%)	5 (3.6%)
SINUSITIS	4 (6.0%)	1 (1.4%)	5 (3.6%)
WEIGHT GAIN	2 (3.0%)	3 (4.2%)	5 (3.6%)
DIARRHEA	3 (4.5%)	1 (1.4%)	4 (2.9%)
BACK PAIN	1 (1.5%)	3 (4.2%)	4 (2.9%)
RASH	1 (1.5%)	3 (4.2%)	4 (2.9%)
AGITATION	2 (3.0%)	1 (1.4%)	3 (2.2%)
ALBUMINURIA	2 (3.0%)	1 (1.4%)	3 (2.2%)
ALLERGIC REACTION	1 (1.5%)	2 (2.8%)	3 (2.2%)
ASTHENIA	1 (1.5%)	2 (2.8%)	3 (2.2%)
DIZZINESS	1 (1.5%)	2 (2.8%)	3 (2.2%)
URINARY INCONTINENCE	1 (1.5%)	2 (2.8%)	3 (2.2%)
VOMITING	1 (1.5%)	2 (2.8%)	3 (2.2%)
VASODILATATION	0	3 (4.2%)	3 (2.2%)
ACNE	2 (3.0%)	0	2 (1.4%)
ARTHRALGIA	2 (3.0%)	0	2 (1.4%)
DRY MOUTH	2 (3.0%)	0	2 (1.4%)
ANXIETY	1 (1.5%)	1 (1.4%)	2 (1.4%)
CONTACT DERMATITIS	1 (1.5%)	1 (1.4%)	2 (1.4%)
DEPRESSION	1 (1.5%)	1 (1.4%)	2 (1.4%)
HOSTILITY	1 (1.5%)	1 (1.4%)	2 (1.4%)
LEUKOPENIA	1 (1.5%)	1 (1.4%)	2 (1.4%)
OTITIS EXTERNA	1 (1.5%)	1 (1.4%)	2 (1.4%)
OTITIS MEDIA	1 (1.5%)	1 (1.4%)	2 (1.4%)
EPISTAXIS	0	2 (2.8%)	2 (1.4%)
GASTROENTERITIS	0	2 (2.8%)	2 (1.4%)
TOOTH CARIES	0	2 (2.8%)	2 (1.4%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Preferred Term			
VERTIGO	0	2 (2.8%)	2 (1.4%)
ASTHMA	1 (1.5%)	0	1 (0.7%)
CONCENTRATION IMPAIRED	1 (1.5%)	0	1 (0.7%)
FACE EDEMA	1 (1.5%)	0	1 (0.7%)
HALLUCINATIONS	1 (1.5%)	0	1 (0.7%)
INCREASED APPETITE	1 (1.5%)	0	1 (0.7%)
MYALGIA	1 (1.5%)	0	1 (0.7%)
NEUROSIS	1 (1.5%)	0	1 (0.7%)
ABNORMAL VISION	0	1 (1.4%)	1 (0.7%)
FLATULENCE	0	1 (1.4%)	1 (0.7%)
HAEMATURIA	0	1 (1.4%)	1 (0.7%)
HYPESTHESIA	0	1 (1.4%)	1 (0.7%)
PRURITUS	0	1 (1.4%)	1 (0.7%)
SOMNOLENCE	0	1 (1.4%)	1 (0.7%)
TREMOR	0	1 (1.4%)	1 (0.7%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
TOTAL	40 (59.7%)	40 (55.6%)	80 (57.6%)
INFECTION	6 (9.0%)	8 (11.1%)	14 (10.1%)
RESPIRATORY DISORDER	7 (10.4%)	6 (8.3%)	13 (9.4%)
HEADACHE	8 (11.9%)	3 (4.2%)	11 (7.9%)
TRAUMA	8 (11.9%)	2 (2.8%)	10 (7.2%)
NERVOUSNESS	4 (6.0%)	6 (8.3%)	10 (7.2%)
VOMITING	7 (10.4%)	2 (2.8%)	9 (6.5%)
ABDOMINAL PAIN	5 (7.5%)	2 (2.8%)	7 (5.0%)
HYPERKINESIA	4 (6.0%)	3 (4.2%)	7 (5.0%)
FEVER	5 (7.5%)	1 (1.4%)	6 (4.3%)
OTITIS MEDIA	5 (7.5%)	1 (1.4%)	6 (4.3%)
PHARYNGITIS	5 (7.5%)	1 (1.4%)	6 (4.3%)
HOSTILITY	3 (4.5%)	3 (4.2%)	6 (4.3%)
PAIN	2 (3.0%)	2 (2.8%)	4 (2.9%)
WEIGHT GAIN	2 (3.0%)	2 (2.8%)	4 (2.9%)
AGITATION	1 (1.5%)	3 (4.2%)	4 (2.9%)
ALLERGIC REACTION	2 (3.0%)	1 (1.4%)	3 (2.2%)
COUGH INCREASED	2 (3.0%)	1 (1.4%)	3 (2.2%)
RHINITIS	2 (3.0%)	1 (1.4%)	3 (2.2%)
SINUSITIS	2 (3.0%)	1 (1.4%)	3 (2.2%)
CONTACT DERMATITIS	1 (1.5%)	2 (2.8%)	3 (2.2%)
SOMNOLENCE	1 (1.5%)	2 (2.8%)	3 (2.2%)
ANXIETY	0	3 (4.2%)	3 (2.2%)
ACNE	2 (3.0%)	0	2 (1.4%)
DEPRESSION	2 (3.0%)	0	2 (1.4%)
DIARRHEA	2 (3.0%)	0	2 (1.4%)
NAUSEA	0	2 (2.8%)	2 (1.4%)
ASTHENIA	1 (1.5%)	0	1 (0.7%)
CONSTIPATION	1 (1.5%)	0	1 (0.7%)
EMOTIONAL LABILITY	1 (1.5%)	0	1 (0.7%)
FACE EDEMA	1 (1.5%)	0	1 (0.7%)
OTITIS EXTERNA	1 (1.5%)	0	1 (0.7%)
TOOTH DISORDER	1 (1.5%)	0	1 (0.7%)
URINARY INCONTINENCE	1 (1.5%)	0	1 (0.7%)
BRONCHITIS	0	1 (1.4%)	1 (0.7%)
CONCENTRATION IMPAIRED	0	1 (1.4%)	1 (0.7%)
DIZZINESS	0	1 (1.4%)	1 (0.7%)
DYSPEPSIA	0	1 (1.4%)	1 (0.7%)
HALLUCINATIONS	0	1 (1.4%)	1 (0.7%)
HYPESTHESIA	0	1 (1.4%)	1 (0.7%)
INSOMNIA	0	1 (1.4%)	1 (0.7%)
LEUKOPENIA	0	1 (1.4%)	1 (0.7%)
MYALGIA	0	1 (1.4%)	1 (0.7%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Preferred Term			
PNEUMONIA	0	1 (1.4%)	1 (0.7%)
SYNCOPE	0	1 (1.4%)	1 (0.7%)
TOOTH CARIES	0	1 (1.4%)	1 (0.7%)
TREMOR	0	1 (1.4%)	1 (0.7%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Preferred Term			
TOTAL	5 (7.5%)	11 (15.3%)	16 (11.5%)
HOSTILITY	2 (3.0%)	2 (2.8%)	4 (2.9%)
TRAUMA	0	2 (2.8%)	2 (1.4%)
URINARY INCONTINENCE	0	2 (2.8%)	2 (1.4%)
DEPRESSION	1 (1.5%)	0	1 (0.7%)
EMOTIONAL LABILITY	1 (1.5%)	0	1 (0.7%)
INFECTION	1 (1.5%)	0	1 (0.7%)
PHARYNGITIS	1 (1.5%)	0	1 (0.7%)
AGITATION	0	1 (1.4%)	1 (0.7%)
ASTHMA	0	1 (1.4%)	1 (0.7%)
HYPERKINESIA	0	1 (1.4%)	1 (0.7%)
NERVOUSNESS	0	1 (1.4%)	1 (0.7%)
OTITIS MEDIA	0	1 (1.4%)	1 (0.7%)
RASH	0	1 (1.4%)	1 (0.7%)
WEIGHT GAIN	0	1 (1.4%)	1 (0.7%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
Preferred Term			
TOTAL	0	1 (3.7%)	1 (1.6%)
DYSMENORRHEA	0	1 (3.7%)	1 (1.6%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
TOTAL	1 (2.9%)	0	1 (1.6%)
DYSMENORRHEA	1 (2.9%)	0	1 (1.6%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
TOTAL	26 (61.9%)	17 (56.7%)	43 (59.7%)
HEADACHE	7 (16.7%)	5 (16.7%)	12 (16.7%)
RESPIRATORY DISORDER	5 (11.9%)	7 (23.3%)	12 (16.7%)
NAUSEA	5 (11.9%)	2 (6.7%)	7 (9.7%)
ALLERGIC REACTION	4 (9.5%)	0	4 (5.6%)
SOMNOLENCE	4 (9.5%)	0	4 (5.6%)
ALBUMINURIA	3 (7.1%)	1 (3.3%)	4 (5.6%)
DIZZINESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
PHARYNGITIS	3 (7.1%)	1 (3.3%)	4 (5.6%)
RHINITIS	3 (7.1%)	1 (3.3%)	4 (5.6%)
ABDOMINAL PAIN	3 (7.1%)	0	3 (4.2%)
CHEST PAIN	3 (7.1%)	0	3 (4.2%)
FEVER	3 (7.1%)	0	3 (4.2%)
NERVOUSNESS	3 (7.1%)	0	3 (4.2%)
VOMITING	3 (7.1%)	0	3 (4.2%)
DIARRHEA	2 (4.8%)	1 (3.3%)	3 (4.2%)
DYSPEPSIA	2 (4.8%)	1 (3.3%)	3 (4.2%)
ASTHMA	1 (2.4%)	2 (6.7%)	3 (4.2%)
DECREASED APPETITE	1 (2.4%)	2 (6.7%)	3 (4.2%)
INSOMNIA	1 (2.4%)	2 (6.7%)	3 (4.2%)
TRAUMA	1 (2.4%)	2 (6.7%)	3 (4.2%)
WEIGHT GAIN	0	3 (10.0%)	3 (4.2%)
SINUSITIS	2 (4.8%)	0	2 (2.8%)
COUGH INCREASED	1 (2.4%)	1 (3.3%)	2 (2.8%)
EMOTIONAL LABILITY	1 (2.4%)	1 (3.3%)	2 (2.8%)
HAEMATURIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
PRURITUS	1 (2.4%)	1 (3.3%)	2 (2.8%)
ASTHENIA	0	2 (6.7%)	2 (2.8%)
INCREASED APPETITE	0	2 (6.7%)	2 (2.8%)
BACK PAIN	1 (2.4%)	0	1 (1.4%)
CONTACT DERMATITIS	1 (2.4%)	0	1 (1.4%)
DRY MOUTH	1 (2.4%)	0	1 (1.4%)
LEUKOPENIA	1 (2.4%)	0	1 (1.4%)
OTITIS MEDIA	1 (2.4%)	0	1 (1.4%)
TOOTH CARIES	1 (2.4%)	0	1 (1.4%)
VERTIGO	1 (2.4%)	0	1 (1.4%)
AGITATION	0	1 (3.3%)	1 (1.4%)
CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.4%)
INFECTION	0	1 (3.3%)	1 (1.4%)
PAIN	0	1 (3.3%)	1 (1.4%)
SYNCOPE	0	1 (3.3%)	1 (1.4%)
TREMOR	0	1 (3.3%)	1 (1.4%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
TOTAL	26 (61.9%)	9 (30.0%)	35 (48.6%)
HEADACHE	6 (14.3%)	1 (3.3%)	7 (9.7%)
TRAUMA	5 (11.9%)	1 (3.3%)	6 (8.3%)
RESPIRATORY DISORDER	4 (9.5%)	1 (3.3%)	5 (6.9%)
BRONCHITIS	2 (4.8%)	2 (6.7%)	4 (5.6%)
EMOTIONAL LABILITY	2 (4.8%)	2 (6.7%)	4 (5.6%)
INFECTION	2 (4.8%)	1 (3.3%)	3 (4.2%)
SOMNOLENCE	1 (2.4%)	2 (6.7%)	3 (4.2%)
ASTHMA	2 (4.8%)	0	2 (2.8%)
BACK PAIN	2 (4.8%)	0	2 (2.8%)
INSOMNIA	2 (4.8%)	0	2 (2.8%)
NAUSEA	2 (4.8%)	0	2 (2.8%)
VOMITING	2 (4.8%)	0	2 (2.8%)
ABDOMINAL PAIN	1 (2.4%)	1 (3.3%)	2 (2.8%)
ACNE	1 (2.4%)	1 (3.3%)	2 (2.8%)
AGITATION	1 (2.4%)	1 (3.3%)	2 (2.8%)
ASTHENIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
DYSPEPSIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
ANXIETY	1 (2.4%)	0	1 (1.4%)
CHEST PAIN	1 (2.4%)	0	1 (1.4%)
CONTACT DERMATITIS	1 (2.4%)	0	1 (1.4%)
DEPRESSION	1 (2.4%)	0	1 (1.4%)
DIARRHEA	1 (2.4%)	0	1 (1.4%)
MYALGIA	1 (2.4%)	0	1 (1.4%)
PHARYNGITIS	1 (2.4%)	0	1 (1.4%)
PNEUMONIA	1 (2.4%)	0	1 (1.4%)
RHINITIS	1 (2.4%)	0	1 (1.4%)
SINUSITIS	1 (2.4%)	0	1 (1.4%)
WEIGHT GAIN	1 (2.4%)	0	1 (1.4%)
FEVER	0	1 (3.3%)	1 (1.4%)
HOSTILITY	0	1 (3.3%)	1 (1.4%)
NERVOUSNESS	0	1 (3.3%)	1 (1.4%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Preferred Term			
TOTAL	6 (14.3%)	4 (13.3%)	10 (13.9%)
EMOTIONAL LABILITY	3 (7.1%)	1 (3.3%)	4 (5.6%)
AGITATION	1 (2.4%)	0	1 (1.4%)
BACK PAIN	1 (2.4%)	0	1 (1.4%)
INFECTION	1 (2.4%)	0	1 (1.4%)
TRAUMA	1 (2.4%)	0	1 (1.4%)
ANXIETY	0	1 (3.3%)	1 (1.4%)
HALLUCINATIONS	0	1 (3.3%)	1 (1.4%)
TOOTH CARIES	0	1 (3.3%)	1 (1.4%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=14)	 Placebo (N=15)	 Total (N=29)
TOTAL	1 (7.1%)	0	1 (3.4%)
DYSMENORRHEA	1 (7.1%)	0	1 (3.4%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
TOTAL	2 (14.3%)	0	2 (6.9%)
DYSMENORRHEA	2 (14.3%)	0	2 (6.9%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
Preferred Term			
TOTAL	0	0	0

Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=24)	 Placebo (N=28)	 Total (N=52)
TOTAL	15 (62.5%)	16 (57.1%)	31 (59.6%)
HEADACHE	7 (29.2%)	7 (25.0%)	14 (26.9%)
ALLERGIC REACTION	3 (12.5%)	2 (7.1%)	5 (9.6%)
INFECTION	3 (12.5%)	1 (3.6%)	4 (7.7%)
ASTHENIA	2 (8.3%)	2 (7.1%)	4 (7.7%)
RESPIRATORY DISORDER	2 (8.3%)	2 (7.1%)	4 (7.7%)
NAUSEA	1 (4.2%)	3 (10.7%)	4 (7.7%)
ALBUMINURIA	3 (12.5%)	0	3 (5.8%)
INSOMNIA	2 (8.3%)	1 (3.6%)	3 (5.8%)
NEUROSIS	2 (8.3%)	1 (3.6%)	3 (5.8%)
TRAUMA	1 (4.2%)	2 (7.1%)	3 (5.8%)
ABDOMINAL PAIN	2 (8.3%)	0	2 (3.8%)
SINUSITIS	2 (8.3%)	0	2 (3.8%)
ARTHRALGIA	1 (4.2%)	1 (3.6%)	2 (3.8%)
RHINITIS	1 (4.2%)	1 (3.6%)	2 (3.8%)
ACNE	0	2 (7.1%)	2 (3.8%)
DECREASED APPETITE	0	2 (7.1%)	2 (3.8%)
DRY MOUTH	0	2 (7.1%)	2 (3.8%)
DIZZINESS	1 (4.2%)	0	1 (1.9%)
EMOTIONAL LABILITY	1 (4.2%)	0	1 (1.9%)
HAEMATURIA	1 (4.2%)	0	1 (1.9%)
PAIN	1 (4.2%)	0	1 (1.9%)
PHARYNGITIS	1 (4.2%)	0	1 (1.9%)
WEIGHT GAIN	1 (4.2%)	0	1 (1.9%)
ABNORMAL VISION	0	1 (3.6%)	1 (1.9%)
AGITATION	0	1 (3.6%)	1 (1.9%)
ASTHMA	0	1 (3.6%)	1 (1.9%)
CONSTIPATION	0	1 (3.6%)	1 (1.9%)
CONTACT DERMATITIS	0	1 (3.6%)	1 (1.9%)
EPISTAXIS	0	1 (3.6%)	1 (1.9%)
FEVER	0	1 (3.6%)	1 (1.9%)
FLATULENCE	0	1 (3.6%)	1 (1.9%)
HOSTILITY	0	1 (3.6%)	1 (1.9%)
HYPERKINESIA	0	1 (3.6%)	1 (1.9%)
NERVOUSNESS	0	1 (3.6%)	1 (1.9%)
RASH	0	1 (3.6%)	1 (1.9%)
SOMNOLENCE	0	1 (3.6%)	1 (1.9%)
TREMOR	0	1 (3.6%)	1 (1.9%)
VASODILATATION	0	1 (3.6%)	1 (1.9%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
TOTAL	14 (58.3%)	16 (57.1%)	30 (57.7%)
HEADACHE	4 (16.7%)	4 (14.3%)	8 (15.4%)
RESPIRATORY DISORDER	2 (8.3%)	4 (14.3%)	6 (11.5%)
ASTHENIA	2 (8.3%)	2 (7.1%)	4 (7.7%)
INSOMNIA	1 (4.2%)	3 (10.7%)	4 (7.7%)
INFECTION	2 (8.3%)	1 (3.6%)	3 (5.8%)
ABDOMINAL PAIN	1 (4.2%)	2 (7.1%)	3 (5.8%)
ASTHMA	1 (4.2%)	2 (7.1%)	3 (5.8%)
HOSTILITY	1 (4.2%)	2 (7.1%)	3 (5.8%)
NERVOUSNESS	1 (4.2%)	2 (7.1%)	3 (5.8%)
ALLERGIC REACTION	1 (4.2%)	1 (3.6%)	2 (3.8%)
ANXIETY	1 (4.2%)	1 (3.6%)	2 (3.8%)
DIARRHEA	1 (4.2%)	1 (3.6%)	2 (3.8%)
DIZZINESS	1 (4.2%)	1 (3.6%)	2 (3.8%)
EMOTIONAL LABILITY	1 (4.2%)	1 (3.6%)	2 (3.8%)
HYPERKINESIA	1 (4.2%)	1 (3.6%)	2 (3.8%)
TOOTH DISORDER	1 (4.2%)	1 (3.6%)	2 (3.8%)
DYSPEPSIA	0	2 (7.1%)	2 (3.8%)
NAUSEA	0	2 (7.1%)	2 (3.8%)
PHARYNGITIS	0	2 (7.1%)	2 (3.8%)
TRAUMA	0	2 (7.1%)	2 (3.8%)
ACNE	1 (4.2%)	0	1 (1.9%)
ARTHRALGIA	1 (4.2%)	0	1 (1.9%)
BRONCHITIS	1 (4.2%)	0	1 (1.9%)
CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.9%)
CONSTIPATION	1 (4.2%)	0	1 (1.9%)
SINUSITIS	1 (4.2%)	0	1 (1.9%)
VERTIGO	1 (4.2%)	0	1 (1.9%)
WEIGHT GAIN	1 (4.2%)	0	1 (1.9%)
AGITATION	0	1 (3.6%)	1 (1.9%)
BACK PAIN	0	1 (3.6%)	1 (1.9%)
DECREASED APPETITE	0	1 (3.6%)	1 (1.9%)
DEPRESSION	0	1 (3.6%)	1 (1.9%)
FEVER	0	1 (3.6%)	1 (1.9%)
OTITIS MEDIA	0	1 (3.6%)	1 (1.9%)
PNEUMONIA	0	1 (3.6%)	1 (1.9%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Preferred Term			
TOTAL	2 (8.3%)	2 (7.1%)	4 (7.7%)
NEUROSIS	1 (4.2%)	0	1 (1.9%)
SOMNOLENCE	1 (4.2%)	0	1 (1.9%)
ABDOMINAL PAIN	0	1 (3.6%)	1 (1.9%)
HOSTILITY	0	1 (3.6%)	1 (1.9%)
INFECTION	0	1 (3.6%)	1 (1.9%)
NAUSEA	0	1 (3.6%)	1 (1.9%)
SYNCOPE	0	1 (3.6%)	1 (1.9%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
Preferred Term			
TOTAL	3 (25.0%)	0	3 (14.3%)
DYSMENORRHEA	3 (25.0%)	0	3 (14.3%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
TOTAL	41 (62.1%)	33 (56.9%)	74 (59.7%)
HEADACHE	14 (21.2%)	12 (20.7%)	26 (21.0%)
RESPIRATORY DISORDER	7 (10.6%)	9 (15.5%)	16 (12.9%)
NAUSEA	6 (9.1%)	5 (8.6%)	11 (8.9%)
ALLERGIC REACTION	7 (10.6%)	2 (3.4%)	9 (7.3%)
ALBUMINURIA	6 (9.1%)	1 (1.7%)	7 (5.6%)
RHINITIS	4 (6.1%)	2 (3.4%)	6 (4.8%)
INSOMNIA	3 (4.5%)	3 (5.2%)	6 (4.8%)
ASTHENIA	2 (3.0%)	4 (6.9%)	6 (4.8%)
TRAUMA	2 (3.0%)	4 (6.9%)	6 (4.8%)
ABDOMINAL PAIN	5 (7.6%)	0	5 (4.0%)
DIZZINESS	4 (6.1%)	1 (1.7%)	5 (4.0%)
PHARYNGITIS	4 (6.1%)	1 (1.7%)	5 (4.0%)
SOMNOLENCE	4 (6.1%)	1 (1.7%)	5 (4.0%)
INFECTION	3 (4.5%)	2 (3.4%)	5 (4.0%)
DECREASED APPETITE	1 (1.5%)	4 (6.9%)	5 (4.0%)
SINUSITIS	4 (6.1%)	0	4 (3.2%)
FEVER	3 (4.5%)	1 (1.7%)	4 (3.2%)
NERVOUSNESS	3 (4.5%)	1 (1.7%)	4 (3.2%)
ASTHMA	1 (1.5%)	3 (5.2%)	4 (3.2%)
WEIGHT GAIN	1 (1.5%)	3 (5.2%)	4 (3.2%)
CHEST PAIN	3 (4.5%)	0	3 (2.4%)
VOMITING	3 (4.5%)	0	3 (2.4%)
DIARRHEA	2 (3.0%)	1 (1.7%)	3 (2.4%)
DYSPEPSIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
EMOTIONAL LABILITY	2 (3.0%)	1 (1.7%)	3 (2.4%)
HAEMATURIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
NEUROSIS	2 (3.0%)	1 (1.7%)	3 (2.4%)
DRY MOUTH	1 (1.5%)	2 (3.4%)	3 (2.4%)
ARTHRALGIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
CONTACT DERMATITIS	1 (1.5%)	1 (1.7%)	2 (1.6%)
COUGH INCREASED	1 (1.5%)	1 (1.7%)	2 (1.6%)
PAIN	1 (1.5%)	1 (1.7%)	2 (1.6%)
PRURITUS	1 (1.5%)	1 (1.7%)	2 (1.6%)
ACNE	0	2 (3.4%)	2 (1.6%)
AGITATION	0	2 (3.4%)	2 (1.6%)
INCREASED APPETITE	0	2 (3.4%)	2 (1.6%)
TREMOR	0	2 (3.4%)	2 (1.6%)
BACK PAIN	1 (1.5%)	0	1 (0.8%)
LEUKOPENIA	1 (1.5%)	0	1 (0.8%)
OTITIS MEDIA	1 (1.5%)	0	1 (0.8%)
TOOTH CARIES	1 (1.5%)	0	1 (0.8%)
VERTIGO	1 (1.5%)	0	1 (0.8%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=66)	 Placebo (N=58)	 Total (N=124)
ABNORMAL VISION	0	1 (1.7%)	1 (0.8%)
CONCENTRATION IMPAIRED	0	1 (1.7%)	1 (0.8%)
CONSTIPATION	0	1 (1.7%)	1 (0.8%)
EPISTAXIS	0	1 (1.7%)	1 (0.8%)
FLATULENCE	0	1 (1.7%)	1 (0.8%)
HOSTILITY	0	1 (1.7%)	1 (0.8%)
HYPERKINESIA	0	1 (1.7%)	1 (0.8%)
RASH	0	1 (1.7%)	1 (0.8%)
SYNCOPE	0	1 (1.7%)	1 (0.8%)
VASODILATATION	0	1 (1.7%)	1 (0.8%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
TOTAL	40 (60.6%)	25 (43.1%)	65 (52.4%)
HEADACHE	10 (15.2%)	5 (8.6%)	15 (12.1%)
RESPIRATORY DISORDER	6 (9.1%)	5 (8.6%)	11 (8.9%)
TRAUMA	5 (7.6%)	3 (5.2%)	8 (6.5%)
INFECTION	4 (6.1%)	2 (3.4%)	6 (4.8%)
ASTHENIA	3 (4.5%)	3 (5.2%)	6 (4.8%)
EMOTIONAL LABILITY	3 (4.5%)	3 (5.2%)	6 (4.8%)
INSOMNIA	3 (4.5%)	3 (5.2%)	6 (4.8%)
ASTHMA	3 (4.5%)	2 (3.4%)	5 (4.0%)
BRONCHITIS	3 (4.5%)	2 (3.4%)	5 (4.0%)
ABDOMINAL PAIN	2 (3.0%)	3 (5.2%)	5 (4.0%)
NAUSEA	2 (3.0%)	2 (3.4%)	4 (3.2%)
DYSPEPSIA	1 (1.5%)	3 (5.2%)	4 (3.2%)
HOSTILITY	1 (1.5%)	3 (5.2%)	4 (3.2%)
NERVOUSNESS	1 (1.5%)	3 (5.2%)	4 (3.2%)
ACNE	2 (3.0%)	1 (1.7%)	3 (2.4%)
ANXIETY	2 (3.0%)	1 (1.7%)	3 (2.4%)
BACK PAIN	2 (3.0%)	1 (1.7%)	3 (2.4%)
DIARRHEA	2 (3.0%)	1 (1.7%)	3 (2.4%)
AGITATION	1 (1.5%)	2 (3.4%)	3 (2.4%)
PHARYNGITIS	1 (1.5%)	2 (3.4%)	3 (2.4%)
SOMNOLENCE	1 (1.5%)	2 (3.4%)	3 (2.4%)
SINUSITIS	2 (3.0%)	0	2 (1.6%)
VOMITING	2 (3.0%)	0	2 (1.6%)
WEIGHT GAIN	2 (3.0%)	0	2 (1.6%)
ALLERGIC REACTION	1 (1.5%)	1 (1.7%)	2 (1.6%)
DEPRESSION	1 (1.5%)	1 (1.7%)	2 (1.6%)
DIZZINESS	1 (1.5%)	1 (1.7%)	2 (1.6%)
HYPERKINESIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
PNEUMONIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
TOOTH DISORDER	1 (1.5%)	1 (1.7%)	2 (1.6%)
FEVER	0	2 (3.4%)	2 (1.6%)
ARTHRALGIA	1 (1.5%)	0	1 (0.8%)
CHEST PAIN	1 (1.5%)	0	1 (0.8%)
CONCENTRATION IMPAIRED	1 (1.5%)	0	1 (0.8%)
CONSTIPATION	1 (1.5%)	0	1 (0.8%)
CONTACT DERMATITIS	1 (1.5%)	0	1 (0.8%)
MYALGIA	1 (1.5%)	0	1 (0.8%)
RHINITIS	1 (1.5%)	0	1 (0.8%)
VERTIGO	1 (1.5%)	0	1 (0.8%)
DECREASED APPETITE	0	1 (1.7%)	1 (0.8%)
OTITIS MEDIA	0	1 (1.7%)	1 (0.8%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Preferred Term			
TOTAL	8 (12.1%)	6 (10.3%)	14 (11.3%)
EMOTIONAL LABILITY	3 (4.5%)	1 (1.7%)	4 (3.2%)
INFECTION	1 (1.5%)	1 (1.7%)	2 (1.6%)
AGITATION	1 (1.5%)	0	1 (0.8%)
BACK PAIN	1 (1.5%)	0	1 (0.8%)
NEUROSIS	1 (1.5%)	0	1 (0.8%)
SOMNOLENCE	1 (1.5%)	0	1 (0.8%)
TRAUMA	1 (1.5%)	0	1 (0.8%)
ABDOMINAL PAIN	0	1 (1.7%)	1 (0.8%)
ANXIETY	0	1 (1.7%)	1 (0.8%)
HALLUCINATIONS	0	1 (1.7%)	1 (0.8%)
HOSTILITY	0	1 (1.7%)	1 (0.8%)
NAUSEA	0	1 (1.7%)	1 (0.8%)
SYNCOPE	0	1 (1.7%)	1 (0.8%)
TOOTH CARIES	0	1 (1.7%)	1 (0.8%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
TOTAL	1 (3.8%)	0	1 (2.0%)
DYSMENORRHEA	1 (3.8%)	0	1 (2.0%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=26)	 Placebo (N=24)	 Total (N=50)
TOTAL	5 (19.2%)	0	5 (10.0%)
DYSMENORRHEA	5 (19.2%)	0	5 (10.0%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
TOTAL	53 (65.4%)	38 (57.6%)	91 (61.9%)
HEADACHE	15 (18.5%)	8 (12.1%)	23 (15.6%)
RESPIRATORY DISORDER	10 (12.3%)	10 (15.2%)	20 (13.6%)
PHARYNGITIS	9 (11.1%)	5 (7.6%)	14 (9.5%)
TRAUMA	8 (9.9%)	3 (4.5%)	11 (7.5%)
DYSPEPSIA	6 (7.4%)	4 (6.1%)	10 (6.8%)
ABDOMINAL PAIN	7 (8.6%)	2 (3.0%)	9 (6.1%)
NAUSEA	6 (7.4%)	3 (4.5%)	9 (6.1%)
RHINITIS	5 (6.2%)	4 (6.1%)	9 (6.1%)
INSOMNIA	2 (2.5%)	5 (7.6%)	7 (4.8%)
WEIGHT GAIN	2 (2.5%)	5 (7.6%)	7 (4.8%)
INFECTION	1 (1.2%)	6 (9.1%)	7 (4.8%)
ALLERGIC REACTION	5 (6.2%)	1 (1.5%)	6 (4.1%)
FEVER	4 (4.9%)	2 (3.0%)	6 (4.1%)
SINUSITIS	5 (6.2%)	0	5 (3.4%)
ALBUMINURIA	3 (3.7%)	2 (3.0%)	5 (3.4%)
COUGH INCREASED	3 (3.7%)	2 (3.0%)	5 (3.4%)
DIZZINESS	3 (3.7%)	2 (3.0%)	5 (3.4%)
VOMITING	3 (3.7%)	2 (3.0%)	5 (3.4%)
DECREASED APPETITE	2 (2.5%)	3 (4.5%)	5 (3.4%)
ASTHENIA	1 (1.2%)	4 (6.1%)	5 (3.4%)
NERVOUSNESS	4 (4.9%)	0	4 (2.7%)
SOMNOLENCE	4 (4.9%)	0	4 (2.7%)
DIARRHEA	2 (2.5%)	2 (3.0%)	4 (2.7%)
BACK PAIN	1 (1.2%)	3 (4.5%)	4 (2.7%)
CHEST PAIN	3 (3.7%)	0	3 (2.0%)
DRY MOUTH	3 (3.7%)	0	3 (2.0%)
LEUKOPENIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
PAIN	2 (2.5%)	1 (1.5%)	3 (2.0%)
ASTHMA	1 (1.2%)	2 (3.0%)	3 (2.0%)
HAEMATURIA	1 (1.2%)	2 (3.0%)	3 (2.0%)
INCREASED APPETITE	1 (1.2%)	2 (3.0%)	3 (2.0%)
PRURITUS	1 (1.2%)	2 (3.0%)	3 (2.0%)
ACNE	2 (2.5%)	0	2 (1.4%)
ARTHRALGIA	2 (2.5%)	0	2 (1.4%)
CONTACT DERMATITIS	2 (2.5%)	0	2 (1.4%)
OTITIS MEDIA	2 (2.5%)	0	2 (1.4%)
AGITATION	1 (1.2%)	1 (1.5%)	2 (1.4%)
DEPRESSION	1 (1.2%)	1 (1.5%)	2 (1.4%)
EMOTIONAL LABILITY	1 (1.2%)	1 (1.5%)	2 (1.4%)
HYPERKINESIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
RASH	1 (1.2%)	1 (1.5%)	2 (1.4%)
TOOTH CARIES	1 (1.2%)	1 (1.5%)	2 (1.4%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=81)	 Placebo (N=66)	 Total (N=147)
URINARY INCONTINENCE	1 (1.2%)	1 (1.5%)	2 (1.4%)
EPISTAXIS	0	2 (3.0%)	2 (1.4%)
FACE EDEMA	1 (1.2%)	0	1 (0.7%)
HALLUCINATIONS	1 (1.2%)	0	1 (0.7%)
NEUROSIS	1 (1.2%)	0	1 (0.7%)
VERTIGO	1 (1.2%)	0	1 (0.7%)
ABNORMAL VISION	0	1 (1.5%)	1 (0.7%)
ANXIETY	0	1 (1.5%)	1 (0.7%)
CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.7%)
GASTROENTERITIS	0	1 (1.5%)	1 (0.7%)
HYPESTHESIA	0	1 (1.5%)	1 (0.7%)
SYNCOPE	0	1 (1.5%)	1 (0.7%)
TREMOR	0	1 (1.5%)	1 (0.7%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
TOTAL	51 (63.0%)	28 (42.4%)	79 (53.7%)
RESPIRATORY DISORDER	9 (11.1%)	5 (7.6%)	14 (9.5%)
TRAUMA	10 (12.3%)	3 (4.5%)	13 (8.8%)
INFECTION	6 (7.4%)	6 (9.1%)	12 (8.2%)
HEADACHE	9 (11.1%)	2 (3.0%)	11 (7.5%)
VOMITING	9 (11.1%)	2 (3.0%)	11 (7.5%)
ABDOMINAL PAIN	5 (6.2%)	2 (3.0%)	7 (4.8%)
FEVER	4 (4.9%)	2 (3.0%)	6 (4.1%)
NERVOUSNESS	4 (4.9%)	1 (1.5%)	5 (3.4%)
AGITATION	2 (2.5%)	3 (4.5%)	5 (3.4%)
BRONCHITIS	2 (2.5%)	3 (4.5%)	5 (3.4%)
HOSTILITY	3 (3.7%)	1 (1.5%)	4 (2.7%)
WEIGHT GAIN	3 (3.7%)	1 (1.5%)	4 (2.7%)
EMOTIONAL LABILITY	2 (2.5%)	2 (3.0%)	4 (2.7%)
SOMNOLENCE	1 (1.2%)	3 (4.5%)	4 (2.7%)
DIARRHEA	3 (3.7%)	0	3 (2.0%)
PHARYNGITIS	3 (3.7%)	0	3 (2.0%)
RHINITIS	3 (3.7%)	0	3 (2.0%)
ACNE	2 (2.5%)	1 (1.5%)	3 (2.0%)
ALLERGIC REACTION	2 (2.5%)	1 (1.5%)	3 (2.0%)
ASTHENIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
CONTACT DERMATITIS	2 (2.5%)	1 (1.5%)	3 (2.0%)
INSOMNIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
NAUSEA	2 (2.5%)	1 (1.5%)	3 (2.0%)
SINUSITIS	2 (2.5%)	1 (1.5%)	3 (2.0%)
ASTHMA	2 (2.5%)	0	2 (1.4%)
BACK PAIN	2 (2.5%)	0	2 (1.4%)
DEPRESSION	2 (2.5%)	0	2 (1.4%)
OTITIS MEDIA	2 (2.5%)	0	2 (1.4%)
DYSPEPSIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
MYALGIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
PAIN	1 (1.2%)	1 (1.5%)	2 (1.4%)
PNEUMONIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
ANXIETY	1 (1.2%)	0	1 (0.7%)
CHEST PAIN	1 (1.2%)	0	1 (0.7%)
CONSTIPATION	1 (1.2%)	0	1 (0.7%)
COUGH INCREASED	1 (1.2%)	0	1 (0.7%)
FACE EDEMA	1 (1.2%)	0	1 (0.7%)
HYPERKINESIA	1 (1.2%)	0	1 (0.7%)
URINARY INCONTINENCE	1 (1.2%)	0	1 (0.7%)
CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.7%)
HALLUCINATIONS	0	1 (1.5%)	1 (0.7%)
HYPESTHESIA	0	1 (1.5%)	1 (0.7%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
LEUKOPENIA	0	1 (1.5%)	1 (0.7%)
SYNCOPE	0	1 (1.5%)	1 (0.7%)
TOOTH CARIES	0	1 (1.5%)	1 (0.7%)
TREMOR	0	1 (1.5%)	1 (0.7%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Preferred Term			
TOTAL	9 (11.1%)	10 (15.2%)	19 (12.9%)
EMOTIONAL LABILITY	4 (4.9%)	1 (1.5%)	5 (3.4%)
HOSTILITY	2 (2.5%)	1 (1.5%)	3 (2.0%)
AGITATION	1 (1.2%)	1 (1.5%)	2 (1.4%)
TRAUMA	1 (1.2%)	1 (1.5%)	2 (1.4%)
BACK PAIN	1 (1.2%)	0	1 (0.7%)
DEPRESSION	1 (1.2%)	0	1 (0.7%)
INFECTION	1 (1.2%)	0	1 (0.7%)
ANXIETY	0	1 (1.5%)	1 (0.7%)
ASTHMA	0	1 (1.5%)	1 (0.7%)
HALLUCINATIONS	0	1 (1.5%)	1 (0.7%)
OTITIS MEDIA	0	1 (1.5%)	1 (0.7%)
RASH	0	1 (1.5%)	1 (0.7%)
TOOTH CARIES	0	1 (1.5%)	1 (0.7%)
URINARY INCONTINENCE	0	1 (1.5%)	1 (0.7%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=33)	 Placebo (N=29)	 Total (N=62)
TOTAL	1 (3.0%)	0	1 (1.6%)
DYSMENORRHEA	1 (3.0%)	0	1 (1.6%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
TOTAL	2 (6.1%)	0	2 (3.2%)
DYSMENORRHEA	2 (6.1%)	0	2 (3.2%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
TOTAL	33 (63.5%)	38 (59.4%)	71 (61.2%)
HEADACHE	13 (25.0%)	13 (20.3%)	26 (22.4%)
RESPIRATORY DISORDER	3 (5.8%)	8 (12.5%)	11 (9.5%)
RHINITIS	5 (9.6%)	5 (7.8%)	10 (8.6%)
NAUSEA	6 (11.5%)	3 (4.7%)	9 (7.8%)
INSOMNIA	5 (9.6%)	3 (4.7%)	8 (6.9%)
ABDOMINAL PAIN	3 (5.8%)	5 (7.8%)	8 (6.9%)
TRAUMA	3 (5.8%)	5 (7.8%)	8 (6.9%)
PHARYNGITIS	4 (7.7%)	3 (4.7%)	7 (6.0%)
NERVOUSNESS	1 (1.9%)	6 (9.4%)	7 (6.0%)
ALLERGIC REACTION	3 (5.8%)	3 (4.7%)	6 (5.2%)
DECREASED APPETITE	2 (3.8%)	4 (6.3%)	6 (5.2%)
ALBUMINURIA	5 (9.6%)	0	5 (4.3%)
INFECTION	3 (5.8%)	2 (3.1%)	5 (4.3%)
HYPERKINESIA	3 (5.8%)	1 (1.6%)	4 (3.4%)
PAIN	3 (5.8%)	1 (1.6%)	4 (3.4%)
SINUSITIS	3 (5.8%)	1 (1.6%)	4 (3.4%)
ASTHENIA	2 (3.8%)	2 (3.1%)	4 (3.4%)
FEVER	2 (3.8%)	2 (3.1%)	4 (3.4%)
VASODILATATION	0	4 (6.3%)	4 (3.4%)
DIARRHEA	3 (5.8%)	0	3 (2.6%)
DIZZINESS	2 (3.8%)	1 (1.6%)	3 (2.6%)
NEUROSIS	2 (3.8%)	1 (1.6%)	3 (2.6%)
AGITATION	1 (1.9%)	2 (3.1%)	3 (2.6%)
HOSTILITY	1 (1.9%)	2 (3.1%)	3 (2.6%)
RASH	0	3 (4.7%)	3 (2.6%)
COUGH INCREASED	2 (3.8%)	0	2 (1.7%)
DYSPEPSIA	2 (3.8%)	0	2 (1.7%)
ARTHRALGIA	1 (1.9%)	1 (1.6%)	2 (1.7%)
ASTHMA	1 (1.9%)	1 (1.6%)	2 (1.7%)
OTITIS EXTERNA	1 (1.9%)	1 (1.6%)	2 (1.7%)
WEIGHT GAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
ACNE	0	2 (3.1%)	2 (1.7%)
CONTACT DERMATITIS	0	2 (3.1%)	2 (1.7%)
DRY MOUTH	0	2 (3.1%)	2 (1.7%)
FLATULENCE	0	2 (3.1%)	2 (1.7%)
SOMNOLENCE	0	2 (3.1%)	2 (1.7%)
TREMOR	0	2 (3.1%)	2 (1.7%)
VERTIGO	0	2 (3.1%)	2 (1.7%)
ANXIETY	1 (1.9%)	0	1 (0.9%)
BACK PAIN	1 (1.9%)	0	1 (0.9%)
CONCENTRATION IMPAIRED	1 (1.9%)	0	1 (0.9%)
EMOTIONAL LABILITY	1 (1.9%)	0	1 (0.9%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
HAEMATURIA	1 (1.9%)	0	1 (0.9%)
MYALGIA	1 (1.9%)	0	1 (0.9%)
VOMITING	1 (1.9%)	0	1 (0.9%)
ABNORMAL VISION	0	1 (1.6%)	1 (0.9%)
CONSTIPATION	0	1 (1.6%)	1 (0.9%)
EPISTAXIS	0	1 (1.6%)	1 (0.9%)
GASTROENTERITIS	0	1 (1.6%)	1 (0.9%)
OTITIS MEDIA	0	1 (1.6%)	1 (0.9%)
TOOTH CARIES	0	1 (1.6%)	1 (0.9%)
URINARY INCONTINENCE	0	1 (1.6%)	1 (0.9%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Preferred Term			
TOTAL	29 (55.8%)	37 (57.8%)	66 (56.9%)
HEADACHE	9 (17.3%)	6 (9.4%)	15 (12.9%)
RESPIRATORY DISORDER	4 (7.7%)	6 (9.4%)	10 (8.6%)
NERVOUSNESS	1 (1.9%)	8 (12.5%)	9 (7.8%)
HYPERKINESIA	4 (7.7%)	4 (6.3%)	8 (6.9%)
INFECTION	4 (7.7%)	4 (6.3%)	8 (6.9%)
PHARYNGITIS	3 (5.8%)	3 (4.7%)	6 (5.2%)
HOSTILITY	1 (1.9%)	5 (7.8%)	6 (5.2%)
OTITIS MEDIA	3 (5.8%)	2 (3.1%)	5 (4.3%)
TRAUMA	3 (5.8%)	2 (3.1%)	5 (4.3%)
ABDOMINAL PAIN	2 (3.8%)	3 (4.7%)	5 (4.3%)
ANXIETY	1 (1.9%)	4 (6.3%)	5 (4.3%)
ASTHENIA	2 (3.8%)	2 (3.1%)	4 (3.4%)
INSOMNIA	1 (1.9%)	3 (4.7%)	4 (3.4%)
EMOTIONAL LABILITY	2 (3.8%)	1 (1.6%)	3 (2.6%)
TOOTH DISORDER	2 (3.8%)	1 (1.6%)	3 (2.6%)
ASTHMA	1 (1.9%)	2 (3.1%)	3 (2.6%)
DIZZINESS	1 (1.9%)	2 (3.1%)	3 (2.6%)
DYSPEPSIA	0	3 (4.7%)	3 (2.6%)
NAUSEA	0	3 (4.7%)	3 (2.6%)
ACNE	2 (3.8%)	0	2 (1.7%)
SINUSITIS	2 (3.8%)	0	2 (1.7%)
ALLERGIC REACTION	1 (1.9%)	1 (1.6%)	2 (1.7%)
COUGH INCREASED	1 (1.9%)	1 (1.6%)	2 (1.7%)
DEPRESSION	1 (1.9%)	1 (1.6%)	2 (1.7%)
DIARRHEA	1 (1.9%)	1 (1.6%)	2 (1.7%)
FEVER	1 (1.9%)	1 (1.6%)	2 (1.7%)
PAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
SOMNOLENCE	1 (1.9%)	1 (1.6%)	2 (1.7%)
WEIGHT GAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
AGITATION	0	2 (3.1%)	2 (1.7%)
ARTHRALGIA	1 (1.9%)	0	1 (0.9%)
BRONCHITIS	1 (1.9%)	0	1 (0.9%)
CONCENTRATION IMPAIRED	1 (1.9%)	0	1 (0.9%)
CONSTIPATION	1 (1.9%)	0	1 (0.9%)
OTITIS EXTERNA	1 (1.9%)	0	1 (0.9%)
VERTIGO	1 (1.9%)	0	1 (0.9%)
BACK PAIN	0	1 (1.6%)	1 (0.9%)
CONTACT DERMATITIS	0	1 (1.6%)	1 (0.9%)
DECREASED APPETITE	0	1 (1.6%)	1 (0.9%)
PNEUMONIA	0	1 (1.6%)	1 (0.9%)
RHINITIS	0	1 (1.6%)	1 (0.9%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Preferred Term			
TOTAL	4 (7.7%)	7 (10.9%)	11 (9.5%)
INFECTION	1 (1.9%)	1 (1.6%)	2 (1.7%)
HOSTILITY	0	2 (3.1%)	2 (1.7%)
NEUROSIS	1 (1.9%)	0	1 (0.9%)
PHARYNGITIS	1 (1.9%)	0	1 (0.9%)
SOMNOLENCE	1 (1.9%)	0	1 (0.9%)
ABDOMINAL PAIN	0	1 (1.6%)	1 (0.9%)
HYPERKINESIA	0	1 (1.6%)	1 (0.9%)
NAUSEA	0	1 (1.6%)	1 (0.9%)
NERVOUSNESS	0	1 (1.6%)	1 (0.9%)
SYNCOPE	0	1 (1.6%)	1 (0.9%)
TRAUMA	0	1 (1.6%)	1 (0.9%)
URINARY INCONTINENCE	0	1 (1.6%)	1 (0.9%)
WEIGHT GAIN	0	1 (1.6%)	1 (0.9%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
TOTAL	0	1 (4.5%)	1 (2.0%)
DYSMENORRHEA	0	1 (4.5%)	1 (2.0%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
TOTAL	4 (14.3%)	0	4 (8.0%)
DYSMENORRHEA	4 (14.3%)	0	4 (8.0%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
TOTAL	86 (64.7%)	76 (58.5%)	162 (61.6%)
HEADACHE	28 (21.1%)	21 (16.2%)	49 (18.6%)
RESPIRATORY DISORDER	13 (9.8%)	18 (13.8%)	31 (11.8%)
PHARYNGITIS	13 (9.8%)	8 (6.2%)	21 (8.0%)
TRAUMA	11 (8.3%)	8 (6.2%)	19 (7.2%)
RHINITIS	10 (7.5%)	9 (6.9%)	19 (7.2%)
NAUSEA	12 (9.0%)	6 (4.6%)	18 (6.8%)
ABDOMINAL PAIN	10 (7.5%)	7 (5.4%)	17 (6.5%)
INSOMNIA	7 (5.3%)	8 (6.2%)	15 (5.7%)
ALLERGIC REACTION	8 (6.0%)	4 (3.1%)	12 (4.6%)
DYSPEPSIA	8 (6.0%)	4 (3.1%)	12 (4.6%)
INFECTION	4 (3.0%)	8 (6.2%)	12 (4.6%)
NERVOUSNESS	5 (3.8%)	6 (4.6%)	11 (4.2%)
DECREASED APPETITE	4 (3.0%)	7 (5.4%)	11 (4.2%)
ALBUMINURIA	8 (6.0%)	2 (1.5%)	10 (3.8%)
FEVER	6 (4.5%)	4 (3.1%)	10 (3.8%)
SINUSITIS	8 (6.0%)	1 (0.8%)	9 (3.4%)
ASTHENIA	3 (2.3%)	6 (4.6%)	9 (3.4%)
WEIGHT GAIN	3 (2.3%)	6 (4.6%)	9 (3.4%)
DIZZINESS	5 (3.8%)	3 (2.3%)	8 (3.0%)
COUGH INCREASED	5 (3.8%)	2 (1.5%)	7 (2.7%)
DIARRHEA	5 (3.8%)	2 (1.5%)	7 (2.7%)
PAIN	5 (3.8%)	2 (1.5%)	7 (2.7%)
HYPERKINESIA	4 (3.0%)	2 (1.5%)	6 (2.3%)
SOMNOLENCE	4 (3.0%)	2 (1.5%)	6 (2.3%)
VOMITING	4 (3.0%)	2 (1.5%)	6 (2.3%)
DRY MOUTH	3 (2.3%)	2 (1.5%)	5 (1.9%)
AGITATION	2 (1.5%)	3 (2.3%)	5 (1.9%)
ASTHMA	2 (1.5%)	3 (2.3%)	5 (1.9%)
BACK PAIN	2 (1.5%)	3 (2.3%)	5 (1.9%)
RASH	1 (0.8%)	4 (3.1%)	5 (1.9%)
ARTHRALGIA	3 (2.3%)	1 (0.8%)	4 (1.5%)
NEUROSIS	3 (2.3%)	1 (0.8%)	4 (1.5%)
ACNE	2 (1.5%)	2 (1.5%)	4 (1.5%)
CONTACT DERMATITIS	2 (1.5%)	2 (1.5%)	4 (1.5%)
HAEMATURIA	2 (1.5%)	2 (1.5%)	4 (1.5%)
VASODILATATION	0	4 (3.1%)	4 (1.5%)
CHEST PAIN	3 (2.3%)	0	3 (1.1%)
EMOTIONAL LABILITY	2 (1.5%)	1 (0.8%)	3 (1.1%)
LEUKOPENIA	2 (1.5%)	1 (0.8%)	3 (1.1%)
OTITIS MEDIA	2 (1.5%)	1 (0.8%)	3 (1.1%)
HOSTILITY	1 (0.8%)	2 (1.5%)	3 (1.1%)
INCREASED APPETITE	1 (0.8%)	2 (1.5%)	3 (1.1%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
PRURITUS	1 (0.8%)	2 (1.5%)	3 (1.1%)
TOOTH CARIES	1 (0.8%)	2 (1.5%)	3 (1.1%)
URINARY INCONTINENCE	1 (0.8%)	2 (1.5%)	3 (1.1%)
VERTIGO	1 (0.8%)	2 (1.5%)	3 (1.1%)
EPISTAXIS	0	3 (2.3%)	3 (1.1%)
TREMOR	0	3 (2.3%)	3 (1.1%)
ANXIETY	1 (0.8%)	1 (0.8%)	2 (0.8%)
CONCENTRATION IMPAIRED	1 (0.8%)	1 (0.8%)	2 (0.8%)
DEPRESSION	1 (0.8%)	1 (0.8%)	2 (0.8%)
OTITIS EXTERNA	1 (0.8%)	1 (0.8%)	2 (0.8%)
ABNORMAL VISION	0	2 (1.5%)	2 (0.8%)
FLATULENCE	0	2 (1.5%)	2 (0.8%)
GASTROENTERITIS	0	2 (1.5%)	2 (0.8%)
FACE EDEMA	1 (0.8%)	0	1 (0.4%)
HALLUCINATIONS	1 (0.8%)	0	1 (0.4%)
MYALGIA	1 (0.8%)	0	1 (0.4%)
CONSTIPATION	0	1 (0.8%)	1 (0.4%)
HYPESTHESIA	0	1 (0.8%)	1 (0.4%)
SYNCOPE	0	1 (0.8%)	1 (0.4%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
TOTAL	80 (60.2%)	65 (50.0%)	145 (55.1%)
HEADACHE	18 (13.5%)	8 (6.2%)	26 (9.9%)
RESPIRATORY DISORDER	13 (9.8%)	11 (8.5%)	24 (9.1%)
INFECTION	10 (7.5%)	10 (7.7%)	20 (7.6%)
TRAUMA	13 (9.8%)	5 (3.8%)	18 (6.8%)
NERVOUSNESS	5 (3.8%)	9 (6.9%)	14 (5.3%)
ABDOMINAL PAIN	7 (5.3%)	5 (3.8%)	12 (4.6%)
VOMITING	9 (6.8%)	2 (1.5%)	11 (4.2%)
HOSTILITY	4 (3.0%)	6 (4.6%)	10 (3.8%)
PHARYNGITIS	6 (4.5%)	3 (2.3%)	9 (3.4%)
HYPERKINESIA	5 (3.8%)	4 (3.1%)	9 (3.4%)
FEVER	5 (3.8%)	3 (2.3%)	8 (3.0%)
OTITIS MEDIA	5 (3.8%)	2 (1.5%)	7 (2.7%)
ASTHENIA	4 (3.0%)	3 (2.3%)	7 (2.7%)
EMOTIONAL LABILITY	4 (3.0%)	3 (2.3%)	7 (2.7%)
INSOMNIA	3 (2.3%)	4 (3.1%)	7 (2.7%)
AGITATION	2 (1.5%)	5 (3.8%)	7 (2.7%)
WEIGHT GAIN	4 (3.0%)	2 (1.5%)	6 (2.3%)
BRONCHITIS	3 (2.3%)	3 (2.3%)	6 (2.3%)
ANXIETY	2 (1.5%)	4 (3.1%)	6 (2.3%)
NAUSEA	2 (1.5%)	4 (3.1%)	6 (2.3%)
SOMNOLENCE	2 (1.5%)	4 (3.1%)	6 (2.3%)
ACNE	4 (3.0%)	1 (0.8%)	5 (1.9%)
DIARRHEA	4 (3.0%)	1 (0.8%)	5 (1.9%)
SINUSITIS	4 (3.0%)	1 (0.8%)	5 (1.9%)
ALLERGIC REACTION	3 (2.3%)	2 (1.5%)	5 (1.9%)
ASTHMA	3 (2.3%)	2 (1.5%)	5 (1.9%)
DYSPEPSIA	1 (0.8%)	4 (3.1%)	5 (1.9%)
DEPRESSION	3 (2.3%)	1 (0.8%)	4 (1.5%)
RHINITIS	3 (2.3%)	1 (0.8%)	4 (1.5%)
CONTACT DERMATITIS	2 (1.5%)	2 (1.5%)	4 (1.5%)
PAIN	2 (1.5%)	2 (1.5%)	4 (1.5%)
BACK PAIN	2 (1.5%)	1 (0.8%)	3 (1.1%)
COUGH INCREASED	2 (1.5%)	1 (0.8%)	3 (1.1%)
TOOTH DISORDER	2 (1.5%)	1 (0.8%)	3 (1.1%)
DIZZINESS	1 (0.8%)	2 (1.5%)	3 (1.1%)
PNEUMONIA	1 (0.8%)	2 (1.5%)	3 (1.1%)
CONSTIPATION	2 (1.5%)	0	2 (0.8%)
CONCENTRATION IMPAIRED	1 (0.8%)	1 (0.8%)	2 (0.8%)
MYALGIA	1 (0.8%)	1 (0.8%)	2 (0.8%)
ARTHRALGIA	1 (0.8%)	0	1 (0.4%)
CHEST PAIN	1 (0.8%)	0	1 (0.4%)
FACE EDEMA	1 (0.8%)	0	1 (0.4%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
OTITIS EXTERNA	1 (0.8%)	0	1 (0.4%)
URINARY INCONTINENCE	1 (0.8%)	0	1 (0.4%)
VERTIGO	1 (0.8%)	0	1 (0.4%)
DECREASED APPETITE	0	1 (0.8%)	1 (0.4%)
HALLUCINATIONS	0	1 (0.8%)	1 (0.4%)
HYPESTHESIA	0	1 (0.8%)	1 (0.4%)
LEUKOPENIA	0	1 (0.8%)	1 (0.4%)
SYNCOPE	0	1 (0.8%)	1 (0.4%)
TOOTH CARIES	0	1 (0.8%)	1 (0.4%)
TREMOR	0	1 (0.8%)	1 (0.4%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
TOTAL	13 (9.8%)	17 (13.1%)	30 (11.4%)
EMOTIONAL LABILITY	4 (3.0%)	1 (0.8%)	5 (1.9%)
HOSTILITY	2 (1.5%)	3 (2.3%)	5 (1.9%)
INFECTION	2 (1.5%)	1 (0.8%)	3 (1.1%)
TRAUMA	1 (0.8%)	2 (1.5%)	3 (1.1%)
AGITATION	1 (0.8%)	1 (0.8%)	2 (0.8%)
URINARY INCONTINENCE	0	2 (1.5%)	2 (0.8%)
BACK PAIN	1 (0.8%)	0	1 (0.4%)
DEPRESSION	1 (0.8%)	0	1 (0.4%)
NEUROSIS	1 (0.8%)	0	1 (0.4%)
PHARYNGITIS	1 (0.8%)	0	1 (0.4%)
SOMNOLENCE	1 (0.8%)	0	1 (0.4%)
ABDOMINAL PAIN	0	1 (0.8%)	1 (0.4%)
ANXIETY	0	1 (0.8%)	1 (0.4%)
ASTHMA	0	1 (0.8%)	1 (0.4%)
HALLUCINATIONS	0	1 (0.8%)	1 (0.4%)
HYPERKINESIA	0	1 (0.8%)	1 (0.4%)
NAUSEA	0	1 (0.8%)	1 (0.4%)
NERVOUSNESS	0	1 (0.8%)	1 (0.4%)
OTITIS MEDIA	0	1 (0.8%)	1 (0.4%)
RASH	0	1 (0.8%)	1 (0.4%)
SYNCOPE	0	1 (0.8%)	1 (0.4%)
TOOTH CARIES	0	1 (0.8%)	1 (0.4%)
WEIGHT GAIN	0	1 (0.8%)	1 (0.4%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
TOTAL	1 (1.6%)	1 (2.0%)	2 (1.8%)
DYSMENORRHEA	1 (1.6%)	1 (2.0%)	2 (1.8%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
TOTAL	6 (9.8%)	0	6 (5.4%)
DYSMENORRHEA	6 (9.8%)	0	6 (5.4%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Open-Label Treatment Phase by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Preferred Term			
TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=13)	Total (N=22)
Body System	Preferred Term			
TOTAL	TOTAL	2 (22.2%)	1 (7.7%)	3 (13.6%)
Nervous System	TOTAL	1 (11.1%)	0	1 (4.5%)
	DEPRESSION	1 (11.1%)	0	1 (4.5%)
Respiratory System	TOTAL	1 (11.1%)	0	1 (4.5%)
	RESPIRATORY DISORDER	1 (11.1%)	0	1 (4.5%)
Digestive System	TOTAL	0	1 (7.7%)	1 (4.5%)
	NAUSEA	0	1 (7.7%)	1 (4.5%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=13)	Total (N=22)
Body System	Preferred Term			
TOTAL	TOTAL	1 (11.1%)	4 (30.8%)	5 (22.7%)
Nervous System	TOTAL	1 (11.1%)	2 (15.4%)	3 (13.6%)
	DEPRESSION	1 (11.1%)	1 (7.7%)	2 (9.1%)
	HYSTERIA	0	1 (7.7%)	1 (4.5%)
Cardiovascular System	TOTAL	0	1 (7.7%)	1 (4.5%)
	SYNCOPE	0	1 (7.7%)	1 (4.5%)
Special Searches	TOTAL	0	1 (7.7%)	1 (4.5%)
	PUNCTURE SITE PAIN	0	1 (7.7%)	1 (4.5%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=13)	Total (N=22)
Body System	Preferred Term			
TOTAL	TOTAL	1 (11.1%)	0	1 (4.5%)
Body as a Whole	TOTAL	1 (11.1%)	0	1 (4.5%)
	FEVER	1 (11.1%)	0	1 (4.5%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=3)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=3)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=3)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	1 (14.3%)	0	1 (6.7%)
Body as a Whole	TOTAL	1 (14.3%)	0	1 (6.7%)
	ABDOMINAL PAIN	1 (14.3%)	0	1 (6.7%)
	HEADACHE	1 (14.3%)	0	1 (6.7%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	1 (14.3%)	1 (12.5%)	2 (13.3%)
Respiratory System	TOTAL	1 (14.3%)	0	1 (6.7%)
	SINUSITIS	1 (14.3%)	0	1 (6.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (12.5%)	1 (6.7%)
	WEIGHT GAIN	0	1 (12.5%)	1 (6.7%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	1 (14.3%)	1 (12.5%)	2 (13.3%)
Nervous System	TOTAL	1 (14.3%)	0	1 (6.7%)
	NEUROSIS	1 (14.3%)	0	1 (6.7%)
Body as a Whole	TOTAL	0	1 (12.5%)	1 (6.7%)
	INFECTION	0	1 (12.5%)	1 (6.7%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=5)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=5)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=5)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=3)	Total (N=6)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=3)	Total (N=6)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=3)	Total (N=6)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=21)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	3 (18.8%)	1 (4.8%)	4 (10.8%)
Body as a Whole	TOTAL	1 (6.3%)	0	1 (2.7%)
	ABDOMINAL PAIN	1 (6.3%)	0	1 (2.7%)
	HEADACHE	1 (6.3%)	0	1 (2.7%)
Nervous System	TOTAL	1 (6.3%)	0	1 (2.7%)
	DEPRESSION	1 (6.3%)	0	1 (2.7%)
Respiratory System	TOTAL	1 (6.3%)	0	1 (2.7%)
	RESPIRATORY DISORDER	1 (6.3%)	0	1 (2.7%)
Digestive System	TOTAL	0	1 (4.8%)	1 (2.7%)
	NAUSEA	0	1 (4.8%)	1 (2.7%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=21)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	2 (12.5%)	5 (23.8%)	7 (18.9%)
Nervous System	TOTAL	1 (6.3%)	2 (9.5%)	3 (8.1%)
	DEPRESSION	1 (6.3%)	1 (4.8%)	2 (5.4%)
	HYSTERIA	0	1 (4.8%)	1 (2.7%)
Respiratory System	TOTAL	1 (6.3%)	0	1 (2.7%)
	SINUSITIS	1 (6.3%)	0	1 (2.7%)
Cardiovascular System	TOTAL	0	1 (4.8%)	1 (2.7%)
	SYNCOPE	0	1 (4.8%)	1 (2.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (4.8%)	1 (2.7%)
	WEIGHT GAIN	0	1 (4.8%)	1 (2.7%)
Special Searches	TOTAL	0	1 (4.8%)	1 (2.7%)
	PUNCTURE SITE PAIN	0	1 (4.8%)	1 (2.7%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=21)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	2 (12.5%)	1 (4.8%)	3 (8.1%)
Body as a Whole	TOTAL	1 (6.3%)	1 (4.8%)	2 (5.4%)
	FEVER	1 (6.3%)	0	1 (2.7%)
	INFECTION	0	1 (4.8%)	1 (2.7%)
Nervous System	TOTAL	1 (6.3%)	0	1 (2.7%)
	NEUROSIS	1 (6.3%)	0	1 (2.7%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=15)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=15)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=15)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=6)	Total (N=14)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=6)	Total (N=14)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=6)	Total (N=14)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=9)	Total (N=20)
Body System	Preferred Term			
TOTAL	TOTAL	2 (18.2%)	2 (22.2%)	4 (20.0%)
Hemic and Lymphatic System	TOTAL	1 (9.1%)	0	1 (5.0%)
	LEUKOPENIA	1 (9.1%)	0	1 (5.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (9.1%)	0	1 (5.0%)
	WEIGHT GAIN	1 (9.1%)	0	1 (5.0%)
Musculoskeletal System	TOTAL	0	1 (11.1%)	1 (5.0%)
	MYALGIA	0	1 (11.1%)	1 (5.0%)
Nervous System	TOTAL	0	2 (22.2%)	2 (10.0%)
	SOMNOLENCE	0	1 (11.1%)	1 (5.0%)
	WITHDRAWAL SYNDROME	0	1 (11.1%)	1 (5.0%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=9)	Total (N=20)
Body System	Preferred Term			
TOTAL	TOTAL	1 (9.1%)	0	1 (5.0%)
Nervous System	TOTAL	1 (9.1%)	0	1 (5.0%)
	HOSTILITY	1 (9.1%)	0	1 (5.0%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=9)	Total (N=20)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=2)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=2)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=2)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=6)	Total (N=10)
Body System	Preferred Term			
TOTAL	TOTAL	1 (25.0%)	1 (16.7%)	2 (20.0%)
Digestive System	TOTAL	1 (25.0%)	0	1 (10.0%)
	DYSPEPSIA	1 (25.0%)	0	1 (10.0%)
Nervous System	TOTAL	0	1 (16.7%)	1 (10.0%)
	ABNORMAL DREAMS	0	1 (16.7%)	1 (10.0%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=6)	Total (N=10)
Body System	Preferred Term			
TOTAL	TOTAL	1 (25.0%)	2 (33.3%)	3 (30.0%)
Cardiovascular System	TOTAL	1 (25.0%)	0	1 (10.0%)
	BRADYCARDIA	1 (25.0%)	0	1 (10.0%)
Body as a Whole	TOTAL	0	1 (16.7%)	1 (10.0%)
	HEADACHE	0	1 (16.7%)	1 (10.0%)
Nervous System	TOTAL	0	1 (16.7%)	1 (10.0%)
	INSOMNIA	0	1 (16.7%)	1 (10.0%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=6)	Total (N=10)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=15)	Placebo (N=15)	Total (N=30)
Body System	Preferred Term			
TOTAL	TOTAL	3 (20.0%)	3 (20.0%)	6 (20.0%)
Digestive System	TOTAL	1 (6.7%)	0	1 (3.3%)
	DYSPEPSIA	1 (6.7%)	0	1 (3.3%)
Hemic and Lymphatic System	TOTAL	1 (6.7%)	0	1 (3.3%)
	LEUKOPENIA	1 (6.7%)	0	1 (3.3%)
Metabolic and Nutritional Disorders	TOTAL	1 (6.7%)	0	1 (3.3%)
	WEIGHT GAIN	1 (6.7%)	0	1 (3.3%)
Musculoskeletal System	TOTAL	0	1 (6.7%)	1 (3.3%)
	MYALGIA	0	1 (6.7%)	1 (3.3%)
Nervous System	TOTAL	0	3 (20.0%)	3 (10.0%)
	ABNORMAL DREAMS	0	1 (6.7%)	1 (3.3%)
	SOMNOLENCE	0	1 (6.7%)	1 (3.3%)
	WITHDRAWAL SYNDROME	0	1 (6.7%)	1 (3.3%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=15)	Placebo (N=15)	Total (N=30)
Body System	Preferred Term			
TOTAL	TOTAL	2 (13.3%)	2 (13.3%)	4 (13.3%)
Cardiovascular System	TOTAL	1 (6.7%)	0	1 (3.3%)
	BRADYCARDIA	1 (6.7%)	0	1 (3.3%)
Nervous System	TOTAL	1 (6.7%)	1 (6.7%)	2 (6.7%)
	HOSTILITY	1 (6.7%)	0	1 (3.3%)
	INSOMNIA	0	1 (6.7%)	1 (3.3%)
Body as a Whole	TOTAL	0	1 (6.7%)	1 (3.3%)
	HEADACHE	0	1 (6.7%)	1 (3.3%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=15)	Placebo (N=15)	Total (N=30)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=12)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=12)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=12)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=3)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=3)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=3)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	4 (20.0%)	3 (13.6%)	7 (16.7%)
Hemic and Lymphatic System	TOTAL	1 (5.0%)	0	1 (2.4%)
	LEUKOPENIA	1 (5.0%)	0	1 (2.4%)
Metabolic and Nutritional Disorders	TOTAL	1 (5.0%)	0	1 (2.4%)
	WEIGHT GAIN	1 (5.0%)	0	1 (2.4%)
Nervous System	TOTAL	1 (5.0%)	2 (9.1%)	3 (7.1%)
	DEPRESSION	1 (5.0%)	0	1 (2.4%)
	SOMNOLENCE	0	1 (4.5%)	1 (2.4%)
	WITHDRAWAL SYNDROME	0	1 (4.5%)	1 (2.4%)
Respiratory System	TOTAL	1 (5.0%)	0	1 (2.4%)
	RESPIRATORY DISORDER	1 (5.0%)	0	1 (2.4%)
Digestive System	TOTAL	0	1 (4.5%)	1 (2.4%)
	NAUSEA	0	1 (4.5%)	1 (2.4%)
Musculoskeletal System	TOTAL	0	1 (4.5%)	1 (2.4%)
	MYALGIA	0	1 (4.5%)	1 (2.4%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	2 (10.0%)	4 (18.2%)	6 (14.3%)
Nervous System	TOTAL	2 (10.0%)	2 (9.1%)	4 (9.5%)
	DEPRESSION	1 (5.0%)	1 (4.5%)	2 (4.8%)
	HOSTILITY	1 (5.0%)	0	1 (2.4%)
	HYSTERIA	0	1 (4.5%)	1 (2.4%)
Cardiovascular System	TOTAL	0	1 (4.5%)	1 (2.4%)
	SYNCOPE	0	1 (4.5%)	1 (2.4%)
Special Searches	TOTAL	0	1 (4.5%)	1 (2.4%)
	PUNCTURE SITE PAIN	0	1 (4.5%)	1 (2.4%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	1 (5.0%)	0	1 (2.4%)
Body as a Whole	TOTAL	1 (5.0%)	0	1 (2.4%)
	FEVER	1 (5.0%)	0	1 (2.4%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=5)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=5)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=5)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=14)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	2 (18.2%)	1 (7.1%)	3 (12.0%)
Body as a Whole	TOTAL	1 (9.1%)	0	1 (4.0%)
	ABDOMINAL PAIN	1 (9.1%)	0	1 (4.0%)
	HEADACHE	1 (9.1%)	0	1 (4.0%)
Digestive System	TOTAL	1 (9.1%)	0	1 (4.0%)
	DYSPEPSIA	1 (9.1%)	0	1 (4.0%)
Nervous System	TOTAL	0	1 (7.1%)	1 (4.0%)
	ABNORMAL DREAMS	0	1 (7.1%)	1 (4.0%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=14)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	2 (18.2%)	3 (21.4%)	5 (20.0%)
Cardiovascular System	TOTAL	1 (9.1%)	0	1 (4.0%)
	BRADYCARDIA	1 (9.1%)	0	1 (4.0%)
Respiratory System	TOTAL	1 (9.1%)	0	1 (4.0%)
	SINUSITIS	1 (9.1%)	0	1 (4.0%)
Body as a Whole	TOTAL	0	1 (7.1%)	1 (4.0%)
	HEADACHE	0	1 (7.1%)	1 (4.0%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (7.1%)	1 (4.0%)
	WEIGHT GAIN	0	1 (7.1%)	1 (4.0%)
Nervous System	TOTAL	0	1 (7.1%)	1 (4.0%)
	INSOMNIA	0	1 (7.1%)	1 (4.0%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=14)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	1 (9.1%)	1 (7.1%)	2 (8.0%)
Nervous System	TOTAL	1 (9.1%)	0	1 (4.0%)
	NEUROSIS	1 (9.1%)	0	1 (4.0%)
Body as a Whole	TOTAL	0	1 (7.1%)	1 (4.0%)
	INFECTION	0	1 (7.1%)	1 (4.0%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=10)	Total (N=17)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=10)	Total (N=17)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=10)	Total (N=17)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=4)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=4)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=4)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=31)	Placebo (N=36)	Total (N=67)
Body System	Preferred Term			
TOTAL	TOTAL	6 (19.4%)	4 (11.1%)	10 (14.9%)
Body as a Whole	TOTAL	1 (3.2%)	0	1 (1.5%)
	ABDOMINAL PAIN	1 (3.2%)	0	1 (1.5%)
	HEADACHE	1 (3.2%)	0	1 (1.5%)
Digestive System	TOTAL	1 (3.2%)	1 (2.8%)	2 (3.0%)
	DYSPEPSIA	1 (3.2%)	0	1 (1.5%)
	NAUSEA	0	1 (2.8%)	1 (1.5%)
Hemic and Lymphatic System	TOTAL	1 (3.2%)	0	1 (1.5%)
	LEUKOPENIA	1 (3.2%)	0	1 (1.5%)
Metabolic and Nutritional Disorders	TOTAL	1 (3.2%)	0	1 (1.5%)
	WEIGHT GAIN	1 (3.2%)	0	1 (1.5%)
Nervous System	TOTAL	1 (3.2%)	3 (8.3%)	4 (6.0%)
	DEPRESSION	1 (3.2%)	0	1 (1.5%)
	ABNORMAL DREAMS	0	1 (2.8%)	1 (1.5%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.5%)
	WITHDRAWAL SYNDROME	0	1 (2.8%)	1 (1.5%)
Respiratory System	TOTAL	1 (3.2%)	0	1 (1.5%)
	RESPIRATORY DISORDER	1 (3.2%)	0	1 (1.5%)
Musculoskeletal System	TOTAL	0	1 (2.8%)	1 (1.5%)
	MYALGIA	0	1 (2.8%)	1 (1.5%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=31)	Placebo (N=36)	Total (N=67)
Body System	Preferred Term			
TOTAL	TOTAL	4 (12.9%)	7 (19.4%)	11 (16.4%)
Nervous System	TOTAL	2 (6.5%)	3 (8.3%)	5 (7.5%)
	DEPRESSION	1 (3.2%)	1 (2.8%)	2 (3.0%)
	HOSTILITY	1 (3.2%)	0	1 (1.5%)
	HYSTERIA	0	1 (2.8%)	1 (1.5%)
	INSOMNIA	0	1 (2.8%)	1 (1.5%)
Cardiovascular System	TOTAL	1 (3.2%)	1 (2.8%)	2 (3.0%)
	BRADYCARDIA	1 (3.2%)	0	1 (1.5%)
	SYNCOPE	0	1 (2.8%)	1 (1.5%)
Respiratory System	TOTAL	1 (3.2%)	0	1 (1.5%)
	SINUSITIS	1 (3.2%)	0	1 (1.5%)
Body as a Whole	TOTAL	0	1 (2.8%)	1 (1.5%)
	HEADACHE	0	1 (2.8%)	1 (1.5%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.8%)	1 (1.5%)
	WEIGHT GAIN	0	1 (2.8%)	1 (1.5%)
Special Searches	TOTAL	0	1 (2.8%)	1 (1.5%)
	PUNCTURE SITE PAIN	0	1 (2.8%)	1 (1.5%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=31)	Placebo (N=36)	Total (N=67)
Body System	Preferred Term			
TOTAL	TOTAL	2 (6.5%)	1 (2.8%)	3 (4.5%)
Body as a Whole	TOTAL	1 (3.2%)	1 (2.8%)	2 (3.0%)
	FEVER	1 (3.2%)	0	1 (1.5%)
	INFECTION	0	1 (2.8%)	1 (1.5%)
Nervous System	TOTAL	1 (3.2%)	0	1 (1.5%)
	NEUROSIS	1 (3.2%)	0	1 (1.5%)

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=17)	Placebo (N=27)	Total (N=44)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=17)	Placebo (N=27)	Total (N=44)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=17)	Placebo (N=27)	Total (N=44)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=9)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=9)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=9)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=9)	Placebo (N=13)	Total (N=22)
Preferred Term			
TOTAL	2 (22.2%)	1 (7.7%)	3 (13.6%)
DEPRESSION	1 (11.1%)	0	1 (4.5%)
RESPIRATORY DISORDER	1 (11.1%)	0	1 (4.5%)
NAUSEA	0	1 (7.7%)	1 (4.5%)

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=9)	Placebo (N=13)	Total (N=22)
Preferred Term			
TOTAL	1 (11.1%)	4 (30.8%)	5 (22.7%)
DEPRESSION	1 (11.1%)	1 (7.7%)	2 (9.1%)
HYSTERIA	0	1 (7.7%)	1 (4.5%)
PUNCTURE SITE PAIN	0	1 (7.7%)	1 (4.5%)
SYNCOPE	0	1 (7.7%)	1 (4.5%)

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=9)	Placebo (N=13)	Total (N=22)
Preferred Term			
TOTAL	1 (11.1%)	0	1 (4.5%)
FEVER	1 (11.1%)	0	1 (4.5%)

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=5)	Placebo (N=3)	Total (N=8)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=5)	Placebo (N=3)	Total (N=8)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=5)	Placebo (N=3)	Total (N=8)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
Preferred Term			
TOTAL	1 (14.3%)	0	1 (6.7%)
ABDOMINAL PAIN	1 (14.3%)	0	1 (6.7%)
HEADACHE	1 (14.3%)	0	1 (6.7%)

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
Preferred Term			
TOTAL	1 (14.3%)	1 (12.5%)	2 (13.3%)
SINUSITIS	1 (14.3%)	0	1 (6.7%)
WEIGHT GAIN	0	1 (12.5%)	1 (6.7%)

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
Preferred Term			
TOTAL	1 (14.3%)	1 (12.5%)	2 (13.3%)
NEUROSIS	1 (14.3%)	0	1 (6.7%)
INFECTION	0	1 (12.5%)	1 (6.7%)

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=4)	Placebo (N=5)	Total (N=9)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=4)	Placebo (N=5)	Total (N=9)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=4)	Placebo (N=5)	Total (N=9)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=3)	Placebo (N=3)	Total (N=6)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=3)	Placebo (N=3)	Total (N=6)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=3)	Placebo (N=3)	Total (N=6)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=16)	Placebo (N=21)	Total (N=37)
Preferred Term			
TOTAL	3 (18.8%)	1 (4.8%)	4 (10.8%)
ABDOMINAL PAIN	1 (6.3%)	0	1 (2.7%)
DEPRESSION	1 (6.3%)	0	1 (2.7%)
HEADACHE	1 (6.3%)	0	1 (2.7%)
RESPIRATORY DISORDER	1 (6.3%)	0	1 (2.7%)
NAUSEA	0	1 (4.8%)	1 (2.7%)

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=16)	Placebo (N=21)	Total (N=37)
Preferred Term			
TOTAL	2 (12.5%)	5 (23.8%)	7 (18.9%)
DEPRESSION	1 (6.3%)	1 (4.8%)	2 (5.4%)
SINUSITIS	1 (6.3%)	0	1 (2.7%)
HYSTERIA	0	1 (4.8%)	1 (2.7%)
PUNCTURE SITE PAIN	0	1 (4.8%)	1 (2.7%)
SYNCOPE	0	1 (4.8%)	1 (2.7%)
WEIGHT GAIN	0	1 (4.8%)	1 (2.7%)

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=16)	 Placebo (N=21)	 Total (N=37)
TOTAL	2 (12.5%)	1 (4.8%)	3 (8.1%)
FEVER	1 (6.3%)	0	1 (2.7%)
NEUROSIS	1 (6.3%)	0	1 (2.7%)
INFECTION	0	1 (4.8%)	1 (2.7%)

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=8)	 Placebo (N=15)	 Total (N=23)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=8)	 Placebo (N=15)	 Total (N=23)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=8)	 Placebo (N=15)	 Total (N=23)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=8)	Placebo (N=6)	Total (N=14)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=8)	Placebo (N=6)	Total (N=14)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=8)	Placebo (N=6)	Total (N=14)
TOTAL	0	0	0

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=11)	Placebo (N=9)	Total (N=20)
Preferred Term			
TOTAL	2 (18.2%)	2 (22.2%)	4 (20.0%)
LEUKOPENIA	1 (9.1%)	0	1 (5.0%)
WEIGHT GAIN	1 (9.1%)	0	1 (5.0%)
MYALGIA	0	1 (11.1%)	1 (5.0%)
SOMNOLENCE	0	1 (11.1%)	1 (5.0%)
WITHDRAWAL SYNDROME	0	1 (11.1%)	1 (5.0%)

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=11)	Placebo (N=9)	Total (N=20)
Preferred Term			
TOTAL	1 (9.1%)	0	1 (5.0%)
HOSTILITY	1 (9.1%)	0	1 (5.0%)

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=11)	Placebo (N=9)	Total (N=20)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=5)	Placebo (N=2)	Total (N=7)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=5)	Placebo (N=2)	Total (N=7)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=5)	Placebo (N=2)	Total (N=7)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=4)	Placebo (N=6)	Total (N=10)
Preferred Term			
TOTAL	1 (25.0%)	1 (16.7%)	2 (20.0%)
DYSPEPSIA	1 (25.0%)	0	1 (10.0%)
ABNORMAL DREAMS	0	1 (16.7%)	1 (10.0%)

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=4)	Placebo (N=6)	Total (N=10)
Preferred Term			
TOTAL	1 (25.0%)	2 (33.3%)	3 (30.0%)
BRADYCARDIA	1 (25.0%)	0	1 (10.0%)
HEADACHE	0	1 (16.7%)	1 (10.0%)
INSOMNIA	0	1 (16.7%)	1 (10.0%)

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=4)	Placebo (N=6)	Total (N=10)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=15)	Placebo (N=15)	Total (N=30)
Preferred Term			
TOTAL	3 (20.0%)	3 (20.0%)	6 (20.0%)
DYSPEPSIA	1 (6.7%)	0	1 (3.3%)
LEUKOPENIA	1 (6.7%)	0	1 (3.3%)
WEIGHT GAIN	1 (6.7%)	0	1 (3.3%)
ABNORMAL DREAMS	0	1 (6.7%)	1 (3.3%)
MYALGIA	0	1 (6.7%)	1 (3.3%)
SOMNOLENCE	0	1 (6.7%)	1 (3.3%)
WITHDRAWAL SYNDROME	0	1 (6.7%)	1 (3.3%)

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=15)	Placebo (N=15)	Total (N=30)
Preferred Term			
TOTAL	2 (13.3%)	2 (13.3%)	4 (13.3%)
BRADYCARDIA	1 (6.7%)	0	1 (3.3%)
HOSTILITY	1 (6.7%)	0	1 (3.3%)
HEADACHE	0	1 (6.7%)	1 (3.3%)
INSOMNIA	0	1 (6.7%)	1 (3.3%)

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=15)	Placebo (N=15)	Total (N=30)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=9)	 Placebo (N=12)	 Total (N=21)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=12)	Total (N=21)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=9)	Placebo (N=12)	Total (N=21)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=6)	 Placebo (N=3)	 Total (N=9)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=6)	 Placebo (N=3)	 Total (N=9)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=6)	Placebo (N=3)	Total (N=9)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Preferred Term			
TOTAL	4 (20.0%)	3 (13.6%)	7 (16.7%)
DEPRESSION	1 (5.0%)	0	1 (2.4%)
LEUKOPENIA	1 (5.0%)	0	1 (2.4%)
RESPIRATORY DISORDER	1 (5.0%)	0	1 (2.4%)
WEIGHT GAIN	1 (5.0%)	0	1 (2.4%)
MYALGIA	0	1 (4.5%)	1 (2.4%)
NAUSEA	0	1 (4.5%)	1 (2.4%)
SOMNOLENCE	0	1 (4.5%)	1 (2.4%)
WITHDRAWAL SYNDROME	0	1 (4.5%)	1 (2.4%)

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=20)	 Placebo (N=22)	 Total (N=42)
TOTAL	2 (10.0%)	4 (18.2%)	6 (14.3%)
DEPRESSION	1 (5.0%)	1 (4.5%)	2 (4.8%)
HOSTILITY	1 (5.0%)	0	1 (2.4%)
HYSTERIA	0	1 (4.5%)	1 (2.4%)
PUNCTURE SITE PAIN	0	1 (4.5%)	1 (2.4%)
SYNCOPE	0	1 (4.5%)	1 (2.4%)

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Preferred Term			
TOTAL	1 (5.0%)	0	1 (2.4%)
FEVER	1 (5.0%)	0	1 (2.4%)

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=10)	Placebo (N=5)	Total (N=15)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=10)	Placebo (N=5)	Total (N=15)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=10)	 Placebo (N=5)	 Total (N=15)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=11)	Placebo (N=14)	Total (N=25)
Preferred Term			
TOTAL	2 (18.2%)	1 (7.1%)	3 (12.0%)
ABDOMINAL PAIN	1 (9.1%)	0	1 (4.0%)
DYSPEPSIA	1 (9.1%)	0	1 (4.0%)
HEADACHE	1 (9.1%)	0	1 (4.0%)
ABNORMAL DREAMS	0	1 (7.1%)	1 (4.0%)

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=11)	Placebo (N=14)	Total (N=25)
Preferred Term			
TOTAL	2 (18.2%)	3 (21.4%)	5 (20.0%)
BRADYCARDIA	1 (9.1%)	0	1 (4.0%)
SINUSITIS	1 (9.1%)	0	1 (4.0%)
HEADACHE	0	1 (7.1%)	1 (4.0%)
INSOMNIA	0	1 (7.1%)	1 (4.0%)
WEIGHT GAIN	0	1 (7.1%)	1 (4.0%)

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=11)	Placebo (N=14)	Total (N=25)
Preferred Term			
TOTAL	1 (9.1%)	1 (7.1%)	2 (8.0%)
NEUROSIS	1 (9.1%)	0	1 (4.0%)
INFECTION	0	1 (7.1%)	1 (4.0%)

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=7)	Placebo (N=10)	Total (N=17)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=7)	Placebo (N=10)	Total (N=17)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=7)	Placebo (N=10)	Total (N=17)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=4)	Placebo (N=4)	Total (N=8)
Preferred Term			
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=4)	Placebo (N=4)	Total (N=8)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=4)	Placebo (N=4)	Total (N=8)
Preferred Term			
TOTAL	0	0	0

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=31)	Placebo (N=36)	Total (N=67)
Preferred Term			
TOTAL	6 (19.4%)	4 (11.1%)	10 (14.9%)
ABDOMINAL PAIN	1 (3.2%)	0	1 (1.5%)
DEPRESSION	1 (3.2%)	0	1 (1.5%)
DYSPEPSIA	1 (3.2%)	0	1 (1.5%)
HEADACHE	1 (3.2%)	0	1 (1.5%)
LEUKOPENIA	1 (3.2%)	0	1 (1.5%)
RESPIRATORY DISORDER	1 (3.2%)	0	1 (1.5%)
WEIGHT GAIN	1 (3.2%)	0	1 (1.5%)
ABNORMAL DREAMS	0	1 (2.8%)	1 (1.5%)
MYALGIA	0	1 (2.8%)	1 (1.5%)
NAUSEA	0	1 (2.8%)	1 (1.5%)
SOMNOLENCE	0	1 (2.8%)	1 (1.5%)
WITHDRAWAL SYNDROME	0	1 (2.8%)	1 (1.5%)

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=31)	Placebo (N=36)	Total (N=67)
Preferred Term			
TOTAL	4 (12.9%)	7 (19.4%)	11 (16.4%)
DEPRESSION	1 (3.2%)	1 (2.8%)	2 (3.0%)
BRADYCARDIA	1 (3.2%)	0	1 (1.5%)
HOSTILITY	1 (3.2%)	0	1 (1.5%)
SINUSITIS	1 (3.2%)	0	1 (1.5%)
HEADACHE	0	1 (2.8%)	1 (1.5%)
HYSTERIA	0	1 (2.8%)	1 (1.5%)
INSOMNIA	0	1 (2.8%)	1 (1.5%)
PUNCTURE SITE PAIN	0	1 (2.8%)	1 (1.5%)
SYNCOPE	0	1 (2.8%)	1 (1.5%)
WEIGHT GAIN	0	1 (2.8%)	1 (1.5%)

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=31)	Placebo (N=36)	Total (N=67)
Preferred Term			
TOTAL	2 (6.5%)	1 (2.8%)	3 (4.5%)
FEVER	1 (3.2%)	0	1 (1.5%)
NEUROSIS	1 (3.2%)	0	1 (1.5%)
INFECTION	0	1 (2.8%)	1 (1.5%)

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=17)	Placebo (N=27)	Total (N=44)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=17)	Placebo (N=27)	Total (N=44)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=17)	Placebo (N=27)	Total (N=44)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=9)	Total (N=23)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=14)	 Placebo (N=9)	 Total (N=23)
TOTAL	0	0	0

BRL 29060 - 716

Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=14)	Placebo (N=9)	Total (N=23)
TOTAL	0	0	0

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	54 (66.7%)	40 (60.6%)	94 (63.9%)
Body as a Whole	TOTAL	30 (37.0%)	20 (30.3%)	50 (34.0%)
	HEADACHE	15 (18.5%)	8 (12.1%)	23 (15.6%)
	TRAUMA	8 (9.9%)	3 (4.5%)	11 (7.5%)
	ABDOMINAL PAIN	7 (8.6%)	2 (3.0%)	9 (6.1%)
	INFECTION	1 (1.2%)	6 (9.1%)	7 (4.8%)
	ALLERGIC REACTION	5 (6.2%)	1 (1.5%)	6 (4.1%)
	FEVER	4 (4.9%)	2 (3.0%)	6 (4.1%)
	ASTHENIA	1 (1.2%)	4 (6.1%)	5 (3.4%)
	BACK PAIN	1 (1.2%)	3 (4.5%)	4 (2.7%)
	CHEST PAIN	3 (3.7%)	0	3 (2.0%)
	PAIN	2 (2.5%)	1 (1.5%)	3 (2.0%)
	FACE EDEMA	1 (1.2%)	0	1 (0.7%)
	MALAISE	1 (1.2%)	0	1 (0.7%)
Respiratory System	TOTAL	29 (35.8%)	19 (28.8%)	48 (32.7%)
	RESPIRATORY DISORDER	11 (13.6%)	10 (15.2%)	21 (14.3%)
	PHARYNGITIS	9 (11.1%)	5 (7.6%)	14 (9.5%)
	RHINITIS	5 (6.2%)	4 (6.1%)	9 (6.1%)
	SINUSITIS	5 (6.2%)	0	5 (3.4%)
	COUGH INCREASED	3 (3.7%)	2 (3.0%)	5 (3.4%)
	ASTHMA	1 (1.2%)	2 (3.0%)	3 (2.0%)
	EPISTAXIS	0	2 (3.0%)	2 (1.4%)
	DYSPNEA	1 (1.2%)	0	1 (0.7%)
	YAWN	0	1 (1.5%)	1 (0.7%)
Nervous System	TOTAL	20 (24.7%)	12 (18.2%)	32 (21.8%)
	INSOMNIA	2 (2.5%)	5 (7.6%)	7 (4.8%)
	SOMNOLENCE	4 (4.9%)	1 (1.5%)	5 (3.4%)
	DIZZINESS	3 (3.7%)	2 (3.0%)	5 (3.4%)
	NERVOUSNESS	4 (4.9%)	0	4 (2.7%)
	DEPRESSION	2 (2.5%)	1 (1.5%)	3 (2.0%)
	AGITATION	1 (1.2%)	1 (1.5%)	2 (1.4%)
	EMOTIONAL LABILITY	1 (1.2%)	1 (1.5%)	2 (1.4%)
	HYPERKINESIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	HALLUCINATIONS	1 (1.2%)	0	1 (0.7%)
	NEUROSIS	1 (1.2%)	0	1 (0.7%)
	PARESTHESIA	1 (1.2%)	0	1 (0.7%)
	VERTIGO	1 (1.2%)	0	1 (0.7%)
	ANXIETY	0	1 (1.5%)	1 (0.7%)
	CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.7%)
	HYPESTHESIA	0	1 (1.5%)	1 (0.7%)

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
Nervous System	LIBIDO DECREASED	0	1 (1.5%)	1 (0.7%)
	TREMOR	0	1 (1.5%)	1 (0.7%)
	WITHDRAWAL SYNDROME	0	1 (1.5%)	1 (0.7%)
Digestive System	TOTAL	18 (22.2%)	16 (24.2%)	34 (23.1%)
	DYSPEPSIA	6 (7.4%)	4 (6.1%)	10 (6.8%)
	NAUSEA	6 (7.4%)	4 (6.1%)	10 (6.8%)
	VOMITING	3 (3.7%)	2 (3.0%)	5 (3.4%)
	DECREASED APPETITE	2 (2.5%)	3 (4.5%)	5 (3.4%)
	DIARRHEA	2 (2.5%)	2 (3.0%)	4 (2.7%)
	DRY MOUTH	3 (3.7%)	0	3 (2.0%)
	INCREASED APPETITE	1 (1.2%)	2 (3.0%)	3 (2.0%)
	TOOTH CARIES	1 (1.2%)	1 (1.5%)	2 (1.4%)
	GASTRITIS	1 (1.2%)	0	1 (0.7%)
	GASTROENTERITIS	0	1 (1.5%)	1 (0.7%)
	GASTROINTESTINAL DISORDER	0	1 (1.5%)	1 (0.7%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.7%)
Skin and Appendages	TOTAL	7 (8.6%)	3 (4.5%)	10 (6.8%)
	PRURITUS	1 (1.2%)	2 (3.0%)	3 (2.0%)
	ACNE	2 (2.5%)	0	2 (1.4%)
	CONTACT DERMATITIS	2 (2.5%)	0	2 (1.4%)
	RASH	1 (1.2%)	1 (1.5%)	2 (1.4%)
	FUNGAL DERMATITIS	1 (1.2%)	0	1 (0.7%)
	MACULOPAPULAR RASH	0	1 (1.5%)	1 (0.7%)
Urogenital System	TOTAL	5 (6.2%)	4 (6.1%)	9 (6.1%)
	ALBUMINURIA	3 (3.7%)	2 (3.0%)	5 (3.4%)
	HAEMATURIA	1 (1.2%)	2 (3.0%)	3 (2.0%)
	URINARY INCONTINENCE	1 (1.2%)	1 (1.5%)	2 (1.4%)
	PYURIA	1 (1.2%)	0	1 (0.7%)
	CYSTITIS	0	1 (1.5%)	1 (0.7%)
Hemic and Lymphatic System	TOTAL	4 (4.9%)	1 (1.5%)	5 (3.4%)
	LEUKOPENIA	3 (3.7%)	1 (1.5%)	4 (2.7%)
	LYMPHADENOPATHY	1 (1.2%)	0	1 (0.7%)
	ANEMIA	0	1 (1.5%)	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	3 (3.7%)	5 (7.6%)	8 (5.4%)
	WEIGHT GAIN	3 (3.7%)	5 (7.6%)	8 (5.4%)
Musculoskeletal System	TOTAL	2 (2.5%)	1 (1.5%)	3 (2.0%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
Musculoskeletal System	ARTHRALGIA	2 (2.5%)	0	2 (1.4%)
	MYALGIA	0	1 (1.5%)	1 (0.7%)
Special Senses	TOTAL	2 (2.5%)	1 (1.5%)	3 (2.0%)
	OTITIS MEDIA	2 (2.5%)	0	2 (1.4%)
	ABNORMAL VISION	0	1 (1.5%)	1 (0.7%)
Cardiovascular System	TOTAL	0	2 (3.0%)	2 (1.4%)
	BUNDLE BRANCH BLOCK	0	1 (1.5%)	1 (0.7%)
	SYNCOPE	0	1 (1.5%)	1 (0.7%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	55 (67.9%)	28 (42.4%)	83 (56.5%)
Body as a Whole	TOTAL	30 (37.0%)	14 (21.2%)	44 (29.9%)
	TRAUMA	10 (12.3%)	3 (4.5%)	13 (8.8%)
	INFECTION	6 (7.4%)	6 (9.1%)	12 (8.2%)
	HEADACHE	9 (11.1%)	2 (3.0%)	11 (7.5%)
	ABDOMINAL PAIN	5 (6.2%)	2 (3.0%)	7 (4.8%)
	FEVER	4 (4.9%)	2 (3.0%)	6 (4.1%)
	ALLERGIC REACTION	2 (2.5%)	1 (1.5%)	3 (2.0%)
	ASTHENIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
	BACK PAIN	2 (2.5%)	0	2 (1.4%)
	PAIN	1 (1.2%)	1 (1.5%)	2 (1.4%)
	CHEST PAIN	1 (1.2%)	0	1 (0.7%)
	FACE EDEMA	1 (1.2%)	0	1 (0.7%)
Respiratory System	TOTAL	18 (22.2%)	10 (15.2%)	28 (19.0%)
	RESPIRATORY DISORDER	9 (11.1%)	5 (7.6%)	14 (9.5%)
	BRONCHITIS	2 (2.5%)	3 (4.5%)	5 (3.4%)
	PHARYNGITIS	3 (3.7%)	0	3 (2.0%)
	RHINITIS	3 (3.7%)	0	3 (2.0%)
	SINUSITIS	2 (2.5%)	1 (1.5%)	3 (2.0%)
	ASTHMA	2 (2.5%)	0	2 (1.4%)
	PNEUMONIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	COUGH INCREASED	1 (1.2%)	0	1 (0.7%)
Nervous System	TOTAL	17 (21.0%)	14 (21.2%)	31 (21.1%)
	HOSTILITY	4 (4.9%)	1 (1.5%)	5 (3.4%)
	NERVOUSNESS	4 (4.9%)	1 (1.5%)	5 (3.4%)
	AGITATION	2 (2.5%)	3 (4.5%)	5 (3.4%)
	EMOTIONAL LABILITY	2 (2.5%)	2 (3.0%)	4 (2.7%)
	SOMNOLENCE	1 (1.2%)	3 (4.5%)	4 (2.7%)
	DEPRESSION	2 (2.5%)	1 (1.5%)	3 (2.0%)
	INSOMNIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
	ANXIETY	1 (1.2%)	0	1 (0.7%)
	CONVULSION	1 (1.2%)	0	1 (0.7%)
	HYPERKINESIA	1 (1.2%)	0	1 (0.7%)
	VESTIBULAR DISORDER	1 (1.2%)	0	1 (0.7%)
	CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.7%)
	HALLUCINATIONS	0	1 (1.5%)	1 (0.7%)
	HYPESTHESIA	0	1 (1.5%)	1 (0.7%)
	HYSTERIA	0	1 (1.5%)	1 (0.7%)
	TREMOR	0	1 (1.5%)	1 (0.7%)
	WITHDRAWAL SYNDROME	0	1 (1.5%)	1 (0.7%)

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=81)	 Placebo (N=66)	 Total (N=147)
Digestive System	TOTAL	13 (16.0%)	5 (7.6%)	18 (12.2%)
	VOMITING	9 (11.1%)	2 (3.0%)	11 (7.5%)
	DIARRHEA	3 (3.7%)	0	3 (2.0%)
	NAUSEA	2 (2.5%)	1 (1.5%)	3 (2.0%)
	DYSPEPSIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	CONSTIPATION	1 (1.2%)	0	1 (0.7%)
	HEMATEMESIS	1 (1.2%)	0	1 (0.7%)
	STOMATITIS	1 (1.2%)	0	1 (0.7%)
	TOOTH CARIES	0	1 (1.5%)	1 (0.7%)
Skin and Appendages	TOTAL	6 (7.4%)	2 (3.0%)	8 (5.4%)
	ACNE	2 (2.5%)	1 (1.5%)	3 (2.0%)
	CONTACT DERMATITIS	2 (2.5%)	1 (1.5%)	3 (2.0%)
	FURUNCULOSIS	1 (1.2%)	0	1 (0.7%)
	HERPES ZOSTER	1 (1.2%)	0	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	5 (6.2%)	2 (3.0%)	7 (4.8%)
	WEIGHT GAIN	3 (3.7%)	1 (1.5%)	4 (2.7%)
	DEHYDRATION	1 (1.2%)	1 (1.5%)	2 (1.4%)
	WEIGHT LOSS	1 (1.2%)	0	1 (0.7%)
Musculoskeletal System	TOTAL	2 (2.5%)	1 (1.5%)	3 (2.0%)
	MYALGIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	TENDINOUS DISORDER	1 (1.2%)	0	1 (0.7%)
	ARTHROSIS	0	1 (1.5%)	1 (0.7%)
Special Senses	TOTAL	2 (2.5%)	0	2 (1.4%)
	OTITIS MEDIA	2 (2.5%)	0	2 (1.4%)
Urogenital System	TOTAL	2 (2.5%)	0	2 (1.4%)
	URINARY INCONTINENCE	1 (1.2%)	0	1 (0.7%)
	URINARY TRACT INFECTION	1 (1.2%)	0	1 (0.7%)
Cardiovascular System	TOTAL	0	2 (3.0%)	2 (1.4%)
	MIGRAINE	0	1 (1.5%)	1 (0.7%)
	SYNCOPE	0	1 (1.5%)	1 (0.7%)
Hemic and Lymphatic System	TOTAL	0	1 (1.5%)	1 (0.7%)
	LEUKOPENIA	0	1 (1.5%)	1 (0.7%)
Special Searches	TOTAL	0	1 (1.5%)	1 (0.7%)
	PUNCTURE SITE PAIN	0	1 (1.5%)	1 (0.7%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	10 (12.3%)	11 (16.7%)	21 (14.3%)
Nervous System	TOTAL	6 (7.4%)	6 (9.1%)	12 (8.2%)
	EMOTIONAL LABILITY	4 (4.9%)	1 (1.5%)	5 (3.4%)
	HOSTILITY	2 (2.5%)	1 (1.5%)	3 (2.0%)
	AGITATION	1 (1.2%)	1 (1.5%)	2 (1.4%)
	DEPRESSION	1 (1.2%)	0	1 (0.7%)
	LACK OF EMOTION	1 (1.2%)	0	1 (0.7%)
	ANXIETY	0	1 (1.5%)	1 (0.7%)
	EUPHORIA	0	1 (1.5%)	1 (0.7%)
	HALLUCINATIONS	0	1 (1.5%)	1 (0.7%)
	PARALYSIS	0	1 (1.5%)	1 (0.7%)
Body as a Whole	TOTAL	4 (4.9%)	1 (1.5%)	5 (3.4%)
	TRAUMA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	BACK PAIN	1 (1.2%)	0	1 (0.7%)
	FEVER	1 (1.2%)	0	1 (0.7%)
	INFECTION	1 (1.2%)	0	1 (0.7%)
Cardiovascular System	TOTAL	0	1 (1.5%)	1 (0.7%)
	MIGRAINE	0	1 (1.5%)	1 (0.7%)
Digestive System	TOTAL	0	1 (1.5%)	1 (0.7%)
	TOOTH CARIES	0	1 (1.5%)	1 (0.7%)
Respiratory System	TOTAL	0	1 (1.5%)	1 (0.7%)
	ASTHMA	0	1 (1.5%)	1 (0.7%)
Skin and Appendages	TOTAL	0	1 (1.5%)	1 (0.7%)
	RASH	0	1 (1.5%)	1 (0.7%)
Special Senses	TOTAL	0	1 (1.5%)	1 (0.7%)
	OTITIS MEDIA	0	1 (1.5%)	1 (0.7%)
Urogenital System	TOTAL	0	1 (1.5%)	1 (0.7%)
	URINARY INCONTINENCE	0	1 (1.5%)	1 (0.7%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	1 (3.0%)	2 (6.9%)	3 (4.8%)
Urogenital System	TOTAL	1 (3.0%)	2 (6.9%)	3 (4.8%)
	DYSMENORRHEA	1 (3.0%)	0	1 (1.6%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.6%)
	MENSTRUAL DISORDER	0	1 (3.4%)	1 (1.6%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	2 (6.1%)	0	2 (3.2%)
Urogenital System	TOTAL	2 (6.1%)	0	2 (3.2%)
	DYSMENORRHEA	2 (6.1%)	0	2 (3.2%)

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
TOTAL	TOTAL	35 (67.3%)	39 (60.9%)	74 (63.8%)
Body as a Whole	TOTAL	22 (42.3%)	23 (35.9%)	45 (38.8%)
	HEADACHE	13 (25.0%)	13 (20.3%)	26 (22.4%)
	ABDOMINAL PAIN	4 (7.7%)	5 (7.8%)	9 (7.8%)
	TRAUMA	3 (5.8%)	5 (7.8%)	8 (6.9%)
	ALLERGIC REACTION	3 (5.8%)	3 (4.7%)	6 (5.2%)
	INFECTION	3 (5.8%)	2 (3.1%)	5 (4.3%)
	PAIN	3 (5.8%)	1 (1.6%)	4 (3.4%)
	ASTHENIA	2 (3.8%)	2 (3.1%)	4 (3.4%)
	FEVER	2 (3.8%)	2 (3.1%)	4 (3.4%)
	ABNORMAL LABORATORY VALUE	1 (1.9%)	0	1 (0.9%)
	BACK PAIN	1 (1.9%)	0	1 (0.9%)
	SPINA BIFIDA	0	1 (1.6%)	1 (0.9%)
Respiratory System	TOTAL	12 (23.1%)	13 (20.3%)	25 (21.6%)
	RESPIRATORY DISORDER	3 (5.8%)	8 (12.5%)	11 (9.5%)
	RHINITIS	5 (9.6%)	5 (7.8%)	10 (8.6%)
	PHARYNGITIS	4 (7.7%)	3 (4.7%)	7 (6.0%)
	SINUSITIS	3 (5.8%)	1 (1.6%)	4 (3.4%)
	COUGH INCREASED	2 (3.8%)	0	2 (1.7%)
	ASTHMA	1 (1.9%)	1 (1.6%)	2 (1.7%)
	PLEURA DISORDER	1 (1.9%)	0	1 (0.9%)
	EPISTAXIS	0	1 (1.6%)	1 (0.9%)
Nervous System	TOTAL	10 (19.2%)	18 (28.1%)	28 (24.1%)
	INSOMNIA	5 (9.6%)	3 (4.7%)	8 (6.9%)
	NERVOUSNESS	1 (1.9%)	6 (9.4%)	7 (6.0%)
	HYPERKINESIA	3 (5.8%)	1 (1.6%)	4 (3.4%)
	DIZZINESS	2 (3.8%)	1 (1.6%)	3 (2.6%)
	NEUROSIS	2 (3.8%)	1 (1.6%)	3 (2.6%)
	AGITATION	1 (1.9%)	2 (3.1%)	3 (2.6%)
	HOSTILITY	1 (1.9%)	2 (3.1%)	3 (2.6%)
	ABNORMAL DREAMS	1 (1.9%)	1 (1.6%)	2 (1.7%)
	MYOCLONUS	1 (1.9%)	1 (1.6%)	2 (1.7%)
	SOMNOLENCE	0	2 (3.1%)	2 (1.7%)
	TREMOR	0	2 (3.1%)	2 (1.7%)
	VERTIGO	0	2 (3.1%)	2 (1.7%)
	ANXIETY	1 (1.9%)	0	1 (0.9%)
	CONCENTRATION IMPAIRED	1 (1.9%)	0	1 (0.9%)
	EMOTIONAL LABILITY	1 (1.9%)	0	1 (0.9%)
	DYSKINESIA	0	1 (1.6%)	1 (0.9%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
Digestive System	TOTAL	9 (17.3%)	11 (17.2%)	20 (17.2%)
	NAUSEA	6 (11.5%)	3 (4.7%)	9 (7.8%)
	DECREASED APPETITE	2 (3.8%)	4 (6.3%)	6 (5.2%)
	DIARRHEA	3 (5.8%)	0	3 (2.6%)
	DYSPEPSIA	3 (5.8%)	0	3 (2.6%)
	DRY MOUTH	0	2 (3.1%)	2 (1.7%)
	FLATULENCE	0	2 (3.1%)	2 (1.7%)
	VOMITING	1 (1.9%)	0	1 (0.9%)
	CONSTIPATION	0	1 (1.6%)	1 (0.9%)
	GASTROENTERITIS	0	1 (1.6%)	1 (0.9%)
	TOOTH CARIES	0	1 (1.6%)	1 (0.9%)
	ULCERATIVE STOMATITIS	0	1 (1.6%)	1 (0.9%)
Urogenital System	TOTAL	6 (11.5%)	1 (1.6%)	7 (6.0%)
	ALBUMINURIA	5 (9.6%)	0	5 (4.3%)
	DYSURIA	1 (1.9%)	0	1 (0.9%)
	GLYCOSURIA	1 (1.9%)	0	1 (0.9%)
	HAEMATURIA	1 (1.9%)	0	1 (0.9%)
	URINARY INCONTINENCE	0	1 (1.6%)	1 (0.9%)
Musculoskeletal System	TOTAL	3 (5.8%)	1 (1.6%)	4 (3.4%)
	ARTHRALGIA	1 (1.9%)	1 (1.6%)	2 (1.7%)
	ARTHROSIS	1 (1.9%)	0	1 (0.9%)
	MYALGIA	1 (1.9%)	0	1 (0.9%)
Special Senses	TOTAL	3 (5.8%)	5 (7.8%)	8 (6.9%)
	OTITIS EXTERNA	1 (1.9%)	1 (1.6%)	2 (1.7%)
	BLEPHARITIS	1 (1.9%)	0	1 (0.9%)
	EYE PAIN	1 (1.9%)	0	1 (0.9%)
	ABNORMAL VISION	0	1 (1.6%)	1 (0.9%)
	EAR PAIN	0	1 (1.6%)	1 (0.9%)
	OTITIS MEDIA	0	1 (1.6%)	1 (0.9%)
	PHOTOPHOBIA	0	1 (1.6%)	1 (0.9%)
Cardiovascular System	TOTAL	1 (1.9%)	4 (6.3%)	5 (4.3%)
	VASODILATATION	0	4 (6.3%)	4 (3.4%)
	HAEMATOMA	1 (1.9%)	0	1 (0.9%)
Hemic and Lymphatic System	TOTAL	1 (1.9%)	1 (1.6%)	2 (1.7%)
	ANEMIA	1 (1.9%)	0	1 (0.9%)
	LEUKOCYTOSIS	0	1 (1.6%)	1 (0.9%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
Metabolic and Nutritional Disorders	TOTAL	1 (1.9%)	1 (1.6%)	2 (1.7%)
	WEIGHT GAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
Skin and Appendages	TOTAL	1 (1.9%)	6 (9.4%)	7 (6.0%)
	RASH	0	3 (4.7%)	3 (2.6%)
	ACNE	0	2 (3.1%)	2 (1.7%)
	CONTACT DERMATITIS	0	2 (3.1%)	2 (1.7%)
	MACULOPAPULAR RASH	1 (1.9%)	0	1 (0.9%)
	HERPES SIMPLEX	0	1 (1.6%)	1 (0.9%)
	SWEATING	0	1 (1.6%)	1 (0.9%)
	URTICARIA	0	1 (1.6%)	1 (0.9%)

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	29 (55.8%)	40 (62.5%)	69 (59.5%)
Body as a Whole	TOTAL	17 (32.7%)	16 (25.0%)	33 (28.4%)
	HEADACHE	9 (17.3%)	6 (9.4%)	15 (12.9%)
	INFECTION	4 (7.7%)	4 (6.3%)	8 (6.9%)
	TRAUMA	3 (5.8%)	2 (3.1%)	5 (4.3%)
	ABDOMINAL PAIN	2 (3.8%)	3 (4.7%)	5 (4.3%)
	ASTHENIA	2 (3.8%)	2 (3.1%)	4 (3.4%)
	ALLERGIC REACTION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	FEVER	1 (1.9%)	1 (1.6%)	2 (1.7%)
	PAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
	BACK PAIN	0	1 (1.6%)	1 (0.9%)
Nervous System	TOTAL	11 (21.2%)	25 (39.1%)	36 (31.0%)
	NERVOUSNESS	1 (1.9%)	8 (12.5%)	9 (7.8%)
	HYPERKINESIA	4 (7.7%)	4 (6.3%)	8 (6.9%)
	HOSTILITY	1 (1.9%)	5 (7.8%)	6 (5.2%)
	ANXIETY	1 (1.9%)	4 (6.3%)	5 (4.3%)
	INSOMNIA	1 (1.9%)	4 (6.3%)	5 (4.3%)
	EMOTIONAL LABILITY	2 (3.8%)	1 (1.6%)	3 (2.6%)
	DIZZINESS	1 (1.9%)	2 (3.1%)	3 (2.6%)
	DEPRESSION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	MANIC REACTION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	SOMNOLENCE	1 (1.9%)	1 (1.6%)	2 (1.7%)
	AGITATION	0	2 (3.1%)	2 (1.7%)
	CONCENTRATION IMPAIRED	1 (1.9%)	0	1 (0.9%)
	VERTIGO	1 (1.9%)	0	1 (0.9%)
	ABNORMAL DREAMS	0	1 (1.6%)	1 (0.9%)
	LACK OF EMOTION	0	1 (1.6%)	1 (0.9%)
	PSYCHOSIS	0	1 (1.6%)	1 (0.9%)
Respiratory System	TOTAL	9 (17.3%)	9 (14.1%)	18 (15.5%)
	RESPIRATORY DISORDER	4 (7.7%)	6 (9.4%)	10 (8.6%)
	PHARYNGITIS	3 (5.8%)	3 (4.7%)	6 (5.2%)
	SINUSITIS	3 (5.8%)	0	3 (2.6%)
	ASTHMA	1 (1.9%)	2 (3.1%)	3 (2.6%)
	COUGH INCREASED	1 (1.9%)	1 (1.6%)	2 (1.7%)
	BRONCHITIS	1 (1.9%)	0	1 (0.9%)
	PNEUMONIA	0	1 (1.6%)	1 (0.9%)
	RHINITIS	0	1 (1.6%)	1 (0.9%)
Digestive System	TOTAL	4 (7.7%)	7 (10.9%)	11 (9.5%)
	TOOTH DISORDER	2 (3.8%)	1 (1.6%)	3 (2.6%)

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
Digestive System	DYSPEPSIA	0	3 (4.7%)	3 (2.6%)
	NAUSEA	0	3 (4.7%)	3 (2.6%)
	DIARRHEA	1 (1.9%)	1 (1.6%)	2 (1.7%)
	GINGIVITIS	1 (1.9%)	1 (1.6%)	2 (1.7%)
	CONSTIPATION	1 (1.9%)	0	1 (0.9%)
	DECREASED APPETITE	0	1 (1.6%)	1 (0.9%)
Special Senses	TOTAL	4 (7.7%)	2 (3.1%)	6 (5.2%)
	OTITIS MEDIA	3 (5.8%)	2 (3.1%)	5 (4.3%)
	EAR PAIN	1 (1.9%)	0	1 (0.9%)
	OTITIS EXTERNA	1 (1.9%)	0	1 (0.9%)
Skin and Appendages	TOTAL	2 (3.8%)	2 (3.1%)	4 (3.4%)
	ACNE	2 (3.8%)	0	2 (1.7%)
	CONTACT DERMATITIS	0	1 (1.6%)	1 (0.9%)
	FUNGAL DERMATITIS	0	1 (1.6%)	1 (0.9%)
Cardiovascular System	TOTAL	1 (1.9%)	0	1 (0.9%)
	BRADYCARDIA	1 (1.9%)	0	1 (0.9%)
Hemic and Lymphatic System	TOTAL	1 (1.9%)	1 (1.6%)	2 (1.7%)
	PURPURA	1 (1.9%)	0	1 (0.9%)
	EOSINOPHILIA	0	1 (1.6%)	1 (0.9%)
	MONOCYTOSIS	0	1 (1.6%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	1 (1.9%)	2 (3.1%)	3 (2.6%)
	WEIGHT GAIN	1 (1.9%)	1 (1.6%)	2 (1.7%)
	WEIGHT LOSS	0	1 (1.6%)	1 (0.9%)
Musculoskeletal System	TOTAL	1 (1.9%)	0	1 (0.9%)
	ARTHRALGIA	1 (1.9%)	0	1 (0.9%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	5 (9.6%)	8 (12.5%)	13 (11.2%)
Nervous System	TOTAL	3 (5.8%)	4 (6.3%)	7 (6.0%)
	NEUROSIS	2 (3.8%)	0	2 (1.7%)
	HOSTILITY	0	2 (3.1%)	2 (1.7%)
	SOMNOLENCE	1 (1.9%)	0	1 (0.9%)
	HYPERKINESIA	0	1 (1.6%)	1 (0.9%)
	NERVOUSNESS	0	1 (1.6%)	1 (0.9%)
Body as a Whole	TOTAL	2 (3.8%)	3 (4.7%)	5 (4.3%)
	INFECTION	1 (1.9%)	2 (3.1%)	3 (2.6%)
	ABSCESS	1 (1.9%)	0	1 (0.9%)
	ABDOMINAL PAIN	0	1 (1.6%)	1 (0.9%)
	TRAUMA	0	1 (1.6%)	1 (0.9%)
Respiratory System	TOTAL	1 (1.9%)	0	1 (0.9%)
	PHARYNGITIS	1 (1.9%)	0	1 (0.9%)
Cardiovascular System	TOTAL	0	1 (1.6%)	1 (0.9%)
	SYNCOPE	0	1 (1.6%)	1 (0.9%)
Digestive System	TOTAL	0	1 (1.6%)	1 (0.9%)
	NAUSEA	0	1 (1.6%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.6%)	1 (0.9%)
	WEIGHT GAIN	0	1 (1.6%)	1 (0.9%)
Urogenital System	TOTAL	0	1 (1.6%)	1 (0.9%)
	URINARY INCONTINENCE	0	1 (1.6%)	1 (0.9%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (4.5%)	1 (2.0%)
Urogenital System	TOTAL	0	1 (4.5%)	1 (2.0%)
	DYSMENORRHEA	0	1 (4.5%)	1 (2.0%)
	UTERUS DISORDERS	0	1 (4.5%)	1 (2.0%)

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	4 (14.3%)	0	4 (8.0%)
Urogenital System	TOTAL	4 (14.3%)	0	4 (8.0%)
	DYSMENORRHEA	4 (14.3%)	0	4 (8.0%)

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
TOTAL	TOTAL	89 (66.9%)	79 (60.8%)	168 (63.9%)
Body as a Whole	TOTAL	52 (39.1%)	43 (33.1%)	95 (36.1%)
	HEADACHE	28 (21.1%)	21 (16.2%)	49 (18.6%)
	TRAUMA	11 (8.3%)	8 (6.2%)	19 (7.2%)
	ABDOMINAL PAIN	11 (8.3%)	7 (5.4%)	18 (6.8%)
	ALLERGIC REACTION	8 (6.0%)	4 (3.1%)	12 (4.6%)
	INFECTION	4 (3.0%)	8 (6.2%)	12 (4.6%)
	FEVER	6 (4.5%)	4 (3.1%)	10 (3.8%)
	ASTHENIA	3 (2.3%)	6 (4.6%)	9 (3.4%)
	PAIN	5 (3.8%)	2 (1.5%)	7 (2.7%)
	BACK PAIN	2 (1.5%)	3 (2.3%)	5 (1.9%)
	CHEST PAIN	3 (2.3%)	0	3 (1.1%)
	ABNORMAL LABORATORY VALUE	1 (0.8%)	0	1 (0.4%)
	FACE EDEMA	1 (0.8%)	0	1 (0.4%)
	MALAISE	1 (0.8%)	0	1 (0.4%)
	SPINA BIFIDA	0	1 (0.8%)	1 (0.4%)
Respiratory System	TOTAL	41 (30.8%)	32 (24.6%)	73 (27.8%)
	RESPIRATORY DISORDER	14 (10.5%)	18 (13.8%)	32 (12.2%)
	PHARYNGITIS	13 (9.8%)	8 (6.2%)	21 (8.0%)
	RHINITIS	10 (7.5%)	9 (6.9%)	19 (7.2%)
	SINUSITIS	8 (6.0%)	1 (0.8%)	9 (3.4%)
	COUGH INCREASED	5 (3.8%)	2 (1.5%)	7 (2.7%)
	ASTHMA	2 (1.5%)	3 (2.3%)	5 (1.9%)
	EPISTAXIS	0	3 (2.3%)	3 (1.1%)
	DYSPNEA	1 (0.8%)	0	1 (0.4%)
	PLEURA DISORDER	1 (0.8%)	0	1 (0.4%)
	YAWN	0	1 (0.8%)	1 (0.4%)
Nervous System	TOTAL	30 (22.6%)	30 (23.1%)	60 (22.8%)
	INSOMNIA	7 (5.3%)	8 (6.2%)	15 (5.7%)
	NERVOUSNESS	5 (3.8%)	6 (4.6%)	11 (4.2%)
	DIZZINESS	5 (3.8%)	3 (2.3%)	8 (3.0%)
	SOMNOLENCE	4 (3.0%)	3 (2.3%)	7 (2.7%)
	HYPERKINESIA	4 (3.0%)	2 (1.5%)	6 (2.3%)
	AGITATION	2 (1.5%)	3 (2.3%)	5 (1.9%)
	NEUROSIS	3 (2.3%)	1 (0.8%)	4 (1.5%)
	DEPRESSION	2 (1.5%)	1 (0.8%)	3 (1.1%)
	EMOTIONAL LABILITY	2 (1.5%)	1 (0.8%)	3 (1.1%)
	HOSTILITY	1 (0.8%)	2 (1.5%)	3 (1.1%)
	VERTIGO	1 (0.8%)	2 (1.5%)	3 (1.1%)
	TREMOR	0	3 (2.3%)	3 (1.1%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Nervous System	ABNORMAL DREAMS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	ANXIETY	1 (0.8%)	1 (0.8%)	2 (0.8%)
	CONCENTRATION IMPAIRED	1 (0.8%)	1 (0.8%)	2 (0.8%)
	MYOCLONUS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	HALLUCINATIONS	1 (0.8%)	0	1 (0.4%)
	PARESTHESIA	1 (0.8%)	0	1 (0.4%)
	DYSKINESIA	0	1 (0.8%)	1 (0.4%)
	HYPESTHESIA	0	1 (0.8%)	1 (0.4%)
	LIBIDO DECREASED	0	1 (0.8%)	1 (0.4%)
	WITHDRAWAL SYNDROME	0	1 (0.8%)	1 (0.4%)
Digestive System	TOTAL	27 (20.3%)	27 (20.8%)	54 (20.5%)
	NAUSEA	12 (9.0%)	7 (5.4%)	19 (7.2%)
	DYSPEPSIA	9 (6.8%)	4 (3.1%)	13 (4.9%)
	DECREASED APPETITE	4 (3.0%)	7 (5.4%)	11 (4.2%)
	DIARRHEA	5 (3.8%)	2 (1.5%)	7 (2.7%)
	VOMITING	4 (3.0%)	2 (1.5%)	6 (2.3%)
	DRY MOUTH	3 (2.3%)	2 (1.5%)	5 (1.9%)
	INCREASED APPETITE	1 (0.8%)	2 (1.5%)	3 (1.1%)
	TOOTH CARIES	1 (0.8%)	2 (1.5%)	3 (1.1%)
	FLATULENCE	0	2 (1.5%)	2 (0.8%)
	GASTROENTERITIS	0	2 (1.5%)	2 (0.8%)
	GASTRITIS	1 (0.8%)	0	1 (0.4%)
	CONSTIPATION	0	1 (0.8%)	1 (0.4%)
	GASTROINTESTINAL DISORDER	0	1 (0.8%)	1 (0.4%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (0.8%)	1 (0.4%)
	ULCERATIVE STOMATITIS	0	1 (0.8%)	1 (0.4%)
Urogenital System	TOTAL	11 (8.3%)	5 (3.8%)	16 (6.1%)
	ALBUMINURIA	8 (6.0%)	2 (1.5%)	10 (3.8%)
	HAEMATURIA	2 (1.5%)	2 (1.5%)	4 (1.5%)
	URINARY INCONTINENCE	1 (0.8%)	2 (1.5%)	3 (1.1%)
	DYSURIA	1 (0.8%)	0	1 (0.4%)
	GLYCOSURIA	1 (0.8%)	0	1 (0.4%)
	PYURIA	1 (0.8%)	0	1 (0.4%)
	CYSTITIS	0	1 (0.8%)	1 (0.4%)
Skin and Appendages	TOTAL	8 (6.0%)	9 (6.9%)	17 (6.5%)
	RASH	1 (0.8%)	4 (3.1%)	5 (1.9%)
	ACNE	2 (1.5%)	2 (1.5%)	4 (1.5%)
	CONTACT DERMATITIS	2 (1.5%)	2 (1.5%)	4 (1.5%)
	PRURITUS	1 (0.8%)	2 (1.5%)	3 (1.1%)
	MACULOPAPULAR RASH	1 (0.8%)	1 (0.8%)	2 (0.8%)

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Skin and Appendages	FUNGAL DERMATITIS	1 (0.8%)	0	1 (0.4%)
	HERPES SIMPLEX	0	1 (0.8%)	1 (0.4%)
	SWEATING	0	1 (0.8%)	1 (0.4%)
	URTICARIA	0	1 (0.8%)	1 (0.4%)
Hemic and Lymphatic System	TOTAL	5 (3.8%)	2 (1.5%)	7 (2.7%)
	LEUKOPENIA	3 (2.3%)	1 (0.8%)	4 (1.5%)
	ANEMIA	1 (0.8%)	1 (0.8%)	2 (0.8%)
	LYMPHADENOPATHY	1 (0.8%)	0	1 (0.4%)
	LEUKOCYTOSIS	0	1 (0.8%)	1 (0.4%)
Musculoskeletal System	TOTAL	5 (3.8%)	2 (1.5%)	7 (2.7%)
	ARTHRALGIA	3 (2.3%)	1 (0.8%)	4 (1.5%)
	MYALGIA	1 (0.8%)	1 (0.8%)	2 (0.8%)
	ARTHROSIS	1 (0.8%)	0	1 (0.4%)
Special Senses	TOTAL	5 (3.8%)	6 (4.6%)	11 (4.2%)
	OTITIS MEDIA	2 (1.5%)	1 (0.8%)	3 (1.1%)
	OTITIS EXTERNA	1 (0.8%)	1 (0.8%)	2 (0.8%)
	ABNORMAL VISION	0	2 (1.5%)	2 (0.8%)
	BLEPHARITIS	1 (0.8%)	0	1 (0.4%)
	EYE PAIN	1 (0.8%)	0	1 (0.4%)
	EAR PAIN	0	1 (0.8%)	1 (0.4%)
	PHOTOPHOBIA	0	1 (0.8%)	1 (0.4%)
Metabolic and Nutritional Disorders	TOTAL	4 (3.0%)	6 (4.6%)	10 (3.8%)
	WEIGHT GAIN	4 (3.0%)	6 (4.6%)	10 (3.8%)
Cardiovascular System	TOTAL	1 (0.8%)	6 (4.6%)	7 (2.7%)
	VASODILATATION	0	4 (3.1%)	4 (1.5%)
	HAEMATOMA	1 (0.8%)	0	1 (0.4%)
	BUNDLE BRANCH BLOCK	0	1 (0.8%)	1 (0.4%)
	SYNCOPE	0	1 (0.8%)	1 (0.4%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
TOTAL	TOTAL	84 (63.2%)	68 (52.3%)	152 (57.8%)
Body as a Whole	TOTAL	47 (35.3%)	30 (23.1%)	77 (29.3%)
	HEADACHE	18 (13.5%)	8 (6.2%)	26 (9.9%)
	INFECTION	10 (7.5%)	10 (7.7%)	20 (7.6%)
	TRAUMA	13 (9.8%)	5 (3.8%)	18 (6.8%)
	ABDOMINAL PAIN	7 (5.3%)	5 (3.8%)	12 (4.6%)
	FEVER	5 (3.8%)	3 (2.3%)	8 (3.0%)
	ASTHENIA	4 (3.0%)	3 (2.3%)	7 (2.7%)
	ALLERGIC REACTION	3 (2.3%)	2 (1.5%)	5 (1.9%)
	PAIN	2 (1.5%)	2 (1.5%)	4 (1.5%)
	BACK PAIN	2 (1.5%)	1 (0.8%)	3 (1.1%)
	CHEST PAIN	1 (0.8%)	0	1 (0.4%)
	FACE EDEMA	1 (0.8%)	0	1 (0.4%)
Nervous System	TOTAL	28 (21.1%)	39 (30.0%)	67 (25.5%)
	NERVOUSNESS	5 (3.8%)	9 (6.9%)	14 (5.3%)
	HOSTILITY	5 (3.8%)	6 (4.6%)	11 (4.2%)
	HYPERKINESIA	5 (3.8%)	4 (3.1%)	9 (3.4%)
	INSOMNIA	3 (2.3%)	5 (3.8%)	8 (3.0%)
	EMOTIONAL LABILITY	4 (3.0%)	3 (2.3%)	7 (2.7%)
	AGITATION	2 (1.5%)	5 (3.8%)	7 (2.7%)
	ANXIETY	2 (1.5%)	4 (3.1%)	6 (2.3%)
	SOMNOLENCE	2 (1.5%)	4 (3.1%)	6 (2.3%)
	DEPRESSION	3 (2.3%)	2 (1.5%)	5 (1.9%)
	DIZZINESS	1 (0.8%)	2 (1.5%)	3 (1.1%)
	CONCENTRATION IMPAIRED	1 (0.8%)	1 (0.8%)	2 (0.8%)
	MANIC REACTION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	CONVULSION	1 (0.8%)	0	1 (0.4%)
	VERTIGO	1 (0.8%)	0	1 (0.4%)
	VESTIBULAR DISORDER	1 (0.8%)	0	1 (0.4%)
	ABNORMAL DREAMS	0	1 (0.8%)	1 (0.4%)
	HALLUCINATIONS	0	1 (0.8%)	1 (0.4%)
	HYPESTHESIA	0	1 (0.8%)	1 (0.4%)
	HYSTERIA	0	1 (0.8%)	1 (0.4%)
	LACK OF EMOTION	0	1 (0.8%)	1 (0.4%)
	PSYCHOSIS	0	1 (0.8%)	1 (0.4%)
	TREMOR	0	1 (0.8%)	1 (0.4%)
	WITHDRAWAL SYNDROME	0	1 (0.8%)	1 (0.4%)
Respiratory System	TOTAL	27 (20.3%)	19 (14.6%)	46 (17.5%)
	RESPIRATORY DISORDER	13 (9.8%)	11 (8.5%)	24 (9.1%)
	PHARYNGITIS	6 (4.5%)	3 (2.3%)	9 (3.4%)

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Respiratory System	SINUSITIS	5 (3.8%)	1 (0.8%)	6 (2.3%)
	BRONCHITIS	3 (2.3%)	3 (2.3%)	6 (2.3%)
	ASTHMA	3 (2.3%)	2 (1.5%)	5 (1.9%)
	RHINITIS	3 (2.3%)	1 (0.8%)	4 (1.5%)
	COUGH INCREASED	2 (1.5%)	1 (0.8%)	3 (1.1%)
	PNEUMONIA	1 (0.8%)	2 (1.5%)	3 (1.1%)
Digestive System	TOTAL	17 (12.8%)	12 (9.2%)	29 (11.0%)
	VOMITING	9 (6.8%)	2 (1.5%)	11 (4.2%)
	NAUSEA	2 (1.5%)	4 (3.1%)	6 (2.3%)
	DIARRHEA	4 (3.0%)	1 (0.8%)	5 (1.9%)
	DYSPEPSIA	1 (0.8%)	4 (3.1%)	5 (1.9%)
	TOOTH DISORDER	2 (1.5%)	1 (0.8%)	3 (1.1%)
	CONSTIPATION	2 (1.5%)	0	2 (0.8%)
	GINGIVITIS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	HEMATEMESIS	1 (0.8%)	0	1 (0.4%)
	STOMATITIS	1 (0.8%)	0	1 (0.4%)
	DECREASED APPETITE	0	1 (0.8%)	1 (0.4%)
	TOOTH CARIES	0	1 (0.8%)	1 (0.4%)
Skin and Appendages	TOTAL	8 (6.0%)	4 (3.1%)	12 (4.6%)
	ACNE	4 (3.0%)	1 (0.8%)	5 (1.9%)
	CONTACT DERMATITIS	2 (1.5%)	2 (1.5%)	4 (1.5%)
	FURUNCULOSIS	1 (0.8%)	0	1 (0.4%)
	HERPES ZOSTER	1 (0.8%)	0	1 (0.4%)
	FUNGAL DERMATITIS	0	1 (0.8%)	1 (0.4%)
Metabolic and Nutritional Disorders	TOTAL	6 (4.5%)	4 (3.1%)	10 (3.8%)
	WEIGHT GAIN	4 (3.0%)	2 (1.5%)	6 (2.3%)
	DEHYDRATION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	WEIGHT LOSS	1 (0.8%)	1 (0.8%)	2 (0.8%)
Special Senses	TOTAL	6 (4.5%)	2 (1.5%)	8 (3.0%)
	OTITIS MEDIA	5 (3.8%)	2 (1.5%)	7 (2.7%)
	EAR PAIN	1 (0.8%)	0	1 (0.4%)
	OTITIS EXTERNA	1 (0.8%)	0	1 (0.4%)
Musculoskeletal System	TOTAL	3 (2.3%)	1 (0.8%)	4 (1.5%)
	MYALGIA	1 (0.8%)	1 (0.8%)	2 (0.8%)
	ARTHRALGIA	1 (0.8%)	0	1 (0.4%)
	TENDINOUS DISORDER	1 (0.8%)	0	1 (0.4%)
	ARTHROSIS	0	1 (0.8%)	1 (0.4%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Urogenital System	TOTAL	2 (1.5%)	0	2 (0.8%)
	URINARY INCONTINENCE	1 (0.8%)	0	1 (0.4%)
	URINARY TRACT INFECTION	1 (0.8%)	0	1 (0.4%)
Cardiovascular System	TOTAL	1 (0.8%)	2 (1.5%)	3 (1.1%)
	BRADYCARDIA	1 (0.8%)	0	1 (0.4%)
	MIGRAINE	0	1 (0.8%)	1 (0.4%)
	SYNCOPE	0	1 (0.8%)	1 (0.4%)
Hemic and Lymphatic System	TOTAL	1 (0.8%)	2 (1.5%)	3 (1.1%)
	PURPURA	1 (0.8%)	0	1 (0.4%)
	EOSINOPHILIA	0	1 (0.8%)	1 (0.4%)
	LEUKOPENIA	0	1 (0.8%)	1 (0.4%)
	MONOCYTOSIS	0	1 (0.8%)	1 (0.4%)
Special Searches	TOTAL	0	1 (0.8%)	1 (0.4%)
	PUNCTURE SITE PAIN	0	1 (0.8%)	1 (0.4%)

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
TOTAL	TOTAL	15 (11.3%)	19 (14.6%)	34 (12.9%)
Nervous System	TOTAL	9 (6.8%)	10 (7.7%)	19 (7.2%)
	EMOTIONAL LABILITY	4 (3.0%)	1 (0.8%)	5 (1.9%)
	HOSTILITY	2 (1.5%)	3 (2.3%)	5 (1.9%)
	NEUROSIS	2 (1.5%)	0	2 (0.8%)
	AGITATION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	DEPRESSION	1 (0.8%)	0	1 (0.4%)
	LACK OF EMOTION	1 (0.8%)	0	1 (0.4%)
	SOMNOLENCE	1 (0.8%)	0	1 (0.4%)
	ANXIETY	0	1 (0.8%)	1 (0.4%)
	EUPHORIA	0	1 (0.8%)	1 (0.4%)
	HALLUCINATIONS	0	1 (0.8%)	1 (0.4%)
	HYPERKINESIA	0	1 (0.8%)	1 (0.4%)
	NERVOUSNESS	0	1 (0.8%)	1 (0.4%)
	PARALYSIS	0	1 (0.8%)	1 (0.4%)
Body as a Whole	TOTAL	6 (4.5%)	4 (3.1%)	10 (3.8%)
	INFECTION	2 (1.5%)	2 (1.5%)	4 (1.5%)
	TRAUMA	1 (0.8%)	2 (1.5%)	3 (1.1%)
	ABSCESS	1 (0.8%)	0	1 (0.4%)
	BACK PAIN	1 (0.8%)	0	1 (0.4%)
	FEVER	1 (0.8%)	0	1 (0.4%)
	ABDOMINAL PAIN	0	1 (0.8%)	1 (0.4%)
Respiratory System	TOTAL	1 (0.8%)	1 (0.8%)	2 (0.8%)
	PHARYNGITIS	1 (0.8%)	0	1 (0.4%)
	ASTHMA	0	1 (0.8%)	1 (0.4%)
Cardiovascular System	TOTAL	0	2 (1.5%)	2 (0.8%)
	MIGRAINE	0	1 (0.8%)	1 (0.4%)
	SYNCOPE	0	1 (0.8%)	1 (0.4%)
Digestive System	TOTAL	0	2 (1.5%)	2 (0.8%)
	NAUSEA	0	1 (0.8%)	1 (0.4%)
	TOOTH CARIES	0	1 (0.8%)	1 (0.4%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (0.8%)	1 (0.4%)
	WEIGHT GAIN	0	1 (0.8%)	1 (0.4%)
Skin and Appendages	TOTAL	0	1 (0.8%)	1 (0.4%)
	RASH	0	1 (0.8%)	1 (0.4%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Special Senses	TOTAL	0	1 (0.8%)	1 (0.4%)
	OTITIS MEDIA	0	1 (0.8%)	1 (0.4%)
Urogenital System	TOTAL	0	2 (1.5%)	2 (0.8%)
	URINARY INCONTINENCE	0	2 (1.5%)	2 (0.8%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Mild, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	1 (1.6%)	3 (5.9%)	4 (3.6%)
Urogenital System	TOTAL	1 (1.6%)	3 (5.9%)	4 (3.6%)
	DYSMENORRHEA	1 (1.6%)	1 (2.0%)	2 (1.8%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (0.9%)
	MENSTRUAL DISORDER	0	1 (2.0%)	1 (0.9%)
	UTERUS DISORDERS	0	1 (2.0%)	1 (0.9%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	6 (9.8%)	0	6 (5.4%)
Urogenital System	TOTAL	6 (9.8%)	0	6 (5.4%)
	DYSMENORRHEA	6 (9.8%)	0	6 (5.4%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Intensity : Severe, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=34)	Total (N=83)
Body System	Preferred Term			
TOTAL	TOTAL	12 (24.5%)	4 (11.8%)	16 (19.3%)
Respiratory System	TOTAL	5 (10.2%)	1 (2.9%)	6 (7.2%)
	RESPIRATORY DISORDER	3 (6.1%)	1 (2.9%)	4 (4.8%)
	PHARYNGITIS	1 (2.0%)	0	1 (1.2%)
	SINUSITIS	1 (2.0%)	0	1 (1.2%)
Nervous System	TOTAL	4 (8.2%)	0	4 (4.8%)
	DEPRESSION	1 (2.0%)	0	1 (1.2%)
	EMOTIONAL LABILITY	1 (2.0%)	0	1 (1.2%)
	INSOMNIA	1 (2.0%)	0	1 (1.2%)
	WITHDRAWAL SYNDROME	1 (2.0%)	0	1 (1.2%)
Digestive System	TOTAL	3 (6.1%)	2 (5.9%)	5 (6.0%)
	DIARRHEA	1 (2.0%)	1 (2.9%)	2 (2.4%)
	COLITIS	1 (2.0%)	0	1 (1.2%)
	GASTROINTESTINAL DISORDER	1 (2.0%)	0	1 (1.2%)
	VOMITING	1 (2.0%)	0	1 (1.2%)
	FECAL INCONTINENCE	0	1 (2.9%)	1 (1.2%)
	NAUSEA	0	1 (2.9%)	1 (1.2%)
Body as a Whole	TOTAL	1 (2.0%)	2 (5.9%)	3 (3.6%)
	ABDOMINAL PAIN	1 (2.0%)	0	1 (1.2%)
	HEADACHE	1 (2.0%)	0	1 (1.2%)
	ALLERGIC REACTION	0	1 (2.9%)	1 (1.2%)
	INFECTION	0	1 (2.9%)	1 (1.2%)
Musculoskeletal System	TOTAL	1 (2.0%)	0	1 (1.2%)
	MYALGIA	1 (2.0%)	0	1 (1.2%)
Urogenital System	TOTAL	1 (2.0%)	1 (2.9%)	2 (2.4%)
	ALBUMINURIA	1 (2.0%)	0	1 (1.2%)
	URINARY INCONTINENCE	0	1 (2.9%)	1 (1.2%)

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=34)	Total (N=83)
Body System	Preferred Term			
TOTAL	TOTAL	5 (10.2%)	5 (14.7%)	10 (12.0%)
Body as a Whole	TOTAL	2 (4.1%)	0	2 (2.4%)
	ABDOMINAL PAIN	2 (4.1%)	0	2 (2.4%)
	HEADACHE	1 (2.0%)	0	1 (1.2%)
Digestive System	TOTAL	2 (4.1%)	0	2 (2.4%)
	INCREASED APPETITE	1 (2.0%)	0	1 (1.2%)
	NAUSEA	1 (2.0%)	0	1 (1.2%)
	TOOTH DISORDER	1 (2.0%)	0	1 (1.2%)
Cardiovascular System	TOTAL	1 (2.0%)	0	1 (1.2%)
	MIGRAINE	1 (2.0%)	0	1 (1.2%)
Nervous System	TOTAL	1 (2.0%)	2 (5.9%)	3 (3.6%)
	ANXIETY	1 (2.0%)	0	1 (1.2%)
	NERVOUSNESS	1 (2.0%)	0	1 (1.2%)
	CONCENTRATION IMPAIRED	0	1 (2.9%)	1 (1.2%)
	HOSTILITY	0	1 (2.9%)	1 (1.2%)
Respiratory System	TOTAL	1 (2.0%)	2 (5.9%)	3 (3.6%)
	RESPIRATORY DISORDER	0	2 (5.9%)	2 (2.4%)
	ASTHMA	1 (2.0%)	0	1 (1.2%)
Hemic and Lymphatic System	TOTAL	0	1 (2.9%)	1 (1.2%)
	LYMPHOCYTOSIS	0	1 (2.9%)	1 (1.2%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.9%)	1 (1.2%)
	SGOT INCREASED	0	1 (2.9%)	1 (1.2%)

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=34)	Total (N=83)
Body System	Preferred Term			
TOTAL	TOTAL	1 (2.0%)	0	1 (1.2%)
Nervous System	TOTAL	1 (2.0%)	0	1 (1.2%)
	EMOTIONAL LABILITY	1 (2.0%)	0	1 (1.2%)

Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=29)	Placebo (N=18)	Total (N=47)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=29)	Placebo (N=18)	Total (N=47)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=29)	Placebo (N=18)	Total (N=47)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=16)	Total (N=36)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=16)	Total (N=36)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=16)	Total (N=36)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=33)	Total (N=56)
Body System	Preferred Term			
TOTAL	TOTAL	7 (30.4%)	2 (6.1%)	9 (16.1%)
Body as a Whole	TOTAL	3 (13.0%)	0	3 (5.4%)
	FEVER	1 (4.3%)	0	1 (1.8%)
	HEADACHE	1 (4.3%)	0	1 (1.8%)
	PAIN	1 (4.3%)	0	1 (1.8%)
Nervous System	TOTAL	2 (8.7%)	0	2 (3.6%)
	DIZZINESS	1 (4.3%)	0	1 (1.8%)
	NEUROSIS	1 (4.3%)	0	1 (1.8%)
Respiratory System	TOTAL	2 (8.7%)	1 (3.0%)	3 (5.4%)
	RESPIRATORY DISORDER	1 (4.3%)	1 (3.0%)	2 (3.6%)
	COUGH INCREASED	1 (4.3%)	0	1 (1.8%)
Special Senses	TOTAL	1 (4.3%)	0	1 (1.8%)
	EAR PAIN	1 (4.3%)	0	1 (1.8%)
Digestive System	TOTAL	0	1 (3.0%)	1 (1.8%)
	DIARRHEA	0	1 (3.0%)	1 (1.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (3.0%)	1 (1.8%)
	VOMITING	0	1 (3.0%)	1 (1.8%)

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=33)	Total (N=56)
Body System	Preferred Term			
TOTAL	TOTAL	3 (13.0%)	6 (18.2%)	9 (16.1%)
Body as a Whole	TOTAL	1 (4.3%)	3 (9.1%)	4 (7.1%)
	HEADACHE	1 (4.3%)	2 (6.1%)	3 (5.4%)
	FEVER	0	1 (3.0%)	1 (1.8%)
Digestive System	TOTAL	1 (4.3%)	1 (3.0%)	2 (3.6%)
	TOOTH DISORDER	1 (4.3%)	0	1 (1.8%)
	NAUSEA	0	1 (3.0%)	1 (1.8%)
Nervous System	TOTAL	1 (4.3%)	0	1 (1.8%)
	CONCENTRATION IMPAIRED	1 (4.3%)	0	1 (1.8%)
	PARESTHESIA	1 (4.3%)	0	1 (1.8%)
Respiratory System	TOTAL	1 (4.3%)	1 (3.0%)	2 (3.6%)
	SINUSITIS	1 (4.3%)	0	1 (1.8%)
	COUGH INCREASED	0	1 (3.0%)	1 (1.8%)
Skin and Appendages	TOTAL	0	1 (3.0%)	1 (1.8%)
	FUNGAL DERMATITIS	0	1 (3.0%)	1 (1.8%)

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=33)	Total (N=56)
Body System	Preferred Term			
TOTAL	TOTAL	1 (4.3%)	1 (3.0%)	2 (3.6%)
Body as a Whole	TOTAL	1 (4.3%)	1 (3.0%)	2 (3.6%)
	HEADACHE	1 (4.3%)	0	1 (1.8%)
	INFECTION	0	1 (3.0%)	1 (1.8%)

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=21)	Total (N=32)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=21)	Total (N=32)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=21)	Total (N=32)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=12)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=12)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=12)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=67)	Total (N=139)
Body System	Preferred Term			
TOTAL	TOTAL	19 (26.4%)	6 (9.0%)	25 (18.0%)
Respiratory System	TOTAL	7 (9.7%)	2 (3.0%)	9 (6.5%)
	RESPIRATORY DISORDER	4 (5.6%)	2 (3.0%)	6 (4.3%)
	COUGH INCREASED	1 (1.4%)	0	1 (0.7%)
	PHARYNGITIS	1 (1.4%)	0	1 (0.7%)
	SINUSITIS	1 (1.4%)	0	1 (0.7%)
Nervous System	TOTAL	6 (8.3%)	0	6 (4.3%)
	DEPRESSION	1 (1.4%)	0	1 (0.7%)
	DIZZINESS	1 (1.4%)	0	1 (0.7%)
	EMOTIONAL LABILITY	1 (1.4%)	0	1 (0.7%)
	INSOMNIA	1 (1.4%)	0	1 (0.7%)
	NEUROSIS	1 (1.4%)	0	1 (0.7%)
	WITHDRAWAL SYNDROME	1 (1.4%)	0	1 (0.7%)
Body as a Whole	TOTAL	4 (5.6%)	2 (3.0%)	6 (4.3%)
	HEADACHE	2 (2.8%)	0	2 (1.4%)
	ABDOMINAL PAIN	1 (1.4%)	0	1 (0.7%)
	FEVER	1 (1.4%)	0	1 (0.7%)
	PAIN	1 (1.4%)	0	1 (0.7%)
	ALLERGIC REACTION	0	1 (1.5%)	1 (0.7%)
	INFECTION	0	1 (1.5%)	1 (0.7%)
Digestive System	TOTAL	3 (4.2%)	3 (4.5%)	6 (4.3%)
	DIARRHEA	1 (1.4%)	2 (3.0%)	3 (2.2%)
	VOMITING	1 (1.4%)	1 (1.5%)	2 (1.4%)
	COLITIS	1 (1.4%)	0	1 (0.7%)
	GASTROINTESTINAL DISORDER	1 (1.4%)	0	1 (0.7%)
	FECAL INCONTINENCE	0	1 (1.5%)	1 (0.7%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.7%)
	NAUSEA	0	1 (1.5%)	1 (0.7%)
Musculoskeletal System	TOTAL	1 (1.4%)	0	1 (0.7%)
	MYALGIA	1 (1.4%)	0	1 (0.7%)
Special Senses	TOTAL	1 (1.4%)	0	1 (0.7%)
	EAR PAIN	1 (1.4%)	0	1 (0.7%)
Urogenital System	TOTAL	1 (1.4%)	1 (1.5%)	2 (1.4%)
	ALBUMINURIA	1 (1.4%)	0	1 (0.7%)
	URINARY INCONTINENCE	0	1 (1.5%)	1 (0.7%)

Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=67)	Total (N=139)
Body System	Preferred Term			
TOTAL	TOTAL	8 (11.1%)	11 (16.4%)	19 (13.7%)
Body as a Whole	TOTAL	3 (4.2%)	3 (4.5%)	6 (4.3%)
	HEADACHE	2 (2.8%)	2 (3.0%)	4 (2.9%)
	ABDOMINAL PAIN	2 (2.8%)	0	2 (1.4%)
	FEVER	0	1 (1.5%)	1 (0.7%)
Digestive System	TOTAL	3 (4.2%)	1 (1.5%)	4 (2.9%)
	TOOTH DISORDER	2 (2.8%)	0	2 (1.4%)
	NAUSEA	1 (1.4%)	1 (1.5%)	2 (1.4%)
	INCREASED APPETITE	1 (1.4%)	0	1 (0.7%)
Nervous System	TOTAL	2 (2.8%)	2 (3.0%)	4 (2.9%)
	CONCENTRATION IMPAIRED	1 (1.4%)	1 (1.5%)	2 (1.4%)
	ANXIETY	1 (1.4%)	0	1 (0.7%)
	NERVOUSNESS	1 (1.4%)	0	1 (0.7%)
	PARESTHESIA	1 (1.4%)	0	1 (0.7%)
	HOSTILITY	0	1 (1.5%)	1 (0.7%)
Respiratory System	TOTAL	2 (2.8%)	3 (4.5%)	5 (3.6%)
	RESPIRATORY DISORDER	0	2 (3.0%)	2 (1.4%)
	ASTHMA	1 (1.4%)	0	1 (0.7%)
	SINUSITIS	1 (1.4%)	0	1 (0.7%)
	COUGH INCREASED	0	1 (1.5%)	1 (0.7%)
Cardiovascular System	TOTAL	1 (1.4%)	0	1 (0.7%)
	MIGRAINE	1 (1.4%)	0	1 (0.7%)
Hemic and Lymphatic System	TOTAL	0	1 (1.5%)	1 (0.7%)
	LYMPHOCYTOSIS	0	1 (1.5%)	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.5%)	1 (0.7%)
	SGOT INCREASED	0	1 (1.5%)	1 (0.7%)
Skin and Appendages	TOTAL	0	1 (1.5%)	1 (0.7%)
	FUNGAL DERMATITIS	0	1 (1.5%)	1 (0.7%)

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=67)	Total (N=139)
Body System	Preferred Term			
TOTAL	TOTAL	2 (2.8%)	1 (1.5%)	3 (2.2%)
Body as a Whole	TOTAL	1 (1.4%)	1 (1.5%)	2 (1.4%)
	HEADACHE	1 (1.4%)	0	1 (0.7%)
	INFECTION	0	1 (1.5%)	1 (0.7%)
Nervous System	TOTAL	1 (1.4%)	0	1 (0.7%)
	EMOTIONAL LABILITY	1 (1.4%)	0	1 (0.7%)

Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=40)	Placebo (N=39)	Total (N=79)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=40)	Placebo (N=39)	Total (N=79)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=40)	Placebo (N=39)	Total (N=79)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=32)	Placebo (N=28)	Total (N=60)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=32)	Placebo (N=28)	Total (N=60)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=32)	Placebo (N=28)	Total (N=60)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=49)	Placebo (N=34)	Total (N=83)
Preferred Term			
TOTAL	12 (24.5%)	4 (11.8%)	16 (19.3%)
RESPIRATORY DISORDER	3 (6.1%)	1 (2.9%)	4 (4.8%)
DIARRHEA	1 (2.0%)	1 (2.9%)	2 (2.4%)
ABDOMINAL PAIN	1 (2.0%)	0	1 (1.2%)
ALBUMINURIA	1 (2.0%)	0	1 (1.2%)
COLITIS	1 (2.0%)	0	1 (1.2%)
DEPRESSION	1 (2.0%)	0	1 (1.2%)
EMOTIONAL LABILITY	1 (2.0%)	0	1 (1.2%)
GASTROINTESTINAL DISORDER	1 (2.0%)	0	1 (1.2%)
HEADACHE	1 (2.0%)	0	1 (1.2%)
INSOMNIA	1 (2.0%)	0	1 (1.2%)
MYALGIA	1 (2.0%)	0	1 (1.2%)
PHARYNGITIS	1 (2.0%)	0	1 (1.2%)
SINUSITIS	1 (2.0%)	0	1 (1.2%)
VOMITING	1 (2.0%)	0	1 (1.2%)
WITHDRAWAL SYNDROME	1 (2.0%)	0	1 (1.2%)
ALLERGIC REACTION	0	1 (2.9%)	1 (1.2%)
FECAL INCONTINENCE	0	1 (2.9%)	1 (1.2%)
INFECTION	0	1 (2.9%)	1 (1.2%)
NAUSEA	0	1 (2.9%)	1 (1.2%)
URINARY INCONTINENCE	0	1 (2.9%)	1 (1.2%)

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=49)	 Placebo (N=34)	 Total (N=83)
TOTAL	5 (10.2%)	5 (14.7%)	10 (12.0%)
ABDOMINAL PAIN	2 (4.1%)	0	2 (2.4%)
RESPIRATORY DISORDER	0	2 (5.9%)	2 (2.4%)
ANXIETY	1 (2.0%)	0	1 (1.2%)
ASTHMA	1 (2.0%)	0	1 (1.2%)
HEADACHE	1 (2.0%)	0	1 (1.2%)
INCREASED APPETITE	1 (2.0%)	0	1 (1.2%)
MIGRAINE	1 (2.0%)	0	1 (1.2%)
NAUSEA	1 (2.0%)	0	1 (1.2%)
NERVOUSNESS	1 (2.0%)	0	1 (1.2%)
TOOTH DISORDER	1 (2.0%)	0	1 (1.2%)
CONCENTRATION IMPAIRED	0	1 (2.9%)	1 (1.2%)
HOSTILITY	0	1 (2.9%)	1 (1.2%)
LYMPHOCYTOSIS	0	1 (2.9%)	1 (1.2%)
SGOT INCREASED	0	1 (2.9%)	1 (1.2%)

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=49)	Placebo (N=34)	Total (N=83)
Preferred Term			
TOTAL	1 (2.0%)	0	1 (1.2%)
EMOTIONAL LABILITY	1 (2.0%)	0	1 (1.2%)

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=29)	Placebo (N=18)	Total (N=47)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=29)	Placebo (N=18)	Total (N=47)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=29)	Placebo (N=18)	Total (N=47)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=20)	Placebo (N=16)	Total (N=36)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=20)	Placebo (N=16)	Total (N=36)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=20)	Placebo (N=16)	Total (N=36)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=23)	 Placebo (N=33)	 Total (N=56)
TOTAL	7 (30.4%)	2 (6.1%)	9 (16.1%)
RESPIRATORY DISORDER	1 (4.3%)	1 (3.0%)	2 (3.6%)
COUGH INCREASED	1 (4.3%)	0	1 (1.8%)
DIZZINESS	1 (4.3%)	0	1 (1.8%)
EAR PAIN	1 (4.3%)	0	1 (1.8%)
FEVER	1 (4.3%)	0	1 (1.8%)
HEADACHE	1 (4.3%)	0	1 (1.8%)
NEUROSIS	1 (4.3%)	0	1 (1.8%)
PAIN	1 (4.3%)	0	1 (1.8%)
DIARRHEA	0	1 (3.0%)	1 (1.8%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (3.0%)	1 (1.8%)
VOMITING	0	1 (3.0%)	1 (1.8%)

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=23)	 Placebo (N=33)	 Total (N=56)
TOTAL	3 (13.0%)	6 (18.2%)	9 (16.1%)
HEADACHE	1 (4.3%)	2 (6.1%)	3 (5.4%)
CONCENTRATION IMPAIRED	1 (4.3%)	0	1 (1.8%)
PARESTHESIA	1 (4.3%)	0	1 (1.8%)
SINUSITIS	1 (4.3%)	0	1 (1.8%)
TOOTH DISORDER	1 (4.3%)	0	1 (1.8%)
COUGH INCREASED	0	1 (3.0%)	1 (1.8%)
FEVER	0	1 (3.0%)	1 (1.8%)
FUNGAL DERMATITIS	0	1 (3.0%)	1 (1.8%)
NAUSEA	0	1 (3.0%)	1 (1.8%)

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=23)	Placebo (N=33)	Total (N=56)
Preferred Term			
TOTAL	1 (4.3%)	1 (3.0%)	2 (3.6%)
HEADACHE	1 (4.3%)	0	1 (1.8%)
INFECTION	0	1 (3.0%)	1 (1.8%)

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=11)	Placebo (N=21)	Total (N=32)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=11)	Placebo (N=21)	Total (N=32)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=11)	Placebo (N=21)	Total (N=32)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=12)	Total (N=24)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=12)	Total (N=24)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=12)	Total (N=24)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=72)	 Placebo (N=67)	 Total (N=139)
TOTAL	19 (26.4%)	6 (9.0%)	25 (18.0%)
RESPIRATORY DISORDER	4 (5.6%)	2 (3.0%)	6 (4.3%)
DIARRHEA	1 (1.4%)	2 (3.0%)	3 (2.2%)
HEADACHE	2 (2.8%)	0	2 (1.4%)
VOMITING	1 (1.4%)	1 (1.5%)	2 (1.4%)
ABDOMINAL PAIN	1 (1.4%)	0	1 (0.7%)
ALBUMINURIA	1 (1.4%)	0	1 (0.7%)
COLITIS	1 (1.4%)	0	1 (0.7%)
COUGH INCREASED	1 (1.4%)	0	1 (0.7%)
DEPRESSION	1 (1.4%)	0	1 (0.7%)
DIZZINESS	1 (1.4%)	0	1 (0.7%)
EAR PAIN	1 (1.4%)	0	1 (0.7%)
EMOTIONAL LABILITY	1 (1.4%)	0	1 (0.7%)
FEVER	1 (1.4%)	0	1 (0.7%)
GASTROINTESTINAL DISORDER	1 (1.4%)	0	1 (0.7%)
INSOMNIA	1 (1.4%)	0	1 (0.7%)
MYALGIA	1 (1.4%)	0	1 (0.7%)
NEUROSIS	1 (1.4%)	0	1 (0.7%)
PAIN	1 (1.4%)	0	1 (0.7%)
PHARYNGITIS	1 (1.4%)	0	1 (0.7%)
SINUSITIS	1 (1.4%)	0	1 (0.7%)
WITHDRAWAL SYNDROME	1 (1.4%)	0	1 (0.7%)
ALLERGIC REACTION	0	1 (1.5%)	1 (0.7%)
FECAL INCONTINENCE	0	1 (1.5%)	1 (0.7%)
INFECTION	0	1 (1.5%)	1 (0.7%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.7%)
NAUSEA	0	1 (1.5%)	1 (0.7%)
URINARY INCONTINENCE	0	1 (1.5%)	1 (0.7%)

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=72)	Placebo (N=67)	Total (N=139)
Preferred Term			
TOTAL	8 (11.1%)	11 (16.4%)	19 (13.7%)
HEADACHE	2 (2.8%)	2 (3.0%)	4 (2.9%)
ABDOMINAL PAIN	2 (2.8%)	0	2 (1.4%)
TOOTH DISORDER	2 (2.8%)	0	2 (1.4%)
CONCENTRATION IMPAIRED	1 (1.4%)	1 (1.5%)	2 (1.4%)
NAUSEA	1 (1.4%)	1 (1.5%)	2 (1.4%)
RESPIRATORY DISORDER	0	2 (3.0%)	2 (1.4%)
ANXIETY	1 (1.4%)	0	1 (0.7%)
ASTHMA	1 (1.4%)	0	1 (0.7%)
INCREASED APPETITE	1 (1.4%)	0	1 (0.7%)
MIGRAINE	1 (1.4%)	0	1 (0.7%)
NERVOUSNESS	1 (1.4%)	0	1 (0.7%)
PARESTHESIA	1 (1.4%)	0	1 (0.7%)
SINUSITIS	1 (1.4%)	0	1 (0.7%)
COUGH INCREASED	0	1 (1.5%)	1 (0.7%)
FEVER	0	1 (1.5%)	1 (0.7%)
FUNGAL DERMATITIS	0	1 (1.5%)	1 (0.7%)
HOSTILITY	0	1 (1.5%)	1 (0.7%)
LYMPHOCYTOSIS	0	1 (1.5%)	1 (0.7%)
SGOT INCREASED	0	1 (1.5%)	1 (0.7%)

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=72)	Placebo (N=67)	Total (N=139)
Preferred Term			
TOTAL	2 (2.8%)	1 (1.5%)	3 (2.2%)
EMOTIONAL LABILITY	1 (1.4%)	0	1 (0.7%)
HEADACHE	1 (1.4%)	0	1 (0.7%)
INFECTION	0	1 (1.5%)	1 (0.7%)

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=40)	Placebo (N=39)	Total (N=79)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=40)	Placebo (N=39)	Total (N=79)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=40)	Placebo (N=39)	Total (N=79)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=32)	Placebo (N=28)	Total (N=60)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=32)	Placebo (N=28)	Total (N=60)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-Up Phase
by Intensity, by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=32)	Placebo (N=28)	Total (N=60)
Preferred Term			
TOTAL	0	0	0

Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
TOTAL	TOTAL	20 (51.3%)	14 (38.9%)	34 (45.3%)
Nervous System	TOTAL	10 (25.6%)	5 (13.9%)	15 (20.0%)
	HOSTILITY	3 (7.7%)	0	3 (4.0%)
	NERVOUSNESS	3 (7.7%)	0	3 (4.0%)
	HYPERKINESIA	2 (5.1%)	1 (2.8%)	3 (4.0%)
	AGITATION	1 (2.6%)	1 (2.8%)	2 (2.7%)
	INSOMNIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
	CONVULSION	1 (2.6%)	0	1 (1.3%)
	ANXIETY	0	1 (2.8%)	1 (1.3%)
	DIZZINESS	0	1 (2.8%)	1 (1.3%)
	HYPESTHESIA	0	1 (2.8%)	1 (1.3%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.3%)
	TREMOR	0	1 (2.8%)	1 (1.3%)
Digestive System	TOTAL	5 (12.8%)	4 (11.1%)	9 (12.0%)
	DRY MOUTH	2 (5.1%)	0	2 (2.7%)
	DECREASED APPETITE	1 (2.6%)	1 (2.8%)	2 (2.7%)
	DYSPEPSIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
	CONSTIPATION	1 (2.6%)	0	1 (1.3%)
	INCREASED APPETITE	1 (2.6%)	0	1 (1.3%)
	NAUSEA	0	1 (2.8%)	1 (1.3%)
	VOMITING	0	1 (2.8%)	1 (1.3%)
Body as a Whole	TOTAL	4 (10.3%)	2 (5.6%)	6 (8.0%)
	ABDOMINAL PAIN	2 (5.1%)	1 (2.8%)	3 (4.0%)
	HEADACHE	2 (5.1%)	0	2 (2.7%)
	ASTHENIA	0	1 (2.8%)	1 (1.3%)
Metabolic and Nutritional Disorders	TOTAL	4 (10.3%)	2 (5.6%)	6 (8.0%)
	WEIGHT GAIN	4 (10.3%)	2 (5.6%)	6 (8.0%)
Hemic and Lymphatic System	TOTAL	1 (2.6%)	1 (2.8%)	2 (2.7%)
	LEUKOPENIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
Urogenital System	TOTAL	1 (2.6%)	2 (5.6%)	3 (4.0%)
	URINARY INCONTINENCE	1 (2.6%)	2 (5.6%)	3 (4.0%)
Cardiovascular System	TOTAL	0	1 (2.8%)	1 (1.3%)
	SYNCOPE	0	1 (2.8%)	1 (1.3%)
Respiratory System	TOTAL	0	1 (2.8%)	1 (1.3%)
	YAWN	0	1 (2.8%)	1 (1.3%)

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
Special Senses	TOTAL	0	1 (2.8%)	1 (1.3%)
	ABNORMAL VISION	0	1 (2.8%)	1 (1.3%)

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	17 (60.7%)	23 (63.9%)	40 (62.5%)
Body as a Whole	TOTAL	10 (35.7%)	6 (16.7%)	16 (25.0%)
	HEADACHE	8 (28.6%)	5 (13.9%)	13 (20.3%)
	FEVER	1 (3.6%)	0	1 (1.6%)
	PAIN	1 (3.6%)	0	1 (1.6%)
	TRAUMA	1 (3.6%)	0	1 (1.6%)
	ABDOMINAL PAIN	0	1 (2.8%)	1 (1.6%)
Nervous System	TOTAL	8 (28.6%)	17 (47.2%)	25 (39.1%)
	NERVOUSNESS	1 (3.6%)	9 (25.0%)	10 (15.6%)
	HYPERKINESIA	5 (17.9%)	4 (11.1%)	9 (14.1%)
	INSOMNIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
	ANXIETY	1 (3.6%)	3 (8.3%)	4 (6.3%)
	HOSTILITY	1 (3.6%)	2 (5.6%)	3 (4.7%)
	SOMNOLENCE	1 (3.6%)	2 (5.6%)	3 (4.7%)
	AGITATION	1 (3.6%)	1 (2.8%)	2 (3.1%)
	CONCENTRATION IMPAIRED	1 (3.6%)	0	1 (1.6%)
	DIZZINESS	1 (3.6%)	0	1 (1.6%)
	MYOCLONUS	1 (3.6%)	0	1 (1.6%)
	DYSKINESIA	0	1 (2.8%)	1 (1.6%)
	LACK OF EMOTION	0	1 (2.8%)	1 (1.6%)
	MANIC REACTION	0	1 (2.8%)	1 (1.6%)
	TREMOR	0	1 (2.8%)	1 (1.6%)
Digestive System	TOTAL	7 (25.0%)	2 (5.6%)	9 (14.1%)
	DECREASED APPETITE	2 (7.1%)	2 (5.6%)	4 (6.3%)
	NAUSEA	3 (10.7%)	0	3 (4.7%)
	DIARRHEA	2 (7.1%)	0	2 (3.1%)
	DYSPEPSIA	2 (7.1%)	0	2 (3.1%)
Cardiovascular System	TOTAL	0	3 (8.3%)	3 (4.7%)
	VASODILATATION	0	3 (8.3%)	3 (4.7%)
Metabolic and Nutritional Disorders	TOTAL	0	3 (8.3%)	3 (4.7%)
	WEIGHT GAIN	0	3 (8.3%)	3 (4.7%)
Respiratory System	TOTAL	0	1 (2.8%)	1 (1.6%)
	RHINITIS	0	1 (2.8%)	1 (1.6%)
Urogenital System	TOTAL	0	1 (2.8%)	1 (1.6%)
	URINARY INCONTINENCE	0	1 (2.8%)	1 (1.6%)

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
TOTAL	TOTAL	37 (55.2%)	37 (51.4%)	74 (53.2%)
Nervous System	TOTAL	18 (26.9%)	22 (30.6%)	40 (28.8%)
	NERVOUSNESS	4 (6.0%)	9 (12.5%)	13 (9.4%)
	HYPERKINESIA	7 (10.4%)	5 (6.9%)	12 (8.6%)
	INSOMNIA	4 (6.0%)	3 (4.2%)	7 (5.0%)
	HOSTILITY	4 (6.0%)	2 (2.8%)	6 (4.3%)
	ANXIETY	1 (1.5%)	4 (5.6%)	5 (3.6%)
	AGITATION	2 (3.0%)	2 (2.8%)	4 (2.9%)
	SOMNOLENCE	1 (1.5%)	3 (4.2%)	4 (2.9%)
	DIZZINESS	1 (1.5%)	1 (1.4%)	2 (1.4%)
	TREMOR	0	2 (2.8%)	2 (1.4%)
	CONCENTRATION IMPAIRED	1 (1.5%)	0	1 (0.7%)
	CONVULSION	1 (1.5%)	0	1 (0.7%)
	MYOCLONUS	1 (1.5%)	0	1 (0.7%)
	DYSKINESIA	0	1 (1.4%)	1 (0.7%)
	HYPESTHESIA	0	1 (1.4%)	1 (0.7%)
	LACK OF EMOTION	0	1 (1.4%)	1 (0.7%)
	MANIC REACTION	0	1 (1.4%)	1 (0.7%)
Body as a Whole	TOTAL	14 (20.9%)	8 (11.1%)	22 (15.8%)
	HEADACHE	10 (14.9%)	5 (6.9%)	15 (10.8%)
	ABDOMINAL PAIN	2 (3.0%)	2 (2.8%)	4 (2.9%)
	FEVER	1 (1.5%)	0	1 (0.7%)
	PAIN	1 (1.5%)	0	1 (0.7%)
	TRAUMA	1 (1.5%)	0	1 (0.7%)
	ASTHENIA	0	1 (1.4%)	1 (0.7%)
Digestive System	TOTAL	12 (17.9%)	6 (8.3%)	18 (12.9%)
	DECREASED APPETITE	3 (4.5%)	3 (4.2%)	6 (4.3%)
	DYSPEPSIA	3 (4.5%)	1 (1.4%)	4 (2.9%)
	NAUSEA	3 (4.5%)	1 (1.4%)	4 (2.9%)
	DIARRHEA	2 (3.0%)	0	2 (1.4%)
	DRY MOUTH	2 (3.0%)	0	2 (1.4%)
	CONSTIPATION	1 (1.5%)	0	1 (0.7%)
	INCREASED APPETITE	1 (1.5%)	0	1 (0.7%)
	VOMITING	0	1 (1.4%)	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	4 (6.0%)	5 (6.9%)	9 (6.5%)
	WEIGHT GAIN	4 (6.0%)	5 (6.9%)	9 (6.5%)
Hemic and Lymphatic System	TOTAL	1 (1.5%)	1 (1.4%)	2 (1.4%)
	LEUKOPENIA	1 (1.5%)	1 (1.4%)	2 (1.4%)

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
Urogenital System	TOTAL	1 (1.5%)	3 (4.2%)	4 (2.9%)
	URINARY INCONTINENCE	1 (1.5%)	3 (4.2%)	4 (2.9%)
Cardiovascular System	TOTAL	0	4 (5.6%)	4 (2.9%)
	VASODILATATION	0	3 (4.2%)	3 (2.2%)
	SYNCOPE	0	1 (1.4%)	1 (0.7%)
Respiratory System	TOTAL	0	2 (2.8%)	2 (1.4%)
	RHINITIS	0	1 (1.4%)	1 (0.7%)
	YAWN	0	1 (1.4%)	1 (0.7%)
Special Senses	TOTAL	0	1 (1.4%)	1 (0.7%)
	ABNORMAL VISION	0	1 (1.4%)	1 (0.7%)

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Body System	Preferred Term			
TOTAL	TOTAL	17 (40.5%)	13 (43.3%)	30 (41.7%)
Nervous System	TOTAL	9 (21.4%)	7 (23.3%)	16 (22.2%)
	SOMNOLENCE	4 (9.5%)	2 (6.7%)	6 (8.3%)
	NERVOUSNESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
	EMOTIONAL LABILITY	2 (4.8%)	2 (6.7%)	4 (5.6%)
	INSOMNIA	2 (4.8%)	2 (6.7%)	4 (5.6%)
	AGITATION	1 (2.4%)	1 (3.3%)	2 (2.8%)
	ANXIETY	1 (2.4%)	0	1 (1.4%)
	CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.4%)
	DIZZINESS	0	1 (3.3%)	1 (1.4%)
	HOSTILITY	0	1 (3.3%)	1 (1.4%)
	LIBIDO DECREASED	0	1 (3.3%)	1 (1.4%)
	TREMOR	0	1 (3.3%)	1 (1.4%)
	WITHDRAWAL SYNDROME	0	1 (3.3%)	1 (1.4%)
Digestive System	TOTAL	6 (14.3%)	4 (13.3%)	10 (13.9%)
	NAUSEA	5 (11.9%)	0	5 (6.9%)
	DECREASED APPETITE	1 (2.4%)	2 (6.7%)	3 (4.2%)
	VOMITING	2 (4.8%)	0	2 (2.8%)
	DIARRHEA	0	1 (3.3%)	1 (1.4%)
	INCREASED APPETITE	0	1 (3.3%)	1 (1.4%)
Body as a Whole	TOTAL	5 (11.9%)	5 (16.7%)	10 (13.9%)
	HEADACHE	3 (7.1%)	3 (10.0%)	6 (8.3%)
	ASTHENIA	1 (2.4%)	2 (6.7%)	3 (4.2%)
	ABDOMINAL PAIN	1 (2.4%)	1 (3.3%)	2 (2.8%)
	CHEST PAIN	1 (2.4%)	0	1 (1.4%)
	MALAISE	1 (2.4%)	0	1 (1.4%)
Hemic and Lymphatic System	TOTAL	1 (2.4%)	0	1 (1.4%)
	LEUKOPENIA	1 (2.4%)	0	1 (1.4%)
Metabolic and Nutritional Disorders	TOTAL	1 (2.4%)	3 (10.0%)	4 (5.6%)
	WEIGHT GAIN	1 (2.4%)	3 (10.0%)	4 (5.6%)
Skin and Appendages	TOTAL	0	1 (3.3%)	1 (1.4%)
	ACNE	0	1 (3.3%)	1 (1.4%)

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (6.7%)	1 (3.4%)
Urogenital System	TOTAL	0	1 (6.7%)	1 (3.4%)
	FEMALE GENITAL DISORDERS	0	1 (6.7%)	1 (3.4%)

Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	12 (50.0%)	14 (50.0%)	26 (50.0%)
Body as a Whole	TOTAL	7 (29.2%)	8 (28.6%)	15 (28.8%)
	HEADACHE	5 (20.8%)	5 (17.9%)	10 (19.2%)
	ASTHENIA	2 (8.3%)	2 (7.1%)	4 (7.7%)
	ABDOMINAL PAIN	1 (4.2%)	2 (7.1%)	3 (5.8%)
Nervous System	TOTAL	6 (25.0%)	8 (28.6%)	14 (26.9%)
	NEUROSIS	3 (12.5%)	1 (3.6%)	4 (7.7%)
	INSOMNIA	1 (4.2%)	3 (10.7%)	4 (7.7%)
	DIZZINESS	2 (8.3%)	1 (3.6%)	3 (5.8%)
	HOSTILITY	1 (4.2%)	2 (7.1%)	3 (5.8%)
	HYPERKINESIA	1 (4.2%)	2 (7.1%)	3 (5.8%)
	ABNORMAL DREAMS	1 (4.2%)	1 (3.6%)	2 (3.8%)
	AGITATION	0	2 (7.1%)	2 (3.8%)
	NERVOUSNESS	0	2 (7.1%)	2 (3.8%)
	CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.9%)
	EMOTIONAL LABILITY	1 (4.2%)	0	1 (1.9%)
	MANIC REACTION	1 (4.2%)	0	1 (1.9%)
	SOMNOLENCE	0	1 (3.6%)	1 (1.9%)
	TREMOR	0	1 (3.6%)	1 (1.9%)
Digestive System	TOTAL	2 (8.3%)	9 (32.1%)	11 (21.2%)
	NAUSEA	1 (4.2%)	4 (14.3%)	5 (9.6%)
	CONSTIPATION	1 (4.2%)	1 (3.6%)	2 (3.8%)
	DECREASED APPETITE	0	2 (7.1%)	2 (3.8%)
	DRY MOUTH	0	2 (7.1%)	2 (3.8%)
	DYSPEPSIA	0	2 (7.1%)	2 (3.8%)
	FLATULENCE	0	1 (3.6%)	1 (1.9%)
Metabolic and Nutritional Disorders	TOTAL	2 (8.3%)	1 (3.6%)	3 (5.8%)
	WEIGHT GAIN	2 (8.3%)	0	2 (3.8%)
	WEIGHT LOSS	0	1 (3.6%)	1 (1.9%)
Respiratory System	TOTAL	1 (4.2%)	2 (7.1%)	3 (5.8%)
	RESPIRATORY DISORDER	1 (4.2%)	2 (7.1%)	3 (5.8%)
Skin and Appendages	TOTAL	1 (4.2%)	1 (3.6%)	2 (3.8%)
	ACNE	1 (4.2%)	0	1 (1.9%)
	SWEATING	0	1 (3.6%)	1 (1.9%)
Cardiovascular System	TOTAL	0	1 (3.6%)	1 (1.9%)
	VASODILATATION	0	1 (3.6%)	1 (1.9%)

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
Special Senses	TOTAL	0	1 (3.6%)	1 (1.9%)
	PHOTOPHOBIA	0	1 (3.6%)	1 (1.9%)

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
TOTAL	TOTAL	29 (43.9%)	27 (46.6%)	56 (45.2%)
Nervous System	TOTAL	15 (22.7%)	15 (25.9%)	30 (24.2%)
	INSOMNIA	3 (4.5%)	5 (8.6%)	8 (6.5%)
	SOMNOLENCE	4 (6.1%)	3 (5.2%)	7 (5.6%)
	NERVOUSNESS	3 (4.5%)	3 (5.2%)	6 (4.8%)
	EMOTIONAL LABILITY	3 (4.5%)	2 (3.4%)	5 (4.0%)
	NEUROSIS	3 (4.5%)	1 (1.7%)	4 (3.2%)
	DIZZINESS	2 (3.0%)	2 (3.4%)	4 (3.2%)
	AGITATION	1 (1.5%)	3 (5.2%)	4 (3.2%)
	HOSTILITY	1 (1.5%)	3 (5.2%)	4 (3.2%)
	HYPERKINESIA	1 (1.5%)	2 (3.4%)	3 (2.4%)
	ABNORMAL DREAMS	1 (1.5%)	1 (1.7%)	2 (1.6%)
	CONCENTRATION IMPAIRED	1 (1.5%)	1 (1.7%)	2 (1.6%)
	TREMOR	0	2 (3.4%)	2 (1.6%)
	ANXIETY	1 (1.5%)	0	1 (0.8%)
	MANIC REACTION	1 (1.5%)	0	1 (0.8%)
	LIBIDO DECREASED	0	1 (1.7%)	1 (0.8%)
	WITHDRAWAL SYNDROME	0	1 (1.7%)	1 (0.8%)
Body as a Whole	TOTAL	12 (18.2%)	13 (22.4%)	25 (20.2%)
	HEADACHE	8 (12.1%)	8 (13.8%)	16 (12.9%)
	ASTHENIA	3 (4.5%)	4 (6.9%)	7 (5.6%)
	ABDOMINAL PAIN	2 (3.0%)	3 (5.2%)	5 (4.0%)
	CHEST PAIN	1 (1.5%)	0	1 (0.8%)
	MALAISE	1 (1.5%)	0	1 (0.8%)
Digestive System	TOTAL	8 (12.1%)	13 (22.4%)	21 (16.9%)
	NAUSEA	6 (9.1%)	4 (6.9%)	10 (8.1%)
	DECREASED APPETITE	1 (1.5%)	4 (6.9%)	5 (4.0%)
	VOMITING	2 (3.0%)	0	2 (1.6%)
	CONSTIPATION	1 (1.5%)	1 (1.7%)	2 (1.6%)
	DRY MOUTH	0	2 (3.4%)	2 (1.6%)
	DYSPEPSIA	0	2 (3.4%)	2 (1.6%)
	DIARRHEA	0	1 (1.7%)	1 (0.8%)
	FLATULENCE	0	1 (1.7%)	1 (0.8%)
	INCREASED APPETITE	0	1 (1.7%)	1 (0.8%)
Metabolic and Nutritional Disorders	TOTAL	3 (4.5%)	4 (6.9%)	7 (5.6%)
	WEIGHT GAIN	3 (4.5%)	3 (5.2%)	6 (4.8%)
	WEIGHT LOSS	0	1 (1.7%)	1 (0.8%)
Hemic and Lymphatic System	TOTAL	1 (1.5%)	0	1 (0.8%)

Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
Hemic and Lymphatic System	LEUKOPENIA	1 (1.5%)	0	1 (0.8%)
Respiratory System	TOTAL	1 (1.5%)	2 (3.4%)	3 (2.4%)
	RESPIRATORY DISORDER	1 (1.5%)	2 (3.4%)	3 (2.4%)
Skin and Appendages	TOTAL	1 (1.5%)	2 (3.4%)	3 (2.4%)
	ACNE	1 (1.5%)	1 (1.7%)	2 (1.6%)
	SWEATING	0	1 (1.7%)	1 (0.8%)
Cardiovascular System	TOTAL	0	1 (1.7%)	1 (0.8%)
	VASODILATATION	0	1 (1.7%)	1 (0.8%)
Special Senses	TOTAL	0	1 (1.7%)	1 (0.8%)
	PHOTOPHOBIA	0	1 (1.7%)	1 (0.8%)

Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (4.2%)	1 (2.0%)
Urogenital System	TOTAL	0	1 (4.2%)	1 (2.0%)
	FEMALE GENITAL DISORDERS	0	1 (4.2%)	1 (2.0%)

Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	37 (45.7%)	27 (40.9%)	64 (43.5%)
Nervous System	TOTAL	19 (23.5%)	12 (18.2%)	31 (21.1%)
	NERVOUSNESS	6 (7.4%)	1 (1.5%)	7 (4.8%)
	SOMNOLENCE	4 (4.9%)	3 (4.5%)	7 (4.8%)
	INSOMNIA	3 (3.7%)	3 (4.5%)	6 (4.1%)
	HOSTILITY	3 (3.7%)	1 (1.5%)	4 (2.7%)
	AGITATION	2 (2.5%)	2 (3.0%)	4 (2.7%)
	EMOTIONAL LABILITY	2 (2.5%)	2 (3.0%)	4 (2.7%)
	HYPERKINESIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
	ANXIETY	1 (1.2%)	1 (1.5%)	2 (1.4%)
	DIZZINESS	0	2 (3.0%)	2 (1.4%)
	TREMOR	0	2 (3.0%)	2 (1.4%)
	CONVULSION	1 (1.2%)	0	1 (0.7%)
	CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.7%)
	HYPESTHESIA	0	1 (1.5%)	1 (0.7%)
	LIBIDO DECREASED	0	1 (1.5%)	1 (0.7%)
	WITHDRAWAL SYNDROME	0	1 (1.5%)	1 (0.7%)
Digestive System	TOTAL	11 (13.6%)	8 (12.1%)	19 (12.9%)
	NAUSEA	5 (6.2%)	1 (1.5%)	6 (4.1%)
	DECREASED APPETITE	2 (2.5%)	3 (4.5%)	5 (3.4%)
	VOMITING	2 (2.5%)	1 (1.5%)	3 (2.0%)
	DRY MOUTH	2 (2.5%)	0	2 (1.4%)
	DYSPEPSIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	INCREASED APPETITE	1 (1.2%)	1 (1.5%)	2 (1.4%)
	CONSTIPATION	1 (1.2%)	0	1 (0.7%)
	DIARRHEA	0	1 (1.5%)	1 (0.7%)
Body as a Whole	TOTAL	9 (11.1%)	7 (10.6%)	16 (10.9%)
	HEADACHE	5 (6.2%)	3 (4.5%)	8 (5.4%)
	ABDOMINAL PAIN	3 (3.7%)	2 (3.0%)	5 (3.4%)
	ASTHENIA	1 (1.2%)	3 (4.5%)	4 (2.7%)
	CHEST PAIN	1 (1.2%)	0	1 (0.7%)
	MALAISE	1 (1.2%)	0	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	5 (6.2%)	5 (7.6%)	10 (6.8%)
	WEIGHT GAIN	5 (6.2%)	5 (7.6%)	10 (6.8%)
Hemic and Lymphatic System	TOTAL	2 (2.5%)	1 (1.5%)	3 (2.0%)
	LEUKOPENIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
Urogenital System	TOTAL	1 (1.2%)	2 (3.0%)	3 (2.0%)

Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
Urogenital System	URINARY INCONTINENCE	1 (1.2%)	2 (3.0%)	3 (2.0%)
Cardiovascular System	TOTAL	0	1 (1.5%)	1 (0.7%)
	SYNCOPE	0	1 (1.5%)	1 (0.7%)
Respiratory System	TOTAL	0	1 (1.5%)	1 (0.7%)
	YAWN	0	1 (1.5%)	1 (0.7%)
Skin and Appendages	TOTAL	0	1 (1.5%)	1 (0.7%)
	ACNE	0	1 (1.5%)	1 (0.7%)
Special Senses	TOTAL	0	1 (1.5%)	1 (0.7%)
	ABNORMAL VISION	0	1 (1.5%)	1 (0.7%)

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (3.4%)	1 (1.6%)
Urogenital System	TOTAL	0	1 (3.4%)	1 (1.6%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.6%)

Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	29 (55.8%)	37 (57.8%)	66 (56.9%)
Body as a Whole	TOTAL	17 (32.7%)	14 (21.9%)	31 (26.7%)
	HEADACHE	13 (25.0%)	10 (15.6%)	23 (19.8%)
	ASTHENIA	2 (3.8%)	2 (3.1%)	4 (3.4%)
	ABDOMINAL PAIN	1 (1.9%)	3 (4.7%)	4 (3.4%)
	FEVER	1 (1.9%)	0	1 (0.9%)
	PAIN	1 (1.9%)	0	1 (0.9%)
	TRAUMA	1 (1.9%)	0	1 (0.9%)
Nervous System	TOTAL	14 (26.9%)	25 (39.1%)	39 (33.6%)
	HYPERKINESIA	6 (11.5%)	6 (9.4%)	12 (10.3%)
	NERVOUSNESS	1 (1.9%)	11 (17.2%)	12 (10.3%)
	INSOMNIA	4 (7.7%)	5 (7.8%)	9 (7.8%)
	HOSTILITY	2 (3.8%)	4 (6.3%)	6 (5.2%)
	DIZZINESS	3 (5.8%)	1 (1.6%)	4 (3.4%)
	NEUROSIS	3 (5.8%)	1 (1.6%)	4 (3.4%)
	AGITATION	1 (1.9%)	3 (4.7%)	4 (3.4%)
	ANXIETY	1 (1.9%)	3 (4.7%)	4 (3.4%)
	SOMNOLENCE	1 (1.9%)	3 (4.7%)	4 (3.4%)
	CONCENTRATION IMPAIRED	2 (3.8%)	0	2 (1.7%)
	ABNORMAL DREAMS	1 (1.9%)	1 (1.6%)	2 (1.7%)
	MANIC REACTION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	TREMOR	0	2 (3.1%)	2 (1.7%)
	EMOTIONAL LABILITY	1 (1.9%)	0	1 (0.9%)
	MYOCLONUS	1 (1.9%)	0	1 (0.9%)
	DYSKINESIA	0	1 (1.6%)	1 (0.9%)
	LACK OF EMOTION	0	1 (1.6%)	1 (0.9%)
Digestive System	TOTAL	9 (17.3%)	11 (17.2%)	20 (17.2%)
	NAUSEA	4 (7.7%)	4 (6.3%)	8 (6.9%)
	DECREASED APPETITE	2 (3.8%)	4 (6.3%)	6 (5.2%)
	DYSPEPSIA	2 (3.8%)	2 (3.1%)	4 (3.4%)
	DIARRHEA	2 (3.8%)	0	2 (1.7%)
	CONSTIPATION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	DRY MOUTH	0	2 (3.1%)	2 (1.7%)
	FLATULENCE	0	1 (1.6%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	2 (3.8%)	4 (6.3%)	6 (5.2%)
	WEIGHT GAIN	2 (3.8%)	3 (4.7%)	5 (4.3%)
	WEIGHT LOSS	0	1 (1.6%)	1 (0.9%)
Respiratory System	TOTAL	1 (1.9%)	3 (4.7%)	4 (3.4%)

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
Respiratory System	RESPIRATORY DISORDER	1 (1.9%)	2 (3.1%)	3 (2.6%)
	RHINITIS	0	1 (1.6%)	1 (0.9%)
Skin and Appendages	TOTAL	1 (1.9%)	1 (1.6%)	2 (1.7%)
	ACNE	1 (1.9%)	0	1 (0.9%)
	SWEATING	0	1 (1.6%)	1 (0.9%)
Cardiovascular System	TOTAL	0	4 (6.3%)	4 (3.4%)
	VASODILATATION	0	4 (6.3%)	4 (3.4%)
Special Senses	TOTAL	0	1 (1.6%)	1 (0.9%)
	PHOTOPHOBIA	0	1 (1.6%)	1 (0.9%)
Urogenital System	TOTAL	0	1 (1.6%)	1 (0.9%)
	URINARY INCONTINENCE	0	1 (1.6%)	1 (0.9%)

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
TOTAL	TOTAL	66 (49.6%)	64 (49.2%)	130 (49.4%)
Nervous System	TOTAL	33 (24.8%)	37 (28.5%)	70 (26.6%)
	NERVOUSNESS	7 (5.3%)	12 (9.2%)	19 (7.2%)
	HYPERKINESIA	8 (6.0%)	7 (5.4%)	15 (5.7%)
	INSOMNIA	7 (5.3%)	8 (6.2%)	15 (5.7%)
	SOMNOLENCE	5 (3.8%)	6 (4.6%)	11 (4.2%)
	HOSTILITY	5 (3.8%)	5 (3.8%)	10 (3.8%)
	AGITATION	3 (2.3%)	5 (3.8%)	8 (3.0%)
	DIZZINESS	3 (2.3%)	3 (2.3%)	6 (2.3%)
	ANXIETY	2 (1.5%)	4 (3.1%)	6 (2.3%)
	EMOTIONAL LABILITY	3 (2.3%)	2 (1.5%)	5 (1.9%)
	NEUROSIS	3 (2.3%)	1 (0.8%)	4 (1.5%)
	TREMOR	0	4 (3.1%)	4 (1.5%)
	CONCENTRATION IMPAIRED	2 (1.5%)	1 (0.8%)	3 (1.1%)
	ABNORMAL DREAMS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	MANIC REACTION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	CONVULSION	1 (0.8%)	0	1 (0.4%)
	MYOCLONUS	1 (0.8%)	0	1 (0.4%)
	DYSKINESIA	0	1 (0.8%)	1 (0.4%)
	HYPESTHESIA	0	1 (0.8%)	1 (0.4%)
	LACK OF EMOTION	0	1 (0.8%)	1 (0.4%)
	LIBIDO DECREASED	0	1 (0.8%)	1 (0.4%)
	WITHDRAWAL SYNDROME	0	1 (0.8%)	1 (0.4%)
Body as a Whole	TOTAL	26 (19.5%)	21 (16.2%)	47 (17.9%)
	HEADACHE	18 (13.5%)	13 (10.0%)	31 (11.8%)
	ABDOMINAL PAIN	4 (3.0%)	5 (3.8%)	9 (3.4%)
	ASTHENIA	3 (2.3%)	5 (3.8%)	8 (3.0%)
	CHEST PAIN	1 (0.8%)	0	1 (0.4%)
	FEVER	1 (0.8%)	0	1 (0.4%)
	MALAISE	1 (0.8%)	0	1 (0.4%)
	PAIN	1 (0.8%)	0	1 (0.4%)
	TRAUMA	1 (0.8%)	0	1 (0.4%)
Digestive System	TOTAL	20 (15.0%)	19 (14.6%)	39 (14.8%)
	NAUSEA	9 (6.8%)	5 (3.8%)	14 (5.3%)
	DECREASED APPETITE	4 (3.0%)	7 (5.4%)	11 (4.2%)
	DYSPEPSIA	3 (2.3%)	3 (2.3%)	6 (2.3%)
	DRY MOUTH	2 (1.5%)	2 (1.5%)	4 (1.5%)
	CONSTIPATION	2 (1.5%)	1 (0.8%)	3 (1.1%)
	DIARRHEA	2 (1.5%)	1 (0.8%)	3 (1.1%)
	VOMITING	2 (1.5%)	1 (0.8%)	3 (1.1%)
	INCREASED APPETITE	1 (0.8%)	1 (0.8%)	2 (0.8%)

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Digestive System	FLATULENCE	0	1 (0.8%)	1 (0.4%)
Metabolic and Nutritional Disorders	TOTAL	7 (5.3%)	9 (6.9%)	16 (6.1%)
	WEIGHT GAIN	7 (5.3%)	8 (6.2%)	15 (5.7%)
	WEIGHT LOSS	0	1 (0.8%)	1 (0.4%)
Hemic and Lymphatic System	TOTAL	2 (1.5%)	1 (0.8%)	3 (1.1%)
	LEUKOPENIA	2 (1.5%)	1 (0.8%)	3 (1.1%)
Respiratory System	TOTAL	1 (0.8%)	4 (3.1%)	5 (1.9%)
	RESPIRATORY DISORDER	1 (0.8%)	2 (1.5%)	3 (1.1%)
	RHINITIS	0	1 (0.8%)	1 (0.4%)
	YAWN	0	1 (0.8%)	1 (0.4%)
Skin and Appendages	TOTAL	1 (0.8%)	2 (1.5%)	3 (1.1%)
	ACNE	1 (0.8%)	1 (0.8%)	2 (0.8%)
	SWEATING	0	1 (0.8%)	1 (0.4%)
Urogenital System	TOTAL	1 (0.8%)	3 (2.3%)	4 (1.5%)
	URINARY INCONTINENCE	1 (0.8%)	3 (2.3%)	4 (1.5%)
Cardiovascular System	TOTAL	0	5 (3.8%)	5 (1.9%)
	VASODILATATION	0	4 (3.1%)	4 (1.5%)
	SYNCOPE	0	1 (0.8%)	1 (0.4%)
Special Senses	TOTAL	0	2 (1.5%)	2 (0.8%)
	ABNORMAL VISION	0	1 (0.8%)	1 (0.4%)
	PHOTOPHOBIA	0	1 (0.8%)	1 (0.4%)

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.1

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (2.0%)	1 (0.9%)
Urogenital System	TOTAL	0	1 (2.0%)	1 (0.9%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (0.9%)

Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
TOTAL	20 (51.3%)	12 (33.3%)	32 (42.7%)
WEIGHT GAIN	4 (10.3%)	2 (5.6%)	6 (8.0%)
HOSTILITY	3 (7.7%)	0	3 (4.0%)
NERVOUSNESS	3 (7.7%)	0	3 (4.0%)
ABDOMINAL PAIN	2 (5.1%)	1 (2.8%)	3 (4.0%)
HYPERKINESIA	2 (5.1%)	1 (2.8%)	3 (4.0%)
URINARY INCONTINENCE	1 (2.6%)	2 (5.6%)	3 (4.0%)
DRY MOUTH	2 (5.1%)	0	2 (2.7%)
HEADACHE	2 (5.1%)	0	2 (2.7%)
AGITATION	1 (2.6%)	1 (2.8%)	2 (2.7%)
DECREASED APPETITE	1 (2.6%)	1 (2.8%)	2 (2.7%)
DYSPEPSIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
INSOMNIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
LEUKOPENIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
CONSTIPATION	1 (2.6%)	0	1 (1.3%)
ANXIETY	0	1 (2.8%)	1 (1.3%)
ASTHENIA	0	1 (2.8%)	1 (1.3%)
DIZZINESS	0	1 (2.8%)	1 (1.3%)
NAUSEA	0	1 (2.8%)	1 (1.3%)
SOMNOLENCE	0	1 (2.8%)	1 (1.3%)
TREMOR	0	1 (2.8%)	1 (1.3%)
VOMITING	0	1 (2.8%)	1 (1.3%)

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=28)	 Placebo (N=36)	 Total (N=64)
TOTAL	17 (60.7%)	23 (63.9%)	40 (62.5%)
HEADACHE	8 (28.6%)	5 (13.9%)	13 (20.3%)
NERVOUSNESS	1 (3.6%)	9 (25.0%)	10 (15.6%)
HYPERKINESIA	5 (17.9%)	4 (11.1%)	9 (14.1%)
INSOMNIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
DECREASED APPETITE	2 (7.1%)	2 (5.6%)	4 (6.3%)
ANXIETY	1 (3.6%)	3 (8.3%)	4 (6.3%)
NAUSEA	3 (10.7%)	0	3 (4.7%)
HOSTILITY	1 (3.6%)	2 (5.6%)	3 (4.7%)
SOMNOLENCE	1 (3.6%)	2 (5.6%)	3 (4.7%)
VASODILATATION	0	3 (8.3%)	3 (4.7%)
WEIGHT GAIN	0	3 (8.3%)	3 (4.7%)
DIARRHEA	2 (7.1%)	0	2 (3.1%)
DYSPEPSIA	2 (7.1%)	0	2 (3.1%)
AGITATION	1 (3.6%)	1 (2.8%)	2 (3.1%)
CONCENTRATION IMPAIRED	1 (3.6%)	0	1 (1.6%)
DIZZINESS	1 (3.6%)	0	1 (1.6%)
ABDOMINAL PAIN	0	1 (2.8%)	1 (1.6%)
TREMOR	0	1 (2.8%)	1 (1.6%)
URINARY INCONTINENCE	0	1 (2.8%)	1 (1.6%)

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=67)	 Placebo (N=72)	 Total (N=139)
TOTAL	37 (55.2%)	35 (48.6%)	72 (51.8%)
HEADACHE	10 (14.9%)	5 (6.9%)	15 (10.8%)
NERVOUSNESS	4 (6.0%)	9 (12.5%)	13 (9.4%)
HYPERKINESIA	7 (10.4%)	5 (6.9%)	12 (8.6%)
WEIGHT GAIN	4 (6.0%)	5 (6.9%)	9 (6.5%)
INSOMNIA	4 (6.0%)	3 (4.2%)	7 (5.0%)
HOSTILITY	4 (6.0%)	2 (2.8%)	6 (4.3%)
DECREASED APPETITE	3 (4.5%)	3 (4.2%)	6 (4.3%)
ANXIETY	1 (1.5%)	4 (5.6%)	5 (3.6%)
DYSPEPSIA	3 (4.5%)	1 (1.4%)	4 (2.9%)
NAUSEA	3 (4.5%)	1 (1.4%)	4 (2.9%)
ABDOMINAL PAIN	2 (3.0%)	2 (2.8%)	4 (2.9%)
AGITATION	2 (3.0%)	2 (2.8%)	4 (2.9%)
SOMNOLENCE	1 (1.5%)	3 (4.2%)	4 (2.9%)
URINARY INCONTINENCE	1 (1.5%)	3 (4.2%)	4 (2.9%)
VASODILATATION	0	3 (4.2%)	3 (2.2%)
DIARRHEA	2 (3.0%)	0	2 (1.4%)
DRY MOUTH	2 (3.0%)	0	2 (1.4%)
DIZZINESS	1 (1.5%)	1 (1.4%)	2 (1.4%)
LEUKOPENIA	1 (1.5%)	1 (1.4%)	2 (1.4%)
TREMOR	0	2 (2.8%)	2 (1.4%)
CONCENTRATION IMPAIRED	1 (1.5%)	0	1 (0.7%)
CONSTIPATION	1 (1.5%)	0	1 (0.7%)
ASTHENIA	0	1 (1.4%)	1 (0.7%)
VOMITING	0	1 (1.4%)	1 (0.7%)

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
TOTAL	17 (40.5%)	12 (40.0%)	29 (40.3%)
SOMNOLENCE	4 (9.5%)	2 (6.7%)	6 (8.3%)
HEADACHE	3 (7.1%)	3 (10.0%)	6 (8.3%)
NAUSEA	5 (11.9%)	0	5 (6.9%)
NERVOUSNESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
EMOTIONAL LABILITY	2 (4.8%)	2 (6.7%)	4 (5.6%)
INSOMNIA	2 (4.8%)	2 (6.7%)	4 (5.6%)
WEIGHT GAIN	1 (2.4%)	3 (10.0%)	4 (5.6%)
ASTHENIA	1 (2.4%)	2 (6.7%)	3 (4.2%)
DECREASED APPETITE	1 (2.4%)	2 (6.7%)	3 (4.2%)
VOMITING	2 (4.8%)	0	2 (2.8%)
ABDOMINAL PAIN	1 (2.4%)	1 (3.3%)	2 (2.8%)
AGITATION	1 (2.4%)	1 (3.3%)	2 (2.8%)
ANXIETY	1 (2.4%)	0	1 (1.4%)
LEUKOPENIA	1 (2.4%)	0	1 (1.4%)
CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.4%)
DIARRHEA	0	1 (3.3%)	1 (1.4%)
DIZZINESS	0	1 (3.3%)	1 (1.4%)
HOSTILITY	0	1 (3.3%)	1 (1.4%)
TREMOR	0	1 (3.3%)	1 (1.4%)

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Preferred Term			
TOTAL	12 (50.0%)	14 (50.0%)	26 (50.0%)
HEADACHE	5 (20.8%)	5 (17.9%)	10 (19.2%)
NAUSEA	1 (4.2%)	4 (14.3%)	5 (9.6%)
NEUROSIS	3 (12.5%)	1 (3.6%)	4 (7.7%)
ASTHENIA	2 (8.3%)	2 (7.1%)	4 (7.7%)
INSOMNIA	1 (4.2%)	3 (10.7%)	4 (7.7%)
DIZZINESS	2 (8.3%)	1 (3.6%)	3 (5.8%)
ABDOMINAL PAIN	1 (4.2%)	2 (7.1%)	3 (5.8%)
HOSTILITY	1 (4.2%)	2 (7.1%)	3 (5.8%)
HYPERKINESIA	1 (4.2%)	2 (7.1%)	3 (5.8%)
RESPIRATORY DISORDER	1 (4.2%)	2 (7.1%)	3 (5.8%)
WEIGHT GAIN	2 (8.3%)	0	2 (3.8%)
CONSTIPATION	1 (4.2%)	1 (3.6%)	2 (3.8%)
AGITATION	0	2 (7.1%)	2 (3.8%)
DECREASED APPETITE	0	2 (7.1%)	2 (3.8%)
DRY MOUTH	0	2 (7.1%)	2 (3.8%)
DYSPEPSIA	0	2 (7.1%)	2 (3.8%)
NERVOUSNESS	0	2 (7.1%)	2 (3.8%)
CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.9%)
EMOTIONAL LABILITY	1 (4.2%)	0	1 (1.9%)
SOMNOLENCE	0	1 (3.6%)	1 (1.9%)
TREMOR	0	1 (3.6%)	1 (1.9%)
VASODILATATION	0	1 (3.6%)	1 (1.9%)

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=66)	 Placebo (N=58)	 Total (N=124)
TOTAL	29 (43.9%)	26 (44.8%)	55 (44.4%)
HEADACHE	8 (12.1%)	8 (13.8%)	16 (12.9%)
NAUSEA	6 (9.1%)	4 (6.9%)	10 (8.1%)
INSOMNIA	3 (4.5%)	5 (8.6%)	8 (6.5%)
SOMNOLENCE	4 (6.1%)	3 (5.2%)	7 (5.6%)
ASTHENIA	3 (4.5%)	4 (6.9%)	7 (5.6%)
NERVOUSNESS	3 (4.5%)	3 (5.2%)	6 (4.8%)
WEIGHT GAIN	3 (4.5%)	3 (5.2%)	6 (4.8%)
EMOTIONAL LABILITY	3 (4.5%)	2 (3.4%)	5 (4.0%)
ABDOMINAL PAIN	2 (3.0%)	3 (5.2%)	5 (4.0%)
DECREASED APPETITE	1 (1.5%)	4 (6.9%)	5 (4.0%)
NEUROSIS	3 (4.5%)	1 (1.7%)	4 (3.2%)
DIZZINESS	2 (3.0%)	2 (3.4%)	4 (3.2%)
AGITATION	1 (1.5%)	3 (5.2%)	4 (3.2%)
HOSTILITY	1 (1.5%)	3 (5.2%)	4 (3.2%)
HYPERKINESIA	1 (1.5%)	2 (3.4%)	3 (2.4%)
RESPIRATORY DISORDER	1 (1.5%)	2 (3.4%)	3 (2.4%)
VOMITING	2 (3.0%)	0	2 (1.6%)
CONCENTRATION IMPAIRED	1 (1.5%)	1 (1.7%)	2 (1.6%)
CONSTIPATION	1 (1.5%)	1 (1.7%)	2 (1.6%)
DRY MOUTH	0	2 (3.4%)	2 (1.6%)
DYSPEPSIA	0	2 (3.4%)	2 (1.6%)
TREMOR	0	2 (3.4%)	2 (1.6%)
ANXIETY	1 (1.5%)	0	1 (0.8%)
LEUKOPENIA	1 (1.5%)	0	1 (0.8%)
DIARRHEA	0	1 (1.7%)	1 (0.8%)
VASODILATATION	0	1 (1.7%)	1 (0.8%)

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=81)	 Placebo (N=66)	 Total (N=147)
TOTAL	37 (45.7%)	24 (36.4%)	61 (41.5%)
WEIGHT GAIN	5 (6.2%)	5 (7.6%)	10 (6.8%)
HEADACHE	5 (6.2%)	3 (4.5%)	8 (5.4%)
NERVOUSNESS	6 (7.4%)	1 (1.5%)	7 (4.8%)
SOMNOLENCE	4 (4.9%)	3 (4.5%)	7 (4.8%)
NAUSEA	5 (6.2%)	1 (1.5%)	6 (4.1%)
INSOMNIA	3 (3.7%)	3 (4.5%)	6 (4.1%)
ABDOMINAL PAIN	3 (3.7%)	2 (3.0%)	5 (3.4%)
DECREASED APPETITE	2 (2.5%)	3 (4.5%)	5 (3.4%)
HOSTILITY	3 (3.7%)	1 (1.5%)	4 (2.7%)
AGITATION	2 (2.5%)	2 (3.0%)	4 (2.7%)
EMOTIONAL LABILITY	2 (2.5%)	2 (3.0%)	4 (2.7%)
ASTHENIA	1 (1.2%)	3 (4.5%)	4 (2.7%)
HYPERKINESIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
LEUKOPENIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
VOMITING	2 (2.5%)	1 (1.5%)	3 (2.0%)
URINARY INCONTINENCE	1 (1.2%)	2 (3.0%)	3 (2.0%)
DRY MOUTH	2 (2.5%)	0	2 (1.4%)
ANXIETY	1 (1.2%)	1 (1.5%)	2 (1.4%)
DYSPEPSIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
DIZZINESS	0	2 (3.0%)	2 (1.4%)
TREMOR	0	2 (3.0%)	2 (1.4%)
CONSTIPATION	1 (1.2%)	0	1 (0.7%)
CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.7%)
DIARRHEA	0	1 (1.5%)	1 (0.7%)

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=52)	 Placebo (N=64)	 Total (N=116)
TOTAL	29 (55.8%)	37 (57.8%)	66 (56.9%)
HEADACHE	13 (25.0%)	10 (15.6%)	23 (19.8%)
HYPERKINESIA	6 (11.5%)	6 (9.4%)	12 (10.3%)
NERVOUSNESS	1 (1.9%)	11 (17.2%)	12 (10.3%)
INSOMNIA	4 (7.7%)	5 (7.8%)	9 (7.8%)
NAUSEA	4 (7.7%)	4 (6.3%)	8 (6.9%)
DECREASED APPETITE	2 (3.8%)	4 (6.3%)	6 (5.2%)
HOSTILITY	2 (3.8%)	4 (6.3%)	6 (5.2%)
WEIGHT GAIN	2 (3.8%)	3 (4.7%)	5 (4.3%)
DIZZINESS	3 (5.8%)	1 (1.6%)	4 (3.4%)
NEUROSIS	3 (5.8%)	1 (1.6%)	4 (3.4%)
ASTHENIA	2 (3.8%)	2 (3.1%)	4 (3.4%)
DYSPEPSIA	2 (3.8%)	2 (3.1%)	4 (3.4%)
ABDOMINAL PAIN	1 (1.9%)	3 (4.7%)	4 (3.4%)
AGITATION	1 (1.9%)	3 (4.7%)	4 (3.4%)
ANXIETY	1 (1.9%)	3 (4.7%)	4 (3.4%)
SOMNOLENCE	1 (1.9%)	3 (4.7%)	4 (3.4%)
VASODILATATION	0	4 (6.3%)	4 (3.4%)
RESPIRATORY DISORDER	1 (1.9%)	2 (3.1%)	3 (2.6%)
CONCENTRATION IMPAIRED	2 (3.8%)	0	2 (1.7%)
DIARRHEA	2 (3.8%)	0	2 (1.7%)
CONSTIPATION	1 (1.9%)	1 (1.6%)	2 (1.7%)
DRY MOUTH	0	2 (3.1%)	2 (1.7%)
TREMOR	0	2 (3.1%)	2 (1.7%)
EMOTIONAL LABILITY	1 (1.9%)	0	1 (0.9%)
URINARY INCONTINENCE	0	1 (1.6%)	1 (0.9%)

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=133)	 Placebo (N=130)	 Total (N=263)
TOTAL	66 (49.6%)	61 (46.9%)	127 (48.3%)
HEADACHE	18 (13.5%)	13 (10.0%)	31 (11.8%)
NERVOUSNESS	7 (5.3%)	12 (9.2%)	19 (7.2%)
HYPERKINESIA	8 (6.0%)	7 (5.4%)	15 (5.7%)
INSOMNIA	7 (5.3%)	8 (6.2%)	15 (5.7%)
WEIGHT GAIN	7 (5.3%)	8 (6.2%)	15 (5.7%)
NAUSEA	9 (6.8%)	5 (3.8%)	14 (5.3%)
SOMNOLENCE	5 (3.8%)	6 (4.6%)	11 (4.2%)
DECREASED APPETITE	4 (3.0%)	7 (5.4%)	11 (4.2%)
HOSTILITY	5 (3.8%)	5 (3.8%)	10 (3.8%)
ABDOMINAL PAIN	4 (3.0%)	5 (3.8%)	9 (3.4%)
AGITATION	3 (2.3%)	5 (3.8%)	8 (3.0%)
ASTHENIA	3 (2.3%)	5 (3.8%)	8 (3.0%)
DIZZINESS	3 (2.3%)	3 (2.3%)	6 (2.3%)
DYSPEPSIA	3 (2.3%)	3 (2.3%)	6 (2.3%)
ANXIETY	2 (1.5%)	4 (3.1%)	6 (2.3%)
EMOTIONAL LABILITY	3 (2.3%)	2 (1.5%)	5 (1.9%)
NEUROSIS	3 (2.3%)	1 (0.8%)	4 (1.5%)
DRY MOUTH	2 (1.5%)	2 (1.5%)	4 (1.5%)
URINARY INCONTINENCE	1 (0.8%)	3 (2.3%)	4 (1.5%)
TREMOR	0	4 (3.1%)	4 (1.5%)
VASODILATATION	0	4 (3.1%)	4 (1.5%)
CONCENTRATION IMPAIRED	2 (1.5%)	1 (0.8%)	3 (1.1%)
CONSTIPATION	2 (1.5%)	1 (0.8%)	3 (1.1%)
DIARRHEA	2 (1.5%)	1 (0.8%)	3 (1.1%)
LEUKOPENIA	2 (1.5%)	1 (0.8%)	3 (1.1%)
VOMITING	2 (1.5%)	1 (0.8%)	3 (1.1%)
RESPIRATORY DISORDER	1 (0.8%)	2 (1.5%)	3 (1.1%)

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.4.1.X

Number (%) of Patients with related or possibly related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Open-Label Treatment Phase by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Preferred Term			
TOTAL	0	0	0

Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=13)	Total (N=22)
Body System	Preferred Term			
TOTAL	TOTAL	1 (11.1%)	2 (15.4%)	3 (13.6%)
Nervous System	TOTAL	1 (11.1%)	0	1 (4.5%)
	DEPRESSION	1 (11.1%)	0	1 (4.5%)
Cardiovascular System	TOTAL	0	1 (7.7%)	1 (4.5%)
	SYNCOPE	0	1 (7.7%)	1 (4.5%)
Digestive System	TOTAL	0	1 (7.7%)	1 (4.5%)
	NAUSEA	0	1 (7.7%)	1 (4.5%)

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=10)	Total (N=14)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=3)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=8)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (12.5%)	1 (6.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (12.5%)	1 (6.7%)
	WEIGHT GAIN	0	1 (12.5%)	1 (6.7%)

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=5)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=3)	Total (N=6)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=21)	Total (N=37)
Body System	Preferred Term			
TOTAL	TOTAL	1 (6.3%)	3 (14.3%)	4 (10.8%)
Nervous System	TOTAL	1 (6.3%)	0	1 (2.7%)
	DEPRESSION	1 (6.3%)	0	1 (2.7%)
Cardiovascular System	TOTAL	0	1 (4.8%)	1 (2.7%)
	SYNCOPE	0	1 (4.8%)	1 (2.7%)
Digestive System	TOTAL	0	1 (4.8%)	1 (2.7%)
	NAUSEA	0	1 (4.8%)	1 (2.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (4.8%)	1 (2.7%)
	WEIGHT GAIN	0	1 (4.8%)	1 (2.7%)

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=15)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=8)	Placebo (N=6)	Total (N=14)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=9)	Total (N=20)
Body System	Preferred Term			
TOTAL	TOTAL	3 (27.3%)	2 (22.2%)	5 (25.0%)
Hemic and Lymphatic System	TOTAL	1 (9.1%)	0	1 (5.0%)
	LEUKOPENIA	1 (9.1%)	0	1 (5.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (9.1%)	0	1 (5.0%)
	WEIGHT GAIN	1 (9.1%)	0	1 (5.0%)
Nervous System	TOTAL	1 (9.1%)	2 (22.2%)	3 (15.0%)
	HOSTILITY	1 (9.1%)	0	1 (5.0%)
	SOMNOLENCE	0	1 (11.1%)	1 (5.0%)
	WITHDRAWAL SYNDROME	0	1 (11.1%)	1 (5.0%)
Musculoskeletal System	TOTAL	0	1 (11.1%)	1 (5.0%)
	MYALGIA	0	1 (11.1%)	1 (5.0%)

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=7)	Total (N=13)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=5)	Placebo (N=2)	Total (N=7)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=6)	Total (N=10)
Body System	Preferred Term			
TOTAL	TOTAL	1 (25.0%)	0	1 (10.0%)
Cardiovascular System	TOTAL	1 (25.0%)	0	1 (10.0%)
	BRADYCARDIA	1 (25.0%)	0	1 (10.0%)

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=3)	Placebo (N=5)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=1)	Placebo (N=1)	Total (N=2)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=15)	Placebo (N=15)	Total (N=30)
Body System	Preferred Term			
TOTAL	TOTAL	4 (26.7%)	2 (13.3%)	6 (20.0%)
Cardiovascular System	TOTAL	1 (6.7%)	0	1 (3.3%)
	BRADYCARDIA	1 (6.7%)	0	1 (3.3%)
Hemic and Lymphatic System	TOTAL	1 (6.7%)	0	1 (3.3%)
	LEUKOPENIA	1 (6.7%)	0	1 (3.3%)
Metabolic and Nutritional Disorders	TOTAL	1 (6.7%)	0	1 (3.3%)
	WEIGHT GAIN	1 (6.7%)	0	1 (3.3%)
Nervous System	TOTAL	1 (6.7%)	2 (13.3%)	3 (10.0%)
	HOSTILITY	1 (6.7%)	0	1 (3.3%)
	SOMNOLENCE	0	1 (6.7%)	1 (3.3%)
	WITHDRAWAL SYNDROME	0	1 (6.7%)	1 (3.3%)
Musculoskeletal System	TOTAL	0	1 (6.7%)	1 (3.3%)
	MYALGIA	0	1 (6.7%)	1 (3.3%)

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=9)	Placebo (N=12)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=6)	Placebo (N=3)	Total (N=9)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	4 (20.0%)	4 (18.2%)	8 (19.0%)
Nervous System	TOTAL	2 (10.0%)	2 (9.1%)	4 (9.5%)
	DEPRESSION	1 (5.0%)	0	1 (2.4%)
	HOSTILITY	1 (5.0%)	0	1 (2.4%)
	SOMNOLENCE	0	1 (4.5%)	1 (2.4%)
	WITHDRAWAL SYNDROME	0	1 (4.5%)	1 (2.4%)
Hemic and Lymphatic System	TOTAL	1 (5.0%)	0	1 (2.4%)
	LEUKOPENIA	1 (5.0%)	0	1 (2.4%)
Metabolic and Nutritional Disorders	TOTAL	1 (5.0%)	0	1 (2.4%)
	WEIGHT GAIN	1 (5.0%)	0	1 (2.4%)
Cardiovascular System	TOTAL	0	1 (4.5%)	1 (2.4%)
	SYNCOPE	0	1 (4.5%)	1 (2.4%)
Digestive System	TOTAL	0	1 (4.5%)	1 (2.4%)
	NAUSEA	0	1 (4.5%)	1 (2.4%)
Musculoskeletal System	TOTAL	0	1 (4.5%)	1 (2.4%)
	MYALGIA	0	1 (4.5%)	1 (2.4%)

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=17)	Total (N=27)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=10)	Placebo (N=5)	Total (N=15)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=14)	Total (N=25)
Body System	Preferred Term			
TOTAL	TOTAL	1 (9.1%)	1 (7.1%)	2 (8.0%)
Cardiovascular System	TOTAL	1 (9.1%)	0	1 (4.0%)
	BRADYCARDIA	1 (9.1%)	0	1 (4.0%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (7.1%)	1 (4.0%)
	WEIGHT GAIN	0	1 (7.1%)	1 (4.0%)

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=7)	Placebo (N=10)	Total (N=17)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=4)	Placebo (N=4)	Total (N=8)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=31)	Placebo (N=36)	Total (N=67)
Body System	Preferred Term			
TOTAL	TOTAL	5 (16.1%)	5 (13.9%)	10 (14.9%)
Nervous System	TOTAL	2 (6.5%)	2 (5.6%)	4 (6.0%)
	DEPRESSION	1 (3.2%)	0	1 (1.5%)
	HOSTILITY	1 (3.2%)	0	1 (1.5%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.5%)
	WITHDRAWAL SYNDROME	0	1 (2.8%)	1 (1.5%)
Cardiovascular System	TOTAL	1 (3.2%)	1 (2.8%)	2 (3.0%)
	BRADYCARDIA	1 (3.2%)	0	1 (1.5%)
	SYNCOPE	0	1 (2.8%)	1 (1.5%)
Hemic and Lymphatic System	TOTAL	1 (3.2%)	0	1 (1.5%)
	LEUKOPENIA	1 (3.2%)	0	1 (1.5%)
Metabolic and Nutritional Disorders	TOTAL	1 (3.2%)	1 (2.8%)	2 (3.0%)
	WEIGHT GAIN	1 (3.2%)	1 (2.8%)	2 (3.0%)
Digestive System	TOTAL	0	1 (2.8%)	1 (1.5%)
	NAUSEA	0	1 (2.8%)	1 (1.5%)
Musculoskeletal System	TOTAL	0	1 (2.8%)	1 (1.5%)
	MYALGIA	0	1 (2.8%)	1 (1.5%)

Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=17)	Placebo (N=27)	Total (N=44)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.2

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Taper Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=9)	Total (N=23)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
TOTAL	TOTAL	20 (51.3%)	15 (41.7%)	35 (46.7%)
Nervous System	TOTAL	10 (25.6%)	5 (13.9%)	15 (20.0%)
	HOSTILITY	3 (7.7%)	0	3 (4.0%)
	NERVOUSNESS	3 (7.7%)	0	3 (4.0%)
	HYPERKINESIA	2 (5.1%)	1 (2.8%)	3 (4.0%)
	AGITATION	1 (2.6%)	1 (2.8%)	2 (2.7%)
	INSOMNIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
	CONVULSION	1 (2.6%)	0	1 (1.3%)
	DEPRESSION	1 (2.6%)	0	1 (1.3%)
	ANXIETY	0	1 (2.8%)	1 (1.3%)
	DIZZINESS	0	1 (2.8%)	1 (1.3%)
	HYPESTHESIA	0	1 (2.8%)	1 (1.3%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.3%)
	TREMOR	0	1 (2.8%)	1 (1.3%)
Digestive System	TOTAL	5 (12.8%)	5 (13.9%)	10 (13.3%)
	DRY MOUTH	2 (5.1%)	0	2 (2.7%)
	DECREASED APPETITE	1 (2.6%)	1 (2.8%)	2 (2.7%)
	DYSPEPSIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
	NAUSEA	0	2 (5.6%)	2 (2.7%)
	CONSTIPATION	1 (2.6%)	0	1 (1.3%)
	INCREASED APPETITE	1 (2.6%)	0	1 (1.3%)
	VOMITING	0	1 (2.8%)	1 (1.3%)
Body as a Whole	TOTAL	4 (10.3%)	2 (5.6%)	6 (8.0%)
	ABDOMINAL PAIN	2 (5.1%)	1 (2.8%)	3 (4.0%)
	HEADACHE	2 (5.1%)	0	2 (2.7%)
	ASTHENIA	0	1 (2.8%)	1 (1.3%)
Metabolic and Nutritional Disorders	TOTAL	4 (10.3%)	2 (5.6%)	6 (8.0%)
	WEIGHT GAIN	4 (10.3%)	2 (5.6%)	6 (8.0%)
Hemic and Lymphatic System	TOTAL	1 (2.6%)	1 (2.8%)	2 (2.7%)
	LEUKOPENIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
Urogenital System	TOTAL	1 (2.6%)	2 (5.6%)	3 (4.0%)
	URINARY INCONTINENCE	1 (2.6%)	2 (5.6%)	3 (4.0%)
Cardiovascular System	TOTAL	0	1 (2.8%)	1 (1.3%)
	SYNCOPE	0	1 (2.8%)	1 (1.3%)
Respiratory System	TOTAL	0	1 (2.8%)	1 (1.3%)

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
Respiratory System	YAWN	0	1 (2.8%)	1 (1.3%)
Special Senses	TOTAL	0	1 (2.8%)	1 (1.3%)
	ABNORMAL VISION	0	1 (2.8%)	1 (1.3%)

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	17 (60.7%)	23 (63.9%)	40 (62.5%)
Body as a Whole	TOTAL	10 (35.7%)	6 (16.7%)	16 (25.0%)
	HEADACHE	8 (28.6%)	5 (13.9%)	13 (20.3%)
	FEVER	1 (3.6%)	0	1 (1.6%)
	PAIN	1 (3.6%)	0	1 (1.6%)
	TRAUMA	1 (3.6%)	0	1 (1.6%)
	ABDOMINAL PAIN	0	1 (2.8%)	1 (1.6%)
Nervous System	TOTAL	8 (28.6%)	17 (47.2%)	25 (39.1%)
	NERVOUSNESS	1 (3.6%)	9 (25.0%)	10 (15.6%)
	HYPERKINESIA	5 (17.9%)	4 (11.1%)	9 (14.1%)
	INSOMNIA	3 (10.7%)	2 (5.6%)	5 (7.8%)
	ANXIETY	1 (3.6%)	3 (8.3%)	4 (6.3%)
	HOSTILITY	1 (3.6%)	2 (5.6%)	3 (4.7%)
	SOMNOLENCE	1 (3.6%)	2 (5.6%)	3 (4.7%)
	AGITATION	1 (3.6%)	1 (2.8%)	2 (3.1%)
	CONCENTRATION IMPAIRED	1 (3.6%)	0	1 (1.6%)
	DIZZINESS	1 (3.6%)	0	1 (1.6%)
	MYOCLONUS	1 (3.6%)	0	1 (1.6%)
	DYSKINESIA	0	1 (2.8%)	1 (1.6%)
	LACK OF EMOTION	0	1 (2.8%)	1 (1.6%)
	MANIC REACTION	0	1 (2.8%)	1 (1.6%)
	TREMOR	0	1 (2.8%)	1 (1.6%)
Digestive System	TOTAL	7 (25.0%)	2 (5.6%)	9 (14.1%)
	DECREASED APPETITE	2 (7.1%)	2 (5.6%)	4 (6.3%)
	NAUSEA	3 (10.7%)	0	3 (4.7%)
	DIARRHEA	2 (7.1%)	0	2 (3.1%)
	DYSPEPSIA	2 (7.1%)	0	2 (3.1%)
Cardiovascular System	TOTAL	0	3 (8.3%)	3 (4.7%)
	VASODILATATION	0	3 (8.3%)	3 (4.7%)
Metabolic and Nutritional Disorders	TOTAL	0	3 (8.3%)	3 (4.7%)
	WEIGHT GAIN	0	3 (8.3%)	3 (4.7%)
Respiratory System	TOTAL	0	1 (2.8%)	1 (1.6%)
	RHINITIS	0	1 (2.8%)	1 (1.6%)
Urogenital System	TOTAL	0	1 (2.8%)	1 (1.6%)
	URINARY INCONTINENCE	0	1 (2.8%)	1 (1.6%)

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
TOTAL	TOTAL	37 (55.2%)	38 (52.8%)	75 (54.0%)
Nervous System	TOTAL	18 (26.9%)	22 (30.6%)	40 (28.8%)
	NERVOUSNESS	4 (6.0%)	9 (12.5%)	13 (9.4%)
	HYPERKINESIA	7 (10.4%)	5 (6.9%)	12 (8.6%)
	INSOMNIA	4 (6.0%)	3 (4.2%)	7 (5.0%)
	HOSTILITY	4 (6.0%)	2 (2.8%)	6 (4.3%)
	ANXIETY	1 (1.5%)	4 (5.6%)	5 (3.6%)
	AGITATION	2 (3.0%)	2 (2.8%)	4 (2.9%)
	SOMNOLENCE	1 (1.5%)	3 (4.2%)	4 (2.9%)
	DIZZINESS	1 (1.5%)	1 (1.4%)	2 (1.4%)
	TREMOR	0	2 (2.8%)	2 (1.4%)
	CONCENTRATION IMPAIRED	1 (1.5%)	0	1 (0.7%)
	CONVULSION	1 (1.5%)	0	1 (0.7%)
	DEPRESSION	1 (1.5%)	0	1 (0.7%)
	MYOCLONUS	1 (1.5%)	0	1 (0.7%)
	DYSKINESIA	0	1 (1.4%)	1 (0.7%)
	HYPESTHESIA	0	1 (1.4%)	1 (0.7%)
	LACK OF EMOTION	0	1 (1.4%)	1 (0.7%)
	MANIC REACTION	0	1 (1.4%)	1 (0.7%)
Body as a Whole	TOTAL	14 (20.9%)	8 (11.1%)	22 (15.8%)
	HEADACHE	10 (14.9%)	5 (6.9%)	15 (10.8%)
	ABDOMINAL PAIN	2 (3.0%)	2 (2.8%)	4 (2.9%)
	FEVER	1 (1.5%)	0	1 (0.7%)
	PAIN	1 (1.5%)	0	1 (0.7%)
	TRAUMA	1 (1.5%)	0	1 (0.7%)
	ASTHENIA	0	1 (1.4%)	1 (0.7%)
Digestive System	TOTAL	12 (17.9%)	7 (9.7%)	19 (13.7%)
	DECREASED APPETITE	3 (4.5%)	3 (4.2%)	6 (4.3%)
	NAUSEA	3 (4.5%)	2 (2.8%)	5 (3.6%)
	DYSPEPSIA	3 (4.5%)	1 (1.4%)	4 (2.9%)
	DIARRHEA	2 (3.0%)	0	2 (1.4%)
	DRY MOUTH	2 (3.0%)	0	2 (1.4%)
	CONSTIPATION	1 (1.5%)	0	1 (0.7%)
	INCREASED APPETITE	1 (1.5%)	0	1 (0.7%)
	VOMITING	0	1 (1.4%)	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	4 (6.0%)	5 (6.9%)	9 (6.5%)
	WEIGHT GAIN	4 (6.0%)	5 (6.9%)	9 (6.5%)
Hemic and Lymphatic System	TOTAL	1 (1.5%)	1 (1.4%)	2 (1.4%)

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
Hemic and Lymphatic System	LEUKOPENIA	1 (1.5%)	1 (1.4%)	2 (1.4%)
Urogenital System	TOTAL	1 (1.5%)	3 (4.2%)	4 (2.9%)
	URINARY INCONTINENCE	1 (1.5%)	3 (4.2%)	4 (2.9%)
Cardiovascular System	TOTAL	0	4 (5.6%)	4 (2.9%)
	VASODILATATION	0	3 (4.2%)	3 (2.2%)
	SYNCOPE	0	1 (1.4%)	1 (0.7%)
Respiratory System	TOTAL	0	2 (2.8%)	2 (1.4%)
	RHINITIS	0	1 (1.4%)	1 (0.7%)
	YAWN	0	1 (1.4%)	1 (0.7%)
Special Senses	TOTAL	0	1 (1.4%)	1 (0.7%)
	ABNORMAL VISION	0	1 (1.4%)	1 (0.7%)

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Body System	Preferred Term			
TOTAL	TOTAL	19 (45.2%)	14 (46.7%)	33 (45.8%)
Nervous System	TOTAL	9 (21.4%)	8 (26.7%)	17 (23.6%)
	SOMNOLENCE	4 (9.5%)	3 (10.0%)	7 (9.7%)
	NERVOUSNESS	3 (7.1%)	1 (3.3%)	4 (5.6%)
	EMOTIONAL LABILITY	2 (4.8%)	2 (6.7%)	4 (5.6%)
	INSOMNIA	2 (4.8%)	2 (6.7%)	4 (5.6%)
	AGITATION	1 (2.4%)	1 (3.3%)	2 (2.8%)
	HOSTILITY	1 (2.4%)	1 (3.3%)	2 (2.8%)
	WITHDRAWAL SYNDROME	0	2 (6.7%)	2 (2.8%)
	ANXIETY	1 (2.4%)	0	1 (1.4%)
	CONCENTRATION IMPAIRED	0	1 (3.3%)	1 (1.4%)
	DIZZINESS	0	1 (3.3%)	1 (1.4%)
	LIBIDO DECREASED	0	1 (3.3%)	1 (1.4%)
	TREMOR	0	1 (3.3%)	1 (1.4%)
Digestive System	TOTAL	6 (14.3%)	4 (13.3%)	10 (13.9%)
	NAUSEA	5 (11.9%)	0	5 (6.9%)
	DECREASED APPETITE	1 (2.4%)	2 (6.7%)	3 (4.2%)
	VOMITING	2 (4.8%)	0	2 (2.8%)
	DIARRHEA	0	1 (3.3%)	1 (1.4%)
	INCREASED APPETITE	0	1 (3.3%)	1 (1.4%)
Body as a Whole	TOTAL	5 (11.9%)	5 (16.7%)	10 (13.9%)
	HEADACHE	3 (7.1%)	3 (10.0%)	6 (8.3%)
	ASTHENIA	1 (2.4%)	2 (6.7%)	3 (4.2%)
	ABDOMINAL PAIN	1 (2.4%)	1 (3.3%)	2 (2.8%)
	CHEST PAIN	1 (2.4%)	0	1 (1.4%)
	MALAISE	1 (2.4%)	0	1 (1.4%)
Hemic and Lymphatic System	TOTAL	2 (4.8%)	0	2 (2.8%)
	LEUKOPENIA	2 (4.8%)	0	2 (2.8%)
Metabolic and Nutritional Disorders	TOTAL	2 (4.8%)	3 (10.0%)	5 (6.9%)
	WEIGHT GAIN	2 (4.8%)	3 (10.0%)	5 (6.9%)
Musculoskeletal System	TOTAL	0	1 (3.3%)	1 (1.4%)
	MYALGIA	0	1 (3.3%)	1 (1.4%)
Skin and Appendages	TOTAL	0	1 (3.3%)	1 (1.4%)
	ACNE	0	1 (3.3%)	1 (1.4%)

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (6.7%)	1 (3.4%)
Urogenital System	TOTAL	0	1 (6.7%)	1 (3.4%)
	FEMALE GENITAL DISORDERS	0	1 (6.7%)	1 (3.4%)

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	13 (54.2%)	14 (50.0%)	27 (51.9%)
Body as a Whole	TOTAL	7 (29.2%)	8 (28.6%)	15 (28.8%)
	HEADACHE	5 (20.8%)	5 (17.9%)	10 (19.2%)
	ASTHENIA	2 (8.3%)	2 (7.1%)	4 (7.7%)
	ABDOMINAL PAIN	1 (4.2%)	2 (7.1%)	3 (5.8%)
Nervous System	TOTAL	6 (25.0%)	8 (28.6%)	14 (26.9%)
	NEUROSIS	3 (12.5%)	1 (3.6%)	4 (7.7%)
	INSOMNIA	1 (4.2%)	3 (10.7%)	4 (7.7%)
	DIZZINESS	2 (8.3%)	1 (3.6%)	3 (5.8%)
	HOSTILITY	1 (4.2%)	2 (7.1%)	3 (5.8%)
	HYPERKINESIA	1 (4.2%)	2 (7.1%)	3 (5.8%)
	ABNORMAL DREAMS	1 (4.2%)	1 (3.6%)	2 (3.8%)
	AGITATION	0	2 (7.1%)	2 (3.8%)
	NERVOUSNESS	0	2 (7.1%)	2 (3.8%)
	CONCENTRATION IMPAIRED	1 (4.2%)	0	1 (1.9%)
	EMOTIONAL LABILITY	1 (4.2%)	0	1 (1.9%)
	MANIC REACTION	1 (4.2%)	0	1 (1.9%)
	SOMNOLENCE	0	1 (3.6%)	1 (1.9%)
	TREMOR	0	1 (3.6%)	1 (1.9%)
Digestive System	TOTAL	2 (8.3%)	9 (32.1%)	11 (21.2%)
	NAUSEA	1 (4.2%)	4 (14.3%)	5 (9.6%)
	CONSTIPATION	1 (4.2%)	1 (3.6%)	2 (3.8%)
	DECREASED APPETITE	0	2 (7.1%)	2 (3.8%)
	DRY MOUTH	0	2 (7.1%)	2 (3.8%)
	DYSPEPSIA	0	2 (7.1%)	2 (3.8%)
	FLATULENCE	0	1 (3.6%)	1 (1.9%)
Metabolic and Nutritional Disorders	TOTAL	2 (8.3%)	1 (3.6%)	3 (5.8%)
	WEIGHT GAIN	2 (8.3%)	0	2 (3.8%)
	WEIGHT LOSS	0	1 (3.6%)	1 (1.9%)
Cardiovascular System	TOTAL	1 (4.2%)	1 (3.6%)	2 (3.8%)
	BRADYCARDIA	1 (4.2%)	0	1 (1.9%)
	VASODILATATION	0	1 (3.6%)	1 (1.9%)
Respiratory System	TOTAL	1 (4.2%)	2 (7.1%)	3 (5.8%)
	RESPIRATORY DISORDER	1 (4.2%)	2 (7.1%)	3 (5.8%)
Skin and Appendages	TOTAL	1 (4.2%)	1 (3.6%)	2 (3.8%)
	ACNE	1 (4.2%)	0	1 (1.9%)

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
Skin and Appendages	SWEATING	0	1 (3.6%)	1 (1.9%)
Special Senses	TOTAL	0	1 (3.6%)	1 (1.9%)
	PHOTOPHOBIA	0	1 (3.6%)	1 (1.9%)

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
TOTAL	TOTAL	32 (48.5%)	28 (48.3%)	60 (48.4%)
Nervous System	TOTAL	15 (22.7%)	16 (27.6%)	31 (25.0%)
	SOMNOLENCE	4 (6.1%)	4 (6.9%)	8 (6.5%)
	INSOMNIA	3 (4.5%)	5 (8.6%)	8 (6.5%)
	NERVOUSNESS	3 (4.5%)	3 (5.2%)	6 (4.8%)
	EMOTIONAL LABILITY	3 (4.5%)	2 (3.4%)	5 (4.0%)
	HOSTILITY	2 (3.0%)	3 (5.2%)	5 (4.0%)
	NEUROSIS	3 (4.5%)	1 (1.7%)	4 (3.2%)
	DIZZINESS	2 (3.0%)	2 (3.4%)	4 (3.2%)
	AGITATION	1 (1.5%)	3 (5.2%)	4 (3.2%)
	HYPERKINESIA	1 (1.5%)	2 (3.4%)	3 (2.4%)
	ABNORMAL DREAMS	1 (1.5%)	1 (1.7%)	2 (1.6%)
	CONCENTRATION IMPAIRED	1 (1.5%)	1 (1.7%)	2 (1.6%)
	TREMOR	0	2 (3.4%)	2 (1.6%)
	WITHDRAWAL SYNDROME	0	2 (3.4%)	2 (1.6%)
	ANXIETY	1 (1.5%)	0	1 (0.8%)
	MANIC REACTION	1 (1.5%)	0	1 (0.8%)
	LIBIDO DECREASED	0	1 (1.7%)	1 (0.8%)
Body as a Whole	TOTAL	12 (18.2%)	13 (22.4%)	25 (20.2%)
	HEADACHE	8 (12.1%)	8 (13.8%)	16 (12.9%)
	ASTHENIA	3 (4.5%)	4 (6.9%)	7 (5.6%)
	ABDOMINAL PAIN	2 (3.0%)	3 (5.2%)	5 (4.0%)
	CHEST PAIN	1 (1.5%)	0	1 (0.8%)
	MALAISE	1 (1.5%)	0	1 (0.8%)
Digestive System	TOTAL	8 (12.1%)	13 (22.4%)	21 (16.9%)
	NAUSEA	6 (9.1%)	4 (6.9%)	10 (8.1%)
	DECREASED APPETITE	1 (1.5%)	4 (6.9%)	5 (4.0%)
	VOMITING	2 (3.0%)	0	2 (1.6%)
	CONSTIPATION	1 (1.5%)	1 (1.7%)	2 (1.6%)
	DRY MOUTH	0	2 (3.4%)	2 (1.6%)
	DYSPEPSIA	0	2 (3.4%)	2 (1.6%)
	DIARRHEA	0	1 (1.7%)	1 (0.8%)
	FLATULENCE	0	1 (1.7%)	1 (0.8%)
	INCREASED APPETITE	0	1 (1.7%)	1 (0.8%)
Metabolic and Nutritional Disorders	TOTAL	4 (6.1%)	4 (6.9%)	8 (6.5%)
	WEIGHT GAIN	4 (6.1%)	3 (5.2%)	7 (5.6%)
	WEIGHT LOSS	0	1 (1.7%)	1 (0.8%)
Hemic and Lymphatic System	TOTAL	2 (3.0%)	0	2 (1.6%)

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Hemic and Lymphatic System	LEUKOPENIA	2 (3.0%)	0	2 (1.6%)
Cardiovascular System	TOTAL	1 (1.5%)	1 (1.7%)	2 (1.6%)
	BRADYCARDIA	1 (1.5%)	0	1 (0.8%)
	VASODILATATION	0	1 (1.7%)	1 (0.8%)
Respiratory System	TOTAL	1 (1.5%)	2 (3.4%)	3 (2.4%)
	RESPIRATORY DISORDER	1 (1.5%)	2 (3.4%)	3 (2.4%)
Skin and Appendages	TOTAL	1 (1.5%)	2 (3.4%)	3 (2.4%)
	ACNE	1 (1.5%)	1 (1.7%)	2 (1.6%)
	SWEATING	0	1 (1.7%)	1 (0.8%)
Musculoskeletal System	TOTAL	0	1 (1.7%)	1 (0.8%)
	MYALGIA	0	1 (1.7%)	1 (0.8%)
Special Senses	TOTAL	0	1 (1.7%)	1 (0.8%)
	PHOTOPHOBIA	0	1 (1.7%)	1 (0.8%)

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (4.2%)	1 (2.0%)
Urogenital System	TOTAL	0	1 (4.2%)	1 (2.0%)
	FEMALE GENITAL DISORDERS	0	1 (4.2%)	1 (2.0%)

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	39 (48.1%)	29 (43.9%)	68 (46.3%)
Nervous System	TOTAL	19 (23.5%)	13 (19.7%)	32 (21.8%)
	SOMNOLENCE	4 (4.9%)	4 (6.1%)	8 (5.4%)
	NERVOUSNESS	6 (7.4%)	1 (1.5%)	7 (4.8%)
	INSOMNIA	3 (3.7%)	3 (4.5%)	6 (4.1%)
	HOSTILITY	4 (4.9%)	1 (1.5%)	5 (3.4%)
	AGITATION	2 (2.5%)	2 (3.0%)	4 (2.7%)
	EMOTIONAL LABILITY	2 (2.5%)	2 (3.0%)	4 (2.7%)
	HYPERKINESIA	2 (2.5%)	1 (1.5%)	3 (2.0%)
	ANXIETY	1 (1.2%)	1 (1.5%)	2 (1.4%)
	DIZZINESS	0	2 (3.0%)	2 (1.4%)
	TREMOR	0	2 (3.0%)	2 (1.4%)
	WITHDRAWAL SYNDROME	0	2 (3.0%)	2 (1.4%)
	CONVULSION	1 (1.2%)	0	1 (0.7%)
	DEPRESSION	1 (1.2%)	0	1 (0.7%)
	CONCENTRATION IMPAIRED	0	1 (1.5%)	1 (0.7%)
	HYPESTHESIA	0	1 (1.5%)	1 (0.7%)
	LIBIDO DECREASED	0	1 (1.5%)	1 (0.7%)
Digestive System	TOTAL	11 (13.6%)	9 (13.6%)	20 (13.6%)
	NAUSEA	5 (6.2%)	2 (3.0%)	7 (4.8%)
	DECREASED APPETITE	2 (2.5%)	3 (4.5%)	5 (3.4%)
	VOMITING	2 (2.5%)	1 (1.5%)	3 (2.0%)
	DRY MOUTH	2 (2.5%)	0	2 (1.4%)
	DYSPEPSIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	INCREASED APPETITE	1 (1.2%)	1 (1.5%)	2 (1.4%)
	CONSTIPATION	1 (1.2%)	0	1 (0.7%)
	DIARRHEA	0	1 (1.5%)	1 (0.7%)
Body as a Whole	TOTAL	9 (11.1%)	7 (10.6%)	16 (10.9%)
	HEADACHE	5 (6.2%)	3 (4.5%)	8 (5.4%)
	ABDOMINAL PAIN	3 (3.7%)	2 (3.0%)	5 (3.4%)
	ASTHENIA	1 (1.2%)	3 (4.5%)	4 (2.7%)
	CHEST PAIN	1 (1.2%)	0	1 (0.7%)
	MALAISE	1 (1.2%)	0	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	6 (7.4%)	5 (7.6%)	11 (7.5%)
	WEIGHT GAIN	6 (7.4%)	5 (7.6%)	11 (7.5%)
Hemic and Lymphatic System	TOTAL	3 (3.7%)	1 (1.5%)	4 (2.7%)
	LEUKOPENIA	3 (3.7%)	1 (1.5%)	4 (2.7%)

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
Urogenital System	TOTAL	1 (1.2%)	2 (3.0%)	3 (2.0%)
	URINARY INCONTINENCE	1 (1.2%)	2 (3.0%)	3 (2.0%)
Cardiovascular System	TOTAL	0	1 (1.5%)	1 (0.7%)
	SYNCOPE	0	1 (1.5%)	1 (0.7%)
Musculoskeletal System	TOTAL	0	1 (1.5%)	1 (0.7%)
	MYALGIA	0	1 (1.5%)	1 (0.7%)
Respiratory System	TOTAL	0	1 (1.5%)	1 (0.7%)
	YAWN	0	1 (1.5%)	1 (0.7%)
Skin and Appendages	TOTAL	0	1 (1.5%)	1 (0.7%)
	ACNE	0	1 (1.5%)	1 (0.7%)
Special Senses	TOTAL	0	1 (1.5%)	1 (0.7%)
	ABNORMAL VISION	0	1 (1.5%)	1 (0.7%)

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (3.4%)	1 (1.6%)
Urogenital System	TOTAL	0	1 (3.4%)	1 (1.6%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.6%)

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	30 (57.7%)	37 (57.8%)	67 (57.8%)
Body as a Whole	TOTAL	17 (32.7%)	14 (21.9%)	31 (26.7%)
	HEADACHE	13 (25.0%)	10 (15.6%)	23 (19.8%)
	ASTHENIA	2 (3.8%)	2 (3.1%)	4 (3.4%)
	ABDOMINAL PAIN	1 (1.9%)	3 (4.7%)	4 (3.4%)
	FEVER	1 (1.9%)	0	1 (0.9%)
	PAIN	1 (1.9%)	0	1 (0.9%)
	TRAUMA	1 (1.9%)	0	1 (0.9%)
Nervous System	TOTAL	14 (26.9%)	25 (39.1%)	39 (33.6%)
	HYPERKINESIA	6 (11.5%)	6 (9.4%)	12 (10.3%)
	NERVOUSNESS	1 (1.9%)	11 (17.2%)	12 (10.3%)
	INSOMNIA	4 (7.7%)	5 (7.8%)	9 (7.8%)
	HOSTILITY	2 (3.8%)	4 (6.3%)	6 (5.2%)
	DIZZINESS	3 (5.8%)	1 (1.6%)	4 (3.4%)
	NEUROSIS	3 (5.8%)	1 (1.6%)	4 (3.4%)
	AGITATION	1 (1.9%)	3 (4.7%)	4 (3.4%)
	ANXIETY	1 (1.9%)	3 (4.7%)	4 (3.4%)
	SOMNOLENCE	1 (1.9%)	3 (4.7%)	4 (3.4%)
	CONCENTRATION IMPAIRED	2 (3.8%)	0	2 (1.7%)
	ABNORMAL DREAMS	1 (1.9%)	1 (1.6%)	2 (1.7%)
	MANIC REACTION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	TREMOR	0	2 (3.1%)	2 (1.7%)
	EMOTIONAL LABILITY	1 (1.9%)	0	1 (0.9%)
	MYOCLONUS	1 (1.9%)	0	1 (0.9%)
	DYSKINESIA	0	1 (1.6%)	1 (0.9%)
	LACK OF EMOTION	0	1 (1.6%)	1 (0.9%)
Digestive System	TOTAL	9 (17.3%)	11 (17.2%)	20 (17.2%)
	NAUSEA	4 (7.7%)	4 (6.3%)	8 (6.9%)
	DECREASED APPETITE	2 (3.8%)	4 (6.3%)	6 (5.2%)
	DYSPEPSIA	2 (3.8%)	2 (3.1%)	4 (3.4%)
	DIARRHEA	2 (3.8%)	0	2 (1.7%)
	CONSTIPATION	1 (1.9%)	1 (1.6%)	2 (1.7%)
	DRY MOUTH	0	2 (3.1%)	2 (1.7%)
	FLATULENCE	0	1 (1.6%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	2 (3.8%)	4 (6.3%)	6 (5.2%)
	WEIGHT GAIN	2 (3.8%)	3 (4.7%)	5 (4.3%)
	WEIGHT LOSS	0	1 (1.6%)	1 (0.9%)
Cardiovascular System	TOTAL	1 (1.9%)	4 (6.3%)	5 (4.3%)

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
Cardiovascular System	VASODILATATION	0	4 (6.3%)	4 (3.4%)
	BRADYCARDIA	1 (1.9%)	0	1 (0.9%)
Respiratory System	TOTAL	1 (1.9%)	3 (4.7%)	4 (3.4%)
	RESPIRATORY DISORDER	1 (1.9%)	2 (3.1%)	3 (2.6%)
	RHINITIS	0	1 (1.6%)	1 (0.9%)
Skin and Appendages	TOTAL	1 (1.9%)	1 (1.6%)	2 (1.7%)
	ACNE	1 (1.9%)	0	1 (0.9%)
	SWEATING	0	1 (1.6%)	1 (0.9%)
Special Senses	TOTAL	0	1 (1.6%)	1 (0.9%)
	PHOTOPHOBIA	0	1 (1.6%)	1 (0.9%)
Urogenital System	TOTAL	0	1 (1.6%)	1 (0.9%)
	URINARY INCONTINENCE	0	1 (1.6%)	1 (0.9%)

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
TOTAL	TOTAL	69 (51.9%)	66 (50.8%)	135 (51.3%)
Nervous System	TOTAL	33 (24.8%)	38 (29.2%)	71 (27.0%)
	NERVOUSNESS	7 (5.3%)	12 (9.2%)	19 (7.2%)
	HYPERKINESIA	8 (6.0%)	7 (5.4%)	15 (5.7%)
	INSOMNIA	7 (5.3%)	8 (6.2%)	15 (5.7%)
	SOMNOLENCE	5 (3.8%)	7 (5.4%)	12 (4.6%)
	HOSTILITY	6 (4.5%)	5 (3.8%)	11 (4.2%)
	AGITATION	3 (2.3%)	5 (3.8%)	8 (3.0%)
	DIZZINESS	3 (2.3%)	3 (2.3%)	6 (2.3%)
	ANXIETY	2 (1.5%)	4 (3.1%)	6 (2.3%)
	EMOTIONAL LABILITY	3 (2.3%)	2 (1.5%)	5 (1.9%)
	NEUROSIS	3 (2.3%)	1 (0.8%)	4 (1.5%)
	TREMOR	0	4 (3.1%)	4 (1.5%)
	CONCENTRATION IMPAIRED	2 (1.5%)	1 (0.8%)	3 (1.1%)
	ABNORMAL DREAMS	1 (0.8%)	1 (0.8%)	2 (0.8%)
	MANIC REACTION	1 (0.8%)	1 (0.8%)	2 (0.8%)
	WITHDRAWAL SYNDROME	0	2 (1.5%)	2 (0.8%)
	CONVULSION	1 (0.8%)	0	1 (0.4%)
	DEPRESSION	1 (0.8%)	0	1 (0.4%)
	MYOCLONUS	1 (0.8%)	0	1 (0.4%)
	DYSKINESIA	0	1 (0.8%)	1 (0.4%)
	HYPESTHESIA	0	1 (0.8%)	1 (0.4%)
	LACK OF EMOTION	0	1 (0.8%)	1 (0.4%)
	LIBIDO DECREASED	0	1 (0.8%)	1 (0.4%)
Body as a Whole	TOTAL	26 (19.5%)	21 (16.2%)	47 (17.9%)
	HEADACHE	18 (13.5%)	13 (10.0%)	31 (11.8%)
	ABDOMINAL PAIN	4 (3.0%)	5 (3.8%)	9 (3.4%)
	ASTHENIA	3 (2.3%)	5 (3.8%)	8 (3.0%)
	CHEST PAIN	1 (0.8%)	0	1 (0.4%)
	FEVER	1 (0.8%)	0	1 (0.4%)
	MALAISE	1 (0.8%)	0	1 (0.4%)
	PAIN	1 (0.8%)	0	1 (0.4%)
	TRAUMA	1 (0.8%)	0	1 (0.4%)
Digestive System	TOTAL	20 (15.0%)	20 (15.4%)	40 (15.2%)
	NAUSEA	9 (6.8%)	6 (4.6%)	15 (5.7%)
	DECREASED APPETITE	4 (3.0%)	7 (5.4%)	11 (4.2%)
	DYSPEPSIA	3 (2.3%)	3 (2.3%)	6 (2.3%)
	DRY MOUTH	2 (1.5%)	2 (1.5%)	4 (1.5%)
	CONSTIPATION	2 (1.5%)	1 (0.8%)	3 (1.1%)
	DIARRHEA	2 (1.5%)	1 (0.8%)	3 (1.1%)
	VOMITING	2 (1.5%)	1 (0.8%)	3 (1.1%)

Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
Digestive System	INCREASED APPETITE	1 (0.8%)	1 (0.8%)	2 (0.8%)
	FLATULENCE	0	1 (0.8%)	1 (0.4%)
Metabolic and Nutritional Disorders	TOTAL	8 (6.0%)	9 (6.9%)	17 (6.5%)
	WEIGHT GAIN	8 (6.0%)	8 (6.2%)	16 (6.1%)
	WEIGHT LOSS	0	1 (0.8%)	1 (0.4%)
Hemic and Lymphatic System	TOTAL	3 (2.3%)	1 (0.8%)	4 (1.5%)
	LEUKOPENIA	3 (2.3%)	1 (0.8%)	4 (1.5%)
Cardiovascular System	TOTAL	1 (0.8%)	5 (3.8%)	6 (2.3%)
	VASODILATATION	0	4 (3.1%)	4 (1.5%)
	BRADYCARDIA	1 (0.8%)	0	1 (0.4%)
	SYNCOPE	0	1 (0.8%)	1 (0.4%)
Respiratory System	TOTAL	1 (0.8%)	4 (3.1%)	5 (1.9%)
	RESPIRATORY DISORDER	1 (0.8%)	2 (1.5%)	3 (1.1%)
	RHINITIS	0	1 (0.8%)	1 (0.4%)
	YAWN	0	1 (0.8%)	1 (0.4%)
Skin and Appendages	TOTAL	1 (0.8%)	2 (1.5%)	3 (1.1%)
	ACNE	1 (0.8%)	1 (0.8%)	2 (0.8%)
	SWEATING	0	1 (0.8%)	1 (0.4%)
Urogenital System	TOTAL	1 (0.8%)	3 (2.3%)	4 (1.5%)
	URINARY INCONTINENCE	1 (0.8%)	3 (2.3%)	4 (1.5%)
Musculoskeletal System	TOTAL	0	1 (0.8%)	1 (0.4%)
	MYALGIA	0	1 (0.8%)	1 (0.4%)
Special Senses	TOTAL	0	2 (1.5%)	2 (0.8%)
	ABNORMAL VISION	0	1 (0.8%)	1 (0.4%)
	PHOTOPHOBIA	0	1 (0.8%)	1 (0.4%)

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.3

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Open-Label Treatment Phase or Taper Phase by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (2.0%)	1 (0.9%)
Urogenital System	TOTAL	0	1 (2.0%)	1 (0.9%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (0.9%)

Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=49)	Placebo (N=34)	Total (N=83)
Body System	Preferred Term			
TOTAL	TOTAL	3 (6.1%)	2 (5.9%)	5 (6.0%)
Nervous System	TOTAL	2 (4.1%)	0	2 (2.4%)
	ANXIETY	1 (2.0%)	0	1 (1.2%)
	INSOMNIA	1 (2.0%)	0	1 (1.2%)
	NERVOUSNESS	1 (2.0%)	0	1 (1.2%)
	WITHDRAWAL SYNDROME	1 (2.0%)	0	1 (1.2%)
Body as a Whole	TOTAL	1 (2.0%)	0	1 (1.2%)
	HEADACHE	1 (2.0%)	0	1 (1.2%)
Digestive System	TOTAL	1 (2.0%)	0	1 (1.2%)
	INCREASED APPETITE	1 (2.0%)	0	1 (1.2%)
Musculoskeletal System	TOTAL	1 (2.0%)	0	1 (1.2%)
	MYALGIA	1 (2.0%)	0	1 (1.2%)
Hemic and Lymphatic System	TOTAL	0	1 (2.9%)	1 (1.2%)
	LYMPHOCYTOSIS	0	1 (2.9%)	1 (1.2%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (2.9%)	1 (1.2%)
	SGOT INCREASED	0	1 (2.9%)	1 (1.2%)

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Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=29)	Placebo (N=18)	Total (N=47)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=16)	Total (N=36)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=23)	Placebo (N=33)	Total (N=56)
Body System	Preferred Term			
TOTAL	TOTAL	5 (21.7%)	3 (9.1%)	8 (14.3%)
Nervous System	TOTAL	3 (13.0%)	0	3 (5.4%)
	CONCENTRATION IMPAIRED	1 (4.3%)	0	1 (1.8%)
	DIZZINESS	1 (4.3%)	0	1 (1.8%)
	NEUROSIS	1 (4.3%)	0	1 (1.8%)
	PARESTHESIA	1 (4.3%)	0	1 (1.8%)
Body as a Whole	TOTAL	1 (4.3%)	2 (6.1%)	3 (5.4%)
	HEADACHE	1 (4.3%)	2 (6.1%)	3 (5.4%)
Respiratory System	TOTAL	1 (4.3%)	0	1 (1.8%)
	RESPIRATORY DISORDER	1 (4.3%)	0	1 (1.8%)
Digestive System	TOTAL	0	1 (3.0%)	1 (1.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (3.0%)	1 (1.8%)

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Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=11)	Placebo (N=21)	Total (N=32)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=12)	Total (N=24)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=67)	Total (N=139)
Body System	Preferred Term			
TOTAL	TOTAL	8 (11.1%)	5 (7.5%)	13 (9.4%)
Nervous System	TOTAL	5 (6.9%)	0	5 (3.6%)
	ANXIETY	1 (1.4%)	0	1 (0.7%)
	CONCENTRATION IMPAIRED	1 (1.4%)	0	1 (0.7%)
	DIZZINESS	1 (1.4%)	0	1 (0.7%)
	INSOMNIA	1 (1.4%)	0	1 (0.7%)
	NERVOUSNESS	1 (1.4%)	0	1 (0.7%)
	NEUROSIS	1 (1.4%)	0	1 (0.7%)
	PARESTHESIA	1 (1.4%)	0	1 (0.7%)
	WITHDRAWAL SYNDROME	1 (1.4%)	0	1 (0.7%)
Body as a Whole	TOTAL	2 (2.8%)	2 (3.0%)	4 (2.9%)
	HEADACHE	2 (2.8%)	2 (3.0%)	4 (2.9%)
Digestive System	TOTAL	1 (1.4%)	1 (1.5%)	2 (1.4%)
	INCREASED APPETITE	1 (1.4%)	0	1 (0.7%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.5%)	1 (0.7%)
Musculoskeletal System	TOTAL	1 (1.4%)	0	1 (0.7%)
	MYALGIA	1 (1.4%)	0	1 (0.7%)
Respiratory System	TOTAL	1 (1.4%)	0	1 (0.7%)
	RESPIRATORY DISORDER	1 (1.4%)	0	1 (0.7%)
Hemic and Lymphatic System	TOTAL	0	1 (1.5%)	1 (0.7%)
	LYMPHOCYTOSIS	0	1 (1.5%)	1 (0.7%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.5%)	1 (0.7%)
	SGOT INCREASED	0	1 (1.5%)	1 (0.7%)

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Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=40)	Placebo (N=39)	Total (N=79)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.4.4

Number (%) of Patients with related or possibly related Emergent Adverse Experiences During the Follow-Up Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=32)	Placebo (N=28)	Total (N=60)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
TOTAL	TOTAL	5 (12.8%)	4 (11.1%)	9 (12.0%)
Nervous System	TOTAL	4 (10.3%)	3 (8.3%)	7 (9.3%)
	HOSTILITY	2 (5.1%)	1 (2.8%)	3 (4.0%)
	CONVULSION	1 (2.6%)	0	1 (1.3%)
	DEPRESSION	1 (2.6%)	0	1 (1.3%)
	EMOTIONAL LABILITY	1 (2.6%)	0	1 (1.3%)
	AGITATION	0	1 (2.8%)	1 (1.3%)
	HALLUCINATIONS	0	1 (2.8%)	1 (1.3%)
Digestive System	TOTAL	1 (2.6%)	0	1 (1.3%)
	VOMITING	1 (2.6%)	0	1 (1.3%)
Cardiovascular System	TOTAL	0	1 (2.8%)	1 (1.3%)
	BUNDLE BRANCH BLOCK	0	1 (2.8%)	1 (1.3%)

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	1 (3.6%)	8 (22.2%)	9 (14.1%)
Nervous System	TOTAL	1 (3.6%)	7 (19.4%)	8 (12.5%)
	HYPERKINESIA	1 (3.6%)	3 (8.3%)	4 (6.3%)
	HOSTILITY	1 (3.6%)	2 (5.6%)	3 (4.7%)
	CONCENTRATION IMPAIRED	1 (3.6%)	0	1 (1.6%)
	MANIC REACTION	0	1 (2.8%)	1 (1.6%)
	NERVOUSNESS	0	1 (2.8%)	1 (1.6%)
	PSYCHOSIS	0	1 (2.8%)	1 (1.6%)
Body as a Whole	TOTAL	0	1 (2.8%)	1 (1.6%)
	INFECTION	0	1 (2.8%)	1 (1.6%)

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
TOTAL	TOTAL	6 (9.0%)	12 (16.7%)	18 (12.9%)
Nervous System	TOTAL	5 (7.5%)	10 (13.9%)	15 (10.8%)
	HOSTILITY	3 (4.5%)	3 (4.2%)	6 (4.3%)
	HYPERKINESIA	1 (1.5%)	3 (4.2%)	4 (2.9%)
	CONCENTRATION IMPAIRED	1 (1.5%)	0	1 (0.7%)
	CONVULSION	1 (1.5%)	0	1 (0.7%)
	DEPRESSION	1 (1.5%)	0	1 (0.7%)
	EMOTIONAL LABILITY	1 (1.5%)	0	1 (0.7%)
	AGITATION	0	1 (1.4%)	1 (0.7%)
	HALLUCINATIONS	0	1 (1.4%)	1 (0.7%)
	MANIC REACTION	0	1 (1.4%)	1 (0.7%)
	NERVOUSNESS	0	1 (1.4%)	1 (0.7%)
	PSYCHOSIS	0	1 (1.4%)	1 (0.7%)
Digestive System	TOTAL	1 (1.5%)	0	1 (0.7%)
	VOMITING	1 (1.5%)	0	1 (0.7%)
Body as a Whole	TOTAL	0	1 (1.4%)	1 (0.7%)
	INFECTION	0	1 (1.4%)	1 (0.7%)
Cardiovascular System	TOTAL	0	1 (1.4%)	1 (0.7%)
	BUNDLE BRANCH BLOCK	0	1 (1.4%)	1 (0.7%)

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Body System	Preferred Term			
TOTAL	TOTAL	3 (7.1%)	4 (13.3%)	7 (9.7%)
Nervous System	TOTAL	2 (4.8%)	4 (13.3%)	6 (8.3%)
	EMOTIONAL LABILITY	2 (4.8%)	0	2 (2.8%)
	ANXIETY	0	1 (3.3%)	1 (1.4%)
	HALLUCINATIONS	0	1 (3.3%)	1 (1.4%)
	HOSTILITY	0	1 (3.3%)	1 (1.4%)
	LIBIDO DECREASED	0	1 (3.3%)	1 (1.4%)
Digestive System	TOTAL	1 (2.4%)	0	1 (1.4%)
	NAUSEA	1 (2.4%)	0	1 (1.4%)

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (6.7%)	1 (3.4%)
Urogenital System	TOTAL	0	1 (6.7%)	1 (3.4%)
	FEMALE GENITAL DISORDERS	0	1 (6.7%)	1 (3.4%)

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	1 (4.2%)	5 (17.9%)	6 (11.5%)
Nervous System	TOTAL	1 (4.2%)	4 (14.3%)	5 (9.6%)
	EMOTIONAL LABILITY	1 (4.2%)	1 (3.6%)	2 (3.8%)
	HOSTILITY	0	2 (7.1%)	2 (3.8%)
	NERVOUSNESS	0	2 (7.1%)	2 (3.8%)
	AGITATION	0	1 (3.6%)	1 (1.9%)
	ANXIETY	0	1 (3.6%)	1 (1.9%)
Body as a Whole	TOTAL	0	1 (3.6%)	1 (1.9%)
	ASTHENIA	0	1 (3.6%)	1 (1.9%)

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
TOTAL	TOTAL	4 (6.1%)	9 (15.5%)	13 (10.5%)
Nervous System	TOTAL	3 (4.5%)	8 (13.8%)	11 (8.9%)
	EMOTIONAL LABILITY	3 (4.5%)	1 (1.7%)	4 (3.2%)
	HOSTILITY	0	3 (5.2%)	3 (2.4%)
	ANXIETY	0	2 (3.4%)	2 (1.6%)
	NERVOUSNESS	0	2 (3.4%)	2 (1.6%)
	AGITATION	0	1 (1.7%)	1 (0.8%)
	HALLUCINATIONS	0	1 (1.7%)	1 (0.8%)
	LIBIDO DECREASED	0	1 (1.7%)	1 (0.8%)
Digestive System	TOTAL	1 (1.5%)	0	1 (0.8%)
	NAUSEA	1 (1.5%)	0	1 (0.8%)
Body as a Whole	TOTAL	0	1 (1.7%)	1 (0.8%)
	ASTHENIA	0	1 (1.7%)	1 (0.8%)

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (4.2%)	1 (2.0%)
Urogenital System	TOTAL	0	1 (4.2%)	1 (2.0%)
	FEMALE GENITAL DISORDERS	0	1 (4.2%)	1 (2.0%)

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	8 (9.9%)	8 (12.1%)	16 (10.9%)
Nervous System	TOTAL	6 (7.4%)	7 (10.6%)	13 (8.8%)
	HOSTILITY	2 (2.5%)	2 (3.0%)	4 (2.7%)
	EMOTIONAL LABILITY	3 (3.7%)	0	3 (2.0%)
	HALLUCINATIONS	0	2 (3.0%)	2 (1.4%)
	CONVULSION	1 (1.2%)	0	1 (0.7%)
	DEPRESSION	1 (1.2%)	0	1 (0.7%)
	AGITATION	0	1 (1.5%)	1 (0.7%)
	ANXIETY	0	1 (1.5%)	1 (0.7%)
	LIBIDO DECREASED	0	1 (1.5%)	1 (0.7%)
Digestive System	TOTAL	2 (2.5%)	0	2 (1.4%)
	NAUSEA	1 (1.2%)	0	1 (0.7%)
	VOMITING	1 (1.2%)	0	1 (0.7%)
Cardiovascular System	TOTAL	0	1 (1.5%)	1 (0.7%)
	BUNDLE BRANCH BLOCK	0	1 (1.5%)	1 (0.7%)

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (3.4%)	1 (1.6%)
Urogenital System	TOTAL	0	1 (3.4%)	1 (1.6%)
	FEMALE GENITAL DISORDERS	0	1 (3.4%)	1 (1.6%)

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	2 (3.8%)	13 (20.3%)	15 (12.9%)
Nervous System	TOTAL	2 (3.8%)	11 (17.2%)	13 (11.2%)
	HOSTILITY	1 (1.9%)	4 (6.3%)	5 (4.3%)
	HYPERKINESIA	1 (1.9%)	3 (4.7%)	4 (3.4%)
	NERVOUSNESS	0	3 (4.7%)	3 (2.6%)
	EMOTIONAL LABILITY	1 (1.9%)	1 (1.6%)	2 (1.7%)
	CONCENTRATION IMPAIRED	1 (1.9%)	0	1 (0.9%)
	AGITATION	0	1 (1.6%)	1 (0.9%)
	ANXIETY	0	1 (1.6%)	1 (0.9%)
	MANIC REACTION	0	1 (1.6%)	1 (0.9%)
	PSYCHOSIS	0	1 (1.6%)	1 (0.9%)
Body as a Whole	TOTAL	0	2 (3.1%)	2 (1.7%)
	ASTHENIA	0	1 (1.6%)	1 (0.9%)
	INFECTION	0	1 (1.6%)	1 (0.9%)

Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
Body System	Preferred Term			
TOTAL	TOTAL	10 (7.5%)	21 (16.2%)	31 (11.8%)
Nervous System	TOTAL	8 (6.0%)	18 (13.8%)	26 (9.9%)
	HOSTILITY	3 (2.3%)	6 (4.6%)	9 (3.4%)
	EMOTIONAL LABILITY	4 (3.0%)	1 (0.8%)	5 (1.9%)
	HYPERKINESIA	1 (0.8%)	3 (2.3%)	4 (1.5%)
	NERVOUSNESS	0	3 (2.3%)	3 (1.1%)
	AGITATION	0	2 (1.5%)	2 (0.8%)
	ANXIETY	0	2 (1.5%)	2 (0.8%)
	HALLUCINATIONS	0	2 (1.5%)	2 (0.8%)
	CONCENTRATION IMPAIRED	1 (0.8%)	0	1 (0.4%)
	CONVULSION	1 (0.8%)	0	1 (0.4%)
	DEPRESSION	1 (0.8%)	0	1 (0.4%)
	LIBIDO DECREASED	0	1 (0.8%)	1 (0.4%)
	MANIC REACTION	0	1 (0.8%)	1 (0.4%)
	PSYCHOSIS	0	1 (0.8%)	1 (0.4%)
Digestive System	TOTAL	2 (1.5%)	0	2 (0.8%)
	NAUSEA	1 (0.8%)	0	1 (0.4%)
	VOMITING	1 (0.8%)	0	1 (0.4%)
Body as a Whole	TOTAL	0	2 (1.5%)	2 (0.8%)
	ASTHENIA	0	1 (0.8%)	1 (0.4%)
	INFECTION	0	1 (0.8%)	1 (0.4%)
Cardiovascular System	TOTAL	0	1 (0.8%)	1 (0.4%)
	BUNDLE BRANCH BLOCK	0	1 (0.8%)	1 (0.4%)

Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
by Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	0	1 (2.0%)	1 (0.9%)
Urogenital System	TOTAL	0	1 (2.0%)	1 (0.9%)
	FEMALE GENITAL DISORDERS	0	1 (2.0%)	1 (0.9%)

Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Preferred Term			
TOTAL	3 (7.7%)	3 (8.3%)	6 (8.0%)
HOSTILITY	2 (5.1%)	1 (2.8%)	3 (4.0%)
EMOTIONAL LABILITY	1 (2.6%)	0	1 (1.3%)
AGITATION	0	1 (2.8%)	1 (1.3%)
HALLUCINATIONS	0	1 (2.8%)	1 (1.3%)

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Preferred Term			
TOTAL	1 (3.6%)	6 (16.7%)	7 (10.9%)
HYPERKINESIA	1 (3.6%)	3 (8.3%)	4 (6.3%)
HOSTILITY	1 (3.6%)	2 (5.6%)	3 (4.7%)
NERVOUSNESS	0	1 (2.8%)	1 (1.6%)

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=67)	 Placebo (N=72)	 Total (N=139)
TOTAL	4 (6.0%)	9 (12.5%)	13 (9.4%)
HOSTILITY	3 (4.5%)	3 (4.2%)	6 (4.3%)
HYPERKINESIA	1 (1.5%)	3 (4.2%)	4 (2.9%)
EMOTIONAL LABILITY	1 (1.5%)	0	1 (0.7%)
AGITATION	0	1 (1.4%)	1 (0.7%)
HALLUCINATIONS	0	1 (1.4%)	1 (0.7%)
NERVOUSNESS	0	1 (1.4%)	1 (0.7%)

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Preferred Term			
TOTAL	2 (4.8%)	3 (10.0%)	5 (6.9%)
EMOTIONAL LABILITY	2 (4.8%)	0	2 (2.8%)
ANXIETY	0	1 (3.3%)	1 (1.4%)
HALLUCINATIONS	0	1 (3.3%)	1 (1.4%)
HOSTILITY	0	1 (3.3%)	1 (1.4%)

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Preferred Term			
TOTAL	1 (4.2%)	4 (14.3%)	5 (9.6%)
EMOTIONAL LABILITY	1 (4.2%)	1 (3.6%)	2 (3.8%)
HOSTILITY	0	2 (7.1%)	2 (3.8%)
NERVOUSNESS	0	2 (7.1%)	2 (3.8%)
AGITATION	0	1 (3.6%)	1 (1.9%)
ANXIETY	0	1 (3.6%)	1 (1.9%)

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=66)	 Placebo (N=58)	 Total (N=124)
TOTAL	3 (4.5%)	7 (12.1%)	10 (8.1%)
EMOTIONAL LABILITY	3 (4.5%)	1 (1.7%)	4 (3.2%)
HOSTILITY	0	3 (5.2%)	3 (2.4%)
ANXIETY	0	2 (3.4%)	2 (1.6%)
NERVOUSNESS	0	2 (3.4%)	2 (1.6%)
AGITATION	0	1 (1.7%)	1 (0.8%)
HALLUCINATIONS	0	1 (1.7%)	1 (0.8%)

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group Paroxetine (N=81)	 Placebo (N=66)	 Total (N=147)
TOTAL	5 (6.2%)	6 (9.1%)	11 (7.5%)
HOSTILITY	2 (2.5%)	2 (3.0%)	4 (2.7%)
EMOTIONAL LABILITY	3 (3.7%)	0	3 (2.0%)
HALLUCINATIONS	0	2 (3.0%)	2 (1.4%)
AGITATION	0	1 (1.5%)	1 (0.7%)
ANXIETY	0	1 (1.5%)	1 (0.7%)

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Preferred Term			
TOTAL	2 (3.8%)	10 (15.6%)	12 (10.3%)
HOSTILITY	1 (1.9%)	4 (6.3%)	5 (4.3%)
HYPERKINESIA	1 (1.9%)	3 (4.7%)	4 (3.4%)
NERVOUSNESS	0	3 (4.7%)	3 (2.6%)
EMOTIONAL LABILITY	1 (1.9%)	1 (1.6%)	2 (1.7%)
AGITATION	0	1 (1.6%)	1 (0.9%)
ANXIETY	0	1 (1.6%)	1 (0.9%)

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Preferred Term			
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
TOTAL	7 (5.3%)	16 (12.3%)	23 (8.7%)
HOSTILITY	3 (2.3%)	6 (4.6%)	9 (3.4%)
EMOTIONAL LABILITY	4 (3.0%)	1 (0.8%)	5 (1.9%)
HYPERKINESIA	1 (0.8%)	3 (2.3%)	4 (1.5%)
NERVOUSNESS	0	3 (2.3%)	3 (1.1%)
AGITATION	0	2 (1.5%)	2 (0.8%)
ANXIETY	0	2 (1.5%)	2 (0.8%)
HALLUCINATIONS	0	2 (1.5%)	2 (0.8%)

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

Preferred Term	Acute Study Treatment Group: Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
TOTAL	0	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Open-Label Treatment Phase
Occurring in 1% or More of the Population by Descending Order and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

	Acute Study Treatment Group		
	Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Preferred Term			
TOTAL	0	0	0

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=39)	TRAUMA	0	0.0	2	5.1	0	0.0	0	0.0	2	5.1	0	0.0	0	0.0	5	12.8	1	2.6	1	2.6	0	0.0	0	0.0	11	28.2
	HEADACHE	4	10.3	1	2.6	1	2.6	0	0.0	1	2.6	0	0.0	0	0.0	1	2.6	0	0.0	1	2.6	0	0.0	0	0.0	9	23.1
	RESPIRATORY DISORDER	3	7.7	0	0.0	1	2.6	0	0.0	1	2.6	0	0.0	0	0.0	1	2.6	1	2.6	2	5.1	0	0.0	0	0.0	9	23.1
	PHARYNGITIS	2	5.1	0	0.0	2	5.1	0	0.0	1	2.6	1	2.6	0	0.0	0	0.0	1	2.6	0	0.0	1	2.6	0	0.0	8	20.5
	ABDOMINAL PAIN	0	0.0	3	7.7	2	5.1	0	0.0	2	5.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	7	17.9
	VOMITING	1	2.6	1	2.6	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	2	5.1	0	0.0	0	0.0	2	5.1	0	0.0	7	17.9
	FEVER	0	0.0	1	2.6	1	2.6	1	2.6	2	5.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	12.8
	INFECTION	0	0.0	0	0.0	1	2.6	2	5.1	2	5.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	12.8
	NERVOUSNESS	1	2.6	0	0.0	1	2.6	0	0.0	1	2.6	2	5.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	12.8
	DYSPEPSIA	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	2	5.1	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	4	10.3
	HOSTILITY	1	2.6	0	0.0	0	0.0	0	0.0	2	5.1	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	4	10.3
	RHINITIS	1	2.6	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	1	2.6	0	0.0	0	0.0	4	10.3
	WEIGHT GAIN	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.1	0	0.0	0	0.0	1	2.6	0	0.0	4	10.3
	ALLERGIC REACTION	0	0.0	1	2.6	0	0.0	1	2.6	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	7.7
	COUGH INCREASED	1	2.6	0	0.0	0	0.0	1	2.6	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	7.7
	PAIN	2	5.1	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	7.7
	SINUSITIS	1	2.6	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	3	7.7

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=39)	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	2	5.1
	ARTHRALGIA	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	2	5.1
	ASTHENIA	1	2.6	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.1
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	1	2.6	0	0.0	0	0.0	2	5.1
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	1	2.6	0	0.0	0	0.0	0	0.0	2	5.1
	DIARRHEA	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.1
	DRY MOUTH	2	5.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.1
	FACE EDEMA	0	0.0	1	2.6	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.1
	HYPERKINESIA	1	2.6	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.1
	OTITIS MEDIA	0	0.0	1	2.6	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.1
	AGITATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	1	2.6
	CONSTIPATION	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6
	CONVULSION	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6
	DECREASED APPETITE	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6
	DEHYDRATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	1	2.6
	HALLUCINATIONS	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=39)	HERPES ZOSTER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6
	INCREASED APPETITE	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6
	INSOMNIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6
	NAUSEA	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6
	NEUROSIS	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6
	PYURIA	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6
	RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	1	2.6
	STOMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	1	2.6
	TENDINOUS DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6
	VESTIBULAR DISORDER	0	0.0	0	0.0	1	2.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.6

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=36)	INFECTION	0	0.0	2	5.6	2	5.6	0	0.0	1	2.8	1	2.8	0	0.0	2	5.6	1	2.8	0	0.0	0	0.0	0	0.0	9	25.0
	RESPIRATORY DISORDER	2	5.6	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	6	16.7
	HEADACHE	1	2.8	1	2.8	1	2.8	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	11.1
	PHARYNGITIS	2	5.6	1	2.8	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	11.1
	TRAUMA	1	2.8	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	4	11.1
	VOMITING	2	5.6	0	0.0	0	0.0	1	2.8	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	11.1
	ABDOMINAL PAIN	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	0	0.0	3	8.3
	BACK PAIN	0	0.0	0	0.0	0	0.0	1	2.8	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	3	8.3
	DYSPEPSIA	2	5.6	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	8.3
	INSOMNIA	2	5.6	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	8.3
	RHINITIS	1	2.8	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	8.3
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	1	2.8	0	0.0	1	2.8	0	0.0	0	0.0	3	8.3
	AGITATION	0	0.0	0	0.0	1	2.8	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	1	2.8	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	ASTHENIA	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	EPISTAXIS	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	FEVER	1	2.8	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=36)	HYPESTHESIA	1	2.8	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	1	2.8	0	0.0	2	5.6
	NAUSEA	1	2.8	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	RASH	2	5.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	ABNORMAL VISION	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	ANXIETY	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	ARTHROSIS	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	1	2.8
	BRONCHITIS	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	BUNDLE BRANCH BLOCK	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	1	2.8
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	1	2.8
	COUGH INCREASED	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=36)	CYSTITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	DECREASED APPETITE	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	DEHYDRATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	DIARRHEA	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	DIZZINESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	1	2.8
	EUPHORIA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	GASTROENTERITIS	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	HALLUCINATIONS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	HOSTILITY	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	HYPERKINESIA	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	LIVER FUNCTION TESTS ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	MIGRAINE	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=36)	MYALGIA	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	OTITIS MEDIA	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	PAIN	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	PARALYSIS	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	SINUSITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	SOMNOLENCE	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	SYNCOPE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	TOOTH CARIES	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	TREMOR	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	YAWN	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=20)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=22)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=19)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=14)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=28)	HEADACHE	2	7.1	1	3.6	3	10.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	1	3.6	1	3.6	0	0.0	9	32.1
	HYPERKINESIA	1	3.6	0	0.0	1	3.6	1	3.6	1	3.6	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	5	17.9
	NAUSEA	0	0.0	1	3.6	1	3.6	1	3.6	1	3.6	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	5	17.9
	PHARYNGITIS	0	0.0	1	3.6	0	0.0	0	0.0	1	3.6	1	3.6	0	0.0	1	3.6	1	3.6	0	0.0	0	0.0	0	0.0	5	17.9
	RHINITIS	1	3.6	1	3.6	0	0.0	0	0.0	1	3.6	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	14.3
	TRAUMA	0	0.0	0	0.0	1	3.6	0	0.0	1	3.6	0	0.0	0	0.0	2	7.1	0	0.0	0	0.0	0	0.0	0	0.0	4	14.3
	DIARRHEA	1	3.6	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	3	10.7
	FEVER	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	3	10.7
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	3	10.7
	INSOMNIA	1	3.6	1	3.6	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	10.7
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	1	3.6	0	0.0	0	0.0	1	3.6	0	0.0	3	10.7
	ABDOMINAL PAIN	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	1	3.6	0	0.0	2	7.1
	COUGH INCREASED	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1
	DECREASED APPETITE	2	7.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1
	DYSPEPSIA	0	0.0	1	3.6	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1
	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=28)	PAIN	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1
	RESPIRATORY DISORDER	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	2	7.1
	SINUSITIS	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1
	ABSCESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	1	3.6
	ACNE	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	AGITATION	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	ANXIETY	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	1	3.6
	BACK PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	DEPRESSION	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	DIZZINESS	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	EAR PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	1	3.6
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	GINGIVITIS	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	GLYCOSURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=28)	HAEMATOMA	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	HOSTILITY	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	MYALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	MYOCLONUS	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	NERVOUSNESS	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	PURPURA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	1	3.6
	SOMNOLENCE	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	1	3.6
	VOMITING	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=36)	NERVOUSNESS	2	5.6	0	0.0	3	8.3	0	0.0	2	5.6	1	2.8	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	9	25.0
	HEADACHE	2	5.6	1	2.8	1	2.8	0	0.0	1	2.8	1	2.8	0	0.0	0	0.0	1	2.8	1	2.8	0	0.0	0	0.0	8	22.2
	RESPIRATORY DISORDER	0	0.0	1	2.8	1	2.8	1	2.8	1	2.8	2	5.6	0	0.0	1	2.8	0	0.0	1	2.8	0	0.0	0	0.0	8	22.2
	ABDOMINAL PAIN	1	2.8	2	5.6	2	5.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	13.9
	HOSTILITY	0	0.0	0	0.0	2	5.6	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	4	11.1
	HYPERKINESIA	0	0.0	1	2.8	0	0.0	2	5.6	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	4	11.1
	RHINITIS	0	0.0	1	2.8	0	0.0	1	2.8	0	0.0	1	2.8	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	4	11.1
	TRAUMA	1	2.8	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	4	11.1
	ANXIETY	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	3	8.3
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	1	2.8	1	2.8	0	0.0	0	0.0	0	0.0	3	8.3
	PHARYNGITIS	0	0.0	2	5.6	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	8.3
	VASODILATATION	0	0.0	1	2.8	1	2.8	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	8.3
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	0	0.0	0	0.0	3	8.3
	CONTACT DERMATITIS	1	2.8	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	DECREASED APPETITE	1	2.8	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	DIZZINESS	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=36)	INSOMNIA	0	0.0	1	2.8	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	2	5.6
	RASH	0	0.0	0	0.0	1	2.8	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	SOMNOLENCE	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	VERTIGO	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	2	5.6
	AGITATION	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	COUGH INCREASED	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	DYSKINESIA	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	DYSPEPSIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	EAR PAIN	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	FEVER	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	FLATULENCE	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	FUNGAL DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	GASTROENTERI-TIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=36)	GINGIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	1	2.8
	HERPES SIMPLEX	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	MANIC REACTION	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	MYOCLONUS	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	NAUSEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	OTITIS EXTERNA	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	PSYCHOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	SINUSITIS	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	SPINA BIFIDA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8
	TREMOR	0	0.0	0	0.0	1	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.8

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=12)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=23)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=16)	DYSMENORRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	6.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	6.3

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=13)	DYSMENORRHEA	0	0.0	1	7.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	7.7
	UTERUS DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	7.7	0	0.0	0	0.0	0	0.0	0	0.0	1	7.7

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=67)	HEADACHE	6	9.0	2	3.0	4	6.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5	1	1.5	2	3.0	1	1.5	0	0.0	18	26.9
	TRAUMA	0	0.0	2	3.0	1	1.5	0	0.0	3	4.5	0	0.0	0	0.0	7	10.4	1	1.5	1	1.5	0	0.0	0	0.0	15	22.4
	PHARYNGITIS	2	3.0	1	1.5	2	3.0	0	0.0	2	3.0	2	3.0	0	0.0	1	1.5	2	3.0	0	0.0	1	1.5	0	0.0	13	19.4
	RESPIRATORY DISORDER	3	4.5	0	0.0	1	1.5	1	1.5	1	1.5	0	0.0	0	0.0	1	1.5	1	1.5	2	3.0	1	1.5	0	0.0	11	16.4
	ABDOMINAL PAIN	0	0.0	3	4.5	2	3.0	0	0.0	4	6.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	9	13.4
	FEVER	0	0.0	1	1.5	1	1.5	1	1.5	3	4.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	8	11.9
	INFECTION	0	0.0	0	0.0	1	1.5	2	3.0	3	4.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	8	11.9
	RHINITIS	2	3.0	2	3.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	8	11.9
	VOMITING	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	2	3.0	0	0.0	2	3.0	0	0.0	0	0.0	2	3.0	0	0.0	8	11.9
	HYPERKINESIA	2	3.0	0	0.0	1	1.5	1	1.5	2	3.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	7	10.4
	DYSPEPSIA	0	0.0	1	1.5	0	0.0	2	3.0	0	0.0	2	3.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	6	9.0
	NAUSEA	0	0.0	1	1.5	2	3.0	1	1.5	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	6	9.0
	NERVOUSNESS	2	3.0	0	0.0	1	1.5	0	0.0	1	1.5	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	9.0
	COUGH INCREASED	1	1.5	0	0.0	0	0.0	2	3.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	7.5
	DIARRHEA	2	3.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	5	7.5
	HOSTILITY	1	1.5	0	0.0	0	0.0	1	1.5	2	3.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	5	7.5
	OTITIS MEDIA	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	5	7.5

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=67)	PAIN	2	3.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	5	7.5
	SINUSITIS	1	1.5	1	1.5	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	5	7.5
	INSOMNIA	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.0
	WEIGHT GAIN	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0	0	0.0	0	0.0	1	1.5	0	0.0	4	6.0
	ACNE	0	0.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	3	4.5
	ALLERGIC REACTION	0	0.0	1	1.5	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.5
	DECREASED APPETITE	3	4.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.5
	DEPRESSION	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	3	4.5
	AGITATION	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	2	3.0
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	2	3.0
	ARTHRALGIA	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	2	3.0
	ASTHENIA	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	2	3.0
	DRY MOUTH	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	2	3.0
	FACE EDEMA	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=67)	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	ABSCESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	ANXIETY	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5
	BACK PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	CONSTIPATION	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	CONVULSION	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	DEHYDRATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	DIZZINESS	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	EAR PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5
	GINGIVITIS	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	GLYCOSURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	HAEMATOMA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	HALLUCINATIONS	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	HERPES ZOSTER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=67)	INCREASED APPETITE	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	MYALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	MYOCLONUS	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	NEUROSIS	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	PURPURA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5
	PYURIA	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5
	SOMNOLENCE	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	STOMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5
	TENDINOUS DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	VESTIBULAR DISORDER	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=72)	RESPIRATORY DISORDER	2	2.8	1	1.4	1	1.4	1	1.4	3	4.2	2	2.8	0	0.0	1	1.4	0	0.0	3	4.2	0	0.0	0	0.0	14	19.4
	HEADACHE	3	4.2	2	2.8	2	2.8	1	1.4	1	1.4	1	1.4	0	0.0	0	0.0	1	1.4	1	1.4	0	0.0	0	0.0	12	16.7
	INFECTION	0	0.0	2	2.8	2	2.8	0	0.0	1	1.4	2	2.8	0	0.0	3	4.2	2	2.8	0	0.0	0	0.0	0	0.0	12	16.7
	NERVOUSNESS	2	2.8	0	0.0	3	4.2	0	0.0	2	2.8	1	1.4	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	9	12.5
	ABDOMINAL PAIN	1	1.4	3	4.2	2	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.8	0	0.0	0	0.0	0	0.0	8	11.1
	TRAUMA	2	2.8	1	1.4	0	0.0	0	0.0	2	2.8	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	2	2.8	0	0.0	8	11.1
	PHARYNGITIS	2	2.8	3	4.2	0	0.0	1	1.4	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	7	9.7
	RHINITIS	1	1.4	1	1.4	0	0.0	1	1.4	2	2.8	1	1.4	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	7	9.7
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	1	1.4	1	1.4	0	0.0	0	0.0	3	4.2	0	0.0	1	1.4	0	0.0	0	0.0	6	8.3
	HOSTILITY	0	0.0	0	0.0	2	2.8	2	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	5	6.9
	HYPERKINESIA	0	0.0	2	2.8	0	0.0	2	2.8	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	5	6.9
	INSOMNIA	2	2.8	2	2.8	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	6.9
	ANXIETY	2	2.8	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	4	5.6
	DYSPEPSIA	2	2.8	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	4	5.6
	RASH	2	2.8	0	0.0	1	1.4	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	5.6
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	5.6	0	0.0	0	0.0	0	0.0	0	0.0	4	5.6
	VOMITING	2	2.8	0	0.0	0	0.0	1	1.4	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	5.6

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=72)	AGITATION	1	1.4	0	0.0	1	1.4	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.2
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	2	2.8	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.2
	BACK PAIN	0	0.0	0	0.0	0	0.0	1	1.4	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	3	4.2
	CONTACT DERMATITIS	1	1.4	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	3	4.2
	DECREASED APPETITE	2	2.8	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.2
	DIZZINESS	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	1	1.4	0	0.0	0	0.0	3	4.2
	FEVER	1	1.4	0	0.0	0	0.0	0	0.0	2	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.2
	NAUSEA	1	1.4	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	3	4.2
	OTITIS MEDIA	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	3	4.2
	SOMNOLENCE	0	0.0	0	0.0	0	0.0	1	1.4	1	1.4	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	3	4.2
	VASODILATATION	0	0.0	1	1.4	1	1.4	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.2
	ASTHENIA	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	2	2.8
	COUGH INCREASED	1	1.4	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.8
	EPISTAXIS	0	0.0	0	0.0	0	0.0	0	0.0	2	2.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.8
	GASTROENTERITIS	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.8
	HYPESTHESIA	1	1.4	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.8

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=72)	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	1	1.4	0	0.0	2	2.8
	PAIN	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.8
	SINUSITIS	1	1.4	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.8
	TOOTH CARIES	1	1.4	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.8
	TREMOR	0	0.0	0	0.0	1	1.4	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.8
	VERTIGO	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	2	2.8
	ABNORMAL VISION	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	ARTHROSIS	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	1	1.4
	BRONCHITIS	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	BUNDLE BRANCH BLOCK	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	1	1.4
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	CYSTITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	DEHYDRATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=72)	DIARRHEA	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	DYSKINESIA	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	EAR PAIN	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	EUPHORIA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	FLATULENCE	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	FUNGAL DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	GINGIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	1	1.4
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	HALLUCINATIONS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	HERPES SIMPLEX	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	LIVER FUNCTION TESTS ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	MANIC REACTION	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4

(CONTINUED)

BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=72)	MIGRAINE	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	MYALGIA	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	MYOCLONUS	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	OTITIS EXTERNA	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	PARALYSIS	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	PSYCHOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	SPINA BIFIDA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	SYNCOPE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4
	YAWN	1	1.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=32)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=45)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=35)	DYSMENORRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.9

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=27)	DYSMENORRHEA	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7
	UTERUS DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7

BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=42)	HEADACHE	2	4.8	2	4.8	1	2.4	0	0.0	2	4.8	3	7.1	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	11	26.2
	NAUSEA	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	2	4.8	0	0.0	3	7.1	0	0.0	0	0.0	7	16.7
	RESPIRATORY DISORDER	0	0.0	1	2.4	0	0.0	1	2.4	3	7.1	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	7	16.7
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	3	7.1	1	2.4	0	0.0	0	0.0	2	4.8	0	0.0	0	0.0	0	0.0	6	14.3
	TRAUMA	0	0.0	1	2.4	2	4.8	1	2.4	0	0.0	0	0.0	0	0.0	1	2.4	1	2.4	0	0.0	0	0.0	0	0.0	6	14.3
	SOMNOLENCE	1	2.4	2	4.8	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	5	11.9
	VOMITING	1	2.4	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	2	4.8	0	0.0	1	2.4	0	0.0	0	0.0	5	11.9
	ALLERGIC REACTION	0	0.0	1	2.4	0	0.0	1	2.4	1	2.4	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	4	9.5
	PHARYNGITIS	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	2	4.8	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	4	9.5
	RHINITIS	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	2	4.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	4	9.5
	ABDOMINAL PAIN	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	1	2.4	0	0.0	0	0.0	3	7.1
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	2	4.8	0	0.0	0	0.0	0	0.0	0	0.0	3	7.1
	ASTHMA	1	2.4	0	0.0	0	0.0	2	4.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	7.1
	BACK PAIN	2	4.8	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	7.1
	CHEST PAIN	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	2	4.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	7.1
	DIARRHEA	2	4.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	3	7.1
	DIZZINESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.8	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	3	7.1

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=42)	DYSPEPSIA	0	0.0	1	2.4	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	3	7.1
	FEVER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.8	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	3	7.1
	INFECTION	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	1	2.4	0	0.0	0	0.0	0	0.0	3	7.1
	INSOMNIA	2	4.8	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	7.1
	NERVOUSNESS	2	4.8	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	7.1
	SINUSITIS	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	3	7.1
	AGITATION	1	2.4	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.8
	BRONCHITIS	2	4.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.8
	CONTACT DERMATITIS	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.8
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	ANXIETY	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	ASTHENIA	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	COUGH INCREASED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	DECREASED APPETITE	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	DRY MOUTH	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	DYSPNEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=42)	FUNGAL DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	FURUNCULOSIS	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	GASTRITIS	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	1	2.4
	HEMATEMESIS	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	LYMPHADENOPATHY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	MALAISE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	1	2.4
	MYALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	1	2.4
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	1	2.4
	PARESTHESIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	PNEUMONIA	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	URINARY TRACT INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	VERTIGO	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=42)	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
	WEIGHT LOSS	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=30)	RESPIRATORY DISORDER	2	6.7	0	0.0	1	3.3	0	0.0	2	6.7	1	3.3	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	7	23.3
	HEADACHE	1	3.3	0	0.0	0	0.0	1	3.3	0	0.0	1	3.3	0	0.0	1	3.3	1	3.3	0	0.0	1	3.3	0	0.0	6	20.0
	ASTHENIA	0	0.0	1	3.3	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	3	10.0
	EMOTIONAL LABILITY	0	0.0	1	3.3	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	3	10.0
	WEIGHT GAIN	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	1	3.3	0	0.0	0	0.0	0	0.0	3	10.0
	ASTHMA	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	2	6.7
	BRONCHITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	1	3.3	0	0.0	0	0.0	0	0.0	2	6.7
	DECREASED APPETITE	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	6.7
	INCREASED APPETITE	0	0.0	0	0.0	1	3.3	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	6.7
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	2	6.7
	INSOMNIA	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	2	6.7
	NAUSEA	1	3.3	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	6.7
	SOMNOLENCE	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	2	6.7
	TRAUMA	0	0.0	0	0.0	1	3.3	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	6.7
	ABDOMINAL PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	1	3.3
	ACNE	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=30)	AGITATION	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	1	3.3
	ANXIETY	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	COUGH INCREASED	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	DIARRHEA	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	DIZZINESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	DYSPEPSIA	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	FEVER	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	GASTROINTEST-INAL DISORDER	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	1	3.3
	HALLUCINATIO-NS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	1	3.3
	HOSTILITY	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	LIBIDO DECREASED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	NERVOUSNESS	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	PAIN	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=30)	PHARYNGITIS	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	RHINITIS	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	SYNCOPE	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	TREMOR	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3
	WITHDRAWAL SYNDROME	1	3.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.3

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=28)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																												
Placebo (N=15)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=14)	DYSMENORRHEA	0	0.0	1	7.1	0	0.0	0	0.0	1	7.1	0	0.0	0	0.0	1	7.1	0	0.0	0	0.0	0	0.0	0	0.0	3	21.4

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=15)	FEMALE GENITAL DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	6.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	6.7
	MENSTRUAL DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	6.7	0	0.0	0	0.0	0	0.0	0	0.0	1	6.7

BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=24)	HEADACHE	3	12.5	0	0.0	1	4.2	1	4.2	1	4.2	2	8.3	0	0.0	0	0.0	1	4.2	0	0.0	1	4.2	0	0.0	10	41.7
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.3	0	0.0	2	8.3	0	0.0	0	0.0	1	4.2	0	0.0	5	20.8
	ALLERGIC REACTION	0	0.0	1	4.2	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	2	8.3	0	0.0	0	0.0	0	0.0	0	0.0	4	16.7
	RESPIRATORY DISORDER	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	1	4.2	1	4.2	0	0.0	0	0.0	4	16.7
	ABDOMINAL PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	1	4.2	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	3	12.5
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	4.2	2	8.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	12.5
	ASTHENIA	1	4.2	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	3	12.5
	NEUROSIS	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	3	12.5
	SINUSITIS	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	3	12.5
	ARTHRALGIA	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.3
	DIZZINESS	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	2	8.3
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.3
	INSOMNIA	0	0.0	2	8.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	8.3
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	1	4.2	0	0.0	0	0.0	2	8.3
	ABNORMAL DREAMS	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=24)	ABNORMAL LABORATORY VALUE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	ANXIETY	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	ARTHROSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	BLEPHARITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	BRONCHITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	1	4.2
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	CONSTIPATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	1	4.2
	DIARRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	DYSURIA	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	EYE PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	HOSTILITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	HYPERKINESIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	MANIC REACTION	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	NAUSEA	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2

(CONTINUED)

BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=24)	NERVOUSNESS	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	1	4.2
	PHARYNGITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	PLEURA DISORDER	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	RHINITIS	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	SOMNOLENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	TRAUMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	1	4.2
	VERTIGO	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=28)	HEADACHE	2	7.1	2	7.1	1	3.6	0	0.0	1	3.6	3	10.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	9	32.1
	NAUSEA	1	3.6	1	3.6	0	0.0	0	0.0	1	3.6	2	7.1	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	6	21.4
	RESPIRATORY DISORDER	1	3.6	1	3.6	1	3.6	1	3.6	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	17.9
	ASTHENIA	1	3.6	1	3.6	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	4	14.3
	INSOMNIA	1	3.6	1	3.6	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	4	14.3
	TRAUMA	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	2	7.1	0	0.0	1	3.6	0	0.0	4	14.3
	ABDOMINAL PAIN	1	3.6	0	0.0	1	3.6	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	10.7
	ALLERGIC REACTION	0	0.0	1	3.6	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	3	10.7
	HOSTILITY	0	0.0	0	0.0	1	3.6	1	3.6	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	10.7
	INFECTION	1	3.6	2	7.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	10.7
	NERVOUSNESS	0	0.0	0	0.0	1	3.6	1	3.6	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	10.7
	ACNE	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1
	AGITATION	1	3.6	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1
	ASTHMA	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1
	DECREASED APPETITE	1	3.6	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1
	DRY MOUTH	2	7.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1
	DYSPEPSIA	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=28)	FEVER	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1
	HYPERKINESIA	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1
	PHARYNGITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	7.1	0	0.0	0	0.0	2	7.1
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	ABNORMAL VISION	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	ANXIETY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	1	3.6
	ARTHRALGIA	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	BACK PAIN	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	CONSTIPATION	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	CONTACT DERMATITIS	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	DEPRESSION	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	DIARRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	DIZZINESS	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	EOSINOPHILIA	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	EPISTAXIS	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	FLATULENCE	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=28)	LEUKOCYTOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	1	3.6
	MONOCYTOSIS	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	NEUROSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	1	3.6
	OTITIS MEDIA	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	PHOTOPHOBIA	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	RASH	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	RHINITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	SOMNOLENCE	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	SWEATING	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	SYNCOPE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	1	3.6
	TREMOR	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	ULCERATIVE STOMATITIS	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	URTICARIA	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	VASODILATATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6
	WEIGHT LOSS	0	0.0	0	0.0	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.6

BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																												
Paroxetine (N=12)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=19)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=12)	DYSMENORRHEA	1	8.3	0	0.0	0	0.0	1	8.3	1	8.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	25.0

BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=9)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=66)	HEADACHE	5	7.6	2	3.0	2	3.0	1	1.5	3	4.5	5	7.6	0	0.0	0	0.0	1	1.5	1	1.5	1	1.5	0	0.0	21	31.8
	RESPIRATORY DISORDER	1	1.5	1	1.5	0	0.0	1	1.5	3	4.5	1	1.5	0	0.0	1	1.5	1	1.5	1	1.5	1	1.5	0	0.0	11	16.7
	ALLERGIC REACTION	0	0.0	2	3.0	0	0.0	1	1.5	2	3.0	0	0.0	0	0.0	2	3.0	1	1.5	0	0.0	0	0.0	0	0.0	8	12.1
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	4	6.1	2	3.0	0	0.0	0	0.0	2	3.0	0	0.0	0	0.0	0	0.0	8	12.1
	INFECTION	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0	0	0.0	3	4.5	1	1.5	0	0.0	1	1.5	0	0.0	8	12.1
	NAUSEA	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	2	3.0	0	0.0	3	4.5	0	0.0	0	0.0	8	12.1
	TRAUMA	0	0.0	1	1.5	2	3.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	1	1.5	1	1.5	0	0.0	0	0.0	7	10.6
	ABDOMINAL PAIN	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5	1	1.5	0	0.0	1	1.5	0	0.0	2	3.0	0	0.0	0	0.0	6	9.1
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	2	3.0	2	3.0	0	0.0	0	0.0	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	6	9.1
	SINUSITIS	0	0.0	2	3.0	0	0.0	0	0.0	0	0.0	2	3.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	6	9.1
	SOMNOLENCE	1	1.5	2	3.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	6	9.1
	DIZZINESS	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	2	3.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	5	7.6
	INSOMNIA	2	3.0	3	4.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	7.6
	PHARYNGITIS	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	2	3.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	5	7.6
	RHINITIS	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	5	7.6
	VOMITING	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0	0	0.0	1	1.5	0	0.0	0	0.0	5	7.6
	ASTHENIA	1	1.5	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	4	6.1

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=66)	ASTHMA	1	1.5	0	0.0	0	0.0	2	3.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.1
	DIARRHEA	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	4	6.1
	NERVOUSNESS	2	3.0	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.1
	BACK PAIN	2	3.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.5
	BRONCHITIS	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	3	4.5
	CHEST PAIN	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.5
	DYSPEPSIA	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	3	4.5
	FEVER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	3	4.5
	NEUROSIS	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	3	4.5
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0	0	0.0	1	1.5	0	0.0	0	0.0	3	4.5
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	AGITATION	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	ANXIETY	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	ARTHRALGIA	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	CONTACT DERMATITIS	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	2	3.0
	VERTIGO	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	ABNORMAL DREAMS	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=66)	ABNORMAL LABORATORY VALUE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	ARTHROSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	BLEPHARITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	CONSTIPATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5
	COUGH INCREASED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	DECREASED APPETITE	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	DRY MOUTH	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	DYSPNEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	DYSURIA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	EYE PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	FUNGAL DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	FURUNCULOSIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	GASTRITIS	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	HEMATEMESIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=66)	HOSTILITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	HYPERKINESIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	LYMPHADENOPATHY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	MALAISE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5
	MANIC REACTION	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	MYALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5
	PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5
	PARESTHESIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	PLEURA DISORDER	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	PNEUMONIA	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5

(CONTINUED)

BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=66)	URINARY TRACT INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	WEIGHT LOSS	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=58)	HEADACHE	3	5.2	2	3.4	1	1.7	1	1.7	1	1.7	4	6.9	0	0.0	1	1.7	1	1.7	0	0.0	1	1.7	0	0.0	15	25.9
	RESPIRATORY DISORDER	3	5.2	1	1.7	2	3.4	1	1.7	3	5.2	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	12	20.7
	NAUSEA	2	3.4	1	1.7	1	1.7	0	0.0	1	1.7	2	3.4	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	8	13.8
	ASTHENIA	1	1.7	2	3.4	0	0.0	1	1.7	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7	1	1.7	0	0.0	7	12.1
	INSOMNIA	1	1.7	1	1.7	0	0.0	1	1.7	1	1.7	0	0.0	0	0.0	0	0.0	2	3.4	0	0.0	0	0.0	0	0.0	6	10.3
	TRAUMA	0	0.0	0	0.0	1	1.7	1	1.7	1	1.7	0	0.0	0	0.0	0	0.0	2	3.4	0	0.0	1	1.7	0	0.0	6	10.3
	INFECTION	1	1.7	2	3.4	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	5	8.6
	ABDOMINAL PAIN	1	1.7	0	0.0	1	1.7	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	4	6.9
	ASTHMA	0	0.0	1	1.7	0	0.0	1	1.7	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	4	6.9
	DECREASED APPETITE	2	3.4	0	0.0	0	0.0	0	0.0	1	1.7	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.9
	EMOTIONAL LABILITY	0	0.0	1	1.7	0	0.0	2	3.4	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	4	6.9
	HOSTILITY	0	0.0	0	0.0	1	1.7	1	1.7	2	3.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.9
	NERVOUSNESS	1	1.7	0	0.0	1	1.7	1	1.7	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.9
	ACNE	0	0.0	1	1.7	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	3	5.2
	AGITATION	2	3.4	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	5.2
	ALLERGIC REACTION	0	0.0	1	1.7	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	3	5.2

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=58)	DYSPEPSIA	0	0.0	1	1.7	1	1.7	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	5.2
	FEVER	0	0.0	1	1.7	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	3	5.2
	PHARYNGITIS	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.4	0	0.0	0	0.0	3	5.2
	SOMNOLENCE	0	0.0	0	0.0	2	3.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	3	5.2
	WEIGHT GAIN	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	1	1.7	0	0.0	0	0.0	0	0.0	3	5.2
	ANXIETY	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	2	3.4
	BRONCHITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	1	1.7	0	0.0	0	0.0	0	0.0	2	3.4
	DIARRHEA	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.4
	DIZZINESS	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	2	3.4
	DRY MOUTH	2	3.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.4
	HYPERKINESIA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.4
	INCREASED APPETITE	0	0.0	0	0.0	1	1.7	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.4
	RHINITIS	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.4
	SYNCOPE	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	2	3.4
	TREMOR	2	3.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.4
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	ABNORMAL VISION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=58)	ALBUMINURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	1	1.7
	ARTHRALGIA	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	BACK PAIN	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	CONSTIPATION	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	CONTACT DERMATITIS	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	COUGH INCREASED	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	DEPRESSION	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	EOSINOPHILIA	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	EPISTAXIS	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	FLATULENCE	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	GASTROINTEST-INAL DISORDER	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	1	1.7
	HALLUCINATIO-NS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	1	1.7
	LEUKOCYTOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	1	1.7
	LIBIDO DECREASED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=58)	MONOCYTOSIS	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	NEUROSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7
	OTITIS MEDIA	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	PAIN	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	PHOTOPHOBIA	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	RASH	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	SWEATING	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7
	ULCERATIVE STOMATITIS	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	URTICARIA	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	VASODILATATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	WEIGHT LOSS	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	WITHDRAWAL SYNDROME	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																												
Paroxetine (N=40)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=34)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=26)	DYSMENORRHEA	1	3.8	1	3.8	0	0.0	1	3.8	2	7.7	0	0.0	0	0.0	1	3.8	0	0.0	0	0.0	0	0.0	0	0.0	6	23.1

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=24)	FEMALE GENITAL DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2
	MENSTRUAL DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	0	0.0	0	0.0	0	0.0	1	4.2

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=81)	HEADACHE	6	7.4	3	3.7	2	2.5	0	0.0	3	3.7	3	3.7	0	0.0	1	1.2	0	0.0	2	2.5	0	0.0	0	0.0	20	24.7
	TRAUMA	0	0.0	3	3.7	2	2.5	1	1.2	2	2.5	0	0.0	0	0.0	6	7.4	2	2.5	1	1.2	0	0.0	0	0.0	17	21.0
	RESPIRATORY DISORDER	3	3.7	1	1.2	1	1.2	1	1.2	4	4.9	1	1.2	0	0.0	1	1.2	1	1.2	2	2.5	1	1.2	0	0.0	16	19.8
	PHARYNGITIS	3	3.7	0	0.0	2	2.5	0	0.0	1	1.2	3	3.7	0	0.0	1	1.2	1	1.2	0	0.0	1	1.2	0	0.0	12	14.8
	VOMITING	2	2.5	1	1.2	1	1.2	0	0.0	0	0.0	1	1.2	0	0.0	4	4.9	0	0.0	1	1.2	2	2.5	0	0.0	12	14.8
	ABDOMINAL PAIN	0	0.0	3	3.7	3	3.7	0	0.0	2	2.5	0	0.0	0	0.0	1	1.2	0	0.0	1	1.2	0	0.0	0	0.0	10	12.3
	FEVER	0	0.0	1	1.2	1	1.2	1	1.2	2	2.5	2	2.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	8	9.9
	INFECTION	1	1.2	0	0.0	1	1.2	2	2.5	2	2.5	0	0.0	0	0.0	1	1.2	1	1.2	0	0.0	0	0.0	0	0.0	8	9.9
	NAUSEA	1	1.2	0	0.0	1	1.2	0	0.0	0	0.0	1	1.2	0	0.0	2	2.5	0	0.0	3	3.7	0	0.0	0	0.0	8	9.9
	NERVOUSNESS	3	3.7	1	1.2	1	1.2	0	0.0	1	1.2	2	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	8	9.9
	RHINITIS	1	1.2	1	1.2	0	0.0	1	1.2	0	0.0	2	2.5	0	0.0	0	0.0	1	1.2	1	1.2	1	1.2	0	0.0	8	9.9
	ALLERGIC REACTION	0	0.0	2	2.5	0	0.0	2	2.5	2	2.5	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	7	8.6
	DYSPEPSIA	0	0.0	1	1.2	0	0.0	2	2.5	0	0.0	2	2.5	0	0.0	0	0.0	0	0.0	2	2.5	0	0.0	0	0.0	7	8.6
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	3	3.7	1	1.2	0	0.0	0	0.0	3	3.7	0	0.0	0	0.0	0	0.0	7	8.6
	SINUSITIS	1	1.2	1	1.2	1	1.2	0	0.0	0	0.0	1	1.2	0	0.0	1	1.2	0	0.0	0	0.0	1	1.2	0	0.0	6	7.4
	DIARRHEA	3	3.7	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	5	6.2
	SOMNOLENCE	1	1.2	2	2.5	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	5	6.2

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=81)	WEIGHT GAIN	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3.7	0	0.0	0	0.0	1	1.2	0	0.0	5	6.2
	CONTACT DERMATITIS	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	1	1.2	0	0.0	1	1.2	0	0.0	0	0.0	4	4.9
	COUGH INCREASED	1	1.2	0	0.0	0	0.0	1	1.2	1	1.2	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	4.9
	HOSTILITY	1	1.2	0	0.0	0	0.0	0	0.0	2	2.5	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	4	4.9
	INSOMNIA	2	2.5	1	1.2	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	4.9
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	2	2.5	0	0.0	0	0.0	0	0.0	0	0.0	3	3.7
	AGITATION	1	1.2	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	3	3.7
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	2	2.5	0	0.0	0	0.0	0	0.0	0	0.0	3	3.7
	ASTHENIA	1	1.2	1	1.2	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3.7
	ASTHMA	1	1.2	0	0.0	0	0.0	2	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3.7
	BACK PAIN	2	2.5	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3.7
	CHEST PAIN	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	2	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3.7
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	1	1.2	1	1.2	0	0.0	0	0.0	0	0.0	3	3.7
	DIZZINESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.5	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	3	3.7
	DRY MOUTH	3	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3.7
	OTITIS MEDIA	0	0.0	1	1.2	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	3	3.7
	PAIN	2	2.5	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3.7
	ARTHRALGIA	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	2	2.5

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=81)	BRONCHITIS	2	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.5
	DECREASED APPETITE	1	1.2	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.5
	FACE EDEMA	0	0.0	1	1.2	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.5
	HYPERKINESIA	1	1.2	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.5
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.5
	ANXIETY	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	CONSTIPATION	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	CONVULSION	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	DEHYDRATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	DYSPNEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	FUNGAL DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	FURUNCULOSIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	GASTRITIS	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	1	1.2
	HALLUCINATIONS	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	HEMATEMESIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	HERPES ZOSTER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=81)	INCREASED APPETITE	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	LYMPHADENOPATHY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	MALAISE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	1	1.2
	MYALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	1	1.2
	NEUROSIS	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	PARESTHESIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	PNEUMONIA	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	PYURIA	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	1	1.2
	STOMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	1	1.2
	TENDINOUS DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	URINARY TRACT INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=81)	VERTIGO	0	0.0	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	VESTIBULAR DISORDER	0	0.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2
	WEIGHT LOSS	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.2

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=66)	RESPIRATORY DISORDER	4	6.1	0	0.0	1	1.5	0	0.0	4	6.1	1	1.5	0	0.0	0	0.0	0	0.0	3	4.5	0	0.0	0	0.0	13	19.7
	INFECTION	0	0.0	2	3.0	2	3.0	0	0.0	2	3.0	1	1.5	0	0.0	3	4.5	1	1.5	0	0.0	0	0.0	0	0.0	11	16.7
	HEADACHE	2	3.0	1	1.5	1	1.5	2	3.0	0	0.0	1	1.5	0	0.0	1	1.5	1	1.5	0	0.0	1	1.5	0	0.0	10	15.2
	TRAUMA	1	1.5	0	0.0	1	1.5	1	1.5	2	3.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	6	9.1
	WEIGHT GAIN	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	2	3.0	1	1.5	1	1.5	0	0.0	0	0.0	6	9.1
	ASTHENIA	1	1.5	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	5	7.6
	INSOMNIA	2	3.0	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	5	7.6
	PHARYNGITIS	3	4.5	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	7.6
	ABDOMINAL PAIN	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.5	0	0.0	0	0.0	0	0.0	4	6.1
	DYSPEPSIA	2	3.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.1
	NAUSEA	2	3.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.1
	RHINITIS	1	1.5	1	1.5	0	0.0	0	0.0	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.1
	VOMITING	2	3.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.1
	AGITATION	1	1.5	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.5
	ASTHMA	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	3	4.5
	BACK PAIN	0	0.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	3	4.5
	BRONCHITIS	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	3	4.5

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=66)	DECREASED APPETITE	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.5
	EMOTIONAL LABILITY	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	3	4.5
	FEVER	1	1.5	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.5
	SOMNOLENCE	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	3	4.5
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	2	3.0
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	ANXIETY	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	COUGH INCREASED	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	DIARRHEA	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	DIZZINESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	2	3.0
	EPISTAXIS	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	2	3.0
	HALLUCINATIONS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	2	3.0
	HOSTILITY	0	0.0	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	HYPESTHESIA	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=66)	INCREASED APPETITE	0	0.0	0	0.0	1	1.5	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	2	3.0
	PAIN	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	RASH	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	SYNCOPE	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	TOOTH CARIES	1	1.5	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	TREMOR	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.0
	ABNORMAL VISION	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	ACNE	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	ARTHROSIS	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	BUNDLE BRANCH BLOCK	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	1	1.5
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	1	1.5
	CYSTITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=66)	DEHYDRATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	DEPRESSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	EUPHORIA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	GASTROENTERITIS	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	GASTROINTESTINAL DISORDER	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	HYPERKINESIA	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	LIBIDO DECREASED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	LIVER FUNCTION TESTS ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	MIGRAINE	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	MYALGIA	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	NERVOUSNESS	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	OTITIS MEDIA	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	PARALYSIS	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=66)	SINUSITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	WITHDRAWAL SYNDROME	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5
	YAWN	1	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.5

BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=48)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																												
Placebo (N=37)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=33)	DYSMENORRHEA	0	0.0	1	3.0	0	0.0	0	0.0	1	3.0	0	0.0	0	0.0	1	3.0	0	0.0	0	0.0	0	0.0	0	0.0	3	9.1

BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=29)	FEMALE GENITAL DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.4
	MENSTRUAL DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.4	0	0.0	0	0.0	0	0.0	0	0.0	1	3.4

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=52)	HEADACHE	5	9.6	1	1.9	4	7.7	1	1.9	1	1.9	2	3.8	0	0.0	0	0.0	2	3.8	1	1.9	2	3.8	0	0.0	19	36.5
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	3	5.8	0	0.0	2	3.8	0	0.0	0	0.0	2	3.8	0	0.0	8	15.4
	HYPERKINESIA	1	1.9	0	0.0	1	1.9	1	1.9	1	1.9	0	0.0	0	0.0	2	3.8	0	0.0	0	0.0	0	0.0	0	0.0	6	11.5
	NAUSEA	0	0.0	1	1.9	1	1.9	2	3.8	1	1.9	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	6	11.5
	PHARYNGITIS	0	0.0	1	1.9	0	0.0	0	0.0	2	3.8	1	1.9	0	0.0	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	6	11.5
	RESPIRATORY DISORDER	1	1.9	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9	1	1.9	1	1.9	1	1.9	0	0.0	6	11.5
	ABDOMINAL PAIN	0	0.0	0	0.0	0	0.0	0	0.0	3	5.8	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	5	9.6
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	1.9	2	3.8	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9	0	0.0	5	9.6
	INSOMNIA	1	1.9	3	5.8	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	9.6
	RHINITIS	1	1.9	1	1.9	1	1.9	0	0.0	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	9.6
	SINUSITIS	0	0.0	2	3.8	0	0.0	0	0.0	0	0.0	2	3.8	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	5	9.6
	TRAUMA	0	0.0	0	0.0	1	1.9	0	0.0	1	1.9	0	0.0	0	0.0	2	3.8	0	0.0	1	1.9	0	0.0	0	0.0	5	9.6
	ALLERGIC REACTION	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	2	3.8	0	0.0	0	0.0	0	0.0	0	0.0	4	7.7
	DIARRHEA	1	1.9	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	4	7.7
	ASTHENIA	1	1.9	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	3	5.8
	DIZZINESS	1	1.9	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	3	5.8
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	1	1.9	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	5.8

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=52)	FEVER	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	3	5.8
	NEUROSIS	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	3	5.8
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9	0	0.0	3	5.8
	PAIN	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	3	5.8
	ACNE	0	0.0	0	0.0	0	0.0	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8
	ANXIETY	1	1.9	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8
	ARTHRALGIA	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	2	3.8
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8
	COUGH INCREASED	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8
	DECREASED APPETITE	2	3.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8
	DYSPEPSIA	0	0.0	1	1.9	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8
	HOSTILITY	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8
	NERVOUSNESS	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8
	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8
	SOMNOLENCE	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=52)	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	1	1.9	0	0.0	0	0.0	2	3.8
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	1	1.9	0	0.0	0	0.0	2	3.8
	ABNORMAL DREAMS	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	ABNORMAL LABORATORY VALUE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	ABSCESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	1	1.9
	AGITATION	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	ARTHROSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	BACK PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	BLEPHARITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	BRONCHITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9
	CONSTIPATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9
	DEPRESSION	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	DYSURIA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	EAR PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	1	1.9
	EYE PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	GINGIVITIS	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9

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BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=52)	GLYCOSURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	HAEMATOMA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	MANIC REACTION	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	MYALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	MYOCLONUS	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	PLEURA DISORDER	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	PURPURA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9
	VERTIGO	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	VOMITING	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=64)	HEADACHE	4	6.3	3	4.7	2	3.1	0	0.0	2	3.1	4	6.3	0	0.0	0	0.0	1	1.6	1	1.6	0	0.0	0	0.0	17	26.6
	RESPIRATORY DISORDER	1	1.6	2	3.1	2	3.1	2	3.1	2	3.1	2	3.1	0	0.0	1	1.6	0	0.0	1	1.6	0	0.0	0	0.0	13	20.3
	NERVOUSNESS	2	3.1	0	0.0	4	6.3	1	1.6	3	4.7	1	1.6	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	12	18.8
	ABDOMINAL PAIN	2	3.1	2	3.1	3	4.7	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	8	12.5
	TRAUMA	1	1.6	1	1.6	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	2	3.1	0	0.0	3	4.7	0	0.0	8	12.5
	HOSTILITY	0	0.0	0	0.0	3	4.7	2	3.1	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	7	10.9
	NAUSEA	1	1.6	1	1.6	0	0.0	0	0.0	1	1.6	2	3.1	0	0.0	2	3.1	0	0.0	0	0.0	0	0.0	0	0.0	7	10.9
	HYPERKINESIA	0	0.0	1	1.6	0	0.0	2	3.1	1	1.6	1	1.6	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	6	9.4
	INFECTION	1	1.6	2	3.1	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	1	1.6	1	1.6	0	0.0	0	0.0	0	0.0	6	9.4
	INSOMNIA	1	1.6	2	3.1	0	0.0	2	3.1	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	6	9.4
	PHARYNGITIS	0	0.0	2	3.1	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	2	3.1	0	0.0	0	0.0	5	7.8
	RHINITIS	0	0.0	1	1.6	0	0.0	1	1.6	0	0.0	2	3.1	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	5	7.8
	ALLERGIC REACTION	0	0.0	1	1.6	0	0.0	1	1.6	1	1.6	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	4	6.3
	ANXIETY	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	1	1.6	0	0.0	1	1.6	0	0.0	0	0.0	4	6.3
	ASTHENIA	1	1.6	1	1.6	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	4	6.3
	DECREASED APPETITE	2	3.1	1	1.6	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.3

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=64)	VASODILATATION	0	0.0	1	1.6	1	1.6	0	0.0	0	0.0	2	3.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.3
	AGITATION	2	3.1	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.7
	CONTACT DERMATITIS	1	1.6	0	0.0	2	3.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.7
	DIZZINESS	2	3.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	3	4.7
	DYSPEPSIA	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	1	1.6	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	3	4.7
	FEVER	0	0.0	1	1.6	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	3	4.7
	OTITIS MEDIA	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	3	4.7
	RASH	1	1.6	0	0.0	1	1.6	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	4.7
	SOMNOLENCE	0	0.0	0	0.0	1	1.6	1	1.6	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	3	4.7
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	2	3.1	0	0.0	0	0.0	0	0.0	0	0.0	3	4.7
	ACNE	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	2	3.1
	ASTHMA	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.1
	DRY MOUTH	2	3.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.1
	FLATULENCE	0	0.0	1	1.6	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.1
	TREMOR	1	1.6	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.1
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.1	0	0.0	0	0.0	0	0.0	0	0.0	2	3.1
	VERTIGO	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	2	3.1

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=64)	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	ABNORMAL VISION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	ARTHRALGIA	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	BACK PAIN	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	CONSTIPATION	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	COUGH INCREASED	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	DEPRESSION	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	DIARRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	DYSKINESIA	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	EAR PAIN	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	EOSINOPHILIA	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	EPISTAXIS	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	FUNGAL DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	GASTROENTERI-TIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	GINGIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	1	1.6

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=64)	HERPES SIMPLEX	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	LEUKOCYTOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	1	1.6
	MANIC REACTION	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	MONOCYTOSIS	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	MYOCLONUS	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	NEUROSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	1	1.6
	OTITIS EXTERNA	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	PHOTOPHOBIA	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	PSYCHOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	SINUSITIS	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	SPINA BIFIDA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	SWEATING	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	SYNCOPE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=64)	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	1	1.6
	ULCERATIVE STOMATITIS	0	0.0	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	URTICARIA	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6
	WEIGHT LOSS	0	0.0	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.6

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=24)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=42)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=28)	DYSMENORRHEA	1	3.6	0	0.0	0	0.0	1	3.6	1	3.6	1	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	14.3

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=22)	DYSMENORRHEA	0	0.0	1	4.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.5
	UTERUS DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	4.5	0	0.0	0	0.0	0	0.0	0	0.0	1	4.5

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=133)	HEADACHE	11	8.3	4	3.0	6	4.5	1	0.8	4	3.0	5	3.8	0	0.0	1	0.8	2	1.5	3	2.3	2	1.5	0	0.0	39	29.3
	RESPIRATORY DISORDER	4	3.0	1	0.8	1	0.8	2	1.5	4	3.0	1	0.8	0	0.0	2	1.5	2	1.5	3	2.3	2	1.5	0	0.0	22	16.5
	TRAUMA	0	0.0	3	2.3	3	2.3	1	0.8	3	2.3	0	0.0	0	0.0	8	6.0	2	1.5	2	1.5	0	0.0	0	0.0	22	16.5
	PHARYNGITIS	3	2.3	1	0.8	2	1.5	0	0.0	3	2.3	4	3.0	0	0.0	2	1.5	2	1.5	0	0.0	1	0.8	0	0.0	18	13.5
	INFECTION	1	0.8	0	0.0	1	0.8	2	1.5	3	2.3	3	2.3	0	0.0	3	2.3	1	0.8	0	0.0	2	1.5	0	0.0	16	12.0
	ABDOMINAL PAIN	0	0.0	3	2.3	3	2.3	0	0.0	5	3.8	1	0.8	0	0.0	1	0.8	0	0.0	2	1.5	0	0.0	0	0.0	15	11.3
	NAUSEA	1	0.8	1	0.8	2	1.5	2	1.5	1	0.8	1	0.8	0	0.0	3	2.3	0	0.0	3	2.3	0	0.0	0	0.0	14	10.5
	RHINITIS	2	1.5	2	1.5	1	0.8	1	0.8	1	0.8	3	2.3	0	0.0	0	0.0	1	0.8	1	0.8	1	0.8	0	0.0	13	9.8
	VOMITING	2	1.5	1	0.8	1	0.8	0	0.0	0	0.0	2	1.5	0	0.0	4	3.0	0	0.0	1	0.8	2	1.5	0	0.0	13	9.8
	ALLERGIC REACTION	0	0.0	3	2.3	0	0.0	2	1.5	3	2.3	0	0.0	0	0.0	2	1.5	1	0.8	0	0.0	0	0.0	0	0.0	11	8.3
	FEVER	0	0.0	1	0.8	1	0.8	1	0.8	3	2.3	3	2.3	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5	0	0.0	11	8.3
	SINUSITIS	1	0.8	3	2.3	1	0.8	0	0.0	0	0.0	3	2.3	0	0.0	2	1.5	0	0.0	0	0.0	1	0.8	0	0.0	11	8.3
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	1	0.8	4	3.0	2	1.5	0	0.0	0	0.0	3	2.3	0	0.0	0	0.0	0	0.0	10	7.5
	NERVOUSNESS	4	3.0	2	1.5	1	0.8	0	0.0	1	0.8	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	10	7.5
	DIARRHEA	4	3.0	0	0.0	1	0.8	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	9	6.8
	DYSPEPSIA	0	0.0	2	1.5	0	0.0	3	2.3	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0	9	6.8
	INSOMNIA	3	2.3	4	3.0	0	0.0	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	9	6.8

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=133)	ALBUMINURIA	0	0.0	0	0.0	0	0.0	2	1.5	2	1.5	0	0.0	0	0.0	3	2.3	0	0.0	0	0.0	1	0.8	0	0.0	8	6.0
	HYPERKINESIA	2	1.5	0	0.0	1	0.8	1	0.8	2	1.5	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	8	6.0
	SOMNOLENCE	2	1.5	2	1.5	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	7	5.3
	WEIGHT GAIN	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	3.0	0	0.0	1	0.8	1	0.8	0	0.0	7	5.3
	ASTHENIA	2	1.5	1	0.8	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	6	4.5
	COUGH INCREASED	1	0.8	0	0.0	0	0.0	2	1.5	1	0.8	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	4.5
	DIZZINESS	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	2	1.5	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	6	4.5
	HOSTILITY	1	0.8	0	0.0	0	0.0	1	0.8	2	1.5	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	6	4.5
	OTITIS MEDIA	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	1	0.8	1	0.8	0	0.0	1	0.8	0	0.0	6	4.5
	PAIN	2	1.5	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	6	4.5
	ACNE	0	0.0	0	0.0	0	0.0	1	0.8	2	1.5	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	5	3.8
	ASTHMA	1	0.8	0	0.0	0	0.0	2	1.5	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	5	3.8
	AGITATION	1	0.8	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	4	3.0
	ARTHRALGIA	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	4	3.0
	BACK PAIN	2	1.5	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	3.0
	CONTACT DERMATITIS	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	4	3.0
	DECREASED APPETITE	3	2.3	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	3.0

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=133)	DEPRESSION	0	0.0	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	4	3.0
	NEUROSIS	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	4	3.0
	ANXIETY	2	1.5	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.3
	BRONCHITIS	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	3	2.3
	CHEST PAIN	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.3
	DRY MOUTH	3	2.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.3
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	CONSTIPATION	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	2	1.5
	FACE EDEMA	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	2	1.5
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	MYALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	2	1.5
	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	2	1.5
	VERTIGO	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	ABNORMAL DREAMS	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=133)	ABNORMAL LABORATORY VALUE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	ABSCESS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	ARTHROSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	BLEPHARITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	CONVULSION	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	DEHYDRATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	DYSPNEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	DYSURIA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	EAR PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8
	EYE PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	FUNGAL DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	FURUNCULOSIS	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	GASTRITIS	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	GINGIVITIS	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	GLYCOSURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	HAEMATOMA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Paroxetine (N=133)	HALLUCINATIONS	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	HEMATEMESIS	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	HERPES ZOSTER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	INCREASED APPETITE	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	LYMPHADENOPATHY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	MALAISE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8
	MANIC REACTION	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	MYOCLONUS	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	PARESTHESIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	PLEURA DISORDER	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	PNEUMONIA	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	PURPURA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=133)	PYURIA	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8
	STOMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8
	TENDINOUS DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	URINARY TRACT INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	VESTIBULAR DISORDER	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	WEIGHT LOSS	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=130)	HEADACHE	6	4.6	4	3.1	3	2.3	2	1.5	2	1.5	5	3.8	0	0.0	1	0.8	2	1.5	1	0.8	1	0.8	0	0.0	27	20.8
	RESPIRATORY DISORDER	5	3.8	2	1.5	3	2.3	2	1.5	6	4.6	3	2.3	0	0.0	1	0.8	0	0.0	4	3.1	0	0.0	0	0.0	26	20.0
	INFECTION	1	0.8	4	3.1	2	1.5	0	0.0	2	1.5	2	1.5	0	0.0	4	3.1	2	1.5	0	0.0	0	0.0	0	0.0	17	13.1
	TRAUMA	2	1.5	1	0.8	1	0.8	1	0.8	3	2.3	0	0.0	0	0.0	1	0.8	2	1.5	0	0.0	3	2.3	0	0.0	14	10.8
	NERVOUSNESS	3	2.3	0	0.0	4	3.1	1	0.8	3	2.3	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	13	10.0
	ABDOMINAL PAIN	2	1.5	3	2.3	3	2.3	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	3	2.3	0	0.0	0	0.0	0	0.0	12	9.2
	INSOMNIA	3	2.3	3	2.3	0	0.0	2	1.5	1	0.8	0	0.0	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	11	8.5
	NAUSEA	3	2.3	1	0.8	1	0.8	0	0.0	2	1.5	2	1.5	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	11	8.5
	PHARYNGITIS	3	2.3	3	2.3	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0	10	7.7
	ASTHENIA	2	1.5	2	1.5	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	1	0.8	1	0.8	0	0.0	9	6.9
	HOSTILITY	0	0.0	0	0.0	3	2.3	3	2.3	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	9	6.9
	RHINITIS	1	0.8	2	1.5	0	0.0	1	0.8	2	1.5	2	1.5	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	9	6.9
	WEIGHT GAIN	1	0.8	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	4	3.1	1	0.8	1	0.8	0	0.0	0	0.0	9	6.9
	DECREASED APPETITE	4	3.1	1	0.8	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	7	5.4
	DYSPEPSIA	2	1.5	1	0.8	2	1.5	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	7	5.4
	HYPERKINESIA	0	0.0	2	1.5	0	0.0	2	1.5	1	0.8	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	7	5.4
	AGITATION	3	2.3	0	0.0	1	0.8	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	4.6

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=130)	ALLERGIC REACTION	0	0.0	1	0.8	0	0.0	2	1.5	2	1.5	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	6	4.6
	ANXIETY	2	1.5	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	6	4.6
	FEVER	1	0.8	1	0.8	1	0.8	0	0.0	2	1.5	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	6	4.6
	SOMNOLENCE	0	0.0	0	0.0	2	1.5	1	0.8	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	6	4.6
	ASTHMA	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	5	3.8
	DIZZINESS	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5	0	0.0	1	0.8	0	0.0	0	0.0	5	3.8
	RASH	3	2.3	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	3.8
	BACK PAIN	0	0.0	0	0.0	1	0.8	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	4	3.1
	CONTACT DERMATITIS	1	0.8	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	4	3.1
	EMOTIONAL LABILITY	0	0.0	1	0.8	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	4	3.1
	OTITIS MEDIA	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	4	3.1
	TREMOR	2	1.5	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	3.1
	URINARY INCONTINENCE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	3.1	0	0.0	0	0.0	0	0.0	0	0.0	4	3.1
	VASODILATATION	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	3.1
	VOMITING	2	1.5	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	3.1
	ACNE	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	3	2.3

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=130)	BRONCHITIS	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	3	2.3
	COUGH INCREASED	1	0.8	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.3
	DIARRHEA	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.3
	EPISTAXIS	0	0.0	1	0.8	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.3
	PAIN	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.3
	SYNCOPE	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	3	2.3
	TOOTH CARIES	1	0.8	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.3
	ABNORMAL VISION	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	2	1.5
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	DEPRESSION	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	DRY MOUTH	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	FLATULENCE	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	GASTROENTERITIS	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	2	1.5
	HALLUCINATIONS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	2	1.5

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=130)	HYPESTHESIA	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	INCREASED APPETITE	0	0.0	0	0.0	1	0.8	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8	0	0.0	2	1.5
	PNEUMONIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	PRURITUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	SINUSITIS	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	VERTIGO	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	2	1.5
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	ARTHRALGIA	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	ARTHROSIS	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	BUNDLE BRANCH BLOCK	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8
	CONSTIPATION	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	CYSTITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	DEHYDRATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	DYSKINESIA	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	EAR PAIN	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=130)	EOSINOPHILIA	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	EUPHORIA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	FUNGAL DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	GASTROINTEST-INAL DISORDER	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	GINGIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	1	0.8
	HERPES SIMPLEX	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	LEUKOCYTOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	1	0.8
	LIBIDO DECREASED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	LIVER FUNCTION TESTS ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	MACULOPAPULAR RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	MANIC REACTION	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	MIGRAINE	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	MONOCYTOSIS	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Acute Study Treatment Group	Preferred Term	Week 1 N	Week 1 %	Week 2 N	Week 2 %	Week 3 N	Week 3 %	Week 4 N	Week 4 %	Week 6 N	Week 6 %	Week 8 N	Week 8 %	Week 10 N	Week 10 %	Week 12 N	Week 12 %	Week 16 N	Week 16 %	Week 20 N	Week 20 %	Week 24 N	Week 24 %	Post Week 24 N	Post Week 24 %	Total N	Total %
Placebo (N=130)	MYALGIA	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	MYOCLONUS	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	NEUROSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8
	OTITIS EXTERNA	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	PARALYSIS	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	PHOTOPHOBIA	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	PSYCHOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	SPINA BIFIDA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	SWEATING	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	1	0.8
	ULCERATIVE STOMATITIS	0	0.0	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	URTICARIA	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	WEIGHT LOSS	0	0.0	0	0.0	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	WITHDRAWAL SYNDROME	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8
	YAWN	1	0.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.8

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=72)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																												
Placebo (N=79)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

BRL 29060 - 716

Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Paroxetine (N=61)	DYSMENORRHEA	1	1.6	1	1.6	0	0.0	1	1.6	2	3.3	1	1.6	0	0.0	1	1.6	0	0.0	0	0.0	0	0.0	0	0.0	7	11.5

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Open-Label Treatment Phase (including Taper) by the Time of First Occurrence
by Descending Order of Paroxetine (Number (%) of Patients) by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Week 20		Week 24		Post Week 24		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Acute Study Treatment Group	Preferred Term																										
Placebo (N=51)	DYSMENORRHEA	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	FEMALE GENITAL DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	MENSTRUAL DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	UTERUS DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=81), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	51	63.0	53	65.4	9	11.1
Body as a Whole	TOTAL	26	32.1	30	37.0	3	3.7
	ABDOMINAL PAIN	5	6.2	5	6.2	0	0.0
	ALLERGIC REACTION	5	6.2	2	2.5	0	0.0
	ASTHENIA	1	1.2	2	2.5	0	0.0
	BACK PAIN	0	0.0	2	2.5	1	1.2
	CHEST PAIN	2	2.5	1	1.2	0	0.0
	FACE EDEMA	1	1.2	1	1.2	0	0.0
	FEVER	4	4.9	4	4.9	0	0.0
	HEADACHE	11	13.6	9	11.1	0	0.0
	INFECTION	1	1.2	6	7.4	1	1.2
	MALAISE	1	1.2	0	0.0	0	0.0
	PAIN	2	2.5	1	1.2	0	0.0
	TRAUMA	7	8.6	9	11.1	1	1.2
Digestive System	TOTAL	18	22.2	13	16.0	0	0.0
	CONSTIPATION	0	0.0	1	1.2	0	0.0
	DECREASED APPETITE	2	2.5	0	0.0	0	0.0
	DIARRHEA	2	2.5	3	3.7	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=81), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DRY MOUTH	3	3.7	0	0.0	0	0.0
	DYSPEPSIA	6	7.4	1	1.2	0	0.0
	GASTRITIS	1	1.2	0	0.0	0	0.0
	HEMATEMESIS	0	0.0	1	1.2	0	0.0
	INCREASED APPETITE	1	1.2	0	0.0	0	0.0
	NAUSEA	6	7.4	2	2.5	0	0.0
	STOMATITIS	0	0.0	1	1.2	0	0.0
	TOOTH CARIES	1	1.2	0	0.0	0	0.0
	VOMITING	3	3.7	9	11.1	0	0.0
Hemic and Lymphatic System	TOTAL	3	3.7	0	0.0	0	0.0
	LEUKOPENIA	2	2.5	0	0.0	0	0.0
	LYMPHADENOPATHY	1	1.2	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	2	2.5	5	6.2	0	0.0
	DEHYDRATION	0	0.0	1	1.2	0	0.0
	WEIGHT GAIN	2	2.5	3	3.7	0	0.0
	WEIGHT LOSS	0	0.0	1	1.2	0	0.0
Musculoskeletal System	TOTAL	2	2.5	2	2.5	0	0.0
	ARTHRALGIA	2	2.5	0	0.0	0	0.0

(CONTINUED)

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=81), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Musculoskeletal System	MYALGIA	0	0.0	1	1.2	0	0.0
	TENDINOUS DISORDER	0	0.0	1	1.2	0	0.0
Nervous System	TOTAL	19	23.5	15	18.5	6	7.4
	AGITATION	0	0.0	2	2.5	1	1.2
	ANXIETY	0	0.0	1	1.2	0	0.0
	CONVULSION	0	0.0	1	1.2	0	0.0
	DEPRESSION	0	0.0	2	2.5	1	1.2
	DIZZINESS	3	3.7	0	0.0	0	0.0
	EMOTIONAL LABILITY	1	1.2	2	2.5	4	4.9
	HALLUCINATIONS	1	1.2	0	0.0	0	0.0
	HOSTILITY	0	0.0	2	2.5	2	2.5
	HYPERKINESIA	1	1.2	1	1.2	0	0.0
	INSOMNIA	2	2.5	2	2.5	0	0.0
	LACK OF EMOTION	0	0.0	0	0.0	1	1.2
	NERVOUSNESS	4	4.9	4	4.9	0	0.0
	NEUROSIS	1	1.2	0	0.0	0	0.0
	PARESTHESIA	1	1.2	0	0.0	0	0.0
	SOMNOLENCE	4	4.9	1	1.2	0	0.0

(CONTINUED)

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=81), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	VERTIGO	1	1.2	0	0.0	0	0.0
	VESTIBULAR DISORDER	0	0.0	1	1.2	0	0.0
Respiratory System	TOTAL	26	32.1	18	22.2	0	0.0
	ASTHMA	1	1.2	2	2.5	0	0.0
	BRONCHITIS	0	0.0	2	2.5	0	0.0
	COUGH INCREASED	3	3.7	1	1.2	0	0.0
	DYSPNEA	1	1.2	0	0.0	0	0.0
	PHARYNGITIS	9	11.1	3	3.7	0	0.0
	PNEUMONIA	0	0.0	1	1.2	0	0.0
	RESPIRATORY DISORDER	7	8.6	9	11.1	0	0.0
	RHINITIS	5	6.2	3	3.7	0	0.0
	SINUSITIS	4	4.9	2	2.5	0	0.0
Skin and Appendages	TOTAL	6	7.4	6	7.4	0	0.0
	ACNE	1	1.2	2	2.5	0	0.0
	CONTACT DERMATITIS	2	2.5	2	2.5	0	0.0
	FUNGAL DERMATITIS	1	1.2	0	0.0	0	0.0
	FURUNCULOSIS	0	0.0	1	1.2	0	0.0

(CONTINUED)

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=81), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	HERPES ZOSTER	0	0.0	1	1.2	0	0.0
	PRURITUS	1	1.2	0	0.0	0	0.0
	RASH	1	1.2	0	0.0	0	0.0
Special Senses	TOTAL	1	1.2	2	2.5	0	0.0
	OTITIS MEDIA	1	1.2	2	2.5	0	0.0
Urogenital System	TOTAL	4	4.9	2	2.5	0	0.0
	ALBUMINURIA	3	3.7	0	0.0	0	0.0
	HAEMATURIA	1	1.2	0	0.0	0	0.0
	PYURIA	1	1.2	0	0.0	0	0.0
	URINARY INCONTINENCE	0	0.0	1	1.2	0	0.0
	URINARY TRACT INFECTION	0	0.0	1	1.2	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=48), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=33), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	3.0	2	6.1	0	0.0
Urogenital System	TOTAL	1	3.0	2	6.1	0	0.0
	DYSMENORRHEA	1	3.0	2	6.1	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=52), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	32	61.5	29	55.8	4	7.7
Body as a Whole	TOTAL	17	32.7	17	32.7	2	3.8
	ABDOMINAL PAIN	3	5.8	2	3.8	0	0.0
	ABNORMAL LABORATORY VALUE	1	1.9	0	0.0	0	0.0
	ABSCESS	0	0.0	0	0.0	1	1.9
	ALLERGIC REACTION	3	5.8	1	1.9	0	0.0
	ASTHENIA	1	1.9	2	3.8	0	0.0
	BACK PAIN	1	1.9	0	0.0	0	0.0
	FEVER	2	3.8	1	1.9	0	0.0
	HEADACHE	10	19.2	9	17.3	0	0.0
	INFECTION	3	5.8	4	7.7	1	1.9
	PAIN	2	3.8	1	1.9	0	0.0
	TRAUMA	2	3.8	3	5.8	0	0.0
Cardiovascular System	TOTAL	1	1.9	0	0.0	0	0.0
	HAEMATOMA	1	1.9	0	0.0	0	0.0
Digestive System	TOTAL	9	17.3	4	7.7	0	0.0
	CONSTIPATION	0	0.0	1	1.9	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=52), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DECREASED APPETITE	2	3.8	0	0.0	0	0.0
	DIARRHEA	3	5.8	1	1.9	0	0.0
	DYSPEPSIA	2	3.8	0	0.0	0	0.0
	GINGIVITIS	0	0.0	1	1.9	0	0.0
	NAUSEA	6	11.5	0	0.0	0	0.0
	TOOTH DISORDER	0	0.0	2	3.8	0	0.0
	VOMITING	1	1.9	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.9	1	1.9	0	0.0
	ANEMIA	1	1.9	0	0.0	0	0.0
	PURPURA	0	0.0	1	1.9	0	0.0
Metabolic and Nutritional Disorders	TOTAL	1	1.9	1	1.9	0	0.0
	WEIGHT GAIN	1	1.9	1	1.9	0	0.0
Musculoskeletal System	TOTAL	3	5.8	1	1.9	0	0.0
	ARTHRALGIA	1	1.9	1	1.9	0	0.0
	ARTHROSIS	1	1.9	0	0.0	0	0.0
	MYALGIA	1	1.9	0	0.0	0	0.0
Nervous System	TOTAL	10	19.2	11	21.2	2	3.8
	ABNORMAL DREAMS	1	1.9	0	0.0	0	0.0

(CONTINUED)

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=52), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	AGITATION	1	1.9	0	0.0	0	0.0
	ANXIETY	1	1.9	1	1.9	0	0.0
	CONCENTRATION IMPAIRED	1	1.9	1	1.9	0	0.0
	DEPRESSION	0	0.0	1	1.9	0	0.0
	DIZZINESS	2	3.8	1	1.9	0	0.0
	EMOTIONAL LABILITY	1	1.9	2	3.8	0	0.0
	HOSTILITY	1	1.9	1	1.9	0	0.0
	HYPERKINESIA	2	3.8	4	7.7	0	0.0
	INSOMNIA	5	9.6	1	1.9	0	0.0
	MANIC REACTION	0	0.0	1	1.9	0	0.0
	MYOCLONUS	1	1.9	0	0.0	0	0.0
	NERVOUSNESS	1	1.9	1	1.9	0	0.0
	NEUROSIS	2	3.8	0	0.0	1	1.9
	SOMNOLENCE	0	0.0	1	1.9	1	1.9
	VERTIGO	0	0.0	1	1.9	0	0.0
Respiratory System	TOTAL	10	19.2	8	15.4	1	1.9
	ASTHMA	1	1.9	1	1.9	0	0.0
	BRONCHITIS	0	0.0	1	1.9	0	0.0

(CONTINUED)

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=52), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	COUGH INCREASED	1	1.9	1	1.9	0	0.0
	PHARYNGITIS	2	3.8	3	5.8	1	1.9
	PLEURA DISORDER	1	1.9	0	0.0	0	0.0
	RESPIRATORY DISORDER	2	3.8	4	7.7	0	0.0
	RHINITIS	5	9.6	0	0.0	0	0.0
	SINUSITIS	3	5.8	2	3.8	0	0.0
Skin and Appendages	TOTAL	1	1.9	2	3.8	0	0.0
	ACNE	0	0.0	2	3.8	0	0.0
	MACULOPAPULAR RASH	1	1.9	0	0.0	0	0.0
Special Senses	TOTAL	3	5.8	4	7.7	0	0.0
	BLEPHARITIS	1	1.9	0	0.0	0	0.0
	EAR PAIN	0	0.0	1	1.9	0	0.0
	EYE PAIN	1	1.9	0	0.0	0	0.0
	OTITIS EXTERNA	1	1.9	1	1.9	0	0.0
	OTITIS MEDIA	0	0.0	3	5.8	0	0.0
Urogenital System	TOTAL	6	11.5	0	0.0	0	0.0
	ALBUMINURIA	5	9.6	0	0.0	0	0.0
	DYSURIA	1	1.9	0	0.0	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=52), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Urogenital System	GLYCOSURIA	1	1.9	0	0.0	0	0.0
	HAEMATURIA	1	1.9	0	0.0	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=24), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=28), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	4	14.3	0	0.0
Urogenital System	TOTAL	0	0.0	4	14.3	0	0.0
	DYSMENORRHEA	0	0.0	4	14.3	0	0.0

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=133), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	83	62.4	82	61.7	13	9.8
Body as a Whole	TOTAL	43	32.3	47	35.3	5	3.8
	ABDOMINAL PAIN	8	6.0	7	5.3	0	0.0
	ABNORMAL LABORATORY VALUE	1	0.8	0	0.0	0	0.0
	ABSCESS	0	0.0	0	0.0	1	0.8
	ALLERGIC REACTION	8	6.0	3	2.3	0	0.0
	ASTHENIA	2	1.5	4	3.0	0	0.0
	BACK PAIN	1	0.8	2	1.5	1	0.8
	CHEST PAIN	2	1.5	1	0.8	0	0.0
	FACE EDEMA	1	0.8	1	0.8	0	0.0
	FEVER	6	4.5	5	3.8	0	0.0
	HEADACHE	21	15.8	18	13.5	0	0.0
	INFECTION	4	3.0	10	7.5	2	1.5
	MALAISE	1	0.8	0	0.0	0	0.0
	PAIN	4	3.0	2	1.5	0	0.0
	TRAUMA	9	6.8	12	9.0	1	0.8
Cardiovascular System	TOTAL	1	0.8	0	0.0	0	0.0

(CONTINUED)

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=133), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Cardiovascular System	HAEMATOMA	1	0.8	0	0.0	0	0.0
Digestive System	TOTAL	27	20.3	17	12.8	0	0.0
	CONSTIPATION	0	0.0	2	1.5	0	0.0
	DECREASED APPETITE	4	3.0	0	0.0	0	0.0
	DIARRHEA	5	3.8	4	3.0	0	0.0
	DRY MOUTH	3	2.3	0	0.0	0	0.0
	DYSPEPSIA	8	6.0	1	0.8	0	0.0
	GASTRITIS	1	0.8	0	0.0	0	0.0
	GINGIVITIS	0	0.0	1	0.8	0	0.0
	HEMATEMESIS	0	0.0	1	0.8	0	0.0
	INCREASED APPETITE	1	0.8	0	0.0	0	0.0
	NAUSEA	12	9.0	2	1.5	0	0.0
	STOMATITIS	0	0.0	1	0.8	0	0.0
	TOOTH CARIES	1	0.8	0	0.0	0	0.0
	TOOTH DISORDER	0	0.0	2	1.5	0	0.0
	VOMITING	4	3.0	9	6.8	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=133), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Hemic and Lymphatic System	TOTAL	4	3.0	1	0.8	0	0.0
	ANEMIA	1	0.8	0	0.0	0	0.0
	LEUKOPENIA	2	1.5	0	0.0	0	0.0
	LYMPHADENOPATHY	1	0.8	0	0.0	0	0.0
	PURPURA	0	0.0	1	0.8	0	0.0
Metabolic and Nutritional Disorders	TOTAL	3	2.3	6	4.5	0	0.0
	DEHYDRATION	0	0.0	1	0.8	0	0.0
	WEIGHT GAIN	3	2.3	4	3.0	0	0.0
	WEIGHT LOSS	0	0.0	1	0.8	0	0.0
Musculoskeletal System	TOTAL	5	3.8	3	2.3	0	0.0
	ARTHRALGIA	3	2.3	1	0.8	0	0.0
	ARTHROSIS	1	0.8	0	0.0	0	0.0
	MYALGIA	1	0.8	1	0.8	0	0.0
	TENDINOUS DISORDER	0	0.0	1	0.8	0	0.0
Nervous System	TOTAL	29	21.8	26	19.5	8	6.0
	ABNORMAL DREAMS	1	0.8	0	0.0	0	0.0
	AGITATION	1	0.8	2	1.5	1	0.8
	ANXIETY	1	0.8	2	1.5	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=133), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	CONCENTRATION IMPAIRED	1	0.8	1	0.8	0	0.0
	CONVULSION	0	0.0	1	0.8	0	0.0
	DEPRESSION	0	0.0	3	2.3	1	0.8
	DIZZINESS	5	3.8	1	0.8	0	0.0
	EMOTIONAL LABILITY	2	1.5	4	3.0	4	3.0
	HALLUCINATIONS	1	0.8	0	0.0	0	0.0
	HOSTILITY	1	0.8	3	2.3	2	1.5
	HYPERKINESIA	3	2.3	5	3.8	0	0.0
	INSOMNIA	7	5.3	3	2.3	0	0.0
	LACK OF EMOTION	0	0.0	0	0.0	1	0.8
	MANIC REACTION	0	0.0	1	0.8	0	0.0
	MYOCLONUS	1	0.8	0	0.0	0	0.0
	NERVOUSNESS	5	3.8	5	3.8	0	0.0
	NEUROSIS	3	2.3	0	0.0	1	0.8
	PARESTHESIA	1	0.8	0	0.0	0	0.0
	SOMNOLENCE	4	3.0	2	1.5	1	0.8
	VERTIGO	1	0.8	1	0.8	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=133), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	VESTIBULAR DISORDER	0	0.0	1	0.8	0	0.0
Respiratory System	TOTAL	36	27.1	26	19.5	1	0.8
	ASTHMA	2	1.5	3	2.3	0	0.0
	BRONCHITIS	0	0.0	3	2.3	0	0.0
	COUGH INCREASED	4	3.0	2	1.5	0	0.0
	DYSPNEA	1	0.8	0	0.0	0	0.0
	PHARYNGITIS	11	8.3	6	4.5	1	0.8
	PLEURA DISORDER	1	0.8	0	0.0	0	0.0
	PNEUMONIA	0	0.0	1	0.8	0	0.0
	RESPIRATORY DISORDER	9	6.8	13	9.8	0	0.0
	RHINITIS	10	7.5	3	2.3	0	0.0
	SINUSITIS	7	5.3	4	3.0	0	0.0
Skin and Appendages	TOTAL	7	5.3	8	6.0	0	0.0
	ACNE	1	0.8	4	3.0	0	0.0
	CONTACT DERMATITIS	2	1.5	2	1.5	0	0.0
	FUNGAL DERMATITIS	1	0.8	0	0.0	0	0.0
	FURUNCULOSIS	0	0.0	1	0.8	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=133), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	HERPES ZOSTER	0	0.0	1	0.8	0	0.0
	MACULOPAPULAR RASH	1	0.8	0	0.0	0	0.0
	PRURITUS	1	0.8	0	0.0	0	0.0
	RASH	1	0.8	0	0.0	0	0.0
Special Senses	TOTAL	4	3.0	6	4.5	0	0.0
	BLEPHARITIS	1	0.8	0	0.0	0	0.0
	EAR PAIN	0	0.0	1	0.8	0	0.0
	EYE PAIN	1	0.8	0	0.0	0	0.0
	OTITIS EXTERNA	1	0.8	1	0.8	0	0.0
	OTITIS MEDIA	1	0.8	5	3.8	0	0.0
Urogenital System	TOTAL	10	7.5	2	1.5	0	0.0
	ALBUMINURIA	8	6.0	0	0.0	0	0.0
	DYSURIA	1	0.8	0	0.0	0	0.0
	GLYCOSURIA	1	0.8	0	0.0	0	0.0
	HAEMATURIA	2	1.5	0	0.0	0	0.0
	PYURIA	1	0.8	0	0.0	0	0.0
	URINARY INCONTINENCE	0	0.0	1	0.8	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=133), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Urogenital System	URINARY TRACT INFECTION	0	0.0	1	0.8	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=72), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=61), Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	1.6	6	9.8	0	0.0
Urogenital System	TOTAL	1	1.6	6	9.8	0	0.0
	DYSMENORRHEA	1	1.6	6	9.8	0	0.0

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	39	59.1	28	42.4	11	16.7
Body as a Whole	TOTAL	18	27.3	14	21.2	1	1.5
	ABDOMINAL PAIN	2	3.0	2	3.0	0	0.0
	ALLERGIC REACTION	1	1.5	1	1.5	0	0.0
	ASTHENIA	4	6.1	1	1.5	0	0.0
	BACK PAIN	3	4.5	0	0.0	0	0.0
	FEVER	1	1.5	2	3.0	0	0.0
	HEADACHE	8	12.1	2	3.0	0	0.0
	INFECTION	5	7.6	6	9.1	0	0.0
	PAIN	1	1.5	1	1.5	0	0.0
	TRAUMA	2	3.0	3	4.5	1	1.5
Cardiovascular System	TOTAL	2	3.0	1	1.5	1	1.5
	BUNDLE BRANCH BLOCK	1	1.5	0	0.0	0	0.0
	MIGRAINE	0	0.0	0	0.0	1	1.5
	SYNCOPE	1	1.5	1	1.5	0	0.0
Digestive System	TOTAL	15	22.7	5	7.6	1	1.5
	DECREASED APPETITE	3	4.5	0	0.0	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DIARRHEA	2	3.0	0	0.0	0	0.0
	DYSPEPSIA	3	4.5	1	1.5	0	0.0
	GASTROENTERITIS	1	1.5	0	0.0	0	0.0
	GASTROINTESTINAL DISORDER	1	1.5	0	0.0	0	0.0
	INCREASED APPETITE	2	3.0	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	1.5	0	0.0	0	0.0
	NAUSEA	3	4.5	1	1.5	0	0.0
	TOOTH CARIES	1	1.5	1	1.5	1	1.5
	VOMITING	2	3.0	2	3.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.5	1	1.5	0	0.0
	ANEMIA	1	1.5	0	0.0	0	0.0
	LEUKOPENIA	1	1.5	1	1.5	0	0.0
Metabolic and Nutritional Disorders	TOTAL	5	7.6	2	3.0	0	0.0
	DEHYDRATION	0	0.0	1	1.5	0	0.0
	WEIGHT GAIN	5	7.6	1	1.5	0	0.0
Musculoskeletal System	TOTAL	0	0.0	1	1.5	0	0.0
	ARTHROSIS	0	0.0	1	1.5	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Musculoskeletal System	MYALGIA	0	0.0	1	1.5	0	0.0
Nervous System	TOTAL	9	13.6	11	16.7	6	9.1
	AGITATION	0	0.0	2	3.0	1	1.5
	ANXIETY	1	1.5	0	0.0	1	1.5
	CONCENTRATION IMPAIRED	1	1.5	1	1.5	0	0.0
	DEPRESSION	1	1.5	0	0.0	0	0.0
	DIZZINESS	2	3.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	2	3.0	1	1.5
	EUPHORIA	0	0.0	0	0.0	1	1.5
	HALLUCINATIONS	0	0.0	1	1.5	1	1.5
	HOSTILITY	0	0.0	1	1.5	1	1.5
	HYPERKINESIA	1	1.5	0	0.0	0	0.0
	HYPESTHESIA	1	1.5	1	1.5	0	0.0
	INSOMNIA	4	6.1	1	1.5	0	0.0
	LIBIDO DECREASED	1	1.5	0	0.0	0	0.0
	NERVOUSNESS	0	0.0	1	1.5	0	0.0
	PARALYSIS	0	0.0	0	0.0	1	1.5

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	SOMNOLENCE	0	0.0	3	4.5	0	0.0
	TREMOR	1	1.5	1	1.5	0	0.0
	WITHDRAWAL SYNDROME	0	0.0	1	1.5	0	0.0
Respiratory System	TOTAL	18	27.3	10	15.2	1	1.5
	ASTHMA	2	3.0	0	0.0	1	1.5
	BRONCHITIS	0	0.0	3	4.5	0	0.0
	COUGH INCREASED	2	3.0	0	0.0	0	0.0
	EPISTAXIS	2	3.0	0	0.0	0	0.0
	PHARYNGITIS	5	7.6	0	0.0	0	0.0
	PNEUMONIA	0	0.0	1	1.5	0	0.0
	RESPIRATORY DISORDER	8	12.1	5	7.6	0	0.0
	RHINITIS	4	6.1	0	0.0	0	0.0
	SINUSITIS	0	0.0	1	1.5	0	0.0
	YAWN	1	1.5	0	0.0	0	0.0
Skin and Appendages	TOTAL	3	4.5	2	3.0	1	1.5
	ACNE	0	0.0	1	1.5	0	0.0
	CONTACT DERMATITIS	0	0.0	1	1.5	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	MACULOPAPULAR RASH	1	1.5	0	0.0	0	0.0
	PRURITUS	2	3.0	0	0.0	0	0.0
	RASH	1	1.5	0	0.0	1	1.5
Special Senses	TOTAL	1	1.5	0	0.0	1	1.5
	ABNORMAL VISION	1	1.5	0	0.0	0	0.0
	OTITIS MEDIA	0	0.0	0	0.0	1	1.5
Urogenital System	TOTAL	4	6.1	0	0.0	1	1.5
	ALBUMINURIA	2	3.0	0	0.0	0	0.0
	CYSTITIS	1	1.5	0	0.0	0	0.0
	HAEMATURIA	2	3.0	0	0.0	0	0.0
	URINARY INCONTINENCE	1	1.5	0	0.0	1	1.5

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=37), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=29), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	2	6.9	0	0.0	0	0.0
Urogenital System	TOTAL	2	6.9	0	0.0	0	0.0
	FEMALE GENITAL DISORDERS	1	3.4	0	0.0	0	0.0
	MENSTRUAL DISORDER	1	3.4	0	0.0	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=64), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	37	57.8	39	60.9	7	10.9
Body as a Whole	TOTAL	20	31.3	16	25.0	2	3.1
	ABDOMINAL PAIN	4	6.3	3	4.7	1	1.6
	ALLERGIC REACTION	3	4.7	1	1.6	0	0.0
	ASTHENIA	2	3.1	2	3.1	0	0.0
	BACK PAIN	0	0.0	1	1.6	0	0.0
	FEVER	2	3.1	1	1.6	0	0.0
	HEADACHE	11	17.2	6	9.4	0	0.0
	INFECTION	1	1.6	4	6.3	1	1.6
	PAIN	0	0.0	1	1.6	0	0.0
	SPINA BIFIDA	1	1.6	0	0.0	0	0.0
	TRAUMA	5	7.8	2	3.1	1	1.6
Cardiovascular System	TOTAL	4	6.3	0	0.0	1	1.6
	SYNCOPE	0	0.0	0	0.0	1	1.6
	VASODILATATION	4	6.3	0	0.0	0	0.0
Digestive System	TOTAL	11	17.2	7	10.9	1	1.6
	CONSTIPATION	1	1.6	0	0.0	0	0.0
	DECREASED APPETITE	3	4.7	1	1.6	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=64), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DIARRHEA	0	0.0	1	1.6	0	0.0
	DRY MOUTH	2	3.1	0	0.0	0	0.0
	DYSPEPSIA	0	0.0	3	4.7	0	0.0
	FLATULENCE	2	3.1	0	0.0	0	0.0
	GASTROENTERITIS	1	1.6	0	0.0	0	0.0
	GINGIVITIS	0	0.0	1	1.6	0	0.0
	NAUSEA	3	4.7	3	4.7	1	1.6
	TOOTH CARIES	1	1.6	0	0.0	0	0.0
	TOOTH DISORDER	0	0.0	1	1.6	0	0.0
	ULCERATIVE STOMATITIS	1	1.6	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.6	1	1.6	0	0.0
	EOSINOPHILIA	0	0.0	1	1.6	0	0.0
	LEUKOCYTOSIS	1	1.6	0	0.0	0	0.0
	MONOCYTOSIS	0	0.0	1	1.6	0	0.0
Metabolic and Nutritional Disorders	TOTAL	1	1.6	2	3.1	1	1.6
	WEIGHT GAIN	1	1.6	1	1.6	1	1.6
	WEIGHT LOSS	0	0.0	1	1.6	0	0.0
Musculoskeletal System	TOTAL	1	1.6	0	0.0	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=64), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Musculoskeletal System	ARTHRALGIA	1	1.6	0	0.0	0	0.0
Nervous System	TOTAL	14	21.9	23	35.9	4	6.3
	ABNORMAL DREAMS	0	0.0	1	1.6	0	0.0
	AGITATION	1	1.6	2	3.1	0	0.0
	ANXIETY	0	0.0	4	6.3	0	0.0
	DEPRESSION	0	0.0	1	1.6	0	0.0
	DIZZINESS	1	1.6	2	3.1	0	0.0
	DYSKINESIA	1	1.6	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	1	1.6	0	0.0
	HOSTILITY	2	3.1	3	4.7	2	3.1
	HYPERKINESIA	1	1.6	4	6.3	1	1.6
	INSOMNIA	3	4.7	3	4.7	0	0.0
	LACK OF EMOTION	0	0.0	1	1.6	0	0.0
	MANIC REACTION	0	0.0	1	1.6	0	0.0
	MYOCLONUS	1	1.6	0	0.0	0	0.0
	NERVOUSNESS	3	4.7	8	12.5	1	1.6
	NEUROSIS	1	1.6	0	0.0	0	0.0
	PSYCHOSIS	0	0.0	1	1.6	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=64), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	SOMNOLENCE	2	3.1	1	1.6	0	0.0
	TREMOR	2	3.1	0	0.0	0	0.0
	VERTIGO	2	3.1	0	0.0	0	0.0
Respiratory System	TOTAL	11	17.2	9	14.1	0	0.0
	ASTHMA	0	0.0	2	3.1	0	0.0
	COUGH INCREASED	0	0.0	1	1.6	0	0.0
	EPISTAXIS	1	1.6	0	0.0	0	0.0
	PHARYNGITIS	2	3.1	3	4.7	0	0.0
	PNEUMONIA	0	0.0	1	1.6	0	0.0
	RESPIRATORY DISORDER	7	10.9	6	9.4	0	0.0
	RHINITIS	4	6.3	1	1.6	0	0.0
	SINUSITIS	1	1.6	0	0.0	0	0.0
Skin and Appendages	TOTAL	6	9.4	2	3.1	0	0.0
	ACNE	2	3.1	0	0.0	0	0.0
	CONTACT DERMATITIS	2	3.1	1	1.6	0	0.0
	FUNGAL DERMATITIS	0	0.0	1	1.6	0	0.0
	HERPES SIMPLEX	1	1.6	0	0.0	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=64), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	RASH	3	4.7	0	0.0	0	0.0
	SWEATING	1	1.6	0	0.0	0	0.0
	URTICARIA	1	1.6	0	0.0	0	0.0
Special Senses	TOTAL	5	7.8	2	3.1	0	0.0
	ABNORMAL VISION	1	1.6	0	0.0	0	0.0
	EAR PAIN	1	1.6	0	0.0	0	0.0
	OTITIS EXTERNA	1	1.6	0	0.0	0	0.0
	OTITIS MEDIA	1	1.6	2	3.1	0	0.0
	PHOTOPHOBIA	1	1.6	0	0.0	0	0.0
Urogenital System	TOTAL	1	1.6	0	0.0	1	1.6
	URINARY INCONTINENCE	1	1.6	0	0.0	1	1.6

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=42), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=22), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	4.5	0	0.0	0	0.0
Urogenital System	TOTAL	1	4.5	0	0.0	0	0.0
	DYSMENORRHEA	1	4.5	0	0.0	0	0.0
	UTERUS DISORDERS	1	4.5	0	0.0	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=130), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	76	58.5	67	51.5	18	13.8
Body as a Whole	TOTAL	38	29.2	30	23.1	3	2.3
	ABDOMINAL PAIN	6	4.6	5	3.8	1	0.8
	ALLERGIC REACTION	4	3.1	2	1.5	0	0.0
	ASTHENIA	6	4.6	3	2.3	0	0.0
	BACK PAIN	3	2.3	1	0.8	0	0.0
	FEVER	3	2.3	3	2.3	0	0.0
	HEADACHE	19	14.6	8	6.2	0	0.0
	INFECTION	6	4.6	10	7.7	1	0.8
	PAIN	1	0.8	2	1.5	0	0.0
	SPINA BIFIDA	1	0.8	0	0.0	0	0.0
	TRAUMA	7	5.4	5	3.8	2	1.5
Cardiovascular System	TOTAL	6	4.6	1	0.8	2	1.5
	BUNDLE BRANCH BLOCK	1	0.8	0	0.0	0	0.0
	MIGRAINE	0	0.0	0	0.0	1	0.8
	SYNCOPE	1	0.8	1	0.8	1	0.8
	VASODILATATION	4	3.1	0	0.0	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=130), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	TOTAL	26	20.0	12	9.2	2	1.5
	CONSTIPATION	1	0.8	0	0.0	0	0.0
	DECREASED APPETITE	6	4.6	1	0.8	0	0.0
	DIARRHEA	2	1.5	1	0.8	0	0.0
	DRY MOUTH	2	1.5	0	0.0	0	0.0
	DYSPEPSIA	3	2.3	4	3.1	0	0.0
	FLATULENCE	2	1.5	0	0.0	0	0.0
	GASTROENTERITIS	2	1.5	0	0.0	0	0.0
	GASTROINTESTINAL DISORDER	1	0.8	0	0.0	0	0.0
	GINGIVITIS	0	0.0	1	0.8	0	0.0
	INCREASED APPETITE	2	1.5	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	0.8	0	0.0	0	0.0
	NAUSEA	6	4.6	4	3.1	1	0.8
	TOOTH CARIES	2	1.5	1	0.8	1	0.8
	TOOTH DISORDER	0	0.0	1	0.8	0	0.0
	ULCERATIVE STOMATITIS	1	0.8	0	0.0	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=130), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	VOMITING	2	1.5	2	1.5	0	0.0
Hemic and Lymphatic System	TOTAL	2	1.5	2	1.5	0	0.0
	ANEMIA	1	0.8	0	0.0	0	0.0
	EOSINOPHILIA	0	0.0	1	0.8	0	0.0
	LEUKOCYTOSIS	1	0.8	0	0.0	0	0.0
	LEUKOPENIA	1	0.8	1	0.8	0	0.0
	MONOCYTOSIS	0	0.0	1	0.8	0	0.0
Metabolic and Nutritional Disorders	TOTAL	6	4.6	4	3.1	1	0.8
	DEHYDRATION	0	0.0	1	0.8	0	0.0
	WEIGHT GAIN	6	4.6	2	1.5	1	0.8
	WEIGHT LOSS	0	0.0	1	0.8	0	0.0
Musculoskeletal System	TOTAL	1	0.8	1	0.8	0	0.0
	ARTHRALGIA	1	0.8	0	0.0	0	0.0
	ARTHROSIS	0	0.0	1	0.8	0	0.0
	MYALGIA	0	0.0	1	0.8	0	0.0
Nervous System	TOTAL	23	17.7	34	26.2	10	7.7
	ABNORMAL DREAMS	0	0.0	1	0.8	0	0.0
	AGITATION	1	0.8	4	3.1	1	0.8

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=130), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	ANXIETY	1	0.8	4	3.1	1	0.8
	CONCENTRATION IMPAIRED	1	0.8	1	0.8	0	0.0
	DEPRESSION	1	0.8	1	0.8	0	0.0
	DIZZINESS	3	2.3	2	1.5	0	0.0
	DYSKINESIA	1	0.8	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	3	2.3	1	0.8
	EUPHORIA	0	0.0	0	0.0	1	0.8
	HALLUCINATIONS	0	0.0	1	0.8	1	0.8
	HOSTILITY	2	1.5	4	3.1	3	2.3
	HYPERKINESIA	2	1.5	4	3.1	1	0.8
	HYPESTHESIA	1	0.8	1	0.8	0	0.0
	INSOMNIA	7	5.4	4	3.1	0	0.0
	LACK OF EMOTION	0	0.0	1	0.8	0	0.0
	LIBIDO DECREASED	1	0.8	0	0.0	0	0.0
	MANIC REACTION	0	0.0	1	0.8	0	0.0
	MYOCLONUS	1	0.8	0	0.0	0	0.0
	NERVOUSNESS	3	2.3	9	6.9	1	0.8

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=130), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	NEUROSIS	1	0.8	0	0.0	0	0.0
	PARALYSIS	0	0.0	0	0.0	1	0.8
	PSYCHOSIS	0	0.0	1	0.8	0	0.0
	SOMNOLENCE	2	1.5	4	3.1	0	0.0
	TREMOR	3	2.3	1	0.8	0	0.0
	VERTIGO	2	1.5	0	0.0	0	0.0
	WITHDRAWAL SYNDROME	0	0.0	1	0.8	0	0.0
Respiratory System	TOTAL	29	22.3	19	14.6	1	0.8
	ASTHMA	2	1.5	2	1.5	1	0.8
	BRONCHITIS	0	0.0	3	2.3	0	0.0
	COUGH INCREASED	2	1.5	1	0.8	0	0.0
	EPISTAXIS	3	2.3	0	0.0	0	0.0
	PHARYNGITIS	7	5.4	3	2.3	0	0.0
	PNEUMONIA	0	0.0	2	1.5	0	0.0
	RESPIRATORY DISORDER	15	11.5	11	8.5	0	0.0
	RHINITIS	8	6.2	1	0.8	0	0.0
	SINUSITIS	1	0.8	1	0.8	0	0.0
	YAWN	1	0.8	0	0.0	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=130), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	TOTAL	9	6.9	4	3.1	1	0.8
	ACNE	2	1.5	1	0.8	0	0.0
	CONTACT DERMATITIS	2	1.5	2	1.5	0	0.0
	FUNGAL DERMATITIS	0	0.0	1	0.8	0	0.0
	HERPES SIMPLEX	1	0.8	0	0.0	0	0.0
	MACULOPAPULAR RASH	1	0.8	0	0.0	0	0.0
	PRURITUS	2	1.5	0	0.0	0	0.0
	RASH	4	3.1	0	0.0	1	0.8
	SWEATING	1	0.8	0	0.0	0	0.0
	URTICARIA	1	0.8	0	0.0	0	0.0
Special Senses	TOTAL	6	4.6	2	1.5	1	0.8
	ABNORMAL VISION	2	1.5	0	0.0	0	0.0
	EAR PAIN	1	0.8	0	0.0	0	0.0
	OTITIS EXTERNA	1	0.8	0	0.0	0	0.0
	OTITIS MEDIA	1	0.8	2	1.5	1	0.8
	PHOTOPHOBIA	1	0.8	0	0.0	0	0.0
Urogenital System	TOTAL	5	3.8	0	0.0	2	1.5

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=130), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Urogenital System	ALBUMINURIA	2	1.5	0	0.0	0	0.0
	CYSTITIS	1	0.8	0	0.0	0	0.0
	HAEMATURIA	2	1.5	0	0.0	0	0.0
	URINARY INCONTINENCE	2	1.5	0	0.0	2	1.5

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=79), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Open-Label Treatment Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=51), Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	3	5.9	0	0.0	0	0.0
Urogenital System	TOTAL	3	5.9	0	0.0	0	0.0
	DYSMENORRHEA	1	2.0	0	0.0	0	0.0
	FEMALE GENITAL DISORDERS	1	2.0	0	0.0	0	0.0
	MENSTRUAL DISORDER	1	2.0	0	0.0	0	0.0
	UTERUS DISORDERS	1	2.0	0	0.0	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=20), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	4	20.0	2	10.0	1	5.0
Body as a Whole	TOTAL	0	0.0	0	0.0	1	5.0
	FEVER	0	0.0	0	0.0	1	5.0
Hemic and Lymphatic System	TOTAL	1	5.0	0	0.0	0	0.0
	LEUKOPENIA	1	5.0	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	1	5.0	0	0.0	0	0.0
	WEIGHT GAIN	1	5.0	0	0.0	0	0.0
Nervous System	TOTAL	1	5.0	2	10.0	0	0.0
	DEPRESSION	1	5.0	1	5.0	0	0.0
	HOSTILITY	0	0.0	1	5.0	0	0.0
Respiratory System	TOTAL	1	5.0	0	0.0	0	0.0
	RESPIRATORY DISORDER	1	5.0	0	0.0	0	0.0

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Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=10), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=10), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=11), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	2	18.2	2	18.2	1	9.1
Body as a Whole	TOTAL	1	9.1	0	0.0	0	0.0
	ABDOMINAL PAIN	1	9.1	0	0.0	0	0.0
	HEADACHE	1	9.1	0	0.0	0	0.0
Cardiovascular System	TOTAL	0	0.0	1	9.1	0	0.0
	BRADYCARDIA	0	0.0	1	9.1	0	0.0
Digestive System	TOTAL	1	9.1	0	0.0	0	0.0
	DYSPEPSIA	1	9.1	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	0	0.0	1	9.1
	NEUROSIS	0	0.0	0	0.0	1	9.1
Respiratory System	TOTAL	0	0.0	1	9.1	0	0.0
	SINUSITIS	0	0.0	1	9.1	0	0.0

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Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=7), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=4), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=31), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	6	19.4	4	12.9	2	6.5
Body as a Whole	TOTAL	1	3.2	0	0.0	1	3.2
	ABDOMINAL PAIN	1	3.2	0	0.0	0	0.0
	FEVER	0	0.0	0	0.0	1	3.2
	HEADACHE	1	3.2	0	0.0	0	0.0
Cardiovascular System	TOTAL	0	0.0	1	3.2	0	0.0
	BRADYCARDIA	0	0.0	1	3.2	0	0.0
Digestive System	TOTAL	1	3.2	0	0.0	0	0.0
	DYSPEPSIA	1	3.2	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	3.2	0	0.0	0	0.0
	LEUKOPENIA	1	3.2	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	1	3.2	0	0.0	0	0.0
	WEIGHT GAIN	1	3.2	0	0.0	0	0.0
Nervous System	TOTAL	1	3.2	2	6.5	1	3.2
	DEPRESSION	1	3.2	1	3.2	0	0.0
	HOSTILITY	0	0.0	1	3.2	0	0.0
	NEUROSIS	0	0.0	0	0.0	1	3.2
Respiratory System	TOTAL	1	3.2	1	3.2	0	0.0

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Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=31), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	RESPIRATORY DISORDER	1	3.2	0	0.0	0	0.0
	SINUSITIS	0	0.0	1	3.2	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=17), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Paroxetine (N=14), Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=22), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	3	13.6	4	18.2	0	0.0
Cardiovascular System	TOTAL	0	0.0	1	4.5	0	0.0
	SYNCOPE	0	0.0	1	4.5	0	0.0
Digestive System	TOTAL	1	4.5	0	0.0	0	0.0
	NAUSEA	1	4.5	0	0.0	0	0.0
Musculoskeletal System	TOTAL	1	4.5	0	0.0	0	0.0
	MYALGIA	1	4.5	0	0.0	0	0.0
Nervous System	TOTAL	2	9.1	2	9.1	0	0.0
	DEPRESSION	0	0.0	1	4.5	0	0.0
	HYSTERIA	0	0.0	1	4.5	0	0.0
	SOMNOLENCE	1	4.5	0	0.0	0	0.0
	WITHDRAWAL SYNDROME	1	4.5	0	0.0	0	0.0
Special Searches	TOTAL	0	0.0	1	4.5	0	0.0
	PUNCTURE SITE PAIN	0	0.0	1	4.5	0	0.0

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Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=17), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=5), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=14), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	7.1	3	21.4	1	7.1
Body as a Whole	TOTAL	0	0.0	1	7.1	1	7.1
	HEADACHE	0	0.0	1	7.1	0	0.0
	INFECTION	0	0.0	0	0.0	1	7.1
Metabolic and Nutritional Disorders	TOTAL	0	0.0	1	7.1	0	0.0
	WEIGHT GAIN	0	0.0	1	7.1	0	0.0
Nervous System	TOTAL	1	7.1	1	7.1	0	0.0
	ABNORMAL DREAMS	1	7.1	0	0.0	0	0.0
	INSOMNIA	0	0.0	1	7.1	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=10), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=4), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=36), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	4	11.1	7	19.4	1	2.8
Body as a Whole	TOTAL	0	0.0	1	2.8	1	2.8
	HEADACHE	0	0.0	1	2.8	0	0.0
	INFECTION	0	0.0	0	0.0	1	2.8
Cardiovascular System	TOTAL	0	0.0	1	2.8	0	0.0
	SYNCOPE	0	0.0	1	2.8	0	0.0
Digestive System	TOTAL	1	2.8	0	0.0	0	0.0
	NAUSEA	1	2.8	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	1	2.8	0	0.0
	WEIGHT GAIN	0	0.0	1	2.8	0	0.0
Musculoskeletal System	TOTAL	1	2.8	0	0.0	0	0.0
	MYALGIA	1	2.8	0	0.0	0	0.0
Nervous System	TOTAL	3	8.3	3	8.3	0	0.0
	ABNORMAL DREAMS	1	2.8	0	0.0	0	0.0
	DEPRESSION	0	0.0	1	2.8	0	0.0
	HYSTERIA	0	0.0	1	2.8	0	0.0
	INSOMNIA	0	0.0	1	2.8	0	0.0
	SOMNOLENCE	1	2.8	0	0.0	0	0.0

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Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=36), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	WITHDRAWAL SYNDROME	1	2.8	0	0.0	0	0.0
Special Searches	TOTAL	0	0.0	1	2.8	0	0.0
	PUNCTURE SITE						
	PAIN	0	0.0	1	2.8	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=27), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Taper Phase
Acute Study Treatment Group : Placebo (N=9), Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=81), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	52	64.2	54	66.7	10	12.3
Body as a Whole	TOTAL	26	32.1	30	37.0	4	4.9
	ABDOMINAL PAIN	5	6.2	5	6.2	0	0.0
	ALLERGIC REACTION	5	6.2	2	2.5	0	0.0
	ASTHENIA	1	1.2	2	2.5	0	0.0
	BACK PAIN	0	0.0	2	2.5	1	1.2
	CHEST PAIN	2	2.5	1	1.2	0	0.0
	FACE EDEMA	1	1.2	1	1.2	0	0.0
	FEVER	4	4.9	4	4.9	1	1.2
	HEADACHE	11	13.6	9	11.1	0	0.0
	INFECTION	1	1.2	6	7.4	1	1.2
	MALAISE	1	1.2	0	0.0	0	0.0
	PAIN	2	2.5	1	1.2	0	0.0
	TRAUMA	7	8.6	9	11.1	1	1.2
Digestive System	TOTAL	18	22.2	13	16.0	0	0.0
	CONSTIPATION	0	0.0	1	1.2	0	0.0
	DECREASED APPETITE	2	2.5	0	0.0	0	0.0
	DIARRHEA	2	2.5	3	3.7	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=81), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DRY MOUTH	3	3.7	0	0.0	0	0.0
	DYSPEPSIA	6	7.4	1	1.2	0	0.0
	GASTRITIS	1	1.2	0	0.0	0	0.0
	HEMATEMESIS	0	0.0	1	1.2	0	0.0
	INCREASED APPETITE	1	1.2	0	0.0	0	0.0
	NAUSEA	6	7.4	2	2.5	0	0.0
	STOMATITIS	0	0.0	1	1.2	0	0.0
	TOOTH CARIES	1	1.2	0	0.0	0	0.0
	VOMITING	3	3.7	9	11.1	0	0.0
Hemic and Lymphatic System	TOTAL	4	4.9	0	0.0	0	0.0
	LEUKOPENIA	3	3.7	0	0.0	0	0.0
	LYMPHADENOPATHY	1	1.2	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	3	3.7	5	6.2	0	0.0
	DEHYDRATION	0	0.0	1	1.2	0	0.0
	WEIGHT GAIN	3	3.7	3	3.7	0	0.0
	WEIGHT LOSS	0	0.0	1	1.2	0	0.0
Musculoskeletal System	TOTAL	2	2.5	2	2.5	0	0.0
	ARTHRALGIA	2	2.5	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=81), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Musculoskeletal System	MYALGIA	0	0.0	1	1.2	0	0.0
	TENDINOUS DISORDER	0	0.0	1	1.2	0	0.0
Nervous System	TOTAL	20	24.7	16	19.8	6	7.4
	AGITATION	0	0.0	2	2.5	1	1.2
	ANXIETY	0	0.0	1	1.2	0	0.0
	CONVULSION	0	0.0	1	1.2	0	0.0
	DEPRESSION	1	1.2	2	2.5	1	1.2
	DIZZINESS	3	3.7	0	0.0	0	0.0
	EMOTIONAL LABILITY	1	1.2	2	2.5	4	4.9
	HALLUCINATIONS	1	1.2	0	0.0	0	0.0
	HOSTILITY	0	0.0	3	3.7	2	2.5
	HYPERKINESIA	1	1.2	1	1.2	0	0.0
	INSOMNIA	2	2.5	2	2.5	0	0.0
	LACK OF EMOTION	0	0.0	0	0.0	1	1.2
	NERVOUSNESS	4	4.9	4	4.9	0	0.0
	NEUROSIS	1	1.2	0	0.0	0	0.0
	PARESTHESIA	1	1.2	0	0.0	0	0.0
	SOMNOLENCE	4	4.9	1	1.2	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=81), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	VERTIGO	1	1.2	0	0.0	0	0.0
	VESTIBULAR DISORDER	0	0.0	1	1.2	0	0.0
Respiratory System	TOTAL	26	32.1	18	22.2	0	0.0
	ASTHMA	1	1.2	2	2.5	0	0.0
	BRONCHITIS	0	0.0	2	2.5	0	0.0
	COUGH INCREASED	3	3.7	1	1.2	0	0.0
	DYSPNEA	1	1.2	0	0.0	0	0.0
	PHARYNGITIS	9	11.1	3	3.7	0	0.0
	PNEUMONIA	0	0.0	1	1.2	0	0.0
	RESPIRATORY DISORDER	8	9.9	9	11.1	0	0.0
	RHINITIS	5	6.2	3	3.7	0	0.0
	SINUSITIS	4	4.9	2	2.5	0	0.0
Skin and Appendages	TOTAL	6	7.4	6	7.4	0	0.0
	ACNE	1	1.2	2	2.5	0	0.0
	CONTACT DERMATITIS	2	2.5	2	2.5	0	0.0
	FUNGAL DERMATITIS	1	1.2	0	0.0	0	0.0
	FURUNCULOSIS	0	0.0	1	1.2	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=81), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	HERPES ZOSTER	0	0.0	1	1.2	0	0.0
	PRURITUS	1	1.2	0	0.0	0	0.0
	RASH	1	1.2	0	0.0	0	0.0
Special Senses	TOTAL	1	1.2	2	2.5	0	0.0
	OTITIS MEDIA	1	1.2	2	2.5	0	0.0
Urogenital System	TOTAL	4	4.9	2	2.5	0	0.0
	ALBUMINURIA	3	3.7	0	0.0	0	0.0
	HAEMATURIA	1	1.2	0	0.0	0	0.0
	PYURIA	1	1.2	0	0.0	0	0.0
	URINARY INCONTINENCE	0	0.0	1	1.2	0	0.0
	URINARY TRACT INFECTION	0	0.0	1	1.2	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=48), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=33), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	3.0	2	6.1	0	0.0
Urogenital System	TOTAL	1	3.0	2	6.1	0	0.0
	DYSMENORRHEA	1	3.0	2	6.1	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=52), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	32	61.5	29	55.8	5	9.6
Body as a Whole	TOTAL	17	32.7	17	32.7	2	3.8
	ABDOMINAL PAIN	4	7.7	2	3.8	0	0.0
	ABNORMAL LABORATORY VALUE	1	1.9	0	0.0	0	0.0
	ABSCESS	0	0.0	0	0.0	1	1.9
	ALLERGIC REACTION	3	5.8	1	1.9	0	0.0
	ASTHENIA	1	1.9	2	3.8	0	0.0
	BACK PAIN	1	1.9	0	0.0	0	0.0
	FEVER	2	3.8	1	1.9	0	0.0
	HEADACHE	10	19.2	9	17.3	0	0.0
	INFECTION	3	5.8	4	7.7	1	1.9
	PAIN	2	3.8	1	1.9	0	0.0
	TRAUMA	2	3.8	3	5.8	0	0.0
Cardiovascular System	TOTAL	1	1.9	1	1.9	0	0.0
	BRADYCARDIA	0	0.0	1	1.9	0	0.0
	HAEMATOMA	1	1.9	0	0.0	0	0.0
Digestive System	TOTAL	9	17.3	4	7.7	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=52), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	CONSTIPATION	0	0.0	1	1.9	0	0.0
	DECREASED APPETITE	2	3.8	0	0.0	0	0.0
	DIARRHEA	3	5.8	1	1.9	0	0.0
	DYSPEPSIA	3	5.8	0	0.0	0	0.0
	GINGIVITIS	0	0.0	1	1.9	0	0.0
	NAUSEA	6	11.5	0	0.0	0	0.0
	TOOTH DISORDER	0	0.0	2	3.8	0	0.0
	VOMITING	1	1.9	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.9	1	1.9	0	0.0
	ANEMIA	1	1.9	0	0.0	0	0.0
	PURPURA	0	0.0	1	1.9	0	0.0
Metabolic and Nutritional Disorders	TOTAL	1	1.9	1	1.9	0	0.0
	WEIGHT GAIN	1	1.9	1	1.9	0	0.0
Musculoskeletal System	TOTAL	3	5.8	1	1.9	0	0.0
	ARTHRALGIA	1	1.9	1	1.9	0	0.0
	ARTHROSIS	1	1.9	0	0.0	0	0.0
	MYALGIA	1	1.9	0	0.0	0	0.0
Nervous System	TOTAL	10	19.2	11	21.2	3	5.8

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=52), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	ABNORMAL DREAMS	1	1.9	0	0.0	0	0.0
	AGITATION	1	1.9	0	0.0	0	0.0
	ANXIETY	1	1.9	1	1.9	0	0.0
	CONCENTRATION IMPAIRED	1	1.9	1	1.9	0	0.0
	DEPRESSION	0	0.0	1	1.9	0	0.0
	DIZZINESS	2	3.8	1	1.9	0	0.0
	EMOTIONAL LABILITY	1	1.9	2	3.8	0	0.0
	HOSTILITY	1	1.9	1	1.9	0	0.0
	HYPERKINESIA	2	3.8	4	7.7	0	0.0
	INSOMNIA	5	9.6	1	1.9	0	0.0
	MANIC REACTION	0	0.0	1	1.9	0	0.0
	MYOCLONUS	1	1.9	0	0.0	0	0.0
	NERVOUSNESS	1	1.9	1	1.9	0	0.0
	NEUROSIS	2	3.8	0	0.0	2	3.8
	SOMNOLENCE	0	0.0	1	1.9	1	1.9
	VERTIGO	0	0.0	1	1.9	0	0.0
Respiratory System	TOTAL	10	19.2	9	17.3	1	1.9
	ASTHMA	1	1.9	1	1.9	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=52), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	BRONCHITIS	0	0.0	1	1.9	0	0.0
	COUGH INCREASED	1	1.9	1	1.9	0	0.0
	PHARYNGITIS	2	3.8	3	5.8	1	1.9
	PLEURA DISORDER	1	1.9	0	0.0	0	0.0
	RESPIRATORY DISORDER	2	3.8	4	7.7	0	0.0
	RHINITIS	5	9.6	0	0.0	0	0.0
	SINUSITIS	3	5.8	3	5.8	0	0.0
Skin and Appendages	TOTAL	1	1.9	2	3.8	0	0.0
	ACNE	0	0.0	2	3.8	0	0.0
	MACULOPAPULAR RASH	1	1.9	0	0.0	0	0.0
Special Senses	TOTAL	3	5.8	4	7.7	0	0.0
	BLEPHARITIS	1	1.9	0	0.0	0	0.0
	EAR PAIN	0	0.0	1	1.9	0	0.0
	EYE PAIN	1	1.9	0	0.0	0	0.0
	OTITIS EXTERNA	1	1.9	1	1.9	0	0.0
	OTITIS MEDIA	0	0.0	3	5.8	0	0.0
Urogenital System	TOTAL	6	11.5	0	0.0	0	0.0
	ALBUMINURIA	5	9.6	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=52), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Urogenital System	DYSURIA	1	1.9	0	0.0	0	0.0
	GLYCOSURIA	1	1.9	0	0.0	0	0.0
	HAEMATURIA	1	1.9	0	0.0	0	0.0

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=24), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=28), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	4	14.3	0	0.0
Urogenital System	TOTAL	0	0.0	4	14.3	0	0.0
	DYSMENORRHEA	0	0.0	4	14.3	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=133), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	84	63.2	83	62.4	15	11.3
Body as a Whole	TOTAL	43	32.3	47	35.3	6	4.5
	ABDOMINAL PAIN	9	6.8	7	5.3	0	0.0
	ABNORMAL LABORATORY VALUE	1	0.8	0	0.0	0	0.0
	ABSCESS	0	0.0	0	0.0	1	0.8
	ALLERGIC REACTION	8	6.0	3	2.3	0	0.0
	ASTHENIA	2	1.5	4	3.0	0	0.0
	BACK PAIN	1	0.8	2	1.5	1	0.8
	CHEST PAIN	2	1.5	1	0.8	0	0.0
	FACE EDEMA	1	0.8	1	0.8	0	0.0
	FEVER	6	4.5	5	3.8	1	0.8
	HEADACHE	21	15.8	18	13.5	0	0.0
	INFECTION	4	3.0	10	7.5	2	1.5
	MALAISE	1	0.8	0	0.0	0	0.0
	PAIN	4	3.0	2	1.5	0	0.0
	TRAUMA	9	6.8	12	9.0	1	0.8
Cardiovascular System	TOTAL	1	0.8	1	0.8	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=133), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Cardiovascular System	BRADYCARDIA	0	0.0	1	0.8	0	0.0
	HAEMATOMA	1	0.8	0	0.0	0	0.0
Digestive System	TOTAL	27	20.3	17	12.8	0	0.0
	CONSTIPATION	0	0.0	2	1.5	0	0.0
	DECREASED APPETITE	4	3.0	0	0.0	0	0.0
	DIARRHEA	5	3.8	4	3.0	0	0.0
	DRY MOUTH	3	2.3	0	0.0	0	0.0
	DYSPEPSIA	9	6.8	1	0.8	0	0.0
	GASTRITIS	1	0.8	0	0.0	0	0.0
	GINGIVITIS	0	0.0	1	0.8	0	0.0
	HEMATEMESIS	0	0.0	1	0.8	0	0.0
	INCREASED APPETITE	1	0.8	0	0.0	0	0.0
	NAUSEA	12	9.0	2	1.5	0	0.0
	STOMATITIS	0	0.0	1	0.8	0	0.0
	TOOTH CARIES	1	0.8	0	0.0	0	0.0
	TOOTH DISORDER	0	0.0	2	1.5	0	0.0
	VOMITING	4	3.0	9	6.8	0	0.0

(CONTINUED)

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=133), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Hemic and Lymphatic System	TOTAL	5	3.8	1	0.8	0	0.0
	ANEMIA	1	0.8	0	0.0	0	0.0
	LEUKOPENIA	3	2.3	0	0.0	0	0.0
	LYMPHADENOPATHY	1	0.8	0	0.0	0	0.0
	PURPURA	0	0.0	1	0.8	0	0.0
Metabolic and Nutritional Disorders	TOTAL	4	3.0	6	4.5	0	0.0
	DEHYDRATION	0	0.0	1	0.8	0	0.0
	WEIGHT GAIN	4	3.0	4	3.0	0	0.0
	WEIGHT LOSS	0	0.0	1	0.8	0	0.0
Musculoskeletal System	TOTAL	5	3.8	3	2.3	0	0.0
	ARTHRALGIA	3	2.3	1	0.8	0	0.0
	ARTHROSIS	1	0.8	0	0.0	0	0.0
	MYALGIA	1	0.8	1	0.8	0	0.0
	TENDINOUS DISORDER	0	0.0	1	0.8	0	0.0
Nervous System	TOTAL	30	22.6	27	20.3	9	6.8
	ABNORMAL DREAMS	1	0.8	0	0.0	0	0.0
	AGITATION	1	0.8	2	1.5	1	0.8
	ANXIETY	1	0.8	2	1.5	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=133), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	CONCENTRATION IMPAIRED	1	0.8	1	0.8	0	0.0
	CONVULSION	0	0.0	1	0.8	0	0.0
	DEPRESSION	1	0.8	3	2.3	1	0.8
	DIZZINESS	5	3.8	1	0.8	0	0.0
	EMOTIONAL LABILITY	2	1.5	4	3.0	4	3.0
	HALLUCINATIONS	1	0.8	0	0.0	0	0.0
	HOSTILITY	1	0.8	4	3.0	2	1.5
	HYPERKINESIA	3	2.3	5	3.8	0	0.0
	INSOMNIA	7	5.3	3	2.3	0	0.0
	LACK OF EMOTION	0	0.0	0	0.0	1	0.8
	MANIC REACTION	0	0.0	1	0.8	0	0.0
	MYOCLONUS	1	0.8	0	0.0	0	0.0
	NERVOUSNESS	5	3.8	5	3.8	0	0.0
	NEUROSIS	3	2.3	0	0.0	2	1.5
	PARESTHESIA	1	0.8	0	0.0	0	0.0
	SOMNOLENCE	4	3.0	2	1.5	1	0.8
	VERTIGO	1	0.8	1	0.8	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=133), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	VESTIBULAR DISORDER	0	0.0	1	0.8	0	0.0
Respiratory System	TOTAL	36	27.1	27	20.3	1	0.8
	ASTHMA	2	1.5	3	2.3	0	0.0
	BRONCHITIS	0	0.0	3	2.3	0	0.0
	COUGH INCREASED	4	3.0	2	1.5	0	0.0
	DYSPNEA	1	0.8	0	0.0	0	0.0
	PHARYNGITIS	11	8.3	6	4.5	1	0.8
	PLEURA DISORDER	1	0.8	0	0.0	0	0.0
	PNEUMONIA	0	0.0	1	0.8	0	0.0
	RESPIRATORY DISORDER	10	7.5	13	9.8	0	0.0
	RHINITIS	10	7.5	3	2.3	0	0.0
	SINUSITIS	7	5.3	5	3.8	0	0.0
Skin and Appendages	TOTAL	7	5.3	8	6.0	0	0.0
	ACNE	1	0.8	4	3.0	0	0.0
	CONTACT DERMATITIS	2	1.5	2	1.5	0	0.0
	FUNGAL DERMATITIS	1	0.8	0	0.0	0	0.0
	FURUNCULOSIS	0	0.0	1	0.8	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=133), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	HERPES ZOSTER	0	0.0	1	0.8	0	0.0
	MACULOPAPULAR RASH	1	0.8	0	0.0	0	0.0
	PRURITUS	1	0.8	0	0.0	0	0.0
	RASH	1	0.8	0	0.0	0	0.0
Special Senses	TOTAL	4	3.0	6	4.5	0	0.0
	BLEPHARITIS	1	0.8	0	0.0	0	0.0
	EAR PAIN	0	0.0	1	0.8	0	0.0
	EYE PAIN	1	0.8	0	0.0	0	0.0
	OTITIS EXTERNA	1	0.8	1	0.8	0	0.0
	OTITIS MEDIA	1	0.8	5	3.8	0	0.0
Urogenital System	TOTAL	10	7.5	2	1.5	0	0.0
	ALBUMINURIA	8	6.0	0	0.0	0	0.0
	DYSURIA	1	0.8	0	0.0	0	0.0
	GLYCOSURIA	1	0.8	0	0.0	0	0.0
	HAEMATURIA	2	1.5	0	0.0	0	0.0
	PYURIA	1	0.8	0	0.0	0	0.0
	URINARY INCONTINENCE	0	0.0	1	0.8	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=133), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Urogenital System	URINARY TRACT INFECTION	0	0.0	1	0.8	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=72), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Paroxetine (N=61), Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	1.6	6	9.8	0	0.0
Urogenital System	TOTAL	1	1.6	6	9.8	0	0.0
	DYSMENORRHEA	1	1.6	6	9.8	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	39	59.1	28	42.4	11	16.7
Body as a Whole	TOTAL	18	27.3	14	21.2	1	1.5
	ABDOMINAL PAIN	2	3.0	2	3.0	0	0.0
	ALLERGIC REACTION	1	1.5	1	1.5	0	0.0
	ASTHENIA	4	6.1	1	1.5	0	0.0
	BACK PAIN	3	4.5	0	0.0	0	0.0
	FEVER	1	1.5	2	3.0	0	0.0
	HEADACHE	8	12.1	2	3.0	0	0.0
	INFECTION	5	7.6	6	9.1	0	0.0
	PAIN	1	1.5	1	1.5	0	0.0
	TRAUMA	2	3.0	3	4.5	1	1.5
Cardiovascular System	TOTAL	2	3.0	1	1.5	1	1.5
	BUNDLE BRANCH BLOCK	1	1.5	0	0.0	0	0.0
	MIGRAINE	0	0.0	0	0.0	1	1.5
	SYNCOPE	1	1.5	1	1.5	0	0.0
Digestive System	TOTAL	16	24.2	5	7.6	1	1.5
	DECREASED APPETITE	3	4.5	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DIARRHEA	2	3.0	0	0.0	0	0.0
	DYSPEPSIA	3	4.5	1	1.5	0	0.0
	GASTROENTERITIS	1	1.5	0	0.0	0	0.0
	GASTROINTESTINAL DISORDER	1	1.5	0	0.0	0	0.0
	INCREASED APPETITE	2	3.0	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	1.5	0	0.0	0	0.0
	NAUSEA	4	6.1	1	1.5	0	0.0
	TOOTH CARIES	1	1.5	1	1.5	1	1.5
	VOMITING	2	3.0	2	3.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.5	1	1.5	0	0.0
	ANEMIA	1	1.5	0	0.0	0	0.0
	LEUKOPENIA	1	1.5	1	1.5	0	0.0
Metabolic and Nutritional Disorders	TOTAL	5	7.6	2	3.0	0	0.0
	DEHYDRATION	0	0.0	1	1.5	0	0.0
	WEIGHT GAIN	5	7.6	1	1.5	0	0.0
Musculoskeletal System	TOTAL	1	1.5	1	1.5	0	0.0
	ARTHROSIS	0	0.0	1	1.5	0	0.0

(CONTINUED)

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Musculoskeletal System	MYALGIA	1	1.5	1	1.5	0	0.0
Nervous System	TOTAL	9	13.6	13	19.7	6	9.1
	AGITATION	0	0.0	2	3.0	1	1.5
	ANXIETY	1	1.5	0	0.0	1	1.5
	CONCENTRATION IMPAIRED	1	1.5	1	1.5	0	0.0
	DEPRESSION	0	0.0	1	1.5	0	0.0
	DIZZINESS	2	3.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	2	3.0	1	1.5
	EUPHORIA	0	0.0	0	0.0	1	1.5
	HALLUCINATIONS	0	0.0	1	1.5	1	1.5
	HOSTILITY	0	0.0	1	1.5	1	1.5
	HYPERKINESIA	1	1.5	0	0.0	0	0.0
	HYPESTHESIA	1	1.5	1	1.5	0	0.0
	HYSTERIA	0	0.0	1	1.5	0	0.0
	INSOMNIA	4	6.1	1	1.5	0	0.0
	LIBIDO DECREASED	1	1.5	0	0.0	0	0.0
	NERVOUSNESS	0	0.0	1	1.5	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	PARALYSIS	0	0.0	0	0.0	1	1.5
	SOMNOLENCE	1	1.5	3	4.5	0	0.0
	TREMOR	1	1.5	1	1.5	0	0.0
	WITHDRAWAL SYNDROME	1	1.5	1	1.5	0	0.0
Respiratory System	TOTAL	18	27.3	10	15.2	1	1.5
	ASTHMA	2	3.0	0	0.0	1	1.5
	BRONCHITIS	0	0.0	3	4.5	0	0.0
	COUGH INCREASED	2	3.0	0	0.0	0	0.0
	EPISTAXIS	2	3.0	0	0.0	0	0.0
	PHARYNGITIS	5	7.6	0	0.0	0	0.0
	PNEUMONIA	0	0.0	1	1.5	0	0.0
	RESPIRATORY DISORDER	8	12.1	5	7.6	0	0.0
	RHINITIS	4	6.1	0	0.0	0	0.0
	SINUSITIS	0	0.0	1	1.5	0	0.0
	YAWN	1	1.5	0	0.0	0	0.0
Skin and Appendages	TOTAL	3	4.5	2	3.0	1	1.5
	ACNE	0	0.0	1	1.5	0	0.0

(CONTINUED)

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=66), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	CONTACT DERMATITIS	0	0.0	1	1.5	0	0.0
	MACULOPAPULAR RASH	1	1.5	0	0.0	0	0.0
	PRURITUS	2	3.0	0	0.0	0	0.0
	RASH	1	1.5	0	0.0	1	1.5
Special Searches	TOTAL	0	0.0	1	1.5	0	0.0
	PUNCTURE SITE PAIN	0	0.0	1	1.5	0	0.0
Special Senses	TOTAL	1	1.5	0	0.0	1	1.5
	ABNORMAL VISION	1	1.5	0	0.0	0	0.0
	OTITIS MEDIA	0	0.0	0	0.0	1	1.5
Urogenital System	TOTAL	4	6.1	0	0.0	1	1.5
	ALBUMINURIA	2	3.0	0	0.0	0	0.0
	CYSTITIS	1	1.5	0	0.0	0	0.0
	HAEMATURIA	2	3.0	0	0.0	0	0.0
	URINARY INCONTINENCE	1	1.5	0	0.0	1	1.5

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=37), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=29), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	2	6.9	0	0.0	0	0.0
Urogenital System	TOTAL	2	6.9	0	0.0	0	0.0
	FEMALE GENITAL DISORDERS	1	3.4	0	0.0	0	0.0
	MENSTRUAL DISORDER	1	3.4	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=64), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	37	57.8	40	62.5	8	12.5
Body as a Whole	TOTAL	20	31.3	16	25.0	3	4.7
	ABDOMINAL PAIN	4	6.3	3	4.7	1	1.6
	ALLERGIC REACTION	3	4.7	1	1.6	0	0.0
	ASTHENIA	2	3.1	2	3.1	0	0.0
	BACK PAIN	0	0.0	1	1.6	0	0.0
	FEVER	2	3.1	1	1.6	0	0.0
	HEADACHE	11	17.2	6	9.4	0	0.0
	INFECTION	1	1.6	4	6.3	2	3.1
	PAIN	0	0.0	1	1.6	0	0.0
	SPINA BIFIDA	1	1.6	0	0.0	0	0.0
	TRAUMA	5	7.8	2	3.1	1	1.6
Cardiovascular System	TOTAL	4	6.3	0	0.0	1	1.6
	SYNCOPE	0	0.0	0	0.0	1	1.6
	VASODILATATION	4	6.3	0	0.0	0	0.0
Digestive System	TOTAL	11	17.2	7	10.9	1	1.6
	CONSTIPATION	1	1.6	0	0.0	0	0.0
	DECREASED APPETITE	3	4.7	1	1.6	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=64), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DIARRHEA	0	0.0	1	1.6	0	0.0
	DRY MOUTH	2	3.1	0	0.0	0	0.0
	DYSPEPSIA	0	0.0	3	4.7	0	0.0
	FLATULENCE	2	3.1	0	0.0	0	0.0
	GASTROENTERITIS	1	1.6	0	0.0	0	0.0
	GINGIVITIS	0	0.0	1	1.6	0	0.0
	NAUSEA	3	4.7	3	4.7	1	1.6
	TOOTH CARIES	1	1.6	0	0.0	0	0.0
	TOOTH DISORDER	0	0.0	1	1.6	0	0.0
	ULCERATIVE STOMATITIS	1	1.6	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.6	1	1.6	0	0.0
	EOSINOPHILIA	0	0.0	1	1.6	0	0.0
	LEUKOCYTOSIS	1	1.6	0	0.0	0	0.0
	MONOCYTOSIS	0	0.0	1	1.6	0	0.0
Metabolic and Nutritional Disorders	TOTAL	1	1.6	2	3.1	1	1.6
	WEIGHT GAIN	1	1.6	1	1.6	1	1.6
	WEIGHT LOSS	0	0.0	1	1.6	0	0.0
Musculoskeletal System	TOTAL	1	1.6	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=64), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Musculoskeletal System	ARTHRALGIA	1	1.6	0	0.0	0	0.0
Nervous System	TOTAL	15	23.4	24	37.5	4	6.3
	ABNORMAL DREAMS	1	1.6	1	1.6	0	0.0
	AGITATION	1	1.6	2	3.1	0	0.0
	ANXIETY	0	0.0	4	6.3	0	0.0
	DEPRESSION	0	0.0	1	1.6	0	0.0
	DIZZINESS	1	1.6	2	3.1	0	0.0
	DYSKINESIA	1	1.6	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	1	1.6	0	0.0
	HOSTILITY	2	3.1	3	4.7	2	3.1
	HYPERKINESIA	1	1.6	4	6.3	1	1.6
	INSOMNIA	3	4.7	4	6.3	0	0.0
	LACK OF EMOTION	0	0.0	1	1.6	0	0.0
	MANIC REACTION	0	0.0	1	1.6	0	0.0
	MYOCLONUS	1	1.6	0	0.0	0	0.0
	NERVOUSNESS	3	4.7	8	12.5	1	1.6
	NEUROSIS	1	1.6	0	0.0	0	0.0
	PSYCHOSIS	0	0.0	1	1.6	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=64), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	SOMNOLENCE	2	3.1	1	1.6	0	0.0
	TREMOR	2	3.1	0	0.0	0	0.0
	VERTIGO	2	3.1	0	0.0	0	0.0
Respiratory System	TOTAL	11	17.2	9	14.1	0	0.0
	ASTHMA	0	0.0	2	3.1	0	0.0
	COUGH INCREASED	0	0.0	1	1.6	0	0.0
	EPISTAXIS	1	1.6	0	0.0	0	0.0
	PHARYNGITIS	2	3.1	3	4.7	0	0.0
	PNEUMONIA	0	0.0	1	1.6	0	0.0
	RESPIRATORY DISORDER	7	10.9	6	9.4	0	0.0
	RHINITIS	4	6.3	1	1.6	0	0.0
	SINUSITIS	1	1.6	0	0.0	0	0.0
Skin and Appendages	TOTAL	6	9.4	2	3.1	0	0.0
	ACNE	2	3.1	0	0.0	0	0.0
	CONTACT DERMATITIS	2	3.1	1	1.6	0	0.0
	FUNGAL DERMATITIS	0	0.0	1	1.6	0	0.0
	HERPES SIMPLEX	1	1.6	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=64), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	RASH	3	4.7	0	0.0	0	0.0
	SWEATING	1	1.6	0	0.0	0	0.0
	URTICARIA	1	1.6	0	0.0	0	0.0
Special Senses	TOTAL	5	7.8	2	3.1	0	0.0
	ABNORMAL VISION	1	1.6	0	0.0	0	0.0
	EAR PAIN	1	1.6	0	0.0	0	0.0
	OTITIS EXTERNA	1	1.6	0	0.0	0	0.0
	OTITIS MEDIA	1	1.6	2	3.1	0	0.0
	PHOTOPHOBIA	1	1.6	0	0.0	0	0.0
Urogenital System	TOTAL	1	1.6	0	0.0	1	1.6
	URINARY INCONTINENCE	1	1.6	0	0.0	1	1.6

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=42), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=22), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	4.5	0	0.0	0	0.0
Urogenital System	TOTAL	1	4.5	0	0.0	0	0.0
	DYSMENORRHEA	1	4.5	0	0.0	0	0.0
	UTERUS DISORDERS	1	4.5	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=130), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	76	58.5	68	52.3	19	14.6
Body as a Whole	TOTAL	38	29.2	30	23.1	4	3.1
	ABDOMINAL PAIN	6	4.6	5	3.8	1	0.8
	ALLERGIC REACTION	4	3.1	2	1.5	0	0.0
	ASTHENIA	6	4.6	3	2.3	0	0.0
	BACK PAIN	3	2.3	1	0.8	0	0.0
	FEVER	3	2.3	3	2.3	0	0.0
	HEADACHE	19	14.6	8	6.2	0	0.0
	INFECTION	6	4.6	10	7.7	2	1.5
	PAIN	1	0.8	2	1.5	0	0.0
	SPINA BIFIDA	1	0.8	0	0.0	0	0.0
	TRAUMA	7	5.4	5	3.8	2	1.5
Cardiovascular System	TOTAL	6	4.6	1	0.8	2	1.5
	BUNDLE BRANCH BLOCK	1	0.8	0	0.0	0	0.0
	MIGRAINE	0	0.0	0	0.0	1	0.8
	SYNCOPE	1	0.8	1	0.8	1	0.8
	VASODILATATION	4	3.1	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=130), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	TOTAL	27	20.8	12	9.2	2	1.5
	CONSTIPATION	1	0.8	0	0.0	0	0.0
	DECREASED APPETITE	6	4.6	1	0.8	0	0.0
	DIARRHEA	2	1.5	1	0.8	0	0.0
	DRY MOUTH	2	1.5	0	0.0	0	0.0
	DYSPEPSIA	3	2.3	4	3.1	0	0.0
	FLATULENCE	2	1.5	0	0.0	0	0.0
	GASTROENTERITIS	2	1.5	0	0.0	0	0.0
	GASTROINTESTINAL DISORDER	1	0.8	0	0.0	0	0.0
	GINGIVITIS	0	0.0	1	0.8	0	0.0
	INCREASED APPETITE	2	1.5	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	0.8	0	0.0	0	0.0
	NAUSEA	7	5.4	4	3.1	1	0.8
	TOOTH CARIES	2	1.5	1	0.8	1	0.8
	TOOTH DISORDER	0	0.0	1	0.8	0	0.0
	ULCERATIVE STOMATITIS	1	0.8	0	0.0	0	0.0

(CONTINUED)

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=130), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	VOMITING	2	1.5	2	1.5	0	0.0
Hemic and Lymphatic System	TOTAL	2	1.5	2	1.5	0	0.0
	ANEMIA	1	0.8	0	0.0	0	0.0
	EOSINOPHILIA	0	0.0	1	0.8	0	0.0
	LEUKOCYTOSIS	1	0.8	0	0.0	0	0.0
	LEUKOPENIA	1	0.8	1	0.8	0	0.0
	MONOCYTOSIS	0	0.0	1	0.8	0	0.0
Metabolic and Nutritional Disorders	TOTAL	6	4.6	4	3.1	1	0.8
	DEHYDRATION	0	0.0	1	0.8	0	0.0
	WEIGHT GAIN	6	4.6	2	1.5	1	0.8
	WEIGHT LOSS	0	0.0	1	0.8	0	0.0
Musculoskeletal System	TOTAL	2	1.5	1	0.8	0	0.0
	ARTHRALGIA	1	0.8	0	0.0	0	0.0
	ARTHROSIS	0	0.0	1	0.8	0	0.0
	MYALGIA	1	0.8	1	0.8	0	0.0
Nervous System	TOTAL	24	18.5	37	28.5	10	7.7
	ABNORMAL DREAMS	1	0.8	1	0.8	0	0.0
	AGITATION	1	0.8	4	3.1	1	0.8

(CONTINUED)

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=130), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	ANXIETY	1	0.8	4	3.1	1	0.8
	CONCENTRATION IMPAIRED	1	0.8	1	0.8	0	0.0
	DEPRESSION	0	0.0	2	1.5	0	0.0
	DIZZINESS	3	2.3	2	1.5	0	0.0
	DYSKINESIA	1	0.8	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	3	2.3	1	0.8
	EUPHORIA	0	0.0	0	0.0	1	0.8
	HALLUCINATIONS	0	0.0	1	0.8	1	0.8
	HOSTILITY	2	1.5	4	3.1	3	2.3
	HYPERKINESIA	2	1.5	4	3.1	1	0.8
	HYPESTHESIA	1	0.8	1	0.8	0	0.0
	HYSTERIA	0	0.0	1	0.8	0	0.0
	INSOMNIA	7	5.4	5	3.8	0	0.0
	LACK OF EMOTION	0	0.0	1	0.8	0	0.0
	LIBIDO DECREASED	1	0.8	0	0.0	0	0.0
	MANIC REACTION	0	0.0	1	0.8	0	0.0
	MYOCLONUS	1	0.8	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=130), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	NERVOUSNESS	3	2.3	9	6.9	1	0.8
	NEUROSIS	1	0.8	0	0.0	0	0.0
	PARALYSIS	0	0.0	0	0.0	1	0.8
	PSYCHOSIS	0	0.0	1	0.8	0	0.0
	SOMNOLENCE	3	2.3	4	3.1	0	0.0
	TREMOR	3	2.3	1	0.8	0	0.0
	VERTIGO	2	1.5	0	0.0	0	0.0
	WITHDRAWAL SYNDROME	1	0.8	1	0.8	0	0.0
Respiratory System	TOTAL	29	22.3	19	14.6	1	0.8
	ASTHMA	2	1.5	2	1.5	1	0.8
	BRONCHITIS	0	0.0	3	2.3	0	0.0
	COUGH INCREASED	2	1.5	1	0.8	0	0.0
	EPISTAXIS	3	2.3	0	0.0	0	0.0
	PHARYNGITIS	7	5.4	3	2.3	0	0.0
	PNEUMONIA	0	0.0	2	1.5	0	0.0
	RESPIRATORY DISORDER	15	11.5	11	8.5	0	0.0
	RHINITIS	8	6.2	1	0.8	0	0.0
	SINUSITIS	1	0.8	1	0.8	0	0.0

(CONTINUED)

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group

Intention-To-Treat Population

Acute Study Treatment Group : Placebo (N=130), Primary Diagnosis : Total MDD & OCD

Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	YAWN	1	0.8	0	0.0	0	0.0
Skin and Appendages	TOTAL	9	6.9	4	3.1	1	0.8
	ACNE	2	1.5	1	0.8	0	0.0
	CONTACT DERMATITIS	2	1.5	2	1.5	0	0.0
	FUNGAL DERMATITIS	0	0.0	1	0.8	0	0.0
	HERPES SIMPLEX	1	0.8	0	0.0	0	0.0
	MACULOPAPULAR RASH	1	0.8	0	0.0	0	0.0
	PRURITUS	2	1.5	0	0.0	0	0.0
	RASH	4	3.1	0	0.0	1	0.8
	SWEATING	1	0.8	0	0.0	0	0.0
	URTICARIA	1	0.8	0	0.0	0	0.0
Special Searches	TOTAL	0	0.0	1	0.8	0	0.0
	PUNCTURE SITE PAIN	0	0.0	1	0.8	0	0.0
Special Senses	TOTAL	6	4.6	2	1.5	1	0.8
	ABNORMAL VISION	2	1.5	0	0.0	0	0.0
	EAR PAIN	1	0.8	0	0.0	0	0.0

(CONTINUED)

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=130), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Special Senses	OTITIS EXTERNA	1	0.8	0	0.0	0	0.0
	OTITIS MEDIA	1	0.8	2	1.5	1	0.8
	PHOTOPHOBIA	1	0.8	0	0.0	0	0.0
Urogenital System	TOTAL	5	3.8	0	0.0	2	1.5
	ALBUMINURIA	2	1.5	0	0.0	0	0.0
	CYSTITIS	1	0.8	0	0.0	0	0.0
	HAEMATURIA	2	1.5	0	0.0	0	0.0
	URINARY INCONTINENCE	2	1.5	0	0.0	2	1.5

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Acute Study Treatment Group : Placebo (N=79), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Open-label Treatment or Taper Phase by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group

Intention-To-Treat Population

Acute Study Treatment Group : Placebo (N=51), Primary Diagnosis : Total MDD & OCD

Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	3	5.9	0	0.0	0	0.0
Urogenital System	TOTAL	3	5.9	0	0.0	0	0.0
	DYSMENORRHEA	1	2.0	0	0.0	0	0.0
	FEMALE GENITAL DISORDERS	1	2.0	0	0.0	0	0.0
	MENSTRUAL DISORDER	1	2.0	0	0.0	0	0.0
	UTERUS DISORDERS	1	2.0	0	0.0	0	0.0

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=49), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	11	22.4	5	10.2	1	2.0
Body as a Whole	TOTAL	1	2.0	2	4.1	0	0.0
	ABDOMINAL PAIN	1	2.0	2	4.1	0	0.0
	HEADACHE	1	2.0	1	2.0	0	0.0
Cardiovascular System	TOTAL	0	0.0	1	2.0	0	0.0
	MIGRAINE	0	0.0	1	2.0	0	0.0
Digestive System	TOTAL	3	6.1	2	4.1	0	0.0
	COLITIS	1	2.0	0	0.0	0	0.0
	DIARRHEA	1	2.0	0	0.0	0	0.0
	GASTROINTESTINAL DISORDER	1	2.0	0	0.0	0	0.0
	INCREASED APPETITE	0	0.0	1	2.0	0	0.0
	NAUSEA	0	0.0	1	2.0	0	0.0
	TOOTH DISORDER	0	0.0	1	2.0	0	0.0
	VOMITING	1	2.0	0	0.0	0	0.0
Musculoskeletal System	TOTAL	1	2.0	0	0.0	0	0.0
	MYALGIA	1	2.0	0	0.0	0	0.0
Nervous System	TOTAL	3	6.1	1	2.0	1	2.0
	ANXIETY	0	0.0	1	2.0	0	0.0

(CONTINUED)

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=49), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	DEPRESSION	1	2.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	1	2.0
	INSOMNIA	1	2.0	0	0.0	0	0.0
	NERVOUSNESS	0	0.0	1	2.0	0	0.0
	WITHDRAWAL SYNDROME	1	2.0	0	0.0	0	0.0
Respiratory System	TOTAL	5	10.2	1	2.0	0	0.0
	ASTHMA	0	0.0	1	2.0	0	0.0
	PHARYNGITIS	1	2.0	0	0.0	0	0.0
	RESPIRATORY DISORDER	3	6.1	0	0.0	0	0.0
	SINUSITIS	1	2.0	0	0.0	0	0.0
Urogenital System	TOTAL	1	2.0	0	0.0	0	0.0
	ALBUMINURIA	1	2.0	0	0.0	0	0.0

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=29), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=20), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=23), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	7	30.4	3	13.0	1	4.3
Body as a Whole	TOTAL	3	13.0	1	4.3	1	4.3
	FEVER	1	4.3	0	0.0	0	0.0
	HEADACHE	1	4.3	1	4.3	1	4.3
	PAIN	1	4.3	0	0.0	0	0.0
Digestive System	TOTAL	0	0.0	1	4.3	0	0.0
	TOOTH DISORDER	0	0.0	1	4.3	0	0.0
Nervous System	TOTAL	2	8.7	1	4.3	0	0.0
	CONCENTRATION IMPAIRED	0	0.0	1	4.3	0	0.0
	DIZZINESS	1	4.3	0	0.0	0	0.0
	NEUROSIS	1	4.3	0	0.0	0	0.0
	PARESTHESIA	0	0.0	1	4.3	0	0.0
Respiratory System	TOTAL	2	8.7	1	4.3	0	0.0
	COUGH INCREASED	1	4.3	0	0.0	0	0.0
	RESPIRATORY DISORDER	1	4.3	0	0.0	0	0.0
	SINUSITIS	0	0.0	1	4.3	0	0.0
Special Senses	TOTAL	1	4.3	0	0.0	0	0.0
	EAR PAIN	1	4.3	0	0.0	0	0.0

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Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=11), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=12), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=72), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	18	25.0	8	11.1	2	2.8
Body as a Whole	TOTAL	4	5.6	3	4.2	1	1.4
	ABDOMINAL PAIN	1	1.4	2	2.8	0	0.0
	FEVER	1	1.4	0	0.0	0	0.0
	HEADACHE	2	2.8	2	2.8	1	1.4
	PAIN	1	1.4	0	0.0	0	0.0
Cardiovascular System	TOTAL	0	0.0	1	1.4	0	0.0
	MIGRAINE	0	0.0	1	1.4	0	0.0
Digestive System	TOTAL	3	4.2	3	4.2	0	0.0
	COLITIS	1	1.4	0	0.0	0	0.0
	DIARRHEA	1	1.4	0	0.0	0	0.0
	GASTROINTESTIN-AL DISORDER	1	1.4	0	0.0	0	0.0
	INCREASED APPETITE	0	0.0	1	1.4	0	0.0
	NAUSEA	0	0.0	1	1.4	0	0.0
	TOOTH DISORDER	0	0.0	2	2.8	0	0.0
	VOMITING	1	1.4	0	0.0	0	0.0
Musculoskeletal System	TOTAL	1	1.4	0	0.0	0	0.0
	MYALGIA	1	1.4	0	0.0	0	0.0

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Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=72), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	TOTAL	5	6.9	2	2.8	1	1.4
	ANXIETY	0	0.0	1	1.4	0	0.0
	CONCENTRATION IMPAIRED	0	0.0	1	1.4	0	0.0
	DEPRESSION	1	1.4	0	0.0	0	0.0
	DIZZINESS	1	1.4	0	0.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	1	1.4
	INSOMNIA	1	1.4	0	0.0	0	0.0
	NERVOUSNESS	0	0.0	1	1.4	0	0.0
	NEUROSIS	1	1.4	0	0.0	0	0.0
	PARESTHESIA	0	0.0	1	1.4	0	0.0
	WITHDRAWAL SYNDROME	1	1.4	0	0.0	0	0.0
Respiratory System	TOTAL	7	9.7	2	2.8	0	0.0
	ASTHMA	0	0.0	1	1.4	0	0.0
	COUGH INCREASED	1	1.4	0	0.0	0	0.0
	PHARYNGITIS	1	1.4	0	0.0	0	0.0
	RESPIRATORY DISORDER	4	5.6	0	0.0	0	0.0
	SINUSITIS	1	1.4	1	1.4	0	0.0

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Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=72), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Special Senses	TOTAL	1	1.4	0	0.0	0	0.0
	EAR PAIN	1	1.4	0	0.0	0	0.0
Urogenital System	TOTAL	1	1.4	0	0.0	0	0.0
	ALBUMINURIA	1	1.4	0	0.0	0	0.0

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=40), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Paroxetine (N=32), Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=34), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	4	11.8	5	14.7	0	0.0
Body as a Whole	TOTAL	2	5.9	0	0.0	0	0.0
	ALLERGIC REACTION	1	2.9	0	0.0	0	0.0
	INFECTION	1	2.9	0	0.0	0	0.0
Digestive System	TOTAL	2	5.9	0	0.0	0	0.0
	DIARRHEA	1	2.9	0	0.0	0	0.0
	FECAL INCONTINENCE	1	2.9	0	0.0	0	0.0
	NAUSEA	1	2.9	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	0	0.0	1	2.9	0	0.0
	LYMPHOCYTOSIS	0	0.0	1	2.9	0	0.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	1	2.9	0	0.0
	SGOT INCREASED	0	0.0	1	2.9	0	0.0
Nervous System	TOTAL	0	0.0	2	5.9	0	0.0
	CONCENTRATION IMPAIRED	0	0.0	1	2.9	0	0.0
	HOSTILITY	0	0.0	1	2.9	0	0.0
Respiratory System	TOTAL	1	2.9	2	5.9	0	0.0
	RESPIRATORY DISORDER	1	2.9	2	5.9	0	0.0

(CONTINUED)

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=34), Primary Diagnosis : Major Depressive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Urogenital System	TOTAL	1	2.9	0	0.0	0	0.0
	URINARY INCONTINENCE	1	2.9	0	0.0	0	0.0

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=18), Primary Diagnosis : Major Depressive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=16), Primary Diagnosis : Major Depressive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=33), Primary Diagnosis : Obsessive-Compulsive Disorder
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	2	6.1	6	18.2	1	3.0
Body as a Whole	TOTAL	0	0.0	3	9.1	1	3.0
	FEVER	0	0.0	1	3.0	0	0.0
	HEADACHE	0	0.0	2	6.1	0	0.0
	INFECTION	0	0.0	0	0.0	1	3.0
Digestive System	TOTAL	1	3.0	1	3.0	0	0.0
	DIARRHEA	1	3.0	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	3.0	0	0.0	0	0.0
	NAUSEA	0	0.0	1	3.0	0	0.0
	VOMITING	1	3.0	0	0.0	0	0.0
Respiratory System	TOTAL	1	3.0	1	3.0	0	0.0
	COUGH INCREASED	0	0.0	1	3.0	0	0.0
	RESPIRATORY DISORDER	1	3.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	1	3.0	0	0.0
	FUNGAL DERMATITIS	0	0.0	1	3.0	0	0.0

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Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=21), Primary Diagnosis : Obsessive-Compulsive Disorder
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=12), Primary Diagnosis : Obsessive-Compulsive Disorder
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=67), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	6	9.0	11	16.4	1	1.5
Body as a Whole	TOTAL	2	3.0	3	4.5	1	1.5
	ALLERGIC REACTION	1	1.5	0	0.0	0	0.0
	FEVER	0	0.0	1	1.5	0	0.0
	HEADACHE	0	0.0	2	3.0	0	0.0
	INFECTION	1	1.5	0	0.0	1	1.5
Digestive System	TOTAL	3	4.5	1	1.5	0	0.0
	DIARRHEA	2	3.0	0	0.0	0	0.0
	FECAL INCONTINENCE	1	1.5	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	1.5	0	0.0	0	0.0
	NAUSEA	1	1.5	1	1.5	0	0.0
	VOMITING	1	1.5	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	0	0.0	1	1.5	0	0.0
	LYMPHOCYTOSIS	0	0.0	1	1.5	0	0.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	1	1.5	0	0.0
	SGOT INCREASED	0	0.0	1	1.5	0	0.0
Nervous System	TOTAL	0	0.0	2	3.0	0	0.0

(CONTINUED)

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=67), Primary Diagnosis : Total MDD & OCD
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	CONCENTRATION IMPAIRED	0	0.0	1	1.5	0	0.0
	HOSTILITY	0	0.0	1	1.5	0	0.0
Respiratory System	TOTAL	2	3.0	3	4.5	0	0.0
	COUGH INCREASED	0	0.0	1	1.5	0	0.0
	RESPIRATORY DISORDER	2	3.0	2	3.0	0	0.0
Skin and Appendages	TOTAL	0	0.0	1	1.5	0	0.0
	FUNGAL DERMATITIS	0	0.0	1	1.5	0	0.0
Urogenital System	TOTAL	1	1.5	0	0.0	0	0.0
	URINARY INCONTINENCE	1	1.5	0	0.0	0	0.0

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=39), Primary Diagnosis : Total MDD & OCD
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-Up Phase
by Maximum Intensity, Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Acute Study Treatment Group : Placebo (N=28), Primary Diagnosis : Total MDD & OCD
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=39)	Placebo (N=36)	Total (N=75)
Body System	Preferred Term			
TOTAL	TOTAL	8 (20.5%)	5 (13.9%)	13 (17.3%)
Nervous System	TOTAL	7 (17.9%)	3 (8.3%)	10 (13.3%)
	HOSTILITY	3 (7.7%)	0	3 (4.0%)
	NERVOUSNESS	3 (7.7%)	0	3 (4.0%)
	AGITATION	1 (2.6%)	1 (2.8%)	2 (2.7%)
	HYPERKINESIA	1 (2.6%)	0	1 (1.3%)
	NEUROSIS	1 (2.6%)	0	1 (1.3%)
	INSOMNIA	0	1 (2.8%)	1 (1.3%)
	TREMOR	0	1 (2.8%)	1 (1.3%)
Body as a Whole	TOTAL	1 (2.6%)	0	1 (1.3%)
	ASTHENIA	1 (2.6%)	0	1 (1.3%)
Digestive System	TOTAL	1 (2.6%)	2 (5.6%)	3 (4.0%)
	DYSPEPSIA	1 (2.6%)	1 (2.8%)	2 (2.7%)
	NAUSEA	0	1 (2.8%)	1 (1.3%)
	VOMITING	0	1 (2.8%)	1 (1.3%)
Urogenital System	TOTAL	1 (2.6%)	1 (2.8%)	2 (2.7%)
	URINARY INCONTINENCE	1 (2.6%)	1 (2.8%)	2 (2.7%)

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=20)	Placebo (N=22)	Total (N=42)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=19)	Placebo (N=14)	Total (N=33)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=36)	Total (N=64)
Body System	Preferred Term			
TOTAL	TOTAL	4 (14.3%)	12 (33.3%)	16 (25.0%)
Nervous System	TOTAL	3 (10.7%)	11 (30.6%)	14 (21.9%)
	HYPERKINESIA	3 (10.7%)	1 (2.8%)	4 (6.3%)
	NERVOUSNESS	0	4 (11.1%)	4 (6.3%)
	HOSTILITY	0	3 (8.3%)	3 (4.7%)
	ANXIETY	0	2 (5.6%)	2 (3.1%)
	DYSKINESIA	0	1 (2.8%)	1 (1.6%)
	LACK OF EMOTION	0	1 (2.8%)	1 (1.6%)
	SOMNOLENCE	0	1 (2.8%)	1 (1.6%)
	TREMOR	0	1 (2.8%)	1 (1.6%)
Body as a Whole	TOTAL	1 (3.6%)	2 (5.6%)	3 (4.7%)
	HEADACHE	1 (3.6%)	1 (2.8%)	2 (3.1%)
	ABDOMINAL PAIN	0	1 (2.8%)	1 (1.6%)
Metabolic and Nutritional Disorders	TOTAL	0	2 (5.6%)	2 (3.1%)
	WEIGHT GAIN	0	2 (5.6%)	2 (3.1%)

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Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=23)	Total (N=35)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=16)	Placebo (N=13)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=67)	Placebo (N=72)	Total (N=139)
Body System	Preferred Term			
TOTAL	TOTAL	12 (17.9%)	17 (23.6%)	29 (20.9%)
Nervous System	TOTAL	10 (14.9%)	14 (19.4%)	24 (17.3%)
	NERVOUSNESS	3 (4.5%)	4 (5.6%)	7 (5.0%)
	HOSTILITY	3 (4.5%)	3 (4.2%)	6 (4.3%)
	HYPERKINESIA	4 (6.0%)	1 (1.4%)	5 (3.6%)
	AGITATION	1 (1.5%)	1 (1.4%)	2 (1.4%)
	ANXIETY	0	2 (2.8%)	2 (1.4%)
	TREMOR	0	2 (2.8%)	2 (1.4%)
	NEUROSIS	1 (1.5%)	0	1 (0.7%)
	DYSKINESIA	0	1 (1.4%)	1 (0.7%)
	INSOMNIA	0	1 (1.4%)	1 (0.7%)
	LACK OF EMOTION	0	1 (1.4%)	1 (0.7%)
	SOMNOLENCE	0	1 (1.4%)	1 (0.7%)
Body as a Whole	TOTAL	2 (3.0%)	2 (2.8%)	4 (2.9%)
	HEADACHE	1 (1.5%)	1 (1.4%)	2 (1.4%)
	ASTHENIA	1 (1.5%)	0	1 (0.7%)
	ABDOMINAL PAIN	0	1 (1.4%)	1 (0.7%)
Digestive System	TOTAL	1 (1.5%)	2 (2.8%)	3 (2.2%)
	DYSPEPSIA	1 (1.5%)	1 (1.4%)	2 (1.4%)
	NAUSEA	0	1 (1.4%)	1 (0.7%)
	VOMITING	0	1 (1.4%)	1 (0.7%)
Urogenital System	TOTAL	1 (1.5%)	1 (1.4%)	2 (1.4%)
	URINARY INCONTINENCE	1 (1.5%)	1 (1.4%)	2 (1.4%)
Metabolic and Nutritional Disorders	TOTAL	0	2 (2.8%)	2 (1.4%)
	WEIGHT GAIN	0	2 (2.8%)	2 (1.4%)

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Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=32)	Placebo (N=45)	Total (N=77)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=35)	Placebo (N=27)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=42)	Placebo (N=30)	Total (N=72)
Body System	Preferred Term			
TOTAL	TOTAL	5 (11.9%)	3 (10.0%)	8 (11.1%)
Nervous System	TOTAL	4 (9.5%)	3 (10.0%)	7 (9.7%)
	SOMNOLENCE	2 (4.8%)	0	2 (2.8%)
	AGITATION	1 (2.4%)	1 (3.3%)	2 (2.8%)
	INSOMNIA	1 (2.4%)	1 (3.3%)	2 (2.8%)
	NERVOUSNESS	1 (2.4%)	1 (3.3%)	2 (2.8%)
	ANXIETY	1 (2.4%)	0	1 (1.4%)
	EMOTIONAL LABILITY	0	1 (3.3%)	1 (1.4%)
Body as a Whole	TOTAL	1 (2.4%)	1 (3.3%)	2 (2.8%)
	ABDOMINAL PAIN	1 (2.4%)	1 (3.3%)	2 (2.8%)
	HEADACHE	0	1 (3.3%)	1 (1.4%)
Digestive System	TOTAL	1 (2.4%)	0	1 (1.4%)
	NAUSEA	1 (2.4%)	0	1 (1.4%)
	VOMITING	1 (2.4%)	0	1 (1.4%)

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=15)	Total (N=43)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=14)	Placebo (N=15)	Total (N=29)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=28)	Total (N=52)
Body System	Preferred Term			
TOTAL	TOTAL	3 (12.5%)	2 (7.1%)	5 (9.6%)
Nervous System	TOTAL	3 (12.5%)	1 (3.6%)	4 (7.7%)
	HOSTILITY	1 (4.2%)	1 (3.6%)	2 (3.8%)
	HYPERKINESIA	1 (4.2%)	1 (3.6%)	2 (3.8%)
	ANXIETY	1 (4.2%)	0	1 (1.9%)
	INSOMNIA	1 (4.2%)	0	1 (1.9%)
	MANIC REACTION	1 (4.2%)	0	1 (1.9%)
	NERVOUSNESS	1 (4.2%)	0	1 (1.9%)
Body as a Whole	TOTAL	1 (4.2%)	0	1 (1.9%)
	ASTHENIA	1 (4.2%)	0	1 (1.9%)
Digestive System	TOTAL	0	1 (3.6%)	1 (1.9%)
	DECREASED APPETITE	0	1 (3.6%)	1 (1.9%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (3.6%)	1 (1.9%)
	WEIGHT LOSS	0	1 (3.6%)	1 (1.9%)

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=19)	Total (N=31)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=12)	Placebo (N=9)	Total (N=21)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=66)	Placebo (N=58)	Total (N=124)
Body System	Preferred Term			
TOTAL	TOTAL	8 (12.1%)	5 (8.6%)	13 (10.5%)
Nervous System	TOTAL	7 (10.6%)	4 (6.9%)	11 (8.9%)
	INSOMNIA	2 (3.0%)	1 (1.7%)	3 (2.4%)
	NERVOUSNESS	2 (3.0%)	1 (1.7%)	3 (2.4%)
	ANXIETY	2 (3.0%)	0	2 (1.6%)
	SOMNOLENCE	2 (3.0%)	0	2 (1.6%)
	AGITATION	1 (1.5%)	1 (1.7%)	2 (1.6%)
	HOSTILITY	1 (1.5%)	1 (1.7%)	2 (1.6%)
	HYPERKINESIA	1 (1.5%)	1 (1.7%)	2 (1.6%)
	MANIC REACTION	1 (1.5%)	0	1 (0.8%)
	EMOTIONAL LABILITY	0	1 (1.7%)	1 (0.8%)
Body as a Whole	TOTAL	2 (3.0%)	1 (1.7%)	3 (2.4%)
	ABDOMINAL PAIN	1 (1.5%)	1 (1.7%)	2 (1.6%)
	ASTHENIA	1 (1.5%)	0	1 (0.8%)
	HEADACHE	0	1 (1.7%)	1 (0.8%)
Digestive System	TOTAL	1 (1.5%)	1 (1.7%)	2 (1.6%)
	NAUSEA	1 (1.5%)	0	1 (0.8%)
	VOMITING	1 (1.5%)	0	1 (0.8%)
	DECREASED APPETITE	0	1 (1.7%)	1 (0.8%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.7%)	1 (0.8%)
	WEIGHT LOSS	0	1 (1.7%)	1 (0.8%)

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=40)	Placebo (N=34)	Total (N=74)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=26)	Placebo (N=24)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=81)	Placebo (N=66)	Total (N=147)
Body System	Preferred Term			
TOTAL	TOTAL	13 (16.0%)	8 (12.1%)	21 (14.3%)
Nervous System	TOTAL	11 (13.6%)	6 (9.1%)	17 (11.6%)
	NERVOUSNESS	4 (4.9%)	1 (1.5%)	5 (3.4%)
	AGITATION	2 (2.5%)	2 (3.0%)	4 (2.7%)
	HOSTILITY	3 (3.7%)	0	3 (2.0%)
	INSOMNIA	1 (1.2%)	2 (3.0%)	3 (2.0%)
	SOMNOLENCE	2 (2.5%)	0	2 (1.4%)
	ANXIETY	1 (1.2%)	0	1 (0.7%)
	HYPERKINESIA	1 (1.2%)	0	1 (0.7%)
	NEUROSIS	1 (1.2%)	0	1 (0.7%)
	EMOTIONAL LABILITY	0	1 (1.5%)	1 (0.7%)
	TREMOR	0	1 (1.5%)	1 (0.7%)
Body as a Whole	TOTAL	2 (2.5%)	1 (1.5%)	3 (2.0%)
	ABDOMINAL PAIN	1 (1.2%)	1 (1.5%)	2 (1.4%)
	ASTHENIA	1 (1.2%)	0	1 (0.7%)
	HEADACHE	0	1 (1.5%)	1 (0.7%)
Digestive System	TOTAL	2 (2.5%)	2 (3.0%)	4 (2.7%)
	DYSPEPSIA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	NAUSEA	1 (1.2%)	1 (1.5%)	2 (1.4%)
	VOMITING	1 (1.2%)	1 (1.5%)	2 (1.4%)
Urogenital System	TOTAL	1 (1.2%)	1 (1.5%)	2 (1.4%)
	URINARY INCONTINENCE	1 (1.2%)	1 (1.5%)	2 (1.4%)

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=48)	Placebo (N=37)	Total (N=85)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Major Depressive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=33)	Placebo (N=29)	Total (N=62)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Gender Non Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=52)	Placebo (N=64)	Total (N=116)
Body System	Preferred Term			
TOTAL	TOTAL	7 (13.5%)	14 (21.9%)	21 (18.1%)
Nervous System	TOTAL	6 (11.5%)	12 (18.8%)	18 (15.5%)
	HYPERKINESIA	4 (7.7%)	2 (3.1%)	6 (5.2%)
	HOSTILITY	1 (1.9%)	4 (6.3%)	5 (4.3%)
	NERVOUSNESS	1 (1.9%)	4 (6.3%)	5 (4.3%)
	ANXIETY	1 (1.9%)	2 (3.1%)	3 (2.6%)
	INSOMNIA	1 (1.9%)	0	1 (0.9%)
	MANIC REACTION	1 (1.9%)	0	1 (0.9%)
	DYSKINESIA	0	1 (1.6%)	1 (0.9%)
	LACK OF EMOTION	0	1 (1.6%)	1 (0.9%)
	SOMNOLENCE	0	1 (1.6%)	1 (0.9%)
	TREMOR	0	1 (1.6%)	1 (0.9%)
Body as a Whole	TOTAL	2 (3.8%)	2 (3.1%)	4 (3.4%)
	HEADACHE	1 (1.9%)	1 (1.6%)	2 (1.7%)
	ASTHENIA	1 (1.9%)	0	1 (0.9%)
	ABDOMINAL PAIN	0	1 (1.6%)	1 (0.9%)
Digestive System	TOTAL	0	1 (1.6%)	1 (0.9%)
	DECREASED APPETITE	0	1 (1.6%)	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	0	3 (4.7%)	3 (2.6%)
	WEIGHT GAIN	0	2 (3.1%)	2 (1.7%)
	WEIGHT LOSS	0	1 (1.6%)	1 (0.9%)

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=24)	Placebo (N=42)	Total (N=66)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Obsessive-Compulsive Disorder, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=28)	Placebo (N=22)	Total (N=50)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Acute Study Treatment Group Paroxetine (N=133)	Placebo (N=130)	Total (N=263)
TOTAL	TOTAL	20 (15.0%)	22 (16.9%)	42 (16.0%)
Nervous System	TOTAL	17 (12.8%)	18 (13.8%)	35 (13.3%)
	NERVOUSNESS	5 (3.8%)	5 (3.8%)	10 (3.8%)
	HOSTILITY	4 (3.0%)	4 (3.1%)	8 (3.0%)
	HYPERKINESIA	5 (3.8%)	2 (1.5%)	7 (2.7%)
	AGITATION	2 (1.5%)	2 (1.5%)	4 (1.5%)
	ANXIETY	2 (1.5%)	2 (1.5%)	4 (1.5%)
	INSOMNIA	2 (1.5%)	2 (1.5%)	4 (1.5%)
	SOMNOLENCE	2 (1.5%)	1 (0.8%)	3 (1.1%)
	TREMOR	0	2 (1.5%)	2 (0.8%)
	MANIC REACTION	1 (0.8%)	0	1 (0.4%)
	NEUROSIS	1 (0.8%)	0	1 (0.4%)
	DYSKINESIA	0	1 (0.8%)	1 (0.4%)
	EMOTIONAL LABILITY	0	1 (0.8%)	1 (0.4%)
	LACK OF EMOTION	0	1 (0.8%)	1 (0.4%)
Body as a Whole	TOTAL	4 (3.0%)	3 (2.3%)	7 (2.7%)
	ABDOMINAL PAIN	1 (0.8%)	2 (1.5%)	3 (1.1%)
	HEADACHE	1 (0.8%)	2 (1.5%)	3 (1.1%)
	ASTHENIA	2 (1.5%)	0	2 (0.8%)
Digestive System	TOTAL	2 (1.5%)	3 (2.3%)	5 (1.9%)
	DYSPEPSIA	1 (0.8%)	1 (0.8%)	2 (0.8%)
	NAUSEA	1 (0.8%)	1 (0.8%)	2 (0.8%)
	VOMITING	1 (0.8%)	1 (0.8%)	2 (0.8%)
	DECREASED APPETITE	0	1 (0.8%)	1 (0.4%)
Urogenital System	TOTAL	1 (0.8%)	1 (0.8%)	2 (0.8%)
	URINARY INCONTINENCE	1 (0.8%)	1 (0.8%)	2 (0.8%)
Metabolic and Nutritional Disorders	TOTAL	0	3 (2.3%)	3 (1.1%)
	WEIGHT GAIN	0	2 (1.5%)	2 (0.8%)
	WEIGHT LOSS	0	1 (0.8%)	1 (0.4%)

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Male Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=72)	Placebo (N=79)	Total (N=151)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences
During the Open-Label Treatment Phase By Body System, Preferred Term and Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total, Primary Diagnosis : Total MDD & OCD, Female Specific Adverse Experiences

		Acute Study Treatment Group		
		Paroxetine (N=61)	Placebo (N=51)	Total (N=112)
Body System	Preferred Term			
TOTAL	TOTAL	0	0	0

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BRL-029060

Narratives for Patients with Serious Adverse Events

716

Table 15.1.9

SB Document Number: BRL-029060/RSD-101TCX/1

Issue Date: 16 September 2002

PID: 716.004.25405

Protocol: 29060/716

AEGIS number: 2000036595-1

Study medication: Paroxetine 20 mg

Verbatim (preferred term): Left retropharyngeal abscess (MEDRA code abscess NOS; ADECS code abscess NOS)

Case reference number A0340120 (2000036595-1) is a clinical trial report from open-label extension study 29060/716 to assess the long-term safety of paroxetine in children and adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 7-year-old female (patient identification number 716.004.25405).

The patient previously participated in the double-blind acute study 29060/704 (patient identification number 704.004.25405) and was randomized to the paroxetine treatment group.

The patient's medical history included allergies, leg aches, headaches, simple phobia, generalized anxiety disorder, and obsessive-compulsive disorder. Concomitant medications loratadine (Claritin®), multivitamins (One-A-Day Complete Kids®), dextromethorphan hydrobromide/chlorphenamine maleate/ phenylpropanolamine HCl (Triaminic Cold and Cough), and paracetamol (Tylenol).

On 06 July 2000, the patient initiated treatment with flexible-dose study medication, paroxetine 10 mg PO once daily. On 12 July 2000, study medication was up-titrated to 20 mg once daily. On 10 December 2000, 157 days after the start of study medication and 163 days after up-titration to 20 mg, the patient was hospitalized with a left retropharyngeal abscess. The patient underwent an intraoral incision and drainage. Treatment included intravenous clindamycin HCl (Cleocin®), cefuroxime sodium (Zinacef®), morphine sulfate, fentanyl, midazolam HCl (Versed®), and PO codeine phosphate/paracetamol (Tylenol® with codeine), and amoxicillin trihydrate/clavulanic acid (Augmentin®). Treatment with study medication was not stopped due to this event. The event resolved on 17 December 2000.

The investigator reported the left retropharyngeal abscess as not related to treatment with study medication.

On 02 January 2001, the patient completed the study, and received the last dose of study medication.

21 July 2002: Additional clarifying information, available at time of final reporting, is provided below.

This white female patient was 7 years old at the time of entry into acute Study 704 and 8 years old at the time of entry into extension Study 716. The patient's primary diagnosis was OCD.

The serious adverse event, left retropharyngeal abscess, was considered by the investigator to be severe in intensity.

The patient received the last dose of open-label study medication at a dose of 20 mg/day during the active phase of the study on 02 January 2001 (Day 181). The dose was decreased to 10 mg/day (Taper Phase) on 03 January 2001 and the final dose of 10 mg/day was taken on 09 January 2001 (Day 188). The patient had taken paroxetine for 78 days, including taper, during the acute study.

The patient received numerous concomitant medications during the study, including One-A-Day Kids Complete® multivitamins and multi-minerals as dietary supplement; Claritin® (loratadine) for allergies; Cefzil® (cefprozil monohydrate) for earache; Triaminic Triaminicol Cold and Cough Medication®, Triaminic Cough and Cold®, Triaminic Sore Throat Formula®, Children's Sudafed Cough and Cold® (pseudoephedrine HCl, dextromethorphan hydrobromide), Junior Strength Tylenol® (paracetamol) and Children's Tylenol® (paracetamol) for nasal congestion and/or cough, and/or sore throat, and/or headache and/or ear ache and/or pain from abscess; and Tylenol® (paracetamol) for headache and leg aches. The following additional medications were prescribed for treatment of retropharyngeal abscess: Decadron® (dexamethasone), metoclopramide and propofol.

Numerous other non-serious adverse events were reported during the study. Mild headaches occurred on 19 July 2000 (Day 14), 19 August 2000 (Day 45), 07 October 2000 (Day 94), and 14 November 2000 (Day 132). Moderately severe headaches occurred on 29 November 2000 (Day 147). Headaches resolved with treatment in 1, 1, 18 (five episodes/18 days), 1, and 48 (nine episodes/ 48 days) days, respectively. The investigator considered the headache with onset on Day 132 to be unrelated to study medication, headaches on Days 94 and 147 to be

probably unrelated, and headaches on Days 14 and 45 to be possibly related to treatment with study medication.

The patient had mild nausea on 21 July 2000 (Day 16) and on 15 August 2000 (Day 41). Both events resolved without treatment in one day. Onset of nausea on Day 16 was considered by the investigator to be possibly related to treatment with study medication; onset of nausea on Day 41 was considered to be probably unrelated.

Episodes of mild pain (leg ache) occurred on 02 August 2000 (Day 28), 29 October 2000 (Day 116), and 02 November 2000 (Day 120). All were treated and resolved within one day. The investigator considered the event on Day 28 to be possibly related to treatment with study medication, but the events on Days 116 and 120 to be unrelated to treatment with study medication. On 10 January 2001 (one day after the final taper dose of study medication), the patient again reported mild pain (leg pain), which resolved with treatment in one day. This episode was considered by the investigator to be probably unrelated to treatment with study medication.

The patient had mild dyspepsia (upset stomach) on 06 August 2000 (Day 32), which resolved without treatment in one day. The investigator considered this event to be possibly related to treatment with study medication.

Mildly increased cough (cough, cough/congestion), and mild rhinitis (nasal congestion, cough/congestion) each occurred on 06 September 2000 (Day 63) and on 04 December 2000 (Day 152). Each episode resolved with treatment in 3 days and 7 days, respectively. The investigator considered the episodes on Day 63 to be unrelated to treatment with study medication and the episodes on Day 152 to be probably unrelated. On 08 January 2001 (one day before the final dose of study medication during the Taper Phase), the patient had moderately severe sinusitis (sinus infection). The sinusitis continued through the end of the study reporting period despite corrective therapy. The event was considered by the investigator to be probably unrelated to treatment with study medication.

Mild pharyngitis (sore throat) was reported on 10 October 2000 (Day 97). This event resolved with treatment in one day and was considered by the investigator to be unrelated to treatment with study medication. Severe pharyngitis (sore throats) was reported on 29 November 2000 (Day 147). The events resolved with treatment within 20 days (5 episodes in 20 days), and were considered by the investigator to be unrelated to treatment with study medication.

Moderately severe pain (pain secondary to incision and drainage of abscess) was reported 13 December 2000 (Day 161). The pain resolved with treatment in three

days. The investigator considered the event to be probably unrelated to treatment with study medication. Two episodes of mild diarrhea, which lasted one day, were also reported on Day 161. No treatment was given for this condition, which was considered by the investigator to be probably unrelated to treatment with study medication.

Moderately severe ear pain (bilateral earaches) was reported on 09 December 2000 (Day 157). Six episodes occurred over a period continuing through the end of the study. On 28 December 2000 (Day 176), moderately severe otitis media (right ear infection) was reported, which also continued through the end of the study. Both events were treated and considered to be probably unrelated to treatment with study medication

No other adverse events were reported during the study.

PID: 716.013.00701

Protocol: 29060/716

AEGIS number: 2001004050-1

Study medication: Paroxetine (post-therapy)

Verbatim (preferred term): Suicidal ideation (MEDRA code suicidal ideation; ADECS code emotional lability)

Case reference number A0343501 (2001004050-1) is a clinical trial report from open-label extension study 29060/716 to assess the long-term safety of paroxetine in children and adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder. This report refers to a 15-year-old female (patient identification number 716.013.00701).

The patient's medical history included seasonal allergic rhinitis. Concomitant medication included levonorgestrel.

On 12 January 2001, the patient began treatment with flexible-dose study medication, paroxetine 30 mg once daily. On 27 January 2001, the patient was up-titrated to dose level 40 mg. On 01 February 2001, the patient's mother reported that she took the last dose of study medication, and did not taper down the study medication dose. On 04 February 2001, 24 days after starting treatment with study medication and 3 days after stopping study medication, the patient was admitted to the hospital for suicidal ideations. It was reported that the patient had been having sexual relations and was upset over a situation with a boyfriend. The patient was arrested and admitted to the hospital. The patient remained stable, and she was discharged from the hospital. The event was reported as resolved on 09 February 2001.

The investigator reported the suicidal ideations as unlikely to be related to treatment with study medication, and probably associated with the patient's medical history of MDD (major depressive disorder)/psychosocial disorder.

On 10 February 2001, nine days after stopping therapy with study medication, the patient returned home from the 04 February 2001 hospitalization, and was readmitted to the hospital due to an inability to demonstrate a "safe plan." The patient was diagnosed with suicidal ideation. On 15 February 2001, the event resolved.

The investigator reported the suicidal ideation as not related to treatment with study medication, and associated with the patient's medical history of MDD.

21 July 2002: Additional clarifying information, available at time of final reporting, is provided below.

This white female patient with MDD previously participated in open-label pharmacokinetic (PK) Study 715 (patient identification number 715.207.00701) before entry into extension study 716. The patient had taken paroxetine for 42 days and did not taper.

The first reported serious adverse event of suicidal ideation (onset 04 February 01) was considered by the investigator to be severe in intensity. The second event (onset 10 February 01) was considered to be mild in intensity. Both events were considered by the investigator to be probably unrelated to treatment with study medication.

The patient had several other mild non-serious adverse events during the course of the study.

Mild pharyngitis (sore throat) reportedly began on 12 Jan 01 (Day 1) and continued without treatment throughout the study. The investigator considered the event to be unrelated to treatment with study medication.

Mild vomiting occurred on 13 Jan 01 (Day 2) and resolved without treatment in one day. The investigator considered the vomiting to be unrelated to treatment with study medication.

Mild diarrhea was reported on 14 Jan 01 (Day 3). This event resolved without treatment in 3 days and was considered to be unrelated to treatment with study medication.

Mild decreased appetite occurred on 23 Jan 01 (Day 12) and resolved without treatment in one day. This event was considered to be possibly related to treatment with study medication.

Mild somnolence occurred on 25 Jan 01 (Day 14). This event resolved without treatment in one day and was considered to be possibly related to treatment with study medication.

No other adverse events were reported during the study.

The patient withdrew from the study at Week 3 due to protocol violation.

PID: 716.014.25652

Protocol: 29060/716

AEGIS number: 2000036931-1

Study medication: Paroxetine 30 mg

Verbatim (preferred term): Increased depression (MEDRA code depression aggravated; ADECS code depression). Suicidal ideation, held knife to chest (MEDRA code suicidal ideation; ADECS code emotional lability)

Case reference number A0340399 (2000036931-1) is a clinical trial report from open-label extension study 29060/716 to assess the long-term safety of paroxetine in children and adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 9-year-old female (patient identification number 716.014.25652).

The patient previously participated in the double-blind acute study 29060/701 (patient identification number 701.161.25652) and was randomized to the paroxetine treatment group.

The patient's medical history included obesity. No significant concomitant medication use was reported.

On 11 September 2000, the patient initiated treatment with flexible-dose study medication, paroxetine 10 mg once daily. On 14 November 2000, the dose was up-titrated to 30 mg daily. On 27 December 2000, 107 days after starting therapy with study medication and 43 days after up-titration to 30 mg daily, the patient was admitted to the hospital for exacerbation of depressive symptomology and suicidal ideation, with the gesture of holding a knife up to her chest. On 28 December 2000, the event was reported as resolved. The patient was withdrawn from the study and received the last dose of study medication on 29 December 2000.

The patient was diagnosed with increased depression and suicidal ideation. The investigator reported the increased depression and suicidal ideation as not related to treatment with study medication and associated with family discord.

21 July 2002: Additional clarifying information, available at time of final reporting, is provided below.

Patient is a 9-year-old white female with a primary diagnosis of MDD.

The patient had received paroxetine for 54 days during the acute study and did not receive taper medication.

The serious adverse events depression and emotional lability (increased depression, suicidal ideation, held knife to chest) were considered by the investigator to be severe in intensity.

Concomitant medications included Pepto-Bismol® (bismuth subsalicylate) for dyspepsia and Sudafed® (pseudoephedrine HCl) for sinus congestion.

The patient experienced several non-serious adverse events during the study. On 04 October 2000 (Day 24), the patient experienced mild sinusitis (sinus congestion), which continued through the end of the study despite corrective therapy. The investigator considered this event to be unrelated to treatment with study medication.

The patient had mild dyspepsia on 13 October 2000 (Day 33), which resolved with treatment in one day. The investigator considered the dyspepsia to be unrelated to treatment with study medication.

On 12 November 2000 (Day 63), the patient experienced moderately severe herpes Zoster (chicken pox). This event resolved without treatment in 11 days and was considered by the investigator to be unrelated to treatment with study medication.

No other adverse events were reported.

PID: 716.017.00004

Protocol: 29060/716

AEGIS number: 2001013198-1

Study medication: Paroxetine 40 mg

Verbatim (preferred term): Attempted suicide (MEDRA code suicide attempt; ADECS code emotional lability)

Case reference number A0348051 (2001013198-1) is a clinical trial report from open-label study 209060/716 to assess the long-term safety of paroxetine in children and adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 17-year-old male (patient identification number 716.017.00004).

The patient's medical history included asthma and bronchitis. Concomitant medications included salbutamol (Albuterol®), salmeterol hydroxynaphthoate (Serevent®), and montelukast sodium (Singulair®).

On 25 January 2001, the patient initiated treatment with flexible-dose study medication, paroxetine 30 mg. On 23 May 2001, study medication was up-titrated to 40 mg. On 29 May 2001, 124 days after the start of study medication and 6 days after up-titration to 40 mg, the patient attempted suicide by cutting his wrist and was hospitalized.

Treatment with study medication was not stopped due to this event. The investigator reported the attempted suicide as unrelated to treatment with study medication and probably associated with the patient's history of major depressive disorder.

On 24 June 2001, the patient received the last dose of study medication and was considered lost to follow-up.

21 July 2002: Additional clarifying information, available at time of final reporting, is provided below.

Patient is a 16-year-old white male with a primary diagnosis of MDD. The patient previously participated in open-label PK Study 715 (patient identification number 715.200.00004). The patient was 15 years old at the time of entry into

Study 715. The patient had taken paroxetine for 40 days during the PK study and did not taper.

The serious adverse event reportedly resolved without treatment in 3 days and was considered to be severe in intensity.

The patient received the following concomitant medications during the study: Excedrin® (caffeine and paracetamol) for headache, Biaxin XL® (clarithromycin) for bronchitis, Pepcid® (famotidine) for heartburn and hematemesis, Flonase® and Flovent®, (fluticasone propionate) for asthma, and Tylenol® (paracetamol) for headache.

The patient had several other non-serious adverse events during the study. Moderately severe asthma (exacerbation of asthma) occurred on 31 Jan 01 (Day 7) and resolved without treatment in 4 days. The investigator considered this event to be unrelated to treatment with study medication.

Moderately severe bronchitis occurred on 01 February 01 (Day 8). This event resolved in 5 days and was considered to be unrelated to treatment with study medication.

Moderately severe headaches occurred on 04 February 01 (Day 11) and 08 February 01 (Day 15), and 23 February 01 (Day 30). All resolved without treatment in 4 days, 2 days, and 1 day, respectively. The headache on Day 11 was considered by the investigator to be related to treatment with study medication, and the headaches reported on Days 15 and 30 were considered to be possibly related to treatment with study medication.

Moderately severe vomiting occurred on 13 February 01 (Day 20). This event resolved with treatment in one day and was considered by the investigator to be probably unrelated to treatment with study medication.

Moderately severe dyspepsia (heartburn) occurred on 10 February 01 (Day 17) and 07 March 01 (Day 42). These events resolved in 4 days and 2 days, respectively. These events were considered by the investigator to be unrelated (Day 17) and probably unrelated (Day 42) to treatment with study medication.

Moderately severe hematemesis (vomited blood) occurred on 07 March 01 (Day 42). This event resolved with treatment in 2 days. The investigator considered this event to be probably unrelated to treatment with study medication.

Mild pharyngitis (sore throat) occurred on 16 March 01 (Day 51). This event resolved with treatment in 7 days and was considered to be unrelated to treatment with study medication.

Mild albuminuria occurred on 20 Apr 01 (Day 86). This event resolved without treatment in one day and was considered to be unrelated to treatment with study medication.

No other non-serious adverse events were reported during the study.

PID: 716.019.25751

Protocol: 29060/716

AEGIS number: 2000029901-1

Study medication: Paroxetine 20 mg

Verbatim (preferred term): Fractured left ulna and radius (compound fracture of left arm) (MEDRA code injury NOS; ADECS code trauma)

Case reference number A0336448 (2000029901-1) is a clinical trial report from open-label extension study 29060/716 to assess the long-term safety of paroxetine in children and adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 10-year-old male (patient identification number 716.019.25751).

The patient previously participated in the double-blind acute study 29060/701 (patient identification number 701.178.25751) and was randomized to the placebo treatment group.

The patient's medical history included migraine headaches and seasonal allergies. No relevant concomitant medications were reported.

On 23 August 2000, the patient began treatment with flexible-dose study medication, paroxetine 10 mg once daily. On 09 September 2000, the study medication was up-titrated to dose level 20 mg once daily. On 06 October 2000, 44 days after the start of study medication and 27 days after up-titration to 20 mg, the patient fell off of a slide and suffered a compound fracture of the left arm. The patient was admitted via the emergency room, and had surgery to set the arm with placement of two pins. Treatment with study medication was not stopped due to this event.

The investigator reported the compound fracture of the left arm as not related to the treatment with study medication.

The patient received his last dose of study medication on 16 February 2001.

21 July 2002: Additional clarifying information, available at time of final reporting, is provided below.

Patient is a 10-year-old white male with a primary diagnosis of MDD.

The serious adverse event, compound fracture of left arm, was considered by the investigator to be severe in intensity and corrective therapy was provided. The duration of the event was reported to be 43 days.

The patient completed the study as planned and received the last 20 mg/day dose of study medication in the active treatment phase of the study on 16 February 2001 (Day 178). The dose was decreased to 10 mg/day for the Taper Phase of the study beginning on 17 February 2001 (Day 179). The final dose of 10 mg/day was given on 26 February 2001 (Day 188).

Numerous concomitant medications were given for the compound fracture. These medications included intravenous Fentanyl® (fentanyl), Versed® (midazolam HCl), Zofran® (ondansetron HCl), Mepergan® (pethidine HCl), morphine, and propofol for orthopedic pin placement in left arm; Tylenol® and Tylenol #3® (paracetamol, paracetamol/codeine phosphate), and IV meperidine for pain secondary to compound fracture; and topical bacitracin, topical benzocaine, oral cephalexin, and intravenous cefazolin) for compound fracture. Additional concomitant medications included Nyquil® (dextromethorphan hydrobromide, doxylamine succinate, paracetamol, pseudoephedrine HCl) for cold symptoms, Advil® (ibuprofen) for headache, and one 20-mg dose of prescription Paxil® (paroxetine) for MDD on 06 October 2000.

Numerous non-serious adverse events were reported during the study.

On 24 August 2000 (Day 2), the patient had mildly decreased appetite (decreased appetite in AM), which resolved without treatment in 14 days. The investigator considered this event to be possibly related to treatment with study medication.

On 28 August 2000 (Day 6), the patient had rhinitis (runny nose), pharyngitis (sore throat), and migraine (migraine headache, emesis secondary to migraine headache). The rhinitis and pharyngitis were reportedly mild in severity, and each of these resolved without treatment in 5 days. The migraine headache was reportedly severe in intensity; the emesis was reported as moderately severe in intensity. Both of these events resolved without treatment in one day. All four adverse events were considered by the investigator to be unrelated to treatment with study medication.

On 19 October 2000 (Day 58), the patient experienced a moderately severe infection (infection of orthopedic pins), which resolved with treatment in 15 days. The investigator considered this event to be unrelated to treatment with study medication.

On 13 September 2000 (Day 22) and on 06 November 2000 (Day 76), the patient had headaches on Day 22 (mild) and Day 76 (moderately severe), each of which resolved with treatment in one day. The investigator considered the headaches to be probably unrelated to treatment with study medication.

On 11 January 2001 (Day 142), the patient had a moderately severe respiratory disorder (cold symptoms), which resolved with treatment in 3 days. On 05 March 2001 (7 days after the last dose of study medication in the Taper Phase of the study), the patient again reported a moderately severe respiratory disorder (upper respiratory infection), which resolved with treatment in 4 days. The investigator considered both of these events to be unrelated to treatment with study medication.

On 19 January 2001 (Day 150), the patient experienced four episodes of mild dizziness within 28 days that resolved without treatment. The investigator considered the dizziness to be possibly related to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.019.25752

Protocol: 29060/716

AEGIS number: 2000028184-1

Study medication: Paroxetine 20 mg (paralysis); paroxetine 30 mg (hallucination)

Verbatim (preferred term): Temporary paralysis of right leg (MEDRA code monoplegia; ADECS code paralysis). Auditory hallucinations (MEDRA code hallucination, auditory; ADECS code hallucinations)

Case reference number A0335273 (2000028184-1) is a clinical trial report from open-label extension study 29060/716 to assess the long-term safety of paroxetine in children and adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to an 11-year-old male (patient identification number 716.019.25752).

The patient previously participated in the double-blind acute study 29060/701 (patient identification number 701.178.25752) and was randomized to the placebo treatment group.

The patient's medical history included depression, penicillin allergy, seasonal allergies, vocal cord nodules, and canker sores. Concomitant medications included ibuprofen (Advil®).

On 19 August 2000, the patient initiated treatment with flexible-dose study medication, paroxetine 10 mg once daily. On 09 September 2000, study medication was up-titrated to 20 mg once daily. On 18 September 2000, 28 days after the start of study medication and nine days after up-titration to 20 mg, the patient was hit in the back with a helmet during football practice. The patient could not feel or move his right leg. He was admitted to the hospital through the emergency room for observation. All routine laboratory tests and X-rays were within normal limits. Movement returned approximately five hours after sustaining the injury. The pediatric neurologist released the patient with a diagnosis of "psychological trauma" not due to any physiological source. The investigator reported the event as resolved the same day, 18 September 2000. Treatment with study medication was not interrupted due to this event.

The investigator reported the temporary paralysis of the leg as disabling and incapacitating and not related to treatment with study medication.

On 17 October 2000, the patient's dosage was up-titrated to 30 mg once daily. On 24 October 2000, the patient's mother learned that the patient had told a school counselor that a child in the neighborhood had a "hit list" and that the children in his physical education class were trying to "trip and choke him."

On 25 October 2000, 67 days after receiving the first treatment with study medication and eight days after up-titration to 30 mg, the patient was seen by the investigator to assess these allegations. The patient became very irritated and agitated, and ran off. The patient was found and returned home with his parents. Later that day, the patient complained of auditory hallucinations. He reportedly heard voices telling him to "run away" and that "nobody loves you." The patient was hospitalized that evening in a private psychiatric inpatient hospital for evaluation. Per information received on 27 October 2000, the event was reported as ongoing.

Treatment with study medication was discontinued on 25 October 2000 due to this event, and the patient was withdrawn from the study.

The investigator reported the auditory hallucinations as unlikely to be related to treatment with study medication, and probably associated with possible bipolar disorder, incompletely treated depression, or intermittent explosive disorder.

21 July 2002: Additional clarifying information, available at time of final reporting, is provided below.

Patient is an 11-year-old white male with a primary diagnosis of MDD.

The serious adverse event auditory hallucinations was considered by the investigator to be moderately severe in intensity, and no corrective therapy was recorded. Paralysis (temporary paralysis of right leg) was considered by the investigator to be severe in intensity.

The patient received the last 20-mg dose of study medication in the active treatment phase of the study on 16 October 2000 (Day 59). The dose was up-titrated to 30 mg/day on 17 October 2000 (Day 60) and the final dose of study medication (30 mg/day) was given on 25 October 2000 (Week 12, Day 68). The Taper Phase of the study began on 26 October 2000, at which time the patient was down-titrated to 10 mg/day. The final dose of 10 mg/day was given on 27 October 2000 (Day 70).

Concomitant medications included Xanax® (alprazolam) as prophylaxis for MRI; Benadryl® (diphenhydramine HCl) for spider bite; Advil® (ibuprofen) for muscle soreness, left elbow pain due to secondary joint infusion, and pain in left fingers; and Nasonex® nasal spray (mometasone furoate) for cold.

Several other non-serious adverse events were reported during the study. On 20 August 2000 (Day 2), the patient had mild dyspepsia (upset stomach), which resolved without treatment in one day. The investigator considered the dyspepsia to be possibly related to treatment with study medication.

On 21 August 2000 (Day 3), the patient had moderately severe pain (pain in left fingers), which resolved with treatment in 7 days. The investigator considered this event to be unrelated to treatment with study medication.

On 25 August 2000 (Day 7), the patient had moderately severe trauma (spider bite on right eyelid, right armpit, right scalp). These resolved with treatment in 7 days. The investigator considered this event to be unrelated to treatment with study medication.

On 11 September 2000 (Day 24), the patient had moderately severe myalgia (general muscle soreness), which resolved with treatment in 5 days. The investigator considered this event to be unrelated to treatment with study medication.

On 18 September 2000 (Day 31), the patient had moderately severe arthrosis (pain in left elbow secondary to joint effusion), and moderately severe hypesthesia (right leg numbness). Arthrosis resolved with treatment in 6 days, and hypesthesia resolved without treatment in 3 days. On 19 September 2000 (Day 32) the patient had mild back pain that resolved without treatment in 9 days. The investigator considered all three events to be unrelated to treatment with study medication.

On 23 September 2000 (Day 36), the patient had mild respiratory disorder (cold symptoms), which continued through the end of the study reporting period. No corrective therapy was given for this event, which the investigator considered to be unrelated to treatment with study medication.

On 27 September 2000 (Day 40), the patient experienced severe euphoria (disinhibition [Xanax® reaction]), which resolved without treatment in one day. The investigator considered this event to be probably unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.020.25458

Protocol: 29060/716

AEGIS number: 2000034535-1

Study medication: Paroxetine 50 mg

Verbatim (preferred term): Psychosis NOS (MEDRA code psychotic disorder NOS; ADECS code psychosis)

Case reference number A0339082 (2000034535-1) is a clinical trial report from open-label extension study 29060/716 to assess the long-term safety of paroxetine in children and adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to an 11-year-old female (patient identification number 716.020.25458).

The patient previously participated in the double-blind acute study 29060/704 (patient identification number 704.020.25458) and was randomized to the placebo treatment group.

No relevant medical history or concomitant medication use was indicated.

On 19 September 2000, the patient initiated treatment with flexible-dose study medication, paroxetine 10 mg PO once daily. On 10 October 2000, study medication was up-titrated to 50 mg once daily. On 24 November 2000, 66 days after receiving the first treatment with study medication and 45 days after up-titration to 50 mg, the patient presented to the site with superficial cuts and burns to her left hand. The patient did not present as suicidal or homicidal. The patient was voluntarily admitted to a hospital by her parents with complaints of auditory, visual, and tactile hallucinations, as well as self-injurious behavior. The patient tolerated the admission well and was comfortable with the procedure. Treatment with study medication was stopped on 24 November 2000. The patient was treated with risperidone (Risperdal). The final diagnosis was psychosis NOS. Per information received on 13 December 2000, the outcome of the event was not provided.

The investigator reported the psychosis as probably unrelated to treatment with study medication.

21 July 2002: Additional clarifying information, available at time of final reporting, is provided below.

Patient is a white female with a primary diagnosis of OCD.

The serious adverse event, psychosis (psychosis NOS), was considered by the investigator to be moderately severe in intensity.

The patient was up-titrated from 10 mg/day (started on 19 September) to 20 mg/day on 21 September 2000 (Day 3), then to 30 mg/day on 26 September 2000 (Day 8), then to 40 mg/day on 03 October 2000 (Day 15), and then to the highest dose of 50 mg/day on 10 October 2000 (Day 28). The patient remained at 50 mg/day through the end of the study (final dose was given on 24 November 2000, Day 67).

Concomitant medications included risperidone for psychotic episode. Prescription Paxil® (paroxetine) was given post-study for OCD.

No non-serious adverse events were reported during the study.

PID: 716.025.25802

Protocol: 29060/716

AEGIS number: 2000027696-1

Study medication: Paroxetine 30 mg

Verbatim (preferred term): Homicidal ideation (MEDRA code homicidal ideation; ADECS code hostility)

Case reference number A0334967 (2000027696-1) is a clinical trial report from open-label extension study 29060/716 to assess the long-term safety of paroxetine in children and adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 12-year-old male (patient identification number 716.025.25802).

The patient previously participated in the double-blind acute study 29060/701 (patient identification number 701.181.25802) and was randomized to the paroxetine treatment group.

The patient's medical history included seasonal allergies and Achilles tendinitis. Concomitant medications were loratadine (Claritin®) and rofecoxib (Vioxx®).

On 07 August 2000, the patient initiated treatment with flexible-dose study medication, paroxetine 10 mg once daily. On 22 August 2000, study medication was up-titrated to 30 mg once daily. On 17 September 2000, 41 days after the first dose of study medication and 26 days after the dose was up-titrated to 30 mg daily, the patient experienced an outburst of anger, where he put a BB gun to his mom's head and stated that he was going to hurt somebody. It was reported that the patient has had these intermittent outbursts in the past and felt remorseful afterwards. The patient stated that he would like to get more help. He has also been self-mutilating by picking at skin on his hands until bleeding and sore. The patient was admitted to the hospital and was diagnosed with homicidal ideation. Treatment with study medication was stopped on 17 September 2000 due to this event, and the treating physician prescribed citalopram (Celexa®) 20 mg once daily. The event was reported to be resolved on 22 September 2000.

The investigator reported the homicidal ideation as not related to treatment with study medication but associated with another condition (not specified).

21 July 2002: Additional clarifying information, available at time of final reporting, is provided below.

Patient is a 12-year-old white male with a primary diagnosis of MDD.

The patient had received paroxetine for 58 days during the acute study and did not receive taper medication.

The serious adverse event, hostility (homicidal ideation), was considered by the investigator to be severe in intensity and unrelated to treatment with study medication.

The patient was up-titrated from 10 mg/day (started on 07 August 2000) to 20 mg/day on 11 August 2000 (Day 5), and then to 30 mg/day on 22 August 2000 (Day 16). The patient remained at 30 mg/day through the end of the study (final dose was given on 17 September 2000, Day 42).

Other non-serious adverse events were reported during the study. On 17 August 2000 (Day 11), the patient had moderately severe allergic reaction (seasonal allergies). The investigator considered the event to be unrelated to treatment with study medication. The allergies continued through to the end of the study despite treatment.

On 15 September 2000 (Day 40), the patient had moderately severe tendinitis (tendinous disorder). The investigator considered the event to be unrelated to treatment with study medication. The tendinitis continued through to the end of the study despite treatment.

No other non-serious adverse events were reported during the study.

PID: 716.028.27683

Protocol: 29060/716

AEGIS number: 2001007400-1

Study medication: Paroxetine 10 mg

Verbatim (preferred term): Acute exacerbation of MDD (MEDRA code depression aggravated; ADECS code depression)

Case reference number A0345179 (2001007400-1) is a clinical trial report from open-label extension study 29060/716 to assess the long-term safety of paroxetine in children and adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 12-year-old female (patient identification number 716.028.27683).

The patient previously participated in the double-blind acute study 29060/701 (patient identification number 701.185.27683) and was randomized to the placebo treatment group.

The patient's medical history included recurrent headaches, environmental allergies, recurrent sore throat, and asthma. The patient had no significant concomitant medication use.

On 30 December 2000, the patient initiated treatment with flexible-dose study medication, paroxetine 10 mg PO once daily. On 09 February 2001, study medication was up-titrated to 30 mg daily. After the dose change at Visit 8, the patient decompensated with increased irritability, was withdrawn and impulsive, and pulled out her eyelashes and eyebrow hairs (not reported as serious adverse events). A decision was made for early withdrawal of the patient from the study. On 20 February 2001, study medication was decreased to 20 mg daily and the patient received the last dose on 05 March 2001. On 16 March 2001, 11 days after the patient received the last dose of study medication, the patient was hospitalized due to an exacerbation of major depressive disorder. The event was reported as resolved on 20 March 2001.

The investigator reported the exacerbation of major depressive disorder as not related to treatment with study medication, and associated the event with psychosocial factors and the patient's family/living situation.

21 July 2002: Additional clarifying information, available at time of final reporting, is provided below.

Patient is a 12-year-old black female with a primary diagnosis of MDD.

The serious adverse event, depression (acute exacerbation of major depressive disorder), was considered by the investigator to be moderately severe in intensity. Corrective therapy was given for depression.

The patient received the last dose of study medication (20 mg/day) on 05 March 2001, in the active treatment phase of the study. The patient was down-titrated to 10 mg/day on 06 March 2001 (Day 77).

Concomitant medication included Zithromax® (azithromycin), Tylenol® (paracetamol), and Tylenol PM® for sinus infection; Diflucan® (fluconazole) for yeast infection; Tylenol® (paracetamol) for flu, fever, and recurrent headache; Tigan® (trimethobenzamide) for nausea and vomiting; Allegra® (fexofenadine HCl) for seasonal allergies; and salbutamol for asthma. Prescription paroxetine (Paxil®) was given to treat the serious adverse event depression beginning on 17 March 2001.

Several non-serious adverse events were reported during the study. Mild respiratory disorder (upper respiratory infection) was reported 5 days before the first dose of study medication, and mild myalgia (musculoskeletal pain) was reported one day before the first dose of study medication was taken in Study 716. Both resolved one day after the first dose of study medication was given, no corrective therapy was given for either, and the investigator considered both to be unrelated to treatment with study medication.

On 18 January 2001 (Day 20), the patient had a mild infection (flu), which resolved with treatment in 2 days. The investigator considered the flu to be unrelated to treatment with study medication.

On 03 February 2001 (Day 36), the patient experienced moderately severe nausea and mildly severe vomiting (4 episodes over 7 days), which resolved with treatment in 15 days and 7 days, respectively. The dose of study medication was decreased in response to these conditions. The investigator considered the nausea to be probably unrelated and the vomiting to be possibly related to treatment with study medication.

On 06 February 2001 (Day 39), the patient had mild fever and moderately severe sinusitis, which resolved with treatment in 2 days and 5 days, respectively. Both were considered by the investigator to be unrelated to treatment with study medication.

On 27 February 2001 (Day 60), the patient had a mild infection (yeast infection), which resolved with treatment in 7 days. The investigator considered the yeast infection to be unrelated to treatment with study medication.

On 28 February 2001 (Day 61), the patient experienced mild depression (plucking own eyelashes/brows), which resolved without treatment in one day. The investigator considered the depression to be unrelated to treatment with study medication.

No other adverse events were reported during the study.

The patient was withdrawn from the study for lack of efficacy at Week 8.

PID: 716.028.27685

Protocol: 29060/716

AEGIS number: 2001006352-1

Study medication: Paroxetine 20 mg

Verbatim (preferred term): Aggression (MEDRA code aggressive reaction; ADECS code hostility)

Case reference number A0344622 (2001006352-1) is a clinical trial report from open-label extension study 29060/716 to assess the long-term safety of paroxetine in children and adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to an 11-year-old female (patient identification number 716.028.27685).

The patient previously participated in the double-blind acute study 29060/701 (patient identification number 701.185.27685) and was randomized to the placebo treatment group.

The patient's medical history included MDD, headaches, and gastric upset. The patient had no significant concomitant medication use.

On 01 February 2001, the patient initiated treatment with flexible-dose study medication, paroxetine 10 mg PO once daily. On 08 February 2001, study medication was up-titrated to 20 mg once daily. On 08 March 2001, 35 days after the first dose of study medication and 28 days after up-titration, the patient's therapist reported that the patient was "out of control," acting out, and unsafe to herself and others. The patient was admitted to the hospital for evaluation of her aggression. On 13 March 2001, the event was reported as resolved. The study medication was discontinued due to the event, and the investigator site could not confirm if the patient was taking her study medication as instructed.

The investigator reported the aggression as not related to treatment with study medication, and associated with psychosocial factors.

21 July 2002: Additional clarifying information, available at time of final reporting, is provided below.

Patient is an 11-year-old black female with a primary diagnosis of MDD.

The serious adverse event, hostility (aggression), was considered by the investigator to be moderately severe in intensity. Zyprexa® (olanzapine) was given for this condition.

The patient received the 20 mg/day dose of study medication from 08 February 2001 (Day 8) to 07 March 2001 (Day 35), which was the last day of study medication.

Concomitant medication included children's vitamins (non-specified) for prophylaxis, Robitussin DM® (dextromethorphan hydrobromide, ethanol, guaifenesin) for cough and cold, and aspirin (acetylsalicylic acid) for headache.

Other non-serious adverse events were reported during the study. Mild respiratory disorder (recurrent upper respiratory infection) was reported on 30 November 2000, 62 days before the start of study medication in Study 716. The respiratory infection resolved with treatment in 68 days (06 February 2001) and was considered by the investigator to be unrelated to treatment with study medication.

On 15 March 2001 (Day 43, 8 days after the last dose of study medication), mild urinary and fecal incontinence (incontinence stool, urine) were reported. The urinary incontinence was treated and the fecal incontinence was not treated; both resolved in 12 days.

On the same date, moderately severe increased SGOT (elevated liver enzymes) was reported. It was considered by the investigator to be possibly related to treatment with study medication. Liver enzyme values are shown in the table below. None of the values were considered to be of potential clinical concern. All other laboratory test results were within normal limits, except for a slightly decreased absolute lymphocyte count of 0.8 x 10^9/L (reference range 0.85 to 4.1 x 10^9/L) noted at screening in the previous acute study 701.

Analyte	Screening (701) (Day -82)	Week 4 (Day 28)	Week 6 (Day 42)*	Post-Week 24 (Day 219)
Alkaline Phosphatase (IU/L) (reference range 60 to 415 IU/L)	457.0	432.0	412.0	359.0
AST (IU/L) (reference range 0 to 42 IU/L)	47.0	51.0	82.0	48.0
ALT (IU/L) (reference range 0 to 45 IU/L)	17.0	18.0	64.0	20.0

* non-serious AE of elevated liver enzymes reported on Day 43

No other adverse events were reported during the study period.

PID: 716.044.27656

Protocol: 29060/716

AEGIS number: 2001001028-1

Study medication: Paroxetine 50 mg

Verbatim (preferred term): Suicidal (MEDRA code suicide attempt; ADECS code emotional lability)

Case report number A0341922 (2001001028-1) is a clinical trial report from open-label extension study 29060/716 to assess the long-term safety of paroxetine in children and adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 13-year-old male (patient identification number 716.044.27656).

The patient previously participated in the double-blind acute study 29060/701 (patient identification number 701.149.27656) and was randomized to the paroxetine treatment group.

The patient's medical history included borderline hypertension, hypertrophic cardiomyopathy, heart murmur, spinal meningitis, and allergies to clarithromycin (Biaxin®) and cefaclor (Ceclor®). The patient had no concomitant medication use.

On 08 November 2000, the patient initiated treatment with flexible-dosing study medication, paroxetine 20 mg daily. On 08 December 2000, study medication was up-titrated to 50 mg daily. The patient was seen for his regular clinic visit and stated that on 16 December 2000, 38 days after the start of treatment with study medication and eight days after up-titration to 50 mg, he attempted suicide. Multiple scratches were noted over both forearms and chest wall, which the patient claimed were made with a knife. The patient was admitted to the hospital at that time and treated with olanzapine (Zyprexa®), clonidine (Catapres®), and prescription paroxetine (Paxil®). On 22 December 2000, the event resolved, and the patient was discharged from the hospital. Treatment with study medication was stopped due to this event. The last dose of study medication was 20 December 2000.

The investigator reported the suicidal event as not related to treatment with study medication, and to be associated with severe parent/child dysfunction.

21 July 2002: Additional clarifying information, available at time of final reporting, is provided below.

Patient is a black male with a primary diagnosis of MDD. The patient was 12 years old at entry into acute Study 701 and 13 years old at entry into Study 716.

The patient received the 20 mg/day dose of study medication from 08 November 2000 (first dose) to 16 November 2000 (Day 7); the dose was increased to 30 mg/day on 17 November 2000 (Day 8); then increased to 40 mg/day on 01 December 2000 (Day 24); then increased to 50 mg/day on 08 December 2000 (Day 31). The last dose of study medication was taken on 20 December 2000 (Day 43), 4 days after the serious adverse event of emotional lability (suicidal). The patient had received paroxetine for 61 days during the acute study and did not receive taper medication.

On 20 December 2000 (Day 43), the patient experienced a severe lack of emotion (flat affect), moderately severe depression (multiple hesitation scratches over both forearms and chest wall), and severe agitation (dysphoric), all of which continued through the end of the reporting period. No corrective therapy was given for these events, which the investigator considered to be non-serious and to be unrelated to treatment with study medication.

No other adverse events were reported.

PID: 716.049.28149

Protocol: 29060/716

AEGIS number: 2001017308-1

Study medication: Paroxetine 50 mg

Verbatim (preferred term): Unintentional overdose (MEDRA code therapeutic response increased; ADECS code abnormal laboratory value)

Case reference number A0350032 (2001017308-1) is a clinical trial report from open-label extension study 29060/716 to assess the long-term safety of paroxetine in children and adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 14-year-old male (patient identification number 716.049.28149).

The patient previously participated in the double-blind acute study 29060/704 (patient identification number 704.049.28149) and was randomized to the paroxetine treatment group. The patient had taken paroxetine for 87 days, including taper, during the acute study.

The patient's medical history included a small lump behind left nipple. The patient had no concomitant medication use.

On 17 April 2001, the patient initiated treatment with flexible-dose study medication, paroxetine 10 mg daily. From 22 May 2001 until 12 July 2001, the patient received paroxetine 50 mg daily. On 12 July 2001, 86 days after starting therapy with study medication and 51 days after up-titration to dose level 50 mg, the patient inadvertently dosed twice with study medication. At 8:00 AM on 12 July 2001, one of the patient's parents woke the patient to remind him to take his study medication, and he took five pills (50 mg). At 12 noon, the other parent called the patient and reminded him to take his study medication. The patient forgot that he took it in the morning and he took a second dose of study medication (five pills = 50 mg). The patient was evaluated by a physician and it was noted he had no side effects from the overdose. The patient was diagnosed with unintentional, asymptomatic overdose. The event was reported as resolved the same day, 12 July 2001. Treatment with study medication was not stopped due to this event.

The investigator reported the unintentional, asymptomatic overdose as unrelated to treatment with study medication, and probably due to the subject's inadvertent error in carrying out the dosing procedure.

21 July 2002: Additional clarifying information, available at time of final reporting, is provided below.

Patient is a 14-year-old white male with a primary diagnosis of OCD. The patient had taken paroxetine for 87 days, including taper, during the acute study.

The serious adverse event, unintentional overdose, was considered by the investigator to be mild in intensity.

The patient received the 10 mg/day dose of study medication from 17 April 2001 (first dose) to 23 April 2001 (Day 7). The dose was up-titrated to the highest dose of 50 mg/day on 22 May 2001 (Day 36) and remained at that dose until 10 August 2001 (final dose of study medication).

Other non-serious adverse events were reported during the study. On 21 April 2001 (Day 5), the patient had moderately severe respiratory disorder (URI), which resolved without treatment in 9 days. The investigator considered the URI to be probably unrelated to treatment with study medication.

On 27 May 2001 (Day 41), the patient experienced a moderately severe allergic reaction (seasonal allergies/sinus), which resolved with treatment in one day. This event was considered by the investigator to be unrelated to treatment with study medication.

On 24 August 2001 (Day 130), the patient had moderately severe constipation that resolved with treatment in one day. The investigator considered this event to be possibly related to treatment with study medication.

On 07 September 2001 (Day 144), the patient had mild weight gain, which continued through the end of the study. This event was considered by the investigator to be possibly related to treatment with study medication.

On 08 October 2001 (Day 175), the patient experienced mild headache that resolved without treatment in one day. The investigator considered this event to be possibly related to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.151.25607

Protocol: 29060/716

AEGIS number: 2000029447-1

Study medication: Paroxetine 30 mg

Verbatim (preferred term): Hospitalization for suicide attempt (MEDRA code suicide attempt; ADECS code emotional lability)

Case reference number A0336155 (2000029447-1) is a clinical trial report from open-label extension study 29060/716 to assess the long-term safety of paroxetine in children and adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 16-year-old female (patient identification number 716.151.25607).

The patient previously participated in the double-blind acute study 29060/701 (patient identification number 701.151.25607) and was randomized to the placebo treatment group.

The patient had no significant medical history. Concomitant medications included fexofenadine (Allegra®) and loratadine (Claritin®).

On 30 June 2000, the patient initiated treatment with flexible-dose study medication, paroxetine 10 mg once daily. On 21 September 2000, the study medication was up-titrated to 30 mg daily. On 02 October 2000, 94 days after starting therapy with study medication and eleven days after up-titration to 30 mg, the patient ingested thirty ibuprofen. The patient became frightened and informed her mother, who then administered ipecacuanha (Ipecac®). On 02 October 2000, the patient was evaluated by the investigator and was admitted to the hospital for psychiatric care. The last dose of study medication was on 02 October 2000. During hospitalization, the patient was given prescription paroxetine (Paxil®) at a dose of 40 mg. On 04 October 2000, the event was reported as resolved and the patient was discharged from the hospital.

The investigator reported the suicide attempt as not related to treatment with study medication and associated with major depression.

21 July 2002: Additional clarifying information, available at time of final reporting, is provided below.

Patient is a 16-year-old white female with a primary diagnosis of MDD.

The serious adverse event, emotional lability (hospitalization for suicide attempt), was considered by the investigator to be severe in intensity.

The patient received the 10 mg/day dose of study medication from 30 June 2000 (first dose) to 14 July 2000 (Day 15). The dose was up-titrated to 30 mg/day on 21 September 2000 (Day 84) and remained at that dose until 02 October 2000 (final dose of study medication), when the patient was withdrawn from the study due to the serious adverse event.

Concomitant medication also included Tylenol® (paracetamol) for facial pain.

Two non-serious adverse events were reported during the study. On 14 July 2000 (Day 15), the patient had mild asthenia (tiredness), which was not treated and continued through the end of the study reporting period. On 01 August 2000 (Day 33), the patient experienced mild pain (facial pain), which resolved with treatment in 4 days. The investigator considered the asthenia to be possibly related to treatment with study medication and the pain to be unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.176.27678

Protocol: 29060/716

AEGIS number: 2001011534-1

Study medication: Paroxetine 40 mg

Verbatim (preferred term): Worsening of asthma (MEDRA code asthma; ADECS code asthma)

Case reference number A0347159 (2001011534-1) is a clinical trial report from open-label extension study 29060/716 to assess the long-term safety of paroxetine in children and adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 9-year-old male (patient identification number 716.176.27678).

The patient previously participated in the double-blind acute study 29060/701 (patient identification number 701.176.27678) and was randomized to the placebo treatment group.

The patient's medical history included asthma and seasonal allergic rhinitis. Concomitant medications included guaifenesin (Robitussin®) and naphazoline HCl/antazoline phosphate (Vasocon-A®).

On 24 January 2001, the patient initiated treatment with flexible-dose study medication, paroxetine 40 mg once daily. On 08 May 2001, 105 days after the start of study medication, a chest x-ray was performed and the patient was hospitalized with a diagnosis of worsening asthma. The patient was treated with prednisone. On 10 May 2001, the event was reported as resolved. No action was taken with respect to study medication.

The investigator reported the worsening asthma as not related to treatment with study medication.

On 13 June 2001, the patient was up-titrated to dose level 50 mg. On 10 July 2001, the patient completed the study and received the last dose of study medication.

21 July 2002: Additional clarifying information, available at time of final reporting, is provided below.

Patient is a 9-year-old white male with a primary diagnosis of MDD.

The serious adverse event, asthma (worsening of asthma), was considered by the investigator to be severe in intensity.

The patient received a 40 mg/day dose of study medication from 24 January 2001 (first dose) to 12 June 2001 (Day 140). The dose was up-titrated to the highest dose of 50 mg/day on 13 June 2001 (Day 141) and remained at that dose until 10 July 2001 (final dose of study medication in the active treatment phase). The dose of study medication was gradually down-titrated to 10 mg/day during the Taper Phase of the study; the final dose of study medication was taken on 06 August 2001 (Day 195)

Concomitant medication included Children's Tylenol® (paracetamol) and Robitussin® (guaifenesin) for upper respiratory infection; hydroxyzine and Pediapred® (prednisolone sodium phosphate) for poison ivy rash; Vasocon-A® (antazoline phosphate, naphazoline HCl) eye drops for allergic ocular irritation; Flonase® inhaler (fluticasone propionate) and Claritin Reditabs® (loratadine) for seasonal allergic rhinitis; salbutamol inhalation and Serevent® (salmeterol hydroxynaphthoate) inhalation for asthma, and IV Rocephin® (ceftriaxone sodium), IV Solu-Medrol® (methylprednisolone sodium succinate), and prednisone for worsening asthma; and Benadryl® (diphenhydramine HCl) for allergy testing discomfort.

The patient had a history of allergic rhinitis (seasonal allergic rhinitis), mild asthma, and tooth caries.

Mild respiratory disorder (upper respiratory infection) was reported on 30 January 2001 (Day 7), and moderately severe respiratory disorder (upper respiratory infection) was reported on 16 February 2001 (Day 24). Both were treated and resolved in 5 days and 6 days, respectively. Moderately severe respiratory disorder (cold) was reported on 29 April 2001 (Day 96), which was treated and resolved in 10 days. The investigator considered all three events of respiratory disorder to be unrelated to treatment with study medication.

On 27 May 2001 (Day 124), the patient had moderately severe contact dermatitis (poison ivy rash), which resolved with treatment in 14 days. The investigator considered this event to be unrelated to treatment with study medication.

No other adverse events were reported.

PID: 716.201.00109

Protocol: 29060/716

AEGIS number: 2001019585-1

Study medication: Paroxetine 40 mg

Verbatim (preferred term): Suicide attempt (MEDRA code suicide attempt; ADECS code emotional lability)

Case reference number A0351309 (2001019585-1) is a clinical trial report from open-label study 29060/716 to assess the long-term safety of paroxetine in children and adolescents with Major Depressive Disorder (MDD) or Obsessive-Compulsive Disorder (OCD). This report refers to a 17-year-old female (patient identification number 716.201.00109).

The patient had no significant medical history. Concomitant medications included nitrofurantoin (Macrobid®) and acetylsalicylic acid/caffeine/ cinnamedrine hydrochloride (Midol®).

The patient received flexible-dose study medication, paroxetine, from 28 April 2001 to 11 June 2001 at a dose of 20 mg daily. On 26 June 2001, study medication was increased to 40 mg daily. On 09 August 2001, 103 days after initiating treatment with study medication, and 43 days after the study medication was increased to dose level 40 mg, the patient attempted suicide by taking four anti-hypertensive pills (NOS) and indicating she “wanted to die.” The patient was found by her boyfriend and she was noted to be lethargic and her pupils were dilated. At first, the patient refused to go to the hospital; however, she was later admitted to the hospital.

Treatment with study medication was stopped and the last dose was taken on 09 August 2001. The event reportedly resolved within 5 days.

The investigator reported the suicide attempt as life-threatening and unrelated to treatment with study medication.

21 July 2002: Additional clarifying information, available at time of final reporting, is provided below.

This 17-year-old white female previously participated in the open-label PK study 29060/715 (patient identification number 715.201.00109) and took paroxetine for 43 days (no taper). The patient's primary diagnosis was MDD.

The investigator considered the intensity of the serious adverse event to be severe.

Additional concomitant medications included citalopram (Celexa®) for depression, codeine cough syrup for upper respiratory infection, erythromycin for upper respiratory infection, paracetamol (Tylenol®) for headache, and procaine (novocaine) for dental work.

Several non-serious adverse events were reported during the study. Moderately severe respiratory disorder (upper respiratory infection) occurred on 24 May 2001 (Day 27). This event resolved with treatment in 13 days and was considered by the investigator to be unrelated to treatment with study medication.

On 11 June 2001, mild headache was reported. This event resolved with treatment in one day and was considered by the investigator to be unrelated to treatment with study medication.

Mild tooth caries were reported on 25 June 2001 (Day 59). These were treated and resolved in one day. This event was considered the investigator to be unrelated to treatment with study medication by.

Mild chest pain (intermittent chest pain) was reported on 27 June 2001 (Day 61). This condition continued, without treatment, through the end of the study and was considered by the investigator to be unrelated to treatment with study medication.

Mild paresthesia and mild dyspnea were each reported on 29 June 2001 (Day 63). These events both resolved without treatment in two days and were considered by the investigator to be unrelated to treatment with study medication.

Moderately severe urinary tract infection occurred on 23 July 2001 (Day 87). This event resolved with treatment in 7 days and was considered by the investigator to be unrelated to treatment with study medication.

No other non-serious adverse events were reported. The patient was withdrawn from the study at Week 16 for adverse event.

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Paroxetine

BRL-029060

Narratives for Patients with Non-Serious Adverse Events Leading to Withdrawal

716

Table 15.1.10

SB Document Number: BRL-029060/RSD-101TCW/1

Issue Date: 16 September 2002

PID: 716.004.25403

Treatment Group: Placebo (Protocol 704), paroxetine (Protocol 716)

Adverse Event: Hyperkinesia (hyperactivity), manic reaction (hypomanic symptoms)

This 10-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (patient 704.004.25403), and received treatment with placebo in that study.

Concomitant medications included Advil® (ibuprofen) and topical Floxin® (ofloxacin) for otitis externa, Nasacort® (budesonide) nasal spray for allergies, Ritalin® (methylphenidate HCl) for attention deficit hyperactivity disorder (ADHD), Risperdal® (risperidone) for hypomanic symptoms, and Claritin® (loratadine) for allergies. Prescription Paxil® was prescribed for OCD after study medication was discontinued.

The patient received the first dose of study medication on 21 June 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 28 June 2000. The dose was decreased to 10 mg/day on 08 July 2000. The patient discontinued study medication on 11 July 2000 (Week 3, Day 21).

On 06 July 2000 (Day 16), the patient experienced moderately severe hyperkinesia (hyperactivity) and manic reaction (hypomanic symptoms), both of which were considered to be possibly related to treatment with study medication. These events resulted in withdrawal from the study. Treatment included Ritalin® (methylphenidate HCl) for ADHD and Risperdal® (risperidone) for hypomanic symptoms. The conditions were continuing at the time of withdrawal from the study.

On 24 June 2000 (Day 4), the patient reported mild trauma (burned right hand), which resolved without treatment within 14 days. On 07 July 2000 (Day 17) the patient reported mild nausea, which resolved without treatment in one day. Both

of these events were considered to be unrelated to treatment with study medication. Mild otitis media externa was also reported on 07 July 2000 (Day 17). This event resolved with treatment in 6 days and was considered to be unrelated to treatment with study medication by the investigator.

No other adverse events were reported during the study.

PID: 716.006.25418

Treatment Group: Placebo (Protocol 704), paroxetine (Protocol 716)

Adverse Event: Agitation (increased agitation), emotional lability (mood swing), hostility (aggression, temper outburst), nervousness (irritability)

Laboratory Value of Clinical Concern: Increased Alanine Aminotransferase

Laboratory Value Associated Adverse Event Reported: Liver Function Tests Abnormal (elevated liver enzymes)

This 13-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (patient 704.006.25418), and received treatment with placebo in that study.

Concomitant medications included Benadryl® (diphenhydramine HCl) for agitation.

The patient received the first dose of study medication on 28 September 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10mg/week increments, to 30 mg/day by 12 October 2000. The dose was decreased to 20 mg/day on 30 October 2000, and further decreased to 10 mg/day on 01 November 2000. The patient discontinued study medication on 03 November 2000 (Week 6, Day 37).

On 27 October 2000 (Day 30), the patient experienced moderately severe agitation (increased agitation), which was considered to be possibly related to treatment with study medication. Also reported on Day 30 were emotional lability (mood swing), hostility (aggression, temper outburst), and nervousness (irritability), all of which were considered to be probably unrelated to treatment with study medication. These events resulted in withdrawal from the study. Corrective treatment (diphenhydramine) was given for agitation; no treatment was

given for emotional lability, hostility or nervousness. All events were continuing at the time of withdrawal from the study.

On 09 October 2000 (Day 12), the patient reported mild headache, which resolved without treatment in one day. This event was considered to be unrelated to treatment with study medication.

On 12 October 2000 (Day 15), the patient experienced mild fever and headache, which resolved without treatment in two days. These two events were considered to be probably unrelated to treatment with study medication. Also reported on Day 15 was mild nausea. This event resolved without treatment in two days and was considered to be possibly related to treatment with study medication.

On 14 October 2000 (Day 17), the patient experienced moderately severe asthenia (fatigue), considered to be possibly related to treatment with study medication, and for which no treatment was given. The asthenia continued throughout the study.

On 7 November 2000 (Day 41; 4 days after the last dose of study medication), the patient reported mild diarrhea and vomiting, and moderately severe nausea. Diarrhea and nausea resolved within 2 days without treatment; vomiting resolved in one day without treatment. All three events were considered to be probably unrelated to treatment with study medication.

On 09 November 2000 (Day 43; 6 days after the last dose of study medication), the investigator reported an adverse event of abnormal liver function tests (elevated liver enzymes). Laboratory results showed aspartate aminotransferase (AST) of 104 IU/L (reference range 0-42 IU/L) and alanine aminotransferase (ALT) of 169 IU/L (reference range 0–48 IU/L). The ALT value was considered to be of potential clinical concern (defined as >165 IU/L). All other laboratory values on Day 43 and throughout the study were within normal limits, except for a slightly decreased red blood cell (RBC) count of 4.0×10^{12}/L on Day 28 (Week 4). No follow-up laboratory test results were provided. This event was considered to be mild in intensity, and possibly related to treatment with study medication. The condition resolved in 14 days without treatment.

No other adverse events were reported during the study.

PID: 716.008.25644

Treatment Group: Paroxetine (Protocol 701), paroxetine (Protocol 716)

Adverse Event: Somnolence (sedation)

This 16-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (patient 701.158.25644), and received treatment with paroxetine in that study.

No concomitant medications were reported during the study.

The patient received the first dose of study medication at a dose of 10 mg/day on 11 July 2000. The last dose of study medication was taken on 28 July 2000 (Day 18).

On 31 May 2000 (before initiation of study medication in Study 716), the patient experienced moderately severe somnolence (sedation), which continued without treatment for 62 days. This event was considered to be possibly related to treatment with study medication and resulted in withdrawal from the study.

On 17 July 2000 (Day 7), the patient reported moderately severe nausea, which was considered to be possibly related to treatment with study medication. No corrective treatment was given and the nausea continued unresolved at the end of the study.

No other adverse events were reported during the study.

PID: 716.010.25371

Treatment Group: Placebo (Protocol 704), paroxetine (Protocol 716)

Adverse Event: Abnormal ejaculation (delayed ejaculation)

This 16-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. The patient was 15 years old at entry into acute Protocol 704. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (patient 704.010.25371), and received treatment with placebo in that study.

No concomitant medications were reported during this study.

The patient received the first dose of study medication on 29 June 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 06 July 2000. The patient discontinued study medication on 12 July 2000 (Day 14).

On 30 June 2000 (Day 2), the patient experienced mild rash that resolved without treatment in 14 days. This event was considered to be probably unrelated to treatment with study medication. On June 12, 2000 (16 days prior to the start of 716 open-label medication) the patient experienced moderate abnormal ejaculation (delayed ejaculation) which lasted 32 days (July 13, 2000). This event was considered to be related to treatment with study medication and resulted in withdrawal from the study. The patient discontinued study medication on 12 July 2000 (Day 14).

No other adverse events were reported during the study.

PID: 716.010.25606

Treatment Group: Paroxetine (Protocol 701), paroxetine (Protocol 716)

Adverse Event: Hostility (aggression)

This 13-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (patient 701.162.25606), and received treatment with paroxetine in that study.

Concomitant medications included inhaled salbutamol (Albuterol®) for exercise-induced asthma (began approximately 3 months before the first dose of study medication in Protocol 716).

The patient received the first dose of study medication on 05 July 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to 40 mg/day by 24 October 2000 and completed the study as planned. The patient was tapered to 30 mg/day on 07 November 2000 (Day 126), to 20 mg/day on 14 November 2000 (Day 133), and to 10 mg/day on 23 November 2000 (Day 142). The final dose of taper medication was taken on 03 December 2000 (Day 152).

On 01 December 2000 (Day 150), the patient experienced moderately severe hostility (aggression), which resolved without treatment in three days. This event was considered to be possibly related to treatment with study medication, and resulted in withdrawal from the study.

On 04 May 2000 (38 days before Study 716 medication was started), mild somnolence (drowsiness) was reported. This event remained ongoing and was considered to be possibly related to treatment with study medication by the investigator.

On 01 July 2000 (3 days before Study 716 medication was started), mild otitis media was reported. This event resolved without treatment in 13 days and was considered to be unrelated to treatment with study medication by the investigator.

On 21 July 2000 (Day 17), the patient reported mild insomnia, which resolved without treatment in 23 days. This event was considered to be possibly related to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.014.25651

Treatment Group: Placebo (Protocol 701), paroxetine (Protocol 716)

Adverse Event: Hostility (aggression, anger)

This 17-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (patient 704.161.25651), and received treatment with placebo in that study.

Concomitant medications included generic non-specific daytime/nighttime cold medication and Tylenol® (paracetamol) for cold, nitrous oxide as anesthesia for dental extraction, Darvocet-N 100® (dextropropoxyphene) PRN for pain due to dental extraction, and minocycline for acne.

The patient received the first dose of study medication on 26 September 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to 50 mg/day by 23 October 2000 (Day 26). The patient received the last dose of study medication on 03 November 2000.

On 01 November 2000 (Day 37), the patient experienced moderately severe hostility (aggression, anger), which resolved without treatment in one day. The event was considered to be possibly related to treatment with study medication, and resulted in withdrawal from the study.

On 28 September 2000 (Day 3), the patient experienced a mild respiratory disorder (cold, upper respiratory infection), which resolved with treatment in four days. The investigator considered this event to be unrelated to treatment with study medication.

On 03 October 2000 (Day 8), mild tremor (shakes after morning dose) was reported. This event resolved without treatment in one day and was considered to be possibly related to treatment with study medication.

On 10 October 2000 (Day 15), the patient reported moderately severe acne (worsening acne), which was treated but continued throughout the study. The patient also reported moderately severe emotional lability (mood swings) on Day 15, which was untreated and continued through the end of the study. The investigator considered both of these conditions to be possibly related to treatment with study medication.

On 13 October 2000 (Day 18), the patient reported mild emotional lability (patient cut on self [wrist]), which resolved in one day with no treatment. This event was considered by the investigator to be probably unrelated to treatment with study medication.

On 23 October 2000 (Day 28), the patient reported severe dental caries (dental decay), which were treated and resolved in one day. The investigator considered this condition to be unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.015.25464

Treatment Group: Placebo (Protocol 704), paroxetine (Protocol 716)

Adverse Event: Manic reaction (manic activation)

This 7-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (patient 704.015.25464), and received treatment with placebo in that study.

Concomitant medications included Dramamine® (diphenhydramine HCl) for carsickness, Benadryl® (diphenhydramine HCl) for itching rash, and topical hydrocortisone for rash.

The patient received the first dose of study medication on 02 August 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to 30 mg/day by 28 August 2000.

On 14 July 2000 (before Study 716 medication was initiated), the patient experienced moderately severe manic reaction (manic activation), which was considered to be related to treatment with study medication. No treatment was given for this non-serious event, but the condition continued and the patient was withdrawn from the study. The patient discontinued study medication on 05 September 2000 (Week 4, Day 35).

On 05 August 2000 (Day 4), the patient reported two episodes of mild vertigo (carsickness), which resolved with treatment within nine days. On 01 September 2000 (Day 31), the patient reported mild rash, which was treated but remained unresolved at the end of the study. Both of these events were considered to be unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.015.25466

Treatment Group: Placebo (Protocol 704), paroxetine (Protocol 716)

Adverse Event: Nervousness (irritability)

This 13-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (patient 704.015.25466), and received treatment with placebo in that study.

Concomitant medications included Tylenol PM® (diphenhydramine HCl, paracetamol) for insomnia, Tylenol Sinus® (pseudoephedrine HCl, paracetamol) for hives and allergies (allergies continuing from previous protocol), and topical chloroxylenol for left otitis media (continuing from the previous acute protocol).

The patient received the first dose of study medication on 18 August 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10mg/week increments, to 50 mg/day on 30 September 2000 (cumulative dose Day 43). The patient received his last dose of study medication on 12 October 2000 (Day 55).

Mild otitis media, with onset reported on 08 May 2000 (pre-study), continued throughout extension study 716, despite treatment. The investigator considered this event to be unrelated to treatment with study medication.

On 30 September 2000 (relative dose Day 44), the patient experienced moderately severe nervousness (irritability), which was untreated and continued through the end of the study. The investigator considered this condition to be related to treatment with study medication and the patient was withdrawn from the study.

On 19 August 2000 (Day 2), the patient experienced mild dry mouth, which resolved without treatment in 4 days. On 21 August 2000 (Day 4) the patient reported a mildly decreased appetite, which was not treated and continued through the end of the study. On 23 August 2000 (Day 6), the patient reported mild insomnia, which was treated (diphenhydramine, paracetamol) but continued

through the end of the study. All of these events were considered to be possibly related to treatment with study medication.

On 29 August 2000 (Day 12), mild sweating was reported. This event resolved without treatment in 16 days, and was considered to be possibly related to treatment with study medication by the investigator.

On 30 August 2000 (Day 13), the patient reported mild flatulence (flatus), which resolved without treatment in 15 days. The investigator considered this event to be possibly related to treatment with study medication.

On 03 September 2000 (Day 17), the patient reported mild urticaria (hives), which resolved with treatment in one day. The investigator considered urticaria to be unrelated to treatment with study medication.

On 18 September 2000 (Day 32), the patient experienced mild ulcerative stomatitis (oral lesions) and acne (acneiform lesions), which were considered by the investigator to be unrelated to treatment with study medication. The ulcerative stomatitis resolved without treatment in nine days; the acne continued through the end of the study.

No other adverse events were reported during the study.

PID: 716.015.25469

Treatment Group: Paroxetine (Protocol 704), paroxetine (Protocol 716)

Adverse Event: Impaired concentration, hostility, hyperkinesia (exacerbation of ADHD)

This 8-year-old Hispanic male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (patient 704.015.25469), and received treatment with paroxetine in that study.

No concomitant medications were reported during Study 716. The patient underwent speech evaluation for auditory processing on Day 20 (25 October 2000).

The patient received the first dose of study medication on 06 October 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to 40 mg/day by 23 November 2000 (Day 49). The patient received the last dose of study medication on 07 December 2000 (Day 63)

On 08 November 2000 (Day 34), at a dose of 30 mg/day, the patient experienced mildly severe impaired concentration, hostility and hyperkinesias (exacerbation of attention deficit hyperactivity disorder [ADHD]), which were considered to be related to treatment with study medication. No treatment was given for these non-serious events, and the patient was withdrawn from the study. The events were continuing at the time of withdrawal. The patient discontinued study medication on 07 December 2000 (Week 8, Day 63).

On 19 October 2000 (Day 14), at a dose of 20 mg/day, the patient was reported to have experienced mild myoclonus (vocal tic), which resolved without treatment in 4 days. This event was considered to be possibly related to treatment with study medication. No other adverse events were reported during the study.

PID: 716.015.27043

Treatment Group: Paroxetine (Protocol 704), paroxetine (Protocol 716)

Adverse Event: Emotional lability (suicidal ideation)

This 16-year-old white female, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (patient 704.015.27043), and received treatment with paroxetine in that study.

Concomitant medications included amoxicillin for pleurisy, diphenhydramine for viral syndrome and Atuss DM® (chlorpheniramine/dextromethorphan/ phenylephrine), doxylamine/dextromethorphan/acetaminophen/pseudoephedrine and Benadryl® (diphenhydramine HCl) for cough.

The patient received the first dose of study medication on 06 December 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10mg/week increments, to 30 mg/day on 03 January 2000 (Day 30). The dose was reduced to 20 mg/day on 23 January 2000 (Day 50), and further reduced to 10 mg/day on 30 January 2001 (Day 57). The last dose of study medication was taken on 08 February 2001 (Day 66).

On 15 January 2001, the patient experienced moderately severe emotional lability (suicidal ideation), which resolved without treatment in two days. The investigator considered this event to be possibly related to treatment with study medication and the patient was withdrawn from the study.

The patient entered into the extension study with the ongoing adverse events of: pelvic pain (onset 25 November 2000); chest wall pain (onset 27 November 2000); cough (onset 25 November 2000); and upper respiratory infection (onset 25 November 2000). The pelvic pain, cough and upper respiratory infection were considered by the investigator to be unrelated to treatment with study medication; the chest wall pain was considered to be probably unrelated to treatment with

study medication. The pelvic pain, chest wall pain, cough, and upper respiratory infection, resolved in 20, 24, 19 and 47 days, respectively.

On 11 December 2000 (Day 6), mild pleura disorder (pleurisy) was reported. This event resolved with treatment in 14 days, and was considered to be unrelated to treatment with study medication.

On 20 January 2001 (Day 46), the patient experienced mild blepharitis (stye in right eye), which resolved without treatment in four days. The investigator considered this condition to be unrelated to treatment with study medication.

On 04 February 2001 (Day 61), the patient experienced a mild viral infection, which was treated but continued through the end of the study. The investigator considered this event to be unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.016.25447

Treatment Group: Placebo (Protocol 704), paroxetine (Protocol 716)

Adverse Event: Hostility (aggression)

This 7-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (patient 704.016.25447), and received treatment with placebo in that study.

Concomitant medications included ibuprofen for headache; Rhinocort® Inhaler (budesonide) and Rynatan® suspension (chlorphenamine tannate, mepyramine tannate, phenylephrine tannate) and Claritin® syrup (loratadine) for allergies (allergies continued from previous protocol).

The patient received the first dose of study medication on 13 June 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to 30 mg/day by 30 June 2000 (Day 24). The dose was decreased to 20 mg/day on 07 July 2000 (Day 25), and further decreased to 10 mg/day on 01 August 2000 (Day 50). The patient received the last dose of study medication on 06 August 2000 (Day 55).

On 02 July 2000 (Day 20), the patient reported moderately severe hostility (aggression), which resolved without treatment in seven days. The investigator decreased the dose of study medication in response to this event, which was considered to be possibly related to treatment with study medication. On 29 July 2000 (Day 47), the patient experienced severe hostility (aggression), which resolved without treatment in eight days. The investigator considered this event to be possibly related to treatment with study medication and the patient was withdrawn from the study.

On 21 June 2000 (Day 9), the patient reported a moderately severe headache, which persisted continuously for 44 days. The patient was given corrective therapy for this event, and the investigator decreased the dose of study

medication. The investigator considered the headache to be possibly related to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.016.25450

Treatment Group: Placebo (Protocol 704), paroxetine (Protocol 716)

Adverse Event: Nervousness (irritability)

This 11-year-old white female, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (patient 704.016.25450), and received treatment with placebo in that study.

No concomitant medications were reported during the study.

The patient received the first dose of study medication on 10 July 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10mg/week increments, to 30 mg/day on 29 July 2000 (Day 21). The dose was decreased to 20 mg/day on 12 August 2000 (Day 34), and further decreased to 10 mg/day on 26 August 2000 (Day 48). The patient received the last dose of study medication on 30 August 2000 (Day 52).

On 23 August 2000 (Day 45), the patient experienced severe nervousness (irritability), which resolved without treatment in six days. The investigator considered this event to be possibly related to treatment with study medication, and the patient was withdrawn from the study.

On 07 August 2000 (Day 29), the patient experienced moderately severe hyperkinesia (hyperactivity), which resolved without treatment in 22 days. This investigator considered this event to be possibly related to treatment with study medication, and the dose of study medication was decreased.

No other adverse events were reported during the study.

PID: 716.016.27017

Treatment Group: Placebo (Protocol 704), paroxetine (Protocol 716)

Adverse Event: Hostility (oppositional behavior)

This 12-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (patient 704.016.27017), and received treatment with placebo in that study.

Concomitant medications included Tylenol® (paracetamol) for headache.

The patient received the first dose of study medication on 16 December 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to 30 mg/day by 09 January 2001 (Day 25). The dose was decreased to 20 mg/day on 30 January 2001 (Day 46). The patient received the last dose of study medication on 12 February 2001 (Day 59).

On 05 February 2001 (Day 52), the patient experienced severe hostility (oppositional behavior), which resolved without treatment in ten days. The investigator considered this event to be related to treatment with study medication, and the patient was withdrawn from the study.

On 04 December 2000, during treatment in the acute study and before active medication was administered in Study 716, the patient experienced mild leukopenia (slight decrease in white blood cells), which continued into the extension study. The investigator considered this condition to be possibly related to treatment with study medication. No corrective treatment was given for this condition.

On 17 December 2000 (Day 2), the patient reported mild headache, which resolved with treatment in one day. The investigator considered this event to be possibly related to treatment with study medication.

On 23 January 2001 (Day 32), the patient experienced moderately severe hostility (defiant) and hyperkinesia (hyperactivity), which resolved without treatment in five days. The dose of study medication was decreased in response to these events. Both of these events were considered to be related to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.016.27019

Treatment Group: Placebo (Protocol 704), paroxetine (Protocol 716)

Adverse Event: Hyperkinesia (hyperactivity)

This 11-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (patient 704.016.27019), and received treatment with placebo in that study.

Concomitant medications included Tylenol® (paracetamol) for headache and Claritin® (loratadine) for rhinitis.

The patient received the first dose of study medication on 24 January 2001. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to 30 mg/day by 14 February 2001 (Day 16). The dose was decreased to 20 mg/day on 20 March 2001 (Day 56) and further reduced to 10 mg/day on 23 April 2001 (Day 90). The final dose of study medication was taken on 26 April 2001 (Day 93).

On 23 April 2001 (Day 90), the patient experienced moderately severe hyperkinesia (hyperactivity), which resolved without treatment in five days. The investigator considered this event to be related to treatment with study medication and the patient was withdrawn from the study.

On 09 February 2001 (Day 17), the patient experienced mild vasodilation (hot flashes), which resolved in 82 days; no corrective treatment was given. The investigator considered this event to be related to treatment with study medication.

On 12 March 2001 (Day 48), the patient experienced a moderately severe lack of emotion (apathy), which resolved in 55 days; no corrective treatment was given. The investigator considered this condition to be related to treatment with study medication, and the dose of study medication was decreased.

On 17 March 2001 (Day 53), the patient reported mild rhinitis, which continued throughout the study, and mild headache, which resolved in one day; corrective treatment was given for both events. The investigator considered the rhinitis to be probably unrelated to treatment with study medication and the headache to be possibly related to treatment with study medication.

On 23 April 2001 (Day 90), the patient experienced mild urinary incontinence (enuresis), which resolved without treatment in 11 days. The investigator considered this event to be possibly related to treatment with study medication.

On 16 May 2001 (Day 113, 20 days post-treatment), mild neurosis (OCD) was reported. This continued without treatment or resolution at last report, and was considered to be related to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.016.27021

Treatment Group: Placebo (Protocol 704), paroxetine (Protocol 716)

Adverse Event: Hyperkinesia (hyperactivity)

This 8-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (patient 704.016.27021), and received treatment with placebo in that study.

Concomitant medications included oral Diprosone® (betamethasone dipropionate) and topical triamcinolone cream (triamcinolone acetonide) for eczema.

The patient received the first dose of study medication on 05 January 2001. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 16 January 2001 (Day 12). The dose was decreased to 10 mg/day on 01 February 2001 (Day 28). The patient received the last dose of study medication on 03 February 2001 (Day 30).

On 31 January 2001 (Day 27), the patient experienced severe hyperkinesia (hyperactivity), which resolved without treatment in eight days. The investigator considered the event to be related to treatment with study medication, and the patient was withdrawn from the study.

On 07 October 2000, during the previous acute study and 90 days before study medication was given in Protocol 716, the patient had mild myoclonus (tics), considered probably unrelated to treatment with study medication. The condition continued into this extension study.

On 01 August 2000, during the previous acute study and before study medication was given in Protocol 716, the patient reported moderately severe eczema, considered unrelated to treatment with study medication. Corrective treatment was given but the condition persisted throughout this extension study.

On 17 January 2001 (Day 13), the patient reported mild myoclonus (increase in tics), which resolved without treatment in 14 days. The investigator considered this condition to be unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.025.25822

Treatment Group: Placebo (Protocol 701), paroxetine (Protocol 716)

Adverse Event: Agitation (increased agitation)

This 7-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (patient 701.181.25822), and received treatment with placebo in that study.

No concomitant medications were reported during the study.

The patient received the first dose of study medication on 06 September 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to 30 mg/day by 19 September 2000 (Day 14). The last dose was taken on 25 September 2000 (Day 20).

On 25 September 2000 (Day 20), the patient experienced moderately severe agitation (increased agitation), which resolved with treatment (prescription Paxil® was prescribed post-treatment) in 18 days. The investigator considered this condition to be possibly related to treatment with study medication, and the patient was withdrawn from the study.

No other adverse events were reported during the study.

PID: 716.025.27059

Treatment Group: Placebo (Protocol 704), paroxetine (Protocol 716)

Adverse Event: Anxiety (anxiety increased)

This 14-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (patient 704.025.27059), and received treatment with placebo in that study.

Concomitant medications included prednisone for poison ivy.

The patient received the first dose of study medication on 10 October 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 19 October 2000 (Day 10). The patient remained at the dose of 20 mg/day throughout the study and received the last dose of study medication on 01 March 2001 (Day 143).

On 29 October 2000 (Day 20), mild contact dermatitis (poison ivy) was reported. This condition resolved with treatment in 13 days, and was considered to be unrelated to treatment with study medication by the investigator.

On 05 February 2001 (Day 129), the patient experienced moderately severe anxiety (anxiety increased), which continued through the end of the study, and resulted in withdrawal from the study. No corrective treatment was given for this condition, which the investigator considered to be unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.025.27060

Treatment Group: Placebo (Protocol 704), paroxetine (Protocol 716)

Adverse Event: Hostility (oppositional defiant)

This 9-year-old black male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. The patient was 8 years old at entry into acute Protocol 704. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (patient 704.025.27060), and received treatment with placebo in that study.

Concomitant medications included DDAVP® (desmopressin) for bedwetting, and Risperdal® (risperidone) for oppositional defiant behavior. Treatment for bedwetting was started in the previous acute protocol and was continued into extension Protocol 716.

The patient received the first dose of study medication on 12 October 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 05 December 2000 (Day 55). The dose remained at 20 mg/day throughout the study. The final dose of study medication was taken on 01 March 2001 (Day 141).

On 15 February 2001 (Day 127), the patient experienced moderately severe hostility (oppositional defiant), which continued throughout the study. Corrective treatment was given, and the patient was withdrawn from the study. The investigator considered the event to be unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.043.27696

Treatment Group: Placebo (Protocol 701), paroxetine (Protocol 716)

Adverse Event: Hostility (defiant behavior)

This 9-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. The patient was 8 years old at entry into acute Protocol 701. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (patient 701.150.27696), and received treatment with placebo in that study.

Concomitant medications included Tylenol Cough and Cold Medication® (chlorpheniramine maleate, dextromethorphan hydrobromide, paracetamol, pseudoephedrine HCl) and Claritin® (loratadine) for allergic rhinitis, Clonidine® (clonidine) for defiant behavior, and Children's Tylenol® (paracetamol) for sinus allergy (taken since January 1995).

The patient received the first dose of study medication on 17 January 2001. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 31 January 2001 (Day 15). The dose was decreased to 10 mg/day on 07 February 2001 (Day 22). The last dose of study medication was taken on 23 February 2001 (Day 38).

On 12 February 2001 (Day 27), the patient experienced severe hostility (defiant behavior), which resolved with treatment in 24 days. The investigator considered this condition to be unrelated to treatment with study medication, but withdrew the patient from the study.

On 20 November 2000, during the acute study, 58 days before treatment in extension Protocol 716 began, the patient reported mild rhinitis (sniffles), which continued into Study 716. This event was considered to be unrelated to treatment with study medication.

On 16 January 2001 (Day -1), one day before treatment in extension Protocol 716 began, the patient reported moderately severe rhinitis (allergic rhinitis), which resolved with treatment in five days. This event was considered to be unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.044.27655

Treatment Group: Placebo (Protocol 701), paroxetine (Protocol 716)

Adverse Event: Anxiety (post-traumatic syndrome)

This 13-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. The patient was 12 years old at entry into acute Protocol 701. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (patient 701.149.27655), and received treatment with placebo in that study.

Concomitant medications included Risperdal® (risperidone) for post-traumatic syndrome.

The patient received the first dose of study medication on 08 November 2000. The patient began treatment at a dose of 30 mg/day, which was decreased to 20 mg/day on 29 November 2000 (Day 22). The final dose of study medication was taken on 06 December 2000 (Day 29).

On 01 December 2000 (Day 24), the patient experienced severe anxiety (post-traumatic syndrome), which continued through the end of the study. Corrective therapy was given. The investigator considered this to be unrelated to treatment with study medication, but withdrew the patient from the study.

No other adverse events were reported during the study.

PID: 716.047.27156

Treatment Group: Placebo (Protocol 704), paroxetine (Protocol 716)

Adverse Event: Asthenia (fatigue)

This 12-year-old white female, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (patient 704.047.27156), and received treatment with placebo in that study.

Concomitant medications included non-specified multivitamins for nutritional supplement.

The patient received the first dose of study medication on 27 March 2001. The patient began treatment at a dose of 10 mg/day and was given her last dose of study medication on 03 April 2001 (Day 8).

On 27 March 2001 (Day 1), the patient experienced moderately severe asthenia (fatigue), which resolved without treatment in 10 days. The investigator considered this event to be possibly related to treatment with study medication and withdrew the patient from the study. Also, on 27 March 2001 (Day 1), the patient reported moderately severe dizziness, which resolved without treatment in three days. This was also considered to be possibly related to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.164.25721

Treatment Group: Paroxetine (Protocol 701), paroxetine (Protocol 716)

Adverse Event: Nausea

This 14-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (patient 701.164.25721), and received treatment with paroxetine in that study.

Concomitant medications included ibuprofen and Tylenol® (paracetamol) for headache, and Compazine® (prochlorperazine) for nausea.

The patient received the first dose of study medication on 07 July 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 19 July 2000 (Day 13). This dose was maintained throughout the study. The final dose of study medication was taken on 13 October 2000 (Day 99).

On 29 September 2000 (Day 85), the patient experienced moderately severe nausea, which resolved with treatment in 21 days. The investigator considered this event to be possibly related to treatment with study medication and the patient was withdrawn from the study.

On 20 May 2000, and 05 July 2000 (during the previous acute study and before the first dose of study medication in Protocol 716) the patient reported mild left heel pain, and mild left jaw pain, respectively. Both events continued into and through the extension study. No corrective therapy was given, and the investigator considered these events to be unrelated to treatment with study medication.

On 11 July 2000 (Day 5), the patient reported mild headache, which resolved with treatment in one day. The investigator considered the headache to be possibly related to treatment with study medication. On 19 July 2000 (Day 13), the patient reported moderately severe headache, which was treated, and on 26 July 2000

(Day 20), the patient reported mild headache, which was not treated. Both resolved in one day and were considered to be probably unrelated to treatment with study medication.

On 02 October 2000 (Day 88) and again on 03 October 2000 Day (89), the patient reported moderately severe headaches, which each resolved with treatment in one day. These events were considered to be possibly related to treatment with study medication.

On 29 July 2000 (Day 23), the patient reported moderately severe trauma (left wrist contusion), which continued throughout the study. No corrective treatment was given. The investigator considered this event to be unrelated to treatment with study medication.

On 01 October 2000 (Day 87), the patient reported moderately severe vomiting, which resolved without treatment in one day. This was considered to be possibly related to treatment with study medication.

On 16 November 2000 (post-study), the patient experienced moderately severe gastritis, which was continuing at the end of this study reporting period. Corrective therapy (ranitidine [Zantac®]) was given for this condition, which was considered to be possibly related to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.165.25664

Treatment Group: Placebo (Protocol 701), paroxetine (Protocol 716)

Adverse Event: Bundle Branch Block (abnormal ECG)

Laboratory Value of Clinical Concern: Increased Alanine Aminotransferase

Laboratory Value Associated Adverse Event Reported: Abnormal Liver Function Tests (increased liver enzymes)

This 10-year-old Hispanic male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. The patient was 9 years old at entry into acute Protocol 701. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 6-week study Protocol 715 (MDD/OCD), the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (patient 701.165.25664), and received treatment with placebo in that study.

Concomitant medications included Children's Motrin® (ibuprofen) for back pain and Benadryl® (diphenhydramine HCl) for agitation.

The patient received the first dose of study medication on 10 October 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 17 October 2000 (Day 8). The dose was decreased to 10 mg/day on 20 October 2000 (Day 11), and then increased again to 20 mg/day on 25 October 2000 (Day 16). The dose was increased, in 10 mg/week increments, to 50 mg/day by 06 December 2000 (Day 58). The dose was decreased, in 10 mg/week increments, to 10 mg/day by 24 February 2001 (Day 138). The final dose was given on 26 February 2001 (Day 140).

On 13 February 2001 (Day 127), while at a dose of 50 mg/day, the patient was found to have bundle branch block (abnormal electrocardiogram [ECG]), reported as an adverse event. The abnormality was considered to be mild, resolved without treatment in 15 days, and follow-up ECG on Day 141 was normal. Vital signs recorded on 13 February 2001 (Day 127) were within normal limits, except for mildly increased body weight of 38.2 kg. The investigator considered the

abnormal ECG to be unrelated to treatment with study medication, but the patient was withdrawn from the study. Also, on Day 127, the patient reported a mildly increased weight gain, which continued, without treatment, through the end of the study. The investigator considered the weight gain to be probably unrelated to treatment with study medication. The patient's body weight at baseline in the previous acute study (Protocol 701) was 32.7 kg; baseline body weight in Protocol 716 was 34.0 kg; body weight on 13 February 2001 (Day 127) was 38.2 kg. The weight was not considered to be of potential clinical concern. No additional body weight was provided.

On 08 October 2000 (one day before treatment began in Protocol 716), the patient reported mild back pain (neck ache), which resolved without treatment in three days. Mild back pain (back pain) was also reported on 19 November 2000 (Day 41). Back pain resolved with treatment in one day. Both of these events were considered to be unrelated to treatment with study medication.

On 17 October 2000 (Day 8), the patient experienced mild dyspepsia and moderately severe vomiting, both of which resolved without treatment in 15 days. The investigator considered both of these conditions to be probably unrelated to treatment with study medication.

On 16 November 2000 (Day 38), the patient experienced severe agitation, which resolved with treatment in one day. On 26 January 2001 (Day 109), moderately severe agitation (increased agitation) was again reported, which continued through the end of the study despite corrective treatment and decrease in study medication. The investigator considered both events to be unrelated to treatment with study medication.

On 02 January 2001 (Day 85), the investigator reported an adverse event of mildly abnormal liver function tests (increased liver enzymes), which resolved without treatment in 84 days. The investigator considered these abnormal test results to be unrelated to treatment with study medication. At screening of Protocol 716, the patient's aspartate aminotransferase (ASAT) value was 42 IU/L (reference range 0–42 IU/L); alanine aminotransferase (ALAT) was slightly elevated at 46 IU/L (reference range 0–45 IU/L). The values for these analytes throughout the study are provided in the table below. No additional follow-up values were provided. The ALAT value at Day 141 was considered to be of potential clinical concern, defined as a value >165.

Analyte	Screening (Day –69)	Week 4 (Day 29)	Week 12 (Day 85)	Week 20 Day 127)	Follow-up (Day 141)
ASAT	42 IU/L	28 IU/L	54 IU/L	59 IU/L	104 IU/L
ALAT	46 IU/L	16 IU/L	84 IU/L	79 IU/L	179 IU/L

Other out-of-range values were reported at Week 4: slightly increased hemoglobin (170 g/L; reference range 115 to 155 g/L), hematocrit (51%; reference range 35% to 45%), and red blood cell count (6.1 x 10^9/L; reference range 4.0 to 5.2 10^9/L). Absolute monocyte value of 0.16 x 10^9/L; reference range 0.2 to 1.1 x 10^9/L) was also slightly decreased at Week 4. Platelet count (31 x 10^9/L; reference range 130 to 400 x 10^9/L) was also decreased at Week 4; this value met the criteria of potential clinical concern. At Week 12, the platelet count was slightly elevated at 412 x 10^9/L. Except for ALT and AST values, and those reported above, all other laboratory test results were within normal limits at Week 4 and throughout the study.

On 28 February 2001 (Day 142; two days after the final dose of study medication), the patient experienced moderately severe impaired concentration (attention deficit disorder), which was continuing at the time the study ended. Corrective therapy was given for this condition, which was considered to be unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.176.25794

Treatment Group: Placebo (Protocol 701), paroxetine (Protocol 716)

Adverse Event: Syncope (syncope)

This 11-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (patient 701.176.25794), and received treatment with placebo in that study.

Concomitant medications included intravenous saline solution for syncope and dehydration, and non-specified multivitamins for dietary supplementation.

The patient received the first dose of study medication on 22 December 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to 30 mg/day by 19 January 2001 (Day 29). The patient received the last dose of 30 mg/day on 21 February 2001 (Day 62). The dose was tapered down to 20 mg/day, then 10 mg/day and the final dose of study medication was given on 06 March 2001 (Day 75).

On 12 February 2001 (Day 53), 16 February 2001 (Day 57), 19 February 2001 (Day 60), and on 21 February 2001 (Day 62), the patient experienced moderately severe episodes of syncope, all of which resolved in one day. Corrective therapy was provided only for the episode on Day 53. The investigator considered all four episodes to be possibly related to treatment with study medication and the patient was withdrawn from the study following the fourth report of syncope on Day 62.

On 12 February 2001 (Day 53), the patient also experienced moderately severe dehydration, which resolved with treatment in one day. The investigator considered this to be possibly related to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.180.25776

Treatment Group: Paroxetine (Protocol 701), paroxetine (Protocol 716)

Adverse Event: Convulsion (possible seizure)

This 7-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (patient 701.180.25776), and received treatment with paroxetine in that study.

No concomitant medications were reported during the study.

The patient received the first dose of study medication on 26 September 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 04 October 2000 (Day 9). The dose remained at 20 mg/day through the final dose on 16 October 2000 (Day 21).

On 01 October 2000 (Day 6), the patient experienced moderately severe convulsion (possible seizure activity), which reportedly persisted (unknown number of episodes) over a 26-day period. No corrective treatment was given for this event, which the investigator considered to be possibly related to treatment with study medication. The patient was withdrawn from the study due to this event. Also, on Day 6, the patient reported mildly dry mouth, and mild hallucinations, both of which continued through the end of the study. No treatment was given for either event. The investigator considered the dry mouth to be possibly related to treatment with study medication and the hallucinations to be unrelated to treatment with study medication.

On 17 October 2000 (Day 22; one day after the last dose of study medication), the patient reported mild myalgia (intermittent spasms in leg), which continued without treatment through the end of the study reporting period. The investigator considered this condition to be possibly related to treatment with study medication.

On 19 October 2000 (Day 24; 3 days after the last dose of study medication), the patient reported mild abdominal pain (stomach aches) and mild headache (headaches), both of which resolved without treatment in eight days. The investigator considered both of these events to be unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.183.25901

Treatment Group: Placebo (Protocol 701), paroxetine (Protocol 716)

Adverse Event: Libido decreased (decreased libido)

This 17-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (patient 701.183.25901), and received treatment with placebo in that study.

No concomitant medications were reported during the study.

The patient received the first dose of study medication on 26 October 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10mg/week increments, to 30 mg/day by 07 December 2000 (Day 43). The dose remained at 30 mg/day through the final dose of study medication on 31 January 2001 (Day 98).

On 20 December 2000 (Day 56), the patient reported mildly decreased libido (decreased libido, inorgasmia) persisting for 42 days (to Day 98) with no action taken; the same event was reported again on 31 January 2001 (Day 98) and was reported to have continued for 15 days and resulting in withdrawal from the study. Both events were reported as mild continuous episodes. Corrective therapy was not given for either reported event. The investigator considered this condition (both reports) to be related to treatment with study medication.

No other adverse events were reported during the study.

PID: 716.192.25870

Treatment Group: Placebo (Protocol 701), paroxetine (Protocol 716)

Adverse Event: Hallucinations (auditory, visual hallucinations)

This 18-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. The patient was 17 years old at entry into Protocol 701. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (patient 701.192.25870), and received treatment with placebo in that study.

Concomitant medications included Seroquel® (quetiapine) for hallucinations.

The patient received the first dose of study medication on 28 October 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10mg/week increments, to 40 mg/day by 06 December 2000 (Day 40). The dose was decreased to 30 mg/day on 15 March 2001 (Day 139). The final dose of study medication was given on 16 March 2001 (Day 140).

On 03 March 2001 (Day 127), the patient experienced severe auditory and visual hallucinations, which continued through the end of the study. Corrective therapy was given, and the investigator considered the adverse events to be unrelated to treatment with study medication. The patient was withdrawn from the study because of the hallucinations.

On 30 January 2001 (Day 98), the investigator reported an adverse event of mild weight gain, which continued through the end of the study. No corrective therapy was given. The investigator considered the weight gain to be possibly related to treatment with study medication. The patient's body weight at screening in the previous acute study was 67.2 kg, and at baseline in Protocol 716 was 66.0 kg. At Week 12 of Protocol 716 (30 January 2001), body weight was 71.0 kg, and follow-up body weight (14 March 2001) was 75 kg. The patient's weight did not meet the criteria for potential clinical concern. No further values were provided.

No other adverse events were reported during the study.

PID: 716.201.00110

Treatment Group: Paroxetine (Protocol 715), Paroxetine (Protocol 716)

Adverse Event: Hostility (increased behavior problems)

This 9-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. The patient was 17 years old at entry into Protocol 701. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 8-week study Protocol 701 (MDD) or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (patient 715.201.00110), and received treatment with paroxetine in that study.

No concomitant medications were reported during the study.

The patient received the first dose of study medication on 25 April 2001. The patient began treatment at a dose of 30 mg/day, which was decreased to 20 mg/day on 02 May 2001 (Day 8). The dose was decreased to 10 mg/day on 08 May 2001 (Day 14), and remained at that dose through the end of treatment. The final dose of study medication was given on 01 June 2001 (Day 38).

On 25 April 2001 (Day 1) and again on 30 April 2001 (Day 6) moderately severe hostility (intermittent increased disobedience) was reported. These events resolved without treatment in 17 days. In addition, mild neurosis (intermittent disinhibition) was reported on Day 1. The dose of study medication was decreased in response to these events. The investigator considered the hostility and neurosis to be probably unrelated to treatment with study medication. On 24 May 2001 (Day 30), severe hostility (increased behavior problems) was reported. This continued without treatment through the end of the study. The investigator withdrew the patient from the study for this event, which he considered to be possibly related to treatment with study medication.

No other non-serious adverse events were reported during the study.

Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	67	105.8	106.0	11.05	83	133	72	104.0	102.0	11.18	74	137	139	104.9	105.0	11.11	74	137
Change from Acute Study Baseline to 716 :																		
Week 1	54	-2.4	-2.0	11.70	-28	21	61	2.8	2.0	13.09	-26	38	115	0.3	0.0	12.68	-28	38
Week 2	53	-1.3	-1.0	11.01	-30	23	63	1.5	0.0	11.99	-22	26	116	0.3	0.0	11.59	-30	26
Week 3	54	-2.3	-3.5	10.19	-28	22	63	0.6	0.0	15.83	-36	61	117	-0.7	-2.0	13.55	-36	61
Week 4	60	-0.1	0.5	11.29	-27	29	60	5.2	3.0	14.67	-22	49	120	2.6	2.0	13.30	-27	49
Week 6	50	0.0	2.0	10.92	-23	26	54	1.4	0.0	12.95	-30	36	104	0.7	1.5	11.98	-30	36
Week 8	53	0.8	0.0	10.59	-25	30	50	0.2	0.0	12.92	-27	27	103	0.5	0.0	11.72	-27	30
Week 12	38	0.1	0.0	10.71	-20	21	42	0.1	-0.5	14.14	-26	36	80	0.1	0.0	12.55	-26	36
Week 16	32	0.9	2.0	10.52	-20	27	33	0.3	0.0	11.97	-21	22	65	0.6	2.0	11.20	-21	27
Week 20	32	-2.2	1.5	11.29	-24	18	30	-1.1	0.5	11.37	-25	20	62	-1.7	1.0	11.25	-25	20
Week 24	27	-1.1	-1.0	9.76	-30	14	21	-0.2	2.0	11.13	-22	16	48	-0.7	0.5	10.28	-30	16

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	66	111.7	111.5	11.65	88	140	58	111.4	110.0	10.59	90	142	124	111.6	110.0	11.12	88	142
Change from Acute Study Baseline to 716 :																		
Week 1	60	1.2	1.5	11.89	-24	31	49	4.3	4.0	13.47	-31	42	109	2.6	2.0	12.67	-31	42
Week 2	59	0.2	0.0	10.86	-33	31	49	4.0	6.0	10.36	-22	33	108	1.9	2.5	10.76	-33	33
Week 3	55	2.2	2.0	10.12	-25	30	45	3.2	2.0	12.93	-22	40	100	2.6	2.0	11.42	-25	40
Week 4	59	0.4	0.0	10.93	-24	23	50	3.3	2.0	14.62	-26	50	109	1.7	2.0	12.78	-26	50
Week 6	55	1.2	0.0	10.49	-25	21	43	3.6	2.0	11.24	-24	30	98	2.2	0.0	10.84	-25	30
Week 8	55	2.1	2.0	12.11	-31	25	39	4.7	4.0	10.59	-20	30	94	3.2	3.5	11.51	-31	30
Week 12	52	3.2	3.0	10.86	-16	31	35	6.4	6.0	11.03	-26	32	87	4.5	4.0	10.99	-26	32
Week 16	45	2.8	6.0	11.44	-25	21	32	6.4	3.0	12.04	-10	36	77	4.3	4.0	11.75	-25	36
Week 20	36	3.0	2.0	12.20	-23	26	26	6.7	6.0	10.96	-17	38	62	4.5	4.0	11.76	-23	38
Week 24	27	7.7	9.0	11.32	-10	30	21	9.4	6.0	13.28	-13	34	48	8.4	7.0	12.11	-13	34

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

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Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	133	108.7	109.0	11.68	83	140	130	107.3	108.0	11.49	74	142	263	108.0	108.0	11.59	74	142
Change from Acute Study Baseline to 716 :																		
Week 1	114	-0.6	0.0	11.89	-28	31	110	3.5	2.0	13.22	-31	42	224	1.4	1.0	12.70	-31	42
Week 2	112	-0.5	0.0	10.90	-33	31	112	2.6	2.5	11.33	-22	33	224	1.1	0.0	11.20	-33	33
Week 3	109	0.0	0.0	10.35	-28	30	108	1.7	1.5	14.68	-36	61	217	0.8	0.0	12.69	-36	61
Week 4	119	0.1	0.0	11.06	-27	29	110	4.3	2.0	14.61	-26	50	229	2.1	2.0	13.03	-27	50
Week 6	105	0.6	0.0	10.66	-25	26	97	2.4	1.0	12.21	-30	36	202	1.5	0.5	11.44	-30	36
Week 8	108	1.5	0.0	11.36	-31	30	89	2.2	2.0	12.09	-27	30	197	1.8	1.0	11.67	-31	30
Week 12	90	1.8	2.0	10.85	-20	31	77	3.0	2.0	13.12	-26	36	167	2.4	2.0	11.93	-26	36
Week 16	77	2.1	2.0	11.04	-25	27	65	3.3	0.0	12.30	-21	36	142	2.6	2.0	11.61	-25	36
Week 20	68	0.5	2.0	11.98	-24	26	56	2.5	4.0	11.76	-25	38	124	1.4	2.0	11.88	-25	38
Week 24	54	3.3	1.5	11.37	-30	30	42	4.6	5.0	13.04	-22	34	96	3.9	3.0	12.08	-30	34

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	67	64.8	64.0	8.30	44	85	72	66.3	66.0	9.21	40	86	139	65.6	66.0	8.78	40	86
Change from Acute Study Baseline to 716 :																		
Week 1	54	-0.8	0.0	9.35	-24	18	61	1.2	2.0	11.02	-29	26	115	0.3	0.0	10.28	-29	26
Week 2	53	-0.2	0.0	8.43	-31	18	63	-0.6	0.0	10.84	-30	31	116	-0.4	0.0	9.77	-31	31
Week 3	54	-0.3	-0.5	9.99	-21	30	63	-1.7	-2.0	9.72	-24	23	117	-1.0	-1.0	9.83	-24	30
Week 4	60	0.6	1.0	9.57	-31	17	60	0.7	2.0	10.45	-22	24	120	0.6	2.0	9.98	-31	24
Week 6	50	-0.3	0.0	9.45	-24	18	54	1.0	2.5	10.76	-22	24	104	0.4	0.5	10.12	-24	24
Week 8	53	1.4	3.0	10.79	-31	20	50	0.0	0.0	10.94	-22	33	103	0.8	2.0	10.83	-31	33
Week 12	38	-0.4	0.0	8.28	-19	22	42	-0.6	-0.5	11.14	-24	28	80	-0.5	0.0	9.82	-24	28
Week 16	32	0.9	-0.5	10.28	-19	22	33	0.6	2.0	9.86	-22	26	65	0.8	0.0	9.99	-22	26
Week 20	32	1.5	0.5	10.52	-18	24	30	0.5	0.0	11.72	-30	28	62	1.0	0.0	11.04	-30	28
Week 24	27	0.5	0.0	9.91	-18	22	21	-2.1	0.0	10.26	-30	13	48	-0.6	0.0	10.04	-30	22

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

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Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	66	67.6	68.0	8.74	40	86	58	69.1	70.0	9.32	44	86	124	68.3	70.0	9.01	40	86
Change from Acute Study Baseline to 716 :																		
Week 1	60	1.2	2.0	9.90	-25	22	49	2.0	4.0	10.93	-20	26	109	1.6	2.0	10.33	-25	26
Week 2	59	1.5	0.0	8.19	-24	20	49	-0.1	0.0	11.36	-30	28	108	0.8	0.0	9.74	-30	28
Week 3	55	1.8	2.0	5.96	-14	12	45	2.4	2.0	9.96	-22	24	100	2.1	2.0	7.97	-22	24
Week 4	59	0.5	0.0	9.04	-31	30	50	2.5	2.0	9.72	-26	27	109	1.4	2.0	9.37	-31	30
Week 6	55	0.4	3.0	9.28	-24	17	43	2.5	2.0	11.51	-26	37	98	1.3	2.5	10.32	-26	37
Week 8	55	0.8	0.0	7.92	-21	18	39	1.3	2.0	8.82	-19	14	94	1.0	1.5	8.26	-21	18
Week 12	52	2.4	2.0	9.13	-21	20	35	3.6	4.0	8.72	-12	25	87	2.9	2.0	8.94	-21	25
Week 16	45	2.2	2.0	10.29	-24	18	32	1.0	0.0	8.92	-20	23	77	1.7	2.0	9.70	-24	23
Week 20	36	3.9	4.0	11.33	-20	34	26	2.3	2.0	8.31	-18	20	62	3.2	2.5	10.13	-20	34
Week 24	27	3.9	4.0	9.36	-22	18	21	1.7	2.0	7.72	-18	12	48	2.9	3.0	8.66	-22	18

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

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Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	133	66.2	66.0	8.60	40	86	130	67.5	69.0	9.33	40	86	263	66.9	68.0	8.97	40	86
Change from Acute Study Baseline to 716 :																		
Week 1	114	0.3	0.0	9.65	-25	22	110	1.6	2.0	10.94	-29	26	224	0.9	1.0	10.30	-29	26
Week 2	112	0.7	0.0	8.31	-31	20	112	-0.4	0.0	11.02	-30	31	224	0.1	0.0	9.75	-31	31
Week 3	109	0.8	0.0	8.23	-21	30	108	0.0	0.0	9.98	-24	24	217	0.4	0.0	9.13	-24	30
Week 4	119	0.5	0.0	9.27	-31	30	110	1.5	2.0	10.12	-26	27	229	1.0	2.0	9.68	-31	30
Week 6	105	0.1	1.0	9.32	-24	18	97	1.7	2.0	11.06	-26	37	202	0.8	2.0	10.20	-26	37
Week 8	108	1.1	2.0	9.40	-31	20	89	0.6	2.0	10.03	-22	33	197	0.9	2.0	9.67	-31	33
Week 12	90	1.2	1.0	8.85	-21	22	77	1.3	2.0	10.26	-24	28	167	1.3	1.0	9.50	-24	28
Week 16	77	1.7	1.0	10.24	-24	22	65	0.8	0.0	9.34	-22	26	142	1.3	0.5	9.81	-24	26
Week 20	68	2.8	2.0	10.94	-20	34	56	1.3	0.0	10.23	-30	28	124	2.1	2.0	10.61	-30	34
Week 24	54	2.2	2.5	9.70	-22	22	42	-0.2	2.0	9.16	-30	13	96	1.1	2.0	9.49	-30	22

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

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Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	67	83.5	84.0	10.62	60	102	72	81.3	80.0	11.61	52	110	139	82.4	82.0	11.16	52	110
Change from Acute Study Baseline to 716 :																		
Week 1	54	0.8	0.0	11.32	-21	24	61	-1.4	-2.0	11.98	-32	28	115	-0.4	-1.0	11.67	-32	28
Week 2	53	1.2	0.0	12.02	-20	32	63	-1.7	-2.0	11.74	-33	25	116	-0.3	-1.0	11.90	-33	32
Week 3	54	-0.1	2.0	11.59	-26	28	63	0.9	0.0	11.81	-28	24	117	0.4	0.0	11.67	-28	28
Week 4	60	2.1	3.5	11.33	-20	32	60	3.9	3.0	11.68	-30	32	120	3.0	3.5	11.49	-30	32
Week 6	51	3.0	1.0	11.17	-24	28	54	2.8	2.0	11.02	-20	28	105	2.9	2.0	11.04	-24	28
Week 8	53	0.8	0.0	13.64	-29	30	50	3.1	4.0	13.29	-39	29	103	1.9	2.0	13.46	-39	30
Week 12	39	-1.3	-1.0	13.17	-37	26	42	1.8	0.5	12.29	-20	32	81	0.3	0.0	12.74	-37	32
Week 16	32	0.9	-1.0	13.54	-17	48	33	4.7	4.0	12.97	-20	34	65	2.8	0.0	13.28	-20	48
Week 20	32	0.7	2.0	11.75	-17	30	29	2.1	0.0	10.82	-16	22	61	1.3	2.0	11.24	-17	30
Week 24	27	-0.2	0.0	13.38	-24	37	21	0.9	0.0	12.01	-28	25	48	0.3	0.0	12.68	-28	37

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716

Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	66	77.7	79.0	10.21	50	104	58	74.5	76.0	8.96	52	96	124	76.2	76.0	9.74	50	104
Change from Acute Study Baseline to 716 :																		
Week 1	60	1.1	1.0	12.28	-36	28	49	2.1	0.0	12.39	-23	28	109	1.5	0.0	12.28	-36	28
Week 2	59	2.3	0.0	13.36	-20	40	49	1.3	2.0	12.14	-32	32	108	1.8	0.0	12.77	-32	40
Week 3	55	0.5	0.0	13.38	-36	36	45	4.0	2.0	11.87	-20	35	100	2.1	0.5	12.78	-36	36
Week 4	59	3.3	4.0	12.14	-32	28	50	4.1	4.0	10.76	-21	27	109	3.7	4.0	11.48	-32	28
Week 6	55	1.9	0.0	12.56	-32	42	43	4.5	2.0	12.10	-15	40	98	3.0	2.0	12.36	-32	42
Week 8	55	3.5	2.0	11.18	-24	26	39	5.1	4.0	10.43	-28	32	94	4.1	4.0	10.85	-28	32
Week 12	52	3.0	2.0	12.48	-24	36	35	6.7	8.0	10.55	-21	30	87	4.5	4.0	11.82	-24	36
Week 16	45	0.9	2.0	14.04	-36	34	32	3.8	4.0	8.49	-16	20	77	2.1	2.0	12.07	-36	34
Week 20	36	-0.4	-1.0	12.71	-36	33	26	3.5	5.0	13.07	-26	24	62	1.3	0.0	12.90	-36	33
Week 24	27	-2.3	-3.0	11.26	-36	19	21	-0.3	2.0	16.34	-40	26	48	-1.4	0.0	13.59	-40	26

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716

Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	133	80.6	80.0	10.77	50	104	130	78.3	78.0	11.02	52	110	263	79.5	80.0	10.93	50	110
Change from Acute Study Baseline to 716 :																		
Week 1	114	1.0	0.0	11.79	-36	28	110	0.2	0.0	12.23	-32	28	224	0.6	0.0	11.99	-36	28
Week 2	112	1.8	0.0	12.70	-20	40	112	-0.3	0.0	11.95	-33	32	224	0.7	0.0	12.35	-33	40
Week 3	109	0.2	0.0	12.47	-36	36	108	2.2	1.0	11.88	-28	35	217	1.2	0.0	12.19	-36	36
Week 4	119	2.7	4.0	11.71	-32	32	110	4.0	4.0	11.22	-30	32	229	3.3	4.0	11.47	-32	32
Week 6	106	2.5	1.0	11.87	-32	42	97	3.5	2.0	11.48	-20	40	203	3.0	2.0	11.67	-32	42
Week 8	108	2.2	2.0	12.46	-29	30	89	4.0	4.0	12.10	-39	32	197	3.0	4.0	12.30	-39	32
Week 12	91	1.2	0.0	12.89	-37	36	77	4.0	4.0	11.71	-21	32	168	2.5	2.0	12.41	-37	36
Week 16	77	0.9	0.0	13.75	-36	48	65	4.2	4.0	10.92	-20	34	142	2.4	2.0	12.60	-36	48
Week 20	68	0.1	0.0	12.19	-36	33	55	2.8	2.0	11.85	-26	24	123	1.3	1.0	12.06	-36	33
Week 24	54	-1.3	-2.0	12.29	-36	37	42	0.3	1.0	14.18	-40	26	96	-0.6	0.0	13.10	-40	37

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

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Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Height / cm
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	67	141.04	140.00	12.030	114.5	165.0	72	138.89	140.00	10.198	115.6	161.0	139	139.93	140.00	11.130	114.5	165.0
Week 12	35	1.03	1.50	4.616	-23.1	6.4	40	2.96	2.00	4.751	-0.1	24.9	75	2.06	1.50	4.758	-23.1	24.9
Week 24	25	4.56	3.90	8.821	-19.0	39.5	19	4.55	4.10	2.404	0.0	8.9	44	4.55	4.00	6.771	-19.0	39.5

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

BRL 29060 - 716

Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Height / cm
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	66	165.89	165.80	10.001	139.5	188.0	57	165.96	167.60	8.372	149.9	180.3	123	165.92	166.40	9.245	139.5	188.0
Week 12	44	-0.01	0.00	1.871	-5.1	4.4	29	0.78	0.40	1.661	-3.0	5.0	73	0.30	0.10	1.820	-5.1	5.0
Week 24	26	1.23	0.40	2.192	-3.0	5.6	19	1.37	0.50	2.543	-3.0	7.9	45	1.29	0.50	2.319	-3.0	7.9

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

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Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Height / cm
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	133	153.37	155.00	16.647	114.5	188.0	129	150.85	151.10	16.445	115.6	180.3	262	152.13	152.75	16.564	114.5	188.0
Week 12	79	0.45	0.80	3.390	-23.1	6.4	69	2.04	1.00	3.907	-3.0	24.9	148	1.19	1.00	3.714	-23.1	24.9
Week 24	51	2.86	2.90	6.524	-19.0	39.5	38	2.96	2.85	2.924	-3.0	8.9	89	2.90	2.90	5.271	-19.0	39.5

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

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Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	67	42.03	38.10	15.578	20.4	79.5	72	38.77	34.50	14.419	20.5	104.0	139	40.34	35.50	15.023	20.4	104.0
Week 12	35	2.77	2.00	2.669	-1.5	10.5	41	2.14	2.20	2.214	-2.9	8.7	76	2.43	2.05	2.438	-2.9	10.5
Week 24	25	4.89	4.50	2.821	0.0	14.8	19	4.52	4.20	3.469	-0.5	15.8	44	4.73	4.35	3.084	-0.5	15.8

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

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Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	66	69.84	65.00	21.632	30.0	143.8	57	67.68	62.60	19.725	38.2	131.4	123	68.84	63.20	20.714	30.0	143.8
Week 12	44	2.06	1.80	4.587	-16.6	13.7	30	3.17	3.15	3.999	-4.5	14.1	74	2.51	2.20	4.365	-16.6	14.1
Week 24	26	5.32	5.15	6.866	-19.6	21.5	19	4.64	4.50	8.276	-19.1	16.8	45	5.03	5.00	7.411	-19.6	21.5

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

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Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	133	55.83	55.00	23.378	20.4	143.8	129	51.54	46.40	22.212	20.5	131.4	262	53.72	51.85	22.869	20.4	143.8
Week 12	79	2.38	1.80	3.851	-16.6	13.7	71	2.58	2.70	3.113	-4.5	14.1	150	2.47	2.10	3.511	-16.6	14.1
Week 24	51	5.11	4.90	5.238	-19.6	21.5	38	4.58	4.35	6.259	-19.1	16.8	89	4.88	4.50	5.668	-19.6	21.5

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Body Mass Index / kg/m2
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	67	20.57	18.90	5.292	13.9	32.8	72	19.70	18.15	5.217	13.6	40.1	139	20.12	18.30	5.252	13.6	40.1
Week 12	35	1.05	0.80	1.465	-1.7	6.1	40	0.26	0.60	1.541	-5.3	2.3	75	0.63	0.60	1.549	-5.3	6.1
Week 24	25	1.18	1.00	2.232	-5.8	6.4	19	0.81	0.80	1.256	-1.4	3.9	44	1.02	1.00	1.864	-5.8	6.4

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Body Mass Index / kg/m2
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	66	25.17	23.20	6.812	13.8	45.9	57	24.43	22.80	6.321	16.4	45.4	123	24.83	23.00	6.573	13.8	45.9
Week 12	44	0.76	0.75	1.726	-6.2	4.0	29	0.92	0.90	1.193	-1.4	3.1	73	0.82	0.80	1.529	-6.2	4.0
Week 24	26	1.55	1.35	2.651	-9.0	6.5	19	1.19	1.00	2.720	-6.6	5.4	45	1.40	1.30	2.656	-9.0	6.5

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

Table 15.2.1.1

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase and Open Label Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Body Mass Index / kg/m2
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	133	22.85	21.00	6.496	13.8	45.9	129	21.79	20.10	6.175	13.6	45.4	262	22.33	20.80	6.350	13.6	45.9
Week 12	79	0.89	0.80	1.612	-6.2	6.1	69	0.53	0.70	1.434	-5.3	3.1	148	0.73	0.75	1.537	-6.2	6.1
Week 24	51	1.37	1.30	2.437	-9.0	6.5	38	1.00	0.90	2.099	-6.6	5.4	89	1.21	1.10	2.294	-9.0	6.5

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	67	105.8	106.0	11.05	83	133	72	104.0	102.0	11.18	74	137	139	104.9	105.0	11.11	74	137
Change from Acute Study Baseline to 716 :																		
Week 1	1	14.0	14.0	.	14	14	0	.	.	.	.	.	1	14.0	14.0	.	14	14
Week 2	0	.	.	.	.	.	1	-14.0	-14.0	.	-14	-14	1	-14.0	-14.0	.	-14	-14
Week 3	1	18.0	18.0	.	18	18	1	2.0	2.0	.	2	2	2	10.0	10.0	11.31	2	18
Week 4	1	16.0	16.0	.	16	16	4	-6.8	-2.5	10.24	-22	0	5	-2.2	-2.0	13.50	-22	16
Week 6	2	1.5	1.5	9.19	-5	8	4	12.5	13.0	9.15	2	22	6	8.8	8.0	9.97	-5	22
Week 8	3	7.3	10.0	4.62	2	10	4	6.5	4.0	9.98	-2	20	7	6.9	8.0	7.56	-2	20
Week 12	4	-4.5	-4.5	13.03	-18	9	7	5.6	8.0	8.82	-6	18	11	2.5	4.0	10.84	-18	18
Week 16	2	-2.5	-2.5	19.09	-16	11	2	3.3	10.0	13.32	-12	12	4	1.0	10.0	13.78	-16	12
Week 20	0	.	.	.	.	.	3	-7.5	-6.0	9.71	-20	2	3	-7.5	-6.0	9.71	-20	2
Week 24	18	0.6	2.0	12.37	-24	20	15	-1.4	0.0	12.82	-23	20	33	-0.3	0.0	12.44	-24	20
Post Week 24	6	-3.4	-4.0	5.62	-10	6	5	2.0	2.0	6.45	-8	12	11	-0.9	0.0	6.41	-10	12

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	66	111.7	111.5	11.65	88	140	58	111.4	110.0	10.59	90	142	124	111.6	110.0	11.12	88	142
Change from Acute Study Baseline to 716 :																		
Week 1	0	.	.	.	.	.	1	-20.0	-20.0	.	-20	-20	1	-20.0	-20.0	.	-20	-20
Week 3	1	0.0	0.0	.	0	0	1	4.0	4.0	.	4	4	2	2.0	2.0	2.83	0	4
Week 4	1	24.0	24.0	.	24	24	2	-3.0	-3.0	4.24	-6	0	3	6.0	0.0	15.87	-6	24
Week 6	1	-4.0	-4.0	.	-4	-4	3	8.0	8.0	2.00	6	10	4	5.0	7.0	6.22	-4	10
Week 8	1	22.0	22.0	.	22	22	3	1.8	1.0	6.24	-5	10	4	5.8	2.0	10.55	-5	22
Week 12	2	-10.0	-10.0	19.80	-24	4	1	5.0	5.0	.	5	5	3	-5.0	4.0	16.46	-24	5
Week 16	4	6.3	11.0	10.21	-9	12	2	6.0	6.0	19.80	-8	20	6	6.2	11.0	11.87	-9	20
Week 20	2	1.5	1.5	6.36	-3	6	2	0.5	0.5	10.61	-7	8	4	1.0	1.5	7.16	-7	8
Week 24	26	-0.6	-2.0	11.99	-22	30	14	3.6	2.0	13.11	-14	36	40	0.9	-1.0	12.43	-22	36
Post Week 24	7	-1.7	-6.0	11.09	-12	20	2	0.0	2.0	5.29	-6	4	9	-1.2	-3.0	9.43	-12	20

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	133	108.7	109.0	11.68	83	140	130	107.3	108.0	11.49	74	142	263	108.0	108.0	11.59	74	142
Change from Acute Study Baseline to 716 :																		
Week 1	1	14.0	14.0	.	14	14	1	-20.0	-20.0	.	-20	-20	2	-3.0	-3.0	24.04	-20	14
Week 2	0	.	.	.	.	.	1	-14.0	-14.0	.	-14	-14	1	-14.0	-14.0	.	-14	-14
Week 3	2	9.0	9.0	12.73	0	18	2	3.0	3.0	1.41	2	4	4	6.0	3.0	8.16	0	18
Week 4	2	20.0	20.0	5.66	16	24	6	-5.5	-2.5	8.38	-22	0	8	0.9	-1.0	13.93	-22	24
Week 6	3	-0.3	-4.0	7.23	-5	8	7	10.6	8.0	7.00	2	22	10	7.3	8.0	8.49	-5	22
Week 8	4	11.0	10.0	8.25	2	22	7	4.1	1.0	8.11	-5	20	11	6.4	5.0	8.48	-5	22
Week 12	6	-6.3	-4.5	13.72	-24	9	8	5.5	6.5	8.32	-6	18	14	1.1	4.0	11.80	-24	18
Week 16	6	3.3	10.5	12.48	-16	12	4	4.4	10.0	13.74	-12	20	10	3.8	10.0	12.40	-16	20
Week 20	2	1.5	1.5	6.36	-3	6	5	-4.8	-4.5	9.81	-20	8	7	-3.3	-2.5	9.11	-20	8
Week 24	44	-0.1	-2.0	12.03	-24	30	29	1.0	0.0	13.00	-23	36	73	0.3	0.0	12.37	-24	36
Post Week 24	13	-2.6	-4.0	8.49	-12	20	7	1.3	2.0	5.83	-8	12	20	-1.0	0.0	7.67	-12	20

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	67	64.8	64.0	8.30	44	85	72	66.3	66.0	9.21	40	86	139	65.6	66.0	8.78	40	86
Change from Acute Study Baseline to 716 :																		
Week 1	1	14.0	14.0	.	14	14	0	.	.	.	.	.	1	14.0	14.0	.	14	14
Week 2	0	.	.	.	.	.	1	-15.0	-15.0	.	-15	-15	1	-15.0	-15.0	.	-15	-15
Week 3	1	-2.0	-2.0	.	-2	-2	1	4.0	4.0	.	4	4	2	1.0	1.0	4.24	-2	4
Week 4	1	6.0	6.0	.	6	6	4	8.0	6.5	9.83	-1	20	5	7.6	6.0	8.56	-1	20
Week 6	2	-7.5	-7.5	6.36	-12	-3	4	8.0	3.0	16.08	-4	30	6	2.8	-3.5	15.08	-12	30
Week 8	3	3.7	2.0	7.64	-3	12	4	5.5	7.0	8.39	-6	14	7	4.7	6.0	7.45	-6	14
Week 12	4	2.5	2.5	9.26	-6	11	7	5.1	10.0	11.02	-13	16	11	4.3	10.0	10.19	-13	16
Week 16	2	-10.0	-10.0	25.46	-28	8	2	5.7	6.0	4.51	1	10	4	-0.6	6.0	15.68	-28	10
Week 20	0	.	.	.	.	.	3	-5.5	-7.0	5.74	-10	2	3	-5.5	-7.0	5.74	-10	2
Week 24	18	2.9	1.0	10.95	-14	28	15	1.6	0.0	9.96	-12	31	33	2.3	0.0	10.38	-14	31
Post Week 24	6	-0.9	-2.0	8.93	-14	14	5	5.2	6.5	3.37	0	8	11	1.9	2.0	7.38	-14	14

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	66	67.6	68.0	8.74	40	86	58	69.1	70.0	9.32	44	86	124	68.3	70.0	9.01	40	86
Change from Acute Study Baseline to 716 :																		
Week 1	0	.	.	.	.	.	1	0.0	0.0	.	0	0	1	0.0	0.0	.	0	0
Week 3	1	-2.0	-2.0	.	-2	-2	1	2.0	2.0	.	2	2	2	0.0	0.0	2.83	-2	2
Week 4	1	2.0	2.0	.	2	2	2	-3.0	-3.0	7.07	-8	2	3	-1.3	2.0	5.77	-8	2
Week 6	1	-7.0	-7.0	.	-7	-7	3	-2.0	-10.0	13.86	-10	14	4	-3.3	-8.5	11.59	-10	14
Week 8	1	5.0	5.0	.	5	5	3	4.5	2.0	5.00	2	12	4	4.6	2.0	4.34	2	12
Week 12	2	-4.0	-4.0	5.66	-8	0	1	2.0	2.0	.	2	2	3	-2.0	0.0	5.29	-8	2
Week 16	4	7.0	5.0	6.22	2	16	2	7.5	7.5	16.26	-4	19	6	7.2	5.0	8.73	-4	19
Week 20	2	5.0	5.0	4.24	2	8	2	0.5	0.5	6.36	-4	5	4	2.8	3.5	5.12	-4	8
Week 24	26	3.3	2.0	8.91	-13	20	14	1.6	2.0	8.28	-10	18	40	2.7	2.0	8.63	-13	20
Post Week 24	7	0.9	0.0	8.71	-10	18	2	2.0	2.0	2.00	0	4	9	1.2	0.0	7.19	-10	18

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	133	66.2	66.0	8.60	40	86	130	67.5	69.0	9.33	40	86	263	66.9	68.0	8.97	40	86
Change from Acute Study Baseline to 716 :																		
Week 1	1	14.0	14.0	.	14	14	1	0.0	0.0	.	0	0	2	7.0	7.0	9.90	0	14
Week 2	0	.	.	.	.	.	1	-15.0	-15.0	.	-15	-15	1	-15.0	-15.0	.	-15	-15
Week 3	2	-2.0	-2.0	0.00	-2	-2	2	3.0	3.0	1.41	2	4	4	0.5	0.0	3.00	-2	4
Week 4	2	4.0	4.0	2.83	2	6	6	4.3	1.5	10.01	-8	20	8	4.3	2.0	8.53	-8	20
Week 6	3	-7.3	-7.0	4.51	-12	-3	7	3.7	-4.0	14.90	-10	30	10	0.4	-4.0	13.45	-12	30
Week 8	4	4.0	3.5	6.27	-3	12	7	5.0	4.0	6.41	-6	14	11	4.7	3.5	6.10	-6	14
Week 12	6	0.3	-2.5	8.31	-8	11	8	4.8	9.0	10.43	-13	16	14	3.1	5.0	9.66	-13	16
Week 16	6	1.3	5.0	15.16	-28	16	4	6.4	6.0	8.79	-4	19	10	3.6	6.0	12.36	-28	19
Week 20	2	5.0	5.0	4.24	2	8	5	-3.5	-4.0	6.12	-10	5	7	-1.4	-1.0	6.70	-10	8
Week 24	44	3.1	2.0	9.70	-14	28	29	1.6	0.0	9.04	-12	31	73	2.5	1.0	9.41	-14	31
Post Week 24	13	0.0	-1.0	8.52	-14	18	7	4.1	4.0	3.26	0	8	20	1.6	0.0	7.14	-14	18

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	67	83.5	84.0	10.62	60	102	72	81.3	80.0	11.61	52	110	139	82.4	82.0	11.16	52	110
Change from Acute Study Baseline to 716 :																		
Week 1	1	-6.0	-6.0	.	-6	-6	0	.	.	.	.	.	1	-6.0	-6.0	.	-6	-6
Week 2	0	.	.	.	.	.	1	23.0	23.0	.	23	23	1	23.0	23.0	.	23	23
Week 3	1	-20.0	-20.0	.	-20	-20	1	0.0	0.0	.	0	0	2	-10.0	-10.0	14.14	-20	0
Week 4	1	8.0	8.0	.	8	8	4	-5.5	-3.0	8.81	-18	2	5	-2.8	-1.0	9.73	-18	8
Week 6	2	2.5	2.5	7.78	-3	8	4	0.3	2.5	15.84	-18	14	6	1.0	2.5	12.81	-18	14
Week 8	3	5.3	0.0	11.02	-2	18	4	8.3	7.5	13.38	-6	24	7	7.0	1.0	11.50	-6	24
Week 12	4	0.3	0.0	12.28	-14	15	7	1.6	2.0	10.14	-16	16	11	1.2	2.0	10.33	-16	16
Week 16	2	1.5	1.5	4.95	-2	5	2	-3.0	0.0	8.89	-13	4	4	-1.2	0.0	7.19	-13	5
Week 20	0	.	.	.	.	.	3	3.3	4.0	14.68	-15	20	3	3.3	4.0	14.68	-15	20
Week 24	18	3.6	4.5	11.02	-20	22	15	-1.7	0.0	10.21	-16	23	33	1.2	0.0	10.85	-20	23
Post Week 24	6	4.6	4.0	7.46	-8	16	5	1.2	1.0	9.22	-13	12	11	3.0	2.0	8.14	-13	16

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	66	77.7	79.0	10.21	50	104	58	74.5	76.0	8.96	52	96	124	76.2	76.0	9.74	50	104
Change from Acute Study Baseline to 716 :																		
Week 1	0	.	.	.	.	.	1	16.0	16.0	.	16	16	1	16.0	16.0	.	16	16
Week 3	1	8.0	8.0	.	8	8	1	-12.0	-12.0	.	-12	-12	2	-2.0	-2.0	14.14	-12	8
Week 4	1	16.0	16.0	.	16	16	2	-6.0	-6.0	8.49	-12	0	3	1.3	0.0	14.05	-12	16
Week 6	1	6.0	6.0	.	6	6	3	0.7	0.0	13.01	-12	14	4	2.0	3.0	10.95	-12	14
Week 8	1	-38.0	-38.0	.	-38	-38	3	5.0	4.0	6.00	0	12	4	-3.6	0.0	19.92	-38	12
Week 12	2	11.5	11.5	12.02	3	20	1	4.0	4.0	.	4	4	3	9.0	4.0	9.54	3	20
Week 16	4	14.0	12.0	7.66	8	24	2	18.5	18.5	13.44	9	28	6	15.5	12.5	8.76	8	28
Week 20	2	1.5	1.5	7.78	-4	7	2	7.0	7.0	9.90	0	14	4	4.3	3.5	7.93	-4	14
Week 24	26	-1.8	0.0	9.59	-17	20	14	0.1	3.0	14.34	-30	20	40	-1.1	1.0	11.42	-30	20
Post Week 24	7	-1.7	0.0	4.96	-8	4	2	11.0	18.0	13.89	-5	20	9	2.1	1.0	9.85	-8	20

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	133	80.6	80.0	10.77	50	104	130	78.3	78.0	11.02	52	110	263	79.5	80.0	10.93	50	110
Change from Acute Study Baseline to 716 :																		
Week 1	1	-6.0	-6.0	.	-6	-6	1	16.0	16.0	.	16	16	2	5.0	5.0	15.56	-6	16
Week 2	0	.	.	.	.	.	1	23.0	23.0	.	23	23	1	23.0	23.0	.	23	23
Week 3	2	-6.0	-6.0	19.80	-20	8	2	-6.0	-6.0	8.49	-12	0	4	-6.0	-6.0	12.44	-20	8
Week 4	2	12.0	12.0	5.66	8	16	6	-5.7	-3.0	7.81	-18	2	8	-1.3	-0.5	10.73	-18	16
Week 6	3	3.7	6.0	5.86	-3	8	7	0.4	0.0	13.49	-18	14	10	1.4	3.0	11.46	-18	14
Week 8	4	-5.5	-1.0	23.46	-38	18	7	6.6	4.5	9.75	-6	24	11	2.6	0.5	15.69	-38	24
Week 12	6	4.0	3.5	12.38	-14	20	8	1.8	3.0	9.59	-16	16	14	2.6	3.5	10.37	-16	20
Week 16	6	9.8	8.0	9.04	-2	24	4	5.6	4.0	14.94	-13	28	10	7.9	8.0	11.62	-13	28
Week 20	2	1.5	1.5	7.78	-4	7	5	4.5	4.0	12.36	-15	20	7	3.8	3.5	10.94	-15	20
Week 24	44	0.4	2.0	10.45	-20	22	29	-0.8	0.0	12.22	-30	23	73	-0.1	0.0	11.15	-30	23
Post Week 24	13	1.4	2.0	6.90	-8	16	7	4.4	2.0	11.20	-13	20	20	2.6	2.0	8.72	-13	20

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

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Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Height / cm
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	67	141.04	140.00	12.030	114.5	165.0	72	138.89	140.00	10.198	115.6	161.0	139	139.93	140.00	11.130	114.5	165.0
Change from Acute Study Baseline to 716 :																		
Week 1	1	1.50	1.50	.	1.5	1.5	0	.	.	.	.	.	1	1.50	1.50	.	1.5	1.5
Week 2	0	.	.	.	.	.	1	3.30	3.30	.	3.3	3.3	1	3.30	3.30	.	3.3	3.3
Week 3	0	.	.	.	.	.	1	0.50	0.50	.	0.5	0.5	1	0.50	0.50	.	0.5	0.5
Week 4	1	1.30	1.30	.	1.3	1.3	2	1.00	1.00	0.000	1.0	1.0	3	1.10	1.00	0.173	1.0	1.3
Week 6	2	0.50	0.50	0.707	0.0	1.0	2	4.25	4.25	1.768	3.0	5.5	4	2.38	2.00	2.428	0.0	5.5
Week 8	2	1.30	1.30	0.990	0.6	2.0	3	2.80	3.80	1.908	0.6	4.0	5	2.20	2.00	1.655	0.6	4.0
Week 12	4	-3.55	1.25	10.798	-19.7	3.0	2	2.50	2.50	0.707	2.0	3.0	6	-1.53	1.65	8.934	-19.7	3.0
Week 16	1	5.20	5.20	.	5.2	5.2	2	5.00	5.00	2.546	3.2	6.8	3	5.07	5.20	1.804	3.2	6.8
Week 24	6	2.42	2.75	2.200	-1.0	5.0	3	10.07	3.70	14.259	0.1	26.4	9	4.97	3.50	8.276	-1.0	26.4

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Height / cm
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	66	165.89	165.80	10.001	139.5	188.0	57	165.96	167.60	8.372	149.9	180.3	123	165.92	166.40	9.245	139.5	188.0
Change from Acute Study Baseline to 716 :																		
Week 1	0	.	.	.	.	.	1	2.50	2.50	.	2.5	2.5	1	2.50	2.50	.	2.5	2.5
Week 3	1	2.00	2.00	.	2.0	2.0	0	.	.	.	.	.	1	2.00	2.00	.	2.0	2.0
Week 4	0	.	.	.	.	.	2	3.20	3.20	2.687	1.3	5.1	2	3.20	3.20	2.687	1.3	5.1
Week 6	1	6.00	6.00	.	6.0	6.0	3	2.10	0.70	2.600	0.5	5.1	4	3.07	2.90	2.883	0.5	6.0
Week 8	1	1.00	1.00	.	1.0	1.0	2	3.75	3.75	1.061	3.0	4.5	3	2.83	3.00	1.756	1.0	4.5
Week 12	2	1.75	1.75	2.475	0.0	3.5	0	.	.	.	.	.	2	1.75	1.75	2.475	0.0	3.5
Week 16	2	0.55	0.55	0.071	0.5	0.6	1	1.30	1.30	.	1.3	1.3	3	0.80	0.60	0.436	0.5	1.3
Week 20	1	0.60	0.60	.	0.6	0.6	1	1.10	1.10	.	1.1	1.1	2	0.85	0.85	0.354	0.6	1.1
Week 24	11	-0.66	0.00	7.694	-20.9	8.0	3	1.77	1.00	1.779	0.5	3.8	14	-0.14	0.55	6.862	-20.9	8.0

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Height / cm
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	133	153.37	155.00	16.647	114.5	188.0	129	150.85	151.10	16.445	115.6	180.3	262	152.13	152.75	16.564	114.5	188.0
Change from Acute Study Baseline to 716 :																		
Week 1	1	1.50	1.50	.	1.5	1.5	1	2.50	2.50	.	2.5	2.5	2	2.00	2.00	0.707	1.5	2.5
Week 2	0	.	.	.	.	.	1	3.30	3.30	.	3.3	3.3	1	3.30	3.30	.	3.3	3.3
Week 3	1	2.00	2.00	.	2.0	2.0	1	0.50	0.50	.	0.5	0.5	2	1.25	1.25	1.061	0.5	2.0
Week 4	1	1.30	1.30	.	1.3	1.3	4	2.10	1.15	2.005	1.0	5.1	5	1.94	1.30	1.773	1.0	5.1
Week 6	3	2.33	1.00	3.215	0.0	6.0	5	2.96	3.00	2.355	0.5	5.5	8	2.72	2.00	2.496	0.0	6.0
Week 8	3	1.20	1.00	0.721	0.6	2.0	5	3.18	3.80	1.540	0.6	4.5	8	2.44	2.50	1.598	0.6	4.5
Week 12	6	-1.78	1.25	8.870	-19.7	3.5	2	2.50	2.50	0.707	2.0	3.0	8	-0.71	1.65	7.759	-19.7	3.5
Week 16	3	2.10	0.60	2.685	0.5	5.2	3	3.77	3.20	2.793	1.3	6.8	6	2.93	2.25	2.615	0.5	6.8
Week 20	1	0.60	0.60	.	0.6	0.6	1	1.10	1.10	.	1.1	1.1	2	0.85	0.85	0.354	0.6	1.1
Week 24	17	0.42	1.00	6.388	-20.9	8.0	6	5.92	2.35	10.162	0.1	26.4	23	1.86	1.00	7.696	-20.9	26.4

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	67	42.03	38.10	15.578	20.4	79.5	72	38.77	34.50	14.419	20.5	104.0	139	40.34	35.50	15.023	20.4	104.0
Change from Acute Study Baseline to 716 :																		
Week 1	1	2.80	2.80	.	2.8	2.8	0	.	.	.	.	.	1	2.80	2.80	.	2.8	2.8
Week 2	0	.	.	.	.	.	1	3.70	3.70	.	3.7	3.7	1	3.70	3.70	.	3.7	3.7
Week 3	0	.	.	.	.	.	1	1.00	1.00	.	1.0	1.0	1	1.00	1.00	.	1.0	1.0
Week 4	1	0.40	0.40	.	0.4	0.4	2	-0.60	-0.60	1.414	-1.6	0.4	3	-0.27	0.40	1.155	-1.6	0.4
Week 6	2	1.25	1.25	2.333	-0.4	2.9	2	3.80	3.80	1.131	3.0	4.6	4	2.52	2.95	2.100	-0.4	4.6
Week 8	2	1.30	1.30	2.546	-0.5	3.1	3	2.63	3.20	2.695	-0.3	5.0	5	2.10	3.10	2.405	-0.5	5.0
Week 12	4	2.86	2.92	2.797	-0.4	6.0	2	1.10	1.10	2.687	-0.8	3.0	6	2.27	2.35	2.639	-0.8	6.0
Week 16	1	4.10	4.10	.	4.1	4.1	2	2.20	2.20	0.566	1.8	2.6	3	2.83	2.60	1.168	1.8	4.1
Week 24	6	4.33	2.75	4.851	-0.5	12.5	3	8.87	9.60	2.579	6.0	11.0	9	5.84	6.00	4.638	-0.5	12.5

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	66	69.84	65.00	21.632	30.0	143.8	57	67.68	62.60	19.725	38.2	131.4	123	68.84	63.20	20.714	30.0	143.8
Change from Acute Study Baseline to 716 : Week 1	0	.	.	.	.	.	1	5.10	5.10	.	5.1	5.1	1	5.10	5.10	.	5.1	5.1
Week 3	1	-0.10	-0.10	.	-0.1	-0.1	0	.	.	.	.	.	1	-0.10	-0.10	.	-0.1	-0.1
Week 4	1	1.60	1.60	.	1.6	1.6	2	2.05	2.05	2.899	0.0	4.1	3	1.90	1.60	2.066	0.0	4.1
Week 6	1	1.80	1.80	.	1.8	1.8	3	4.87	5.00	4.202	0.6	9.0	4	4.10	3.40	3.758	0.6	9.0
Week 8	1	-0.50	-0.50	.	-0.5	-0.5	2	2.40	2.40	2.687	0.5	4.3	3	1.43	0.50	2.532	-0.5	4.3
Week 12	2	0.85	0.85	7.000	-4.1	5.8	0	.	.	.	.	.	2	0.85	0.85	7.000	-4.1	5.8
Week 16	2	-1.65	-1.65	1.909	-3.0	-0.3	1	0.70	0.70	.	0.7	0.7	3	-0.87	-0.30	1.914	-3.0	0.7
Week 20	1	1.39	1.39	.	1.4	1.4	1	6.80	6.80	.	6.8	6.8	2	4.09	4.09	3.825	1.4	6.8
Week 24	11	3.36	4.90	5.088	-4.8	11.0	3	2.17	0.50	3.329	0.0	6.0	14	3.11	4.00	4.678	-4.8	11.0

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	133	55.83	55.00	23.378	20.4	143.8	129	51.54	46.40	22.212	20.5	131.4	262	53.72	51.85	22.869	20.4	143.8
Change from Acute Study Baseline to 716 :																		
Week 1	1	2.80	2.80	.	2.8	2.8	1	5.10	5.10	.	5.1	5.1	2	3.95	3.95	1.626	2.8	5.1
Week 2	0	.	.	.	.	.	1	3.70	3.70	.	3.7	3.7	1	3.70	3.70	.	3.7	3.7
Week 3	1	-0.10	-0.10	.	-0.1	-0.1	1	1.00	1.00	.	1.0	1.0	2	0.45	0.45	0.778	-0.1	1.0
Week 4	2	1.00	1.00	0.849	0.4	1.6	4	0.72	0.20	2.410	-1.6	4.1	6	0.82	0.40	1.910	-1.6	4.1
Week 6	3	1.43	1.80	1.680	-0.4	2.9	5	4.44	4.60	3.080	0.6	9.0	8	3.31	2.95	2.941	-0.4	9.0
Week 8	3	0.70	-0.50	2.078	-0.5	3.1	5	2.54	3.20	2.335	-0.3	5.0	8	1.85	1.80	2.293	-0.5	5.0
Week 12	6	2.19	2.92	3.946	-4.1	6.0	2	1.10	1.10	2.687	-0.8	3.0	8	1.92	2.35	3.523	-4.1	6.0
Week 16	3	0.27	-0.30	3.584	-3.0	4.1	3	1.70	1.80	0.954	0.7	2.6	6	0.98	1.25	2.473	-3.0	4.1
Week 20	1	1.39	1.39	.	1.4	1.4	1	6.80	6.80	.	6.8	6.8	2	4.09	4.09	3.825	1.4	6.8
Week 24	17	3.71	3.10	4.875	-4.8	12.5	6	5.52	6.00	4.534	0.0	11.0	23	4.18	4.90	4.756	-4.8	12.5

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Body Mass Index / kg/m2
Age Group : Children

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	67	20.57	18.90	5.292	13.9	32.8	72	19.70	18.15	5.217	13.6	40.1	139	20.12	18.30	5.252	13.6	40.1
Change from Acute Study Baseline to 716 :																		
Week 1	1	0.90	0.90	.	0.9	0.9	0	.	.	.	.	.	1	0.90	0.90	.	0.9	0.9
Week 2	0	.	.	.	.	.	1	1.00	1.00	.	1.0	1.0	1	1.00	1.00	.	1.0	1.0
Week 3	0	.	.	.	.	.	1	0.50	0.50	.	0.5	0.5	1	0.50	0.50	.	0.5	0.5
Week 4	1	-0.10	-0.10	.	-0.1	-0.1	2	-0.60	-0.60	0.707	-1.1	-0.1	3	-0.43	-0.10	0.577	-1.1	-0.1
Week 6	2	0.25	0.25	1.202	-0.6	1.1	2	0.65	0.65	1.061	-0.1	1.4	4	0.45	0.50	0.954	-0.6	1.4
Week 8	2	0.05	0.05	0.636	-0.4	0.5	3	0.57	0.80	0.681	-0.2	1.1	5	0.36	0.50	0.643	-0.4	1.1
Week 12	4	3.33	1.85	4.659	-0.5	10.1	2	-0.20	-0.20	0.990	-0.9	0.5	6	2.15	1.00	4.066	-0.9	10.1
Week 16	1	0.10	0.10	.	0.1	0.1	2	-0.10	-0.10	0.990	-0.8	0.6	3	-0.03	0.10	0.709	-0.8	0.6
Week 24	6	1.45	0.55	1.894	-0.2	4.1	3	1.47	3.40	5.273	-4.5	5.5	9	1.46	0.80	3.032	-4.5	5.5

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Body Mass Index / kg/m2
Age Group : Adolescents

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	66	25.17	23.20	6.812	13.8	45.9	57	24.43	22.80	6.321	16.4	45.4	123	24.83	23.00	6.573	13.8	45.9
Change from Acute Study Baseline to 716 :																		
Week 1	0	.	.	.	.	.	1	1.00	1.00	.	1.0	1.0	1	1.00	1.00	.	1.0	1.0
Week 3	1	-0.50	-0.50	.	-0.5	-0.5	0	.	.	.	.	.	1	-0.50	-0.50	.	-0.5	-0.5
Week 4	0	.	.	.	.	.	2	-0.75	-0.75	0.778	-1.3	-0.2	2	-0.75	-0.75	0.778	-1.3	-0.2
Week 6	1	-0.60	-0.60	.	-0.6	-0.6	3	1.30	1.90	1.873	-0.8	2.8	4	0.83	0.65	1.801	-0.8	2.8
Week 8	1	-0.40	-0.40	.	-0.4	-0.4	2	0.00	0.00	0.707	-0.5	0.5	3	-0.13	-0.40	0.551	-0.5	0.5
Week 12	2	-0.55	-0.55	2.051	-2.0	0.9	0	.	.	.	.	.	2	-0.55	-0.55	2.051	-2.0	0.9
Week 16	2	-0.70	-0.70	0.566	-1.1	-0.3	1	-0.10	-0.10	.	-0.1	-0.1	3	-0.50	-0.30	0.529	-1.1	-0.1
Week 20	1	0.20	0.20	.	0.2	0.2	1	2.10	2.10	.	2.1	2.1	2	1.15	1.15	1.344	0.2	2.1
Week 24	11	1.68	0.60	3.481	-2.5	11.0	3	0.30	0.00	0.794	-0.3	1.2	14	1.39	0.60	3.125	-2.5	11.0

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.1.2

Summary Statistics for Acute Study Baseline and Change from Acute Study Baseline for Vital Signs at Each Visit
by Acute Study Treatment Group (Pre-Open Label Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Body Mass Index / kg/m2
Age Group : Total

	Acute Study Treatment Group																	
	Paroxetine						Placebo						Total					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Acute Baseline	133	22.85	21.00	6.496	13.8	45.9	129	21.79	20.10	6.175	13.6	45.4	262	22.33	20.80	6.350	13.6	45.9
Change from Acute Study Baseline to 716 :																		
Week 1	1	0.90	0.90	.	0.9	0.9	1	1.00	1.00	.	1.0	1.0	2	0.95	0.95	0.071	0.9	1.0
Week 2	0	.	.	.	.	.	1	1.00	1.00	.	1.0	1.0	1	1.00	1.00	.	1.0	1.0
Week 3	1	-0.50	-0.50	.	-0.5	-0.5	1	0.50	0.50	.	0.5	0.5	2	0.00	0.00	0.707	-0.5	0.5
Week 4	1	-0.10	-0.10	.	-0.1	-0.1	4	-0.67	-0.65	0.613	-1.3	-0.1	5	-0.56	-0.20	0.590	-1.3	-0.1
Week 6	3	-0.03	-0.60	0.981	-0.6	1.1	5	1.04	1.40	1.471	-0.8	2.8	8	0.64	0.50	1.349	-0.8	2.8
Week 8	3	-0.10	-0.40	0.520	-0.4	0.5	5	0.34	0.50	0.673	-0.5	1.1	8	0.17	0.15	0.623	-0.5	1.1
Week 12	6	2.03	1.20	4.227	-2.0	10.1	2	-0.20	-0.20	0.990	-0.9	0.5	8	1.47	0.70	3.738	-2.0	10.1
Week 16	3	-0.43	-0.30	0.611	-1.1	0.1	3	-0.10	-0.10	0.700	-0.8	0.6	6	-0.27	-0.20	0.615	-1.1	0.6
Week 20	1	0.20	0.20	.	0.2	0.2	1	2.10	2.10	.	2.1	2.1	2	1.15	1.15	1.344	0.2	2.1
Week 24	17	1.60	0.60	2.951	-2.5	11.0	6	0.88	0.60	3.432	-4.5	5.5	23	1.41	0.60	3.019	-4.5	11.0

Note: For height, weight and BMI, the last pre-acute study treatment assessment is taken to be acute study baseline
Patients who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 24') have both assessments
in the summary statistics, but N represents the number of patients at that week.

Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	64	N/A	70	N/A	134	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	64	100.0	70	100.0	134	100.0
Low	31	48.4	27	38.6	58	43.3
Significant Decrease	2	3.1	3	4.3	5	3.7
Low & Significant Decrease	2	3.1	3	4.3	5	3.7
Low & Significant Increase	0	0.0	1	1.4	1	0.7
High	2	3.1	0	0.0	2	1.5
Significant Increase	0	0.0	2	2.9	2	1.5
High & Significant Increase	0	0.0	0	0.0	0	0.0
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

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Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	65	N/A	56	N/A	121	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	65	100.0	56	100.0	121	100.0
Low	14	21.5	5	8.9	19	15.7
Significant Decrease	3	4.6	1	1.8	4	3.3
Low & Significant Decrease	1	1.5	0	0.0	1	0.8
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	3	4.6	2	3.6	5	4.1
Significant Increase	0	0.0	2	3.6	2	1.7
High & Significant Increase	0	0.0	2	3.6	2	1.7
High & Significant Decrease	1	1.5	0	0.0	1	0.8

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

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Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	129	N/A	126	N/A	255	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	129	100.0	126	100.0	255	100.0
Low	45	34.9	32	25.4	77	30.2
Significant Decrease	5	3.9	4	3.2	9	3.5
Low & Significant Decrease	3	2.3	3	2.4	6	2.4
Low & Significant Increase	0	0.0	1	0.8	1	0.4
High	5	3.9	2	1.6	7	2.7
Significant Increase	0	0.0	4	3.2	4	1.6
High & Significant Increase	0	0.0	2	1.6	2	0.8
High & Significant Decrease	1	0.8	0	0.0	1	0.4

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

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Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	64	N/A	70	N/A	134	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	64	100.0	70	100.0	134	100.0
Low	9	14.1	10	14.3	19	14.2
Significant Decrease	6	9.4	7	10.0	13	9.7
Low & Significant Decrease	2	3.1	3	4.3	5	3.7
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	6	9.4	5	7.1	11	8.2
Significant Increase	1	1.6	3	4.3	4	3.0
High & Significant Increase	1	1.6	2	2.9	3	2.2
High & Significant Decrease	1	1.6	0	0.0	1	0.7

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

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Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	65	N/A	56	N/A	121	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	65	100.0	56	100.0	121	100.0
Low	1	1.5	5	8.9	6	5.0
Significant Decrease	4	6.2	5	8.9	9	7.4
Low & Significant Decrease	0	0.0	1	1.8	1	0.8
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	5	7.7	6	10.7	11	9.1
Significant Increase	2	3.1	1	1.8	3	2.5
High & Significant Increase	1	1.5	0	0.0	1	0.8
High & Significant Decrease	0	0.0	1	1.8	1	0.8

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

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Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	129	N/A	126	N/A	255	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	129	100.0	126	100.0	255	100.0
Low	10	7.8	15	11.9	25	9.8
Significant Decrease	10	7.8	12	9.5	22	8.6
Low & Significant Decrease	2	1.6	4	3.2	6	2.4
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	11	8.5	11	8.7	22	8.6
Significant Increase	3	2.3	4	3.2	7	2.7
High & Significant Increase	2	1.6	2	1.6	4	1.6
High & Significant Decrease	1	0.8	1	0.8	2	0.8

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

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Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	64	N/A	70	N/A	134	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	64	100.0	70	100.0	134	100.0
Low	10	15.6	16	22.9	26	19.4
Significant Decrease	2	3.1	2	2.9	4	3.0
Low & Significant Decrease	1	1.6	2	2.9	3	2.2
Low & Significant Increase	0	0.0	1	1.4	1	0.7
High	2	3.1	0	0.0	2	1.5
Significant Increase	3	4.7	4	5.7	7	5.2
High & Significant Increase	2	3.1	0	0.0	2	1.5
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716

Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	65	N/A	56	N/A	121	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	65	100.0	56	100.0	121	100.0
Low	2	3.1	5	8.9	7	5.8
Significant Decrease	2	3.1	3	5.4	5	4.1
Low & Significant Decrease	0	0.0	1	1.8	1	0.8
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	1	1.5	2	3.6	3	2.5
Significant Increase	5	7.7	6	10.7	11	9.1
High & Significant Increase	1	1.5	1	1.8	2	1.7
High & Significant Decrease	0	0.0	1	1.8	1	0.8

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	129	N/A	126	N/A	255	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	129	100.0	126	100.0	255	100.0
Low	12	9.3	21	16.7	33	12.9
Significant Decrease	4	3.1	5	4.0	9	3.5
Low & Significant Decrease	1	0.8	3	2.4	4	1.6
Low & Significant Increase	0	0.0	1	0.8	1	0.4
High	3	2.3	2	1.6	5	2.0
Significant Increase	8	6.2	10	7.9	18	7.1
High & Significant Increase	3	2.3	1	0.8	4	1.6
High & Significant Decrease	0	0.0	1	0.8	1	0.4

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

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Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	43	N/A	53	N/A	96	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	43	100.0	53	100.0	96	100.0
Low	0	0.0	0	0.0	0	0.0
Significant Decrease	0	0.0	0	0.0	0	0.0
Low & Significant Decrease	0	0.0	0	0.0	0	0.0
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	15	34.9	13	24.5	28	29.2
Significant Increase	29	67.4	33	62.3	62	64.6
High & Significant Increase	6	14.0	6	11.3	12	12.5
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

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Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	53	N/A	41	N/A	94	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	53	100.0	40	100.0	93	100.0
Low	1	1.9	0	0.0	1	1.1
Significant Decrease	2	3.8	1	2.5	3	3.2
Low & Significant Decrease	1	1.9	0	0.0	1	1.1
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	23	43.4	13	32.5	36	38.7
Significant Increase	21	39.6	15	37.5	36	38.7
High & Significant Increase	10	18.9	6	15.0	16	17.2
High & Significant Decrease	1	1.9	0	0.0	1	1.1

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716

Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase (including Taper)
by Variable and Acute Study Treatment Group
Intention-To-Treat Population
Vital Signs Variable : Weight / kg
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	96	N/A	94	N/A	190	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	96	100.0	93	100.0	189	100.0
Low	1	1.0	0	0.0	1	0.5
Significant Decrease	2	2.1	1	1.1	3	1.6
Low & Significant Decrease	1	1.0	0	0.0	1	0.5
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	38	39.6	26	28.0	64	33.9
Significant Increase	50	52.1	48	51.6	98	51.9
High & Significant Increase	16	16.7	12	12.9	28	14.8
High & Significant Decrease	1	1.0	0	0.0	1	0.5

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase (including taper).
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	65	N/A	72	N/A	137	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	65	100.0	72	100.0	137	100.0
Low	33	50.8	27	37.5	60	43.8
Significant Decrease	2	3.1	3	4.2	5	3.6
Low & Significant Decrease	2	3.1	3	4.2	5	3.6
Low & Significant Increase	0	0.0	1	1.4	1	0.7
High	2	3.1	0	0.0	2	1.5
Significant Increase	0	0.0	2	2.8	2	1.5
High & Significant Increase	0	0.0	0	0.0	0	0.0
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	65	N/A	57	N/A	122	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	65	100.0	57	100.0	122	100.0
Low	14	21.5	6	10.5	20	16.4
Significant Decrease	3	4.6	1	1.8	4	3.3
Low & Significant Decrease	1	1.5	0	0.0	1	0.8
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	3	4.6	2	3.5	5	4.1
Significant Increase	0	0.0	2	3.5	2	1.6
High & Significant Increase	0	0.0	2	3.5	2	1.6
High & Significant Decrease	1	1.5	0	0.0	1	0.8

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

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Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Systolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	130	N/A	129	N/A	259	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	130	100.0	129	100.0	259	100.0
Low	47	36.2	33	25.6	80	30.9
Significant Decrease	5	3.8	4	3.1	9	3.5
Low & Significant Decrease	3	2.3	3	2.3	6	2.3
Low & Significant Increase	0	0.0	1	0.8	1	0.4
High	5	3.8	2	1.6	7	2.7
Significant Increase	0	0.0	4	3.1	4	1.5
High & Significant Increase	0	0.0	2	1.6	2	0.8
High & Significant Decrease	1	0.8	0	0.0	1	0.4

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

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Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	65	N/A	72	N/A	137	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	65	100.0	72	100.0	137	100.0
Low	10	15.4	10	13.9	20	14.6
Significant Decrease	7	10.8	7	9.7	14	10.2
Low & Significant Decrease	3	4.6	3	4.2	6	4.4
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	6	9.2	5	6.9	11	8.0
Significant Increase	1	1.5	4	5.6	5	3.6
High & Significant Increase	1	1.5	2	2.8	3	2.2
High & Significant Decrease	1	1.5	0	0.0	1	0.7

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

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Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	65	N/A	57	N/A	122	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	65	100.0	57	100.0	122	100.0
Low	1	1.5	5	8.8	6	4.9
Significant Decrease	4	6.2	5	8.8	9	7.4
Low & Significant Decrease	0	0.0	1	1.8	1	0.8
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	5	7.7	7	12.3	12	9.8
Significant Increase	2	3.1	1	1.8	3	2.5
High & Significant Increase	1	1.5	0	0.0	1	0.8
High & Significant Decrease	0	0.0	1	1.8	1	0.8

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	130	N/A	129	N/A	259	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	130	100.0	129	100.0	259	100.0
Low	11	8.5	15	11.6	26	10.0
Significant Decrease	11	8.5	12	9.3	23	8.9
Low & Significant Decrease	3	2.3	4	3.1	7	2.7
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	11	8.5	12	9.3	23	8.9
Significant Increase	3	2.3	5	3.9	8	3.1
High & Significant Increase	2	1.5	2	1.6	4	1.5
High & Significant Decrease	1	0.8	1	0.8	2	0.8

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

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Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	65	N/A	72	N/A	137	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	65	100.0	72	100.0	137	100.0
Low	11	16.9	16	22.2	27	19.7
Significant Decrease	2	3.1	2	2.8	4	2.9
Low & Significant Decrease	1	1.5	2	2.8	3	2.2
Low & Significant Increase	1	1.5	1	1.4	2	1.5
High	3	4.6	0	0.0	3	2.2
Significant Increase	3	4.6	4	5.6	7	5.1
High & Significant Increase	2	3.1	0	0.0	2	1.5
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

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Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	65	N/A	57	N/A	122	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	65	100.0	57	100.0	122	100.0
Low	2	3.1	5	8.8	7	5.7
Significant Decrease	2	3.1	3	5.3	5	4.1
Low & Significant Decrease	0	0.0	1	1.8	1	0.8
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	1	1.5	2	3.5	3	2.5
Significant Increase	5	7.7	6	10.5	11	9.0
High & Significant Increase	1	1.5	1	1.8	2	1.6
High & Significant Decrease	0	0.0	1	1.8	1	0.8

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Heart Rate / BPM
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	130	N/A	129	N/A	259	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	130	100.0	129	100.0	259	100.0
Low	13	10.0	21	16.3	34	13.1
Significant Decrease	4	3.1	5	3.9	9	3.5
Low & Significant Decrease	1	0.8	3	2.3	4	1.5
Low & Significant Increase	1	0.8	1	0.8	2	0.8
High	4	3.1	2	1.6	6	2.3
Significant Increase	8	6.2	10	7.8	18	6.9
High & Significant Increase	3	2.3	1	0.8	4	1.5
High & Significant Decrease	0	0.0	1	0.8	1	0.4

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

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Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Weight / kg
Age Group : Children

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	52	N/A	61	N/A	113	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	52	100.0	61	100.0	113	100.0
Low	0	0.0	0	0.0	0	0.0
Significant Decrease	0	0.0	0	0.0	0	0.0
Low & Significant Decrease	0	0.0	0	0.0	0	0.0
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	19	36.5	15	24.6	34	30.1
Significant Increase	31	59.6	36	59.0	67	59.3
High & Significant Increase	8	15.4	7	11.5	15	13.3
High & Significant Decrease	0	0.0	0	0.0	0	0.0

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716

Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Weight / kg
Age Group : Adolescents

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	60	N/A	48	N/A	108	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	60	100.0	47	100.0	107	100.0
Low	1	1.7	0	0.0	1	0.9
Significant Decrease	2	3.3	1	2.1	3	2.8
Low & Significant Decrease	1	1.7	0	0.0	1	0.9
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	24	40.0	16	34.0	40	37.4
Significant Increase	23	38.3	19	40.4	42	39.3
High & Significant Increase	11	18.3	8	17.0	19	17.8
High & Significant Decrease	1	1.7	0	0.0	1	0.9

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

BRL 29060 - 716

Table 15.2.2.2

Number (%) of Patients with Vital Signs of Potential Clinical Concern During the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Variable and Acute Study Treatment Group
Intention-To-Treatment Population
Vital Signs Variable : Weight / kg
Age Group : Total

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
	n	%	n	%	n	%
Number with Assessment	112	N/A	109	N/A	221	N/A
Number with Acute Study Baseline and Post-716 Baseline Assessment	112	100.0	108	100.0	220	100.0
Low	1	0.9	0	0.0	1	0.5
Significant Decrease	2	1.8	1	0.9	3	1.4
Low & Significant Decrease	1	0.9	0	0.0	1	0.5
Low & Significant Increase	0	0.0	0	0.0	0	0.0
High	43	38.4	31	28.7	74	33.6
Significant Increase	54	48.2	55	50.9	109	49.5
High & Significant Increase	19	17.0	15	13.9	34	15.5
High & Significant Decrease	1	0.9	0	0.0	1	0.5

Number with Assessment = number of patients who had a measurement for this vital sign at any time during the open-label treatment phase, taper phase or follow-up phase.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-18 years), see Clinical Report for Weight Limits used
Significant Increase from Acute Study Baseline: SBP >=40mmHg, DBP >=30mmHg, Pulse >=30, Weight >=7%
Significant Decrease from Acute Study Baseline: SBP >=30mmHg, DBP >=20mmHg, Pulse >=30, Weight >=7%

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Paroxetine

BRL-029060

Narratives for Patients with Vital Signs Associated with an Adverse Event and Meeting the Criteria for Clinical Concern

716

Table 15.2.3

SB Document Number: BRL-029060/RSD-101TCZ/1

Issue Date: 16 September 2002

PID 716.002.27191

Treatment Group: Paroxetine (Protocol 704), Paroxetine (Protocol 716)

Vital Sign Value of Potential Clinical Concern: Increased body weight

Adverse Event Associated with Vital Sign of Concern: Weight gain (weight gain 43 lbs)

This 15-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 6-week study Protocol 715 (OCD/MDD), the 8-week study Protocol 701 (MDD), or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.002.27191), and received treatment with paroxetine in that study.

Concomitant medications included paracetamol (Tylenol®), acetylsalicylic acid (aspirin), and ibuprofen (Advil®) for headache.

The patient received the first dose of study medication on 27 June 2001 at a dose of 10 mg/day and was titrated up to 50 mg/day by 22 August 2001 (Day 57). The patient remained on this dose until the end of the treatment period, 13 December 2001 (Day 170). Taper phase began on 14 December 2001 and ended on 06 January 2002, the last day of study medication. On 26 June 2001 (before study medication was started), an adverse event of moderately severe weight gain was reported. This continued without treatment for 199 days and was considered by the investigator to be possibly related to treatment with study medication.

At screening of the acute study 704 on 15 March 2001, the patient weighed 74.9 kg; reference range for 15-year-old males is 40.9 to 81.4 kg. At baseline of Protocol 716 on 26 June 2001, body weight was 78.5 kg. On 19 September 2001 (Week 12), body weight was 88.6 kg, and at Week 24 (13 December 2001 the patient’s body weight was 96.4 kg.

On 30 July 2001 (Day 34), 05 August 2001 (Day 40), and on 24 November 2001 (Day 151), moderately severe headaches were reported. Each of these were treated and resolved in one day. The investigator considered these events to be probably unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID 716.028.25962

Treatment Group: Paroxetine (Protocol 701), paroxetine (Protocol 716)

Vital Sign Value of Potential Clinical Concern: Decreased body weight

Adverse Event Associated with Vital Sign of Concern: Weight loss (weight loss)

This 15-year-old black female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 6-week study Protocol 715 (OCD/MDD), the 8-week study Protocol 701 (MDD), or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.185.25962), and received treatment with paroxetine in that study.

No concomitant medications were recorded during the study.

The patient received the first dose of study medication on 16 November 2000 at a dose of 10 mg/day and was titrated up to 40 mg/day by 12 January 2001 (Day 58). On 06 February 2001 (Day 83), the patient reported mild nausea and mild vomiting, both of which resolved without treatment in one day. These events were considered to be possibly related to treatment with study medication and the investigator reduced the dose of study medication in response to these events. The dose of study medication was tapered to 30 mg/day on 07 February 2001 (Day 84). The patient was withdrawn from the study on Day 89 for lack of efficacy and continued to taper the medication, to 20 mg/day on 13 February 2001 (Day 90), and then to 10 mg/day on 20 February 2001 (Day 97). The final dose of study medication was taken on 25 February 2001 (Day 102).

At screening of the acute study 701, the patient weighed 40.9 kg; reference range for 15-year-old females is 38.6 to 79.9 kg. At baseline of Protocol 716, body weight remained at 40.9 kg. On 29 November 2000 (Day 14), the investigator reported an adverse event of moderately severe weight loss; no weight is recorded at this visit. The weight loss resolved without treatment in 105 days. The investigator considered the weight loss to be unrelated to treatment with study medication. On 13 February 2001 (Week 12; Day 90), the patient's body weight

decreased to 36.8 kg. The decrease in body weight at Week 12 met the level of potential clinical concern, defined as a body weight above or below normal limits, with an increase or decrease in weight ≥7% from baseline. No follow-up body weight was provided.

On 13 March 2001 (Day 119), 16 days after the last dose of study medication, the patient had an increase in sitting pulse rate of 116 beats/minute, which met the level of potential clinical concern (>110 bpm and an increase of ≥30 from baseline). No adverse event was reported for this value. The pulse rate at baseline in the previous acute study 701 was 68 beats/min; the pulse rate at baseline of Protocol 716 was 76 beats/minute. The range for pulse rate during the study was 76 to 116 beats/minute.

On 12 December 2000 (Day 27), the patient reported mild chest pain (chest pain, heartburn) and mild dyspepsia (chest pain, heartburn), both of which resolved without treatment in 9 days. The investigator considered both events to be unrelated to treatment with study medication.

On 14 December 2000 (Day 29), the investigator reported an adverse event of mild albuminuria (trace protein urine dipstick), which resolved without treatment in one day. The albuminuria was considered to be unrelated to treatment with study medication.

On 21 December 2000 (Day 36), the patient experienced mild respiratory disorder (upper respiratory infection), which resolved without treatment in 10 days. The investigator considered this event to be unrelated to treatment with study medication.

On 04 February 2001 (Day 81), the patient reported mild somnolence (sedation), which resolved without treatment in 10 days. The dose of study medication was reduced in response to this event. The investigator considered sedation to be possibly related to treatment with study medication.

No other adverse events were reported during the study.

PID 716.159.25628

Treatment Group: Placebo (Protocol 701), paroxetine (Protocol 716)

Vital Sign Value of Potential Clinical Concern: Increased body weight

Adverse Event Associated with Vital Sign of Concern: Weight gain (weight gain)

This 14-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 6-week study Protocol 715 (OCD/MDD), the 8-week study Protocol 701 (MDD), or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.159.25628), and received treatment with placebo in that study.

Concomitant medications included aspirin (acetylsalicylic acid) for headache; Theraflu® (chlorphenamine maleate, paracetamol, pseudoephedrine HCl) for upper respiratory infection; and inhaled Flovent® (fluticasone propionate) and inhaled Serevent® (salmeterol hydroxynaphthoate) for asthma.

The patient received the first dose of study medication on 20 June 2000. The patient started study medication at a dose of 10 mg/day and was titrated up to 20 mg/day on 27 June 2000 (Day 8). The dose of study medication was temporarily reduced to 10 mg/day on 18 July 2000 (Day 29), and then increased again to 20 mg/day on 25 July 2000 (Day 26) (reason not provided). The dose remained at 20 mg/day until the end of the active phase of the study, 13 December 2000 (Day 177). The patient completed the study as planned and then tapered to 10 mg/day on 14 December 2000 (Day 178). The final dose of study medication was taken on 27 December 2000 (Day 191).

At acute screening in Protocol 701, the patient weighed 95 kg. Reference range for 14-year-old males is 35.9 to 74.5 kg. At baseline in Protocol 716, the patient's body weight was 102.3 kg, which was reported as an adverse event by the investigator. The investigator considered the weight gain of mild intensity and possibly related to study medication. By Week 12, the patient's weight had increased to 109.1 kg; by Week 24, the weight had increased to 111.8 kg. These

increases in body weight during Protocol 716 met the level of potential clinical concern, defined as a body weight above or below normal limits, with an increase in weight equal to or greater than 7% from baseline. No additional AE of weight gain was reported, and no follow-up body weight was provided.

Systolic blood pressure on 24 July 2000 (Week 5) was 150 mmHg, which was at the level of potential clinical concern, defined as >145 bpm and an increase of ≥40 bpm from baseline. At baseline of the previous acute study, the systolic blood pressure was 100 mmHg. The range of values for systolic blood pressure during the extension study was 122 mmHg to 150 mmHg. No adverse event was reported for systolic blood pressure.

Moderately severe abdominal pain (epigastric pain), mildly increased SGPT (elevated liver enzymes), moderately severe depression (exacerbation of major depressive disorder), and somnolence (insomnia) began during the acute Protocol 701 and continued into extension protocol 716. Somnolence and abdominal pain were considered to be possibly related to treatment with study medication by the investigator; increased SGPT and depression were considered to be unrelated. Abdominal pain resolved with treatment in 113 days; increased SGPT resolved without treatment in 36 days; depression resolved with treatment in 5 days; and somnolence continued throughout Protocol 716.

On 17 August 2000 (Day 59), the patient reported mild respiratory disorder that resolved with treatment in 2 days. On 10 September 2000 (Day 83), the patient reported moderately severe respiratory disorder that resolved without treatment in 11 days. The investigator considered both to be unrelated to treatment with study medication.

Mild intermittent headaches were reported on 18 July 2000 (Day 29) and 17 August 2000 (Day 59). Both resolved with treatment in 11 days and 4 days, respectively. The investigator considered both events to be unrelated to treatment with study medication.

On 03 November 2000 (Day 137), the patient reported mild asthma that continued through the end of the study despite corrective therapy. The investigator considered the asthma to be probably unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID 716.167.25903

Treatment Group: Placebo (Protocol 701), paroxetine (Protocol 716)

Vital Sign Value of Potential Clinical Concern: Increased body weight

Adverse Event Associated with Vital Sign of Concern: Weight gain (weight gain)

This 12-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 6-week study Protocol 715 (OCD/MDD), the 8-week study Protocol 701 (MDD), or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.167.25903), and received treatment with placebo in that study.

Concomitant medications included Zithromax® (azithromycin) for fever; erythromycin for bronchitis; ibuprofen for headache, fever, and rhinitis; pseudoephedrine for rhinitis; Claritin® (loratadine) and salbutamol inhaler for seasonal allergies/wheezing; and Pepto-Bismol® (bismuth subsalicylate) and Tums® (calcium carbonate) for intermittent stomach aches.

The patient received the first dose of study medication on 28 September 2000. The patient started study medication at a dose of 10 mg/day and was titrated up to 30 mg/day by 19 December 2000 (Day 83). The dose remained at 30 mg/day until the end of the study, 12 March 2001 (Day 166). The patient completed the study as planned.

At screening in the previous acute study 701, the patient weighed 60.4 kg, and at baseline of extension Protocol 716, the patient's body weight was unchanged at 60.4 kg. Reference range for 12-year-old females is 28.1 to 63.1 kg. By Week 12, the patient's weight had increased to 63.6 kg, and by Week 24 the body weight was 66.4 kg. This increase in body weight at Week 24 met the level of potential clinical concern, defined as a body weight above or below normal limits, with an increase in weight equal to or greater than 7% from baseline. The weight gain was reported on Day 111 as an adverse event by the investigator, considered

of mild intensity and possibly related to treatment with study medication. No follow-up body weight was provided.

On 14 October 2000 (Day 17), the patient reported mild increased cough (cough), mild rhinitis, and mild asthma (wheezing), all of which were considered to be unrelated to treatment with study medication by the investigator. The cough resolved without treatment in 26 days; the asthma resolved with treatment in 19 days; and the rhinitis continued throughout the study period despite treatment.

On 18 October 2000 (Day 21), the patient reported mild nausea that resolved without treatment in 3 days. On 19 October 2000 (Day 22), the patient reported moderately severe fever that resolved with treatment in 7 days. The investigator considered the fever and nausea to be unrelated to treatment with study medication.

Mild headaches were reported on 17 December 2000 (Day 81), 15 January 2001 (Day 110), and 11 March 2001 (Day 165). The headaches on Day 81 and Day 165 resolved with treatment in one day; the headache on Day 110 resolved without treatment in one day. The investigator considered the headaches to be unrelated to treatment with study medication.

On 23 January 2001, the patient reported bronchitis that resolved with treatment in 4 days. The investigator considered the bronchitis to be unrelated to treatment with study medication.

No other adverse events were reported.

PID 716.176.25668

Treatment Group: Paroxetine (Protocol 701), paroxetine (Protocol 716)

Vital Sign Value of Potential Clinical Concern: Increased body weight

Adverse Event Associated with Vital Sign of Concern: Weight gain (weight gain)

This 11-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 6-week study Protocol 715 (OCD/MDD), the 8-week study Protocol 701 (MDD), or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.176.25668), and received treatment with paroxetine in that study.

Concomitant medications included Zithromax® (azithromycin) for tonsillitis; topical Cleocin® (clindamycin HCl) for acne; and Dayquil® (paracetamol, pseudoephedrine HCl, guaifenesin, dextromethorphan hydrobromide) and promethazine/codeine syrup for upper respiratory tract infection.

The patient received the first dose of study medication on 06 July 2000. The patient started study medication at a dose of 10 mg/day and was titrated up to 50 mg/day by 04 October 2000 (Day 91). The dose remained at 50 mg/day until 28 December 2000 (Day 176), which was the end of the active phase of the study. The patient completed the study as planned and the dose was tapered to 10 mg/day. The last dose of study medication was given on 26 January 2001 (Day 205).

At screening in the previous acute study 701, the patient weighed 67 kg. Reference range for 11-year-old females is 25.0 to 56.3 kg. At baseline of Protocol 716, the patient weighed 73.0 kg. The increase in body weight at baseline of Protocol 716 met the level of potential clinical concern, defined as body weight above or below normal limits, with an increase in weight equal to or greater than 7% from baseline. The investigator reported the weight gain as an adverse event of moderate severity and possibly related to treatment with study medication. No corrective treatment was given for this condition, and the weight

gain continued throughout the study. By Week 12, the patient's weight had increased to 77.5 kg, and by Week 24 the patient's weight had increased further to 81.8 kg. No follow-up body weight was provided.

At Week 24, systolic blood pressure was 92 mmHg. This value met the level of potential clinical concern, defined as absolute value of <95 bpm and a decrease from baseline ≥30 bpm. At baseline in the previous acute study the systolic blood pressure had been 122 mmHg; at baseline in Protocol 716, the systolic blood pressure was 108 mmHg. The range of values during the study was 92-126 mmHg, within reference range. No adverse event was reported for the single low systolic blood pressure value.

On 17 August 2000 (Day 43), the patient reported mild acne that continued, with treatment, for the duration of the study. The investigator considered the acne to be unrelated to treatment with study medication

On 29 August 2000 (Day 55), the patient reported moderately severe pharyngitis (tonsillitis), which resolved with treatment in 5 days. The investigator considered the pharyngitis to be unrelated to treatment with study medication.

On 24 November 2000 (Day 142), the patient experienced a moderately severe respiratory disorder (respiratory tract infection), which resolved with treatment in 8 days. The investigator considered the event to be unrelated to treatment with study medication.

Several other non-serious adverse events were reported after study medication was discontinued.

On 28 January 2001 (Day 207; 31 days after the last dose of study medication), the patient reported moderately severe anxiety that resolved without treatment in 9 days, and mild respiratory disorder (upper respiratory tract infection), which resolved with treatment in 4 days. The investigator considered the respiratory infection to be unrelated to treatment with study medication and the anxiety to be possibly related.

On 29 January 2001 (Day 208; 32 days after study medication was discontinued), the patient reported moderately severe headache that resolved with treatment in 3 days. The investigator considered the headache to be possibly related to treatment with study medication.

On 30 January 2001 (Day 209, 33 days after study medication was discontinued), the patient reported moderately severe abdominal pain, which resolved without

treatment in two days, moderately severe increased appetite, which resolved without treatment in 7 days, mild insomnia, which resolved without treatment in 7 days, moderately severe nervousness (irritability), which resolved without treatment in 7 days, and moderately severe nausea, which resolved without treatment in two days. The investigator considered the abdominal pain and nausea to be unrelated to treatment with study medication and the increased appetite, insomnia and nervousness to be possibly related.

No other adverse events were reported during the study.

PID 716.176.25795

Treatment Group: Paroxetine (Protocol 701), paroxetine (Protocol 716)

Vital Sign Value of Potential Clinical Concern: Increased body weight

Adverse Event Associated with Vital Sign of Concern: Weight gain (weight gain)

This 11-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 6-week study Protocol 715 (OCD/MDD), the 8-week study Protocol 701 (MDD), or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.176.25795), and received treatment with paroxetine in that study.

Concomitant medications included Benadryl® (diphenhydramine HCl) for upper respiratory infection; hydrocortisone cream, and hydroxyzine hydrochloride for poison ivy rash; Claritin® (loratadine) for seasonal allergic rhinitis; and Detrol® (tolterodine tartrate), Ditropan® (oxybutynin) and nitrofurantoin for urinary reflux.

The patient received the first dose of study medication on 11 January 2001. The patient started study medication at a dose of 10 mg/day and was titrated up to 20 mg/day on 18 January 2001 (Day 11). The dose remained at 20 mg/day until 27 June 2001 (Day 168), which was the end of the active phase of the study. The patient completed the study as planned and then tapered to 10 mg/day on 28 June 2001 (Day 169). The final dose of study medication was taken on 05 July 2001 (Day 176).

At screening in the previous acute study, 701, the patient weighed 60 kg, and at baseline in extension Protocol 716, the patient's body weight was 63.2 kg. Reference range for 11-year-old females is 25.0 to 56.3 kg. By Week 12, the patient's weight had increased to 69 kg, which met the level of potential clinical concern, defined as a body weight above or below normal limits, with an increase in weight equal to or greater than 7% from baseline. The weight gain was reported as an adverse event of moderately severe intensity on Day 85, considered

by the investigator to be possibly related to treatment with study medication. The weight gain continued without treatment throughout the study and by Week 24, the patient's weight had increased to 72.5 kg. No follow-up body weight was provided. There were no other vital sign values of potential clinical concern reported.

Moderately severe impaired concentration and moderately severe abnormal kidney function were reported during the previous acute study 701 and continued, with treatment, through Protocol 716. The investigator considered both of these conditions to be unrelated to treatment with study medication.

On 16 February 2001 (Day 37), the patient reported a moderately severe respiratory disorder (upper respiratory infection), which resolved with treatment in 6 days. The investigator considered the event to be unrelated to treatment with study medication.

On 31 March 2001 (Day 80), the patient reported a moderately severe contact dermatitis (poison ivy rash), which resolved with treatment in 42 days. The investigator considered the event to be unrelated to treatment with study medication.

On 01 July 2001 (Day 207; 4 days after the last dose of study medication), the patient experienced mild depression that continued, without treatment, though the end of the study reporting period. The investigator considered the depression to be unrelated to treatment with study medication

No other adverse events were reported.

PID 716.176.27171

Treatment Group: Placebo (Protocol 704), Paroxetine (Protocol 716)

Vital Sign Value of Potential Clinical Concern: Increased body weight

Adverse Event Associated with Vital Sign of Concern: Weight gain (weight gain)

This 11-year-old white female, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. The patient was 10 years old at entry into acute Protocol 704. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 6-week study Protocol 715 (OCD/MDD), the 8-week study Protocol 701 (MDD), or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.176.27171), and received treatment with placebo in that study.

Concomitant medications included amoxicillin for streptococcal throat infection, and dextromethorphan plus doxylamine succinate plus paracetamol plus pseudoephedrine HCl (Osco Brand Night-time Cold/Flu Relief) for upper respiratory infection.

The patient received the first dose of study medication on 13 June 2001. The patient started study medication at a dose of 10 mg/day and was titrated up to 20 mg/day by 22 June 2001 and remained on that dose through the end of the treatment phase of the study. Taper phase began on 30 November 2001 (Day 170) and ended on 06 December 2001 (Day 177).

At screening in the previous acute study 701 on 27 February 2001, the patient weighed 104 kg, and at baseline in Protocol 716 on 12 June 2001, the patient weighed 110 kg. Reference range for 11-year-old females is 25.0 to 56.3 kg. By Week 12 (04 September 2001), the patient's weight had increased to 112.7 kg, and by Week 24 (29 November 2001), the patient's weight had increased to 119.8 kg. The increase in body weight at all timepoints met the level of potential clinical concern, defined as a body weight above or below normal limits, with an increase in weight equal to or greater than 7% from baseline. On 12 July 2001 (Day 30), the investigator reported severe weight gain that continued without treatment through the end of the study. The investigator considered weight gain to be possibly related to treatment with study medication.

On 21 July 2001 (Day 39), mild fever, mild headache, and moderately severe pharyngitis (sore throat) were reported. Fever and headache resolved with treatment in one day; pharyngitis resolved without treatment in 2 days. All events were considered by the investigator to be unrelated to treatment with study medication.

On 26 August 2001 (Day 75), moderately severe pharyngitis (sore throat) was again reported. This event resolved without treatment in two days, and was considered to be unrelated to treatment with study medication.

On 27 August 2001, moderately severe infection (streptococcal throat infection) was reported. This resolved with treatment in 10 days, and was considered to be unrelated to treatment with study medication.

01 September 2001 (Day 81), severe urinary incontinence (worsening enuresis) was reported. This continued with treatment throughout the study. The investigator considered this event to be unrelated to treatment with study medication.

On 11 September 2001 (Day 91), mild spina bifida (newly diagnosed spina bifida occulta) was reported. This continued without treatment through the end of the study.

On 11 November 2001 (Day 152), moderately severe respiratory disorder (upper respiratory infection) was reported. This resolved with treatment in 6 days and was considered by the investigator to be unrelated to treatment with study medication.

No other non-serious adverse events were reported during the study.

PID 716.192.25872

Treatment Group: Paroxetine (Protocol 701), paroxetine (Protocol 716)

Vital Sign Value of Potential Clinical Concern: Increased body weight

Adverse Event Associated with Vital Sign of Concern: Weight gain (weight gain)

This 14-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 6-week study Protocol 715 (OCD/MDD), the 8-week study Protocol 701 (MDD), or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.192.25872), and received treatment with paroxetine in that study.

Concomitant medications included topical aloe for frostbite, both ears, and ampicillin for upper respiratory infection. Respiratory infection began one day before study medication was started and continued for 21 days into Study 716.

The patient received the first dose of study medication on 07 November 2000. The patient started study medication at a dose of 10 mg/day and was titrated up to 50 mg/day by 28 February 2001 (Day 114). The dose remained at 50 mg/day until 23 April 2001 (Day 168), which was the end of the active phase of the study and the patient completed the study as planned. The dose was tapered from 50 mg/day down to 10 mg/day beginning on 24 April 2001 (Day 169), and the last dose of 10 mg/day was given on 21 May 2001 (Day 196).

At screening in the previous acute study, 701, the patient weighed 68 kg, and at baseline in Protocol 716, the patient weighed 69 kg. Reference range for 14-year-old males is 35.9 to 74.5 kg. By Week 12, the patient's weight had increased to 72 kg, and by Week 24, the patient's weight had increased to 79 kg. The increase in body weight at Week 24 met the level of potential clinical concern, defined as a body weight above or below normal limits, with an increase in weight equal to or greater than 7% from baseline. On Day 169, one day after the last dose of study medication, the investigator reported an adverse event of mild weight gain, considered to be possibly related to treatment with study medication. No follow-

up body weight was provided. No other vital signs values met the level of potential clinical concern.

Moderately severe respiratory disorder (upper respiratory infection) began in the previous acute study and continued into Protocol 716. This resolved without treatment in 21 days. The investigator considered this condition to be unrelated to treatment with study medication.

On 22 February 2001 (Day 108), the patient reported moderately severe trauma (frost bite, both ears), which resolved with treatment in 8 days. The investigator considered the event to be unrelated to treatment with study medication.

On 22 March 2001 (Day 136), the patient reported mild dyspepsia (heartburn), mild nausea, and mild dizziness (lightheadedness), all of which resolved without treatment in one day. The investigator considered all three events to be unrelated to treatment with study medication.

No other adverse events were reported.

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Hemoglobin, Unit:G/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	0 .	1 (1.4%)	1 (0.7%)
Number of Patients with Assessment	66 (100.0%)	72 (100.0%)	138 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Hematocrit, Unit:%

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	5 (7.6%)	6 (8.3%)	11 (8.0%)
Number of Patients with Assessment	66 (100.0%)	72 (100.0%)	138 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Red Blood Cell Count, Unit:10^12/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	66 (100.0%)	72 (100.0%)	138 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:White Blood Cell Count, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	66 (100.0%)	72 (100.0%)	138 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Platelets, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	66 (100.0%)	72 (100.0%)	138 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Basophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	66 (100.0%)	72 (100.0%)	138 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Eosinophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	4 (6.1%)	2 (2.8%)	6 (4.3%)
Number of Patients with Assessment	66 (100.0%)	72 (100.0%)	138 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Lymphocytes Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	2 (3.0%)	1 (1.4%)	3 (2.2%)
Number of Patients with Assessment	66 (100.0%)	72 (100.0%)	138 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Monocytes Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	66 (100.0%)	72 (100.0%)	138 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Neutrophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (1.4%)	1 (0.7%)
Low (Extended)	2 (3.0%)	2 (2.8%)	4 (2.9%)
Number of Patients with Assessment	66 (100.0%)	72 (100.0%)	138 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Sodium, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	67 (100.0%)	72 (100.0%)	139 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Potassium, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (1.4%)	1 (0.7%)
Number of Patients with Assessment	67 (100.0%)	72 (100.0%)	139 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Blood Urea Nitrogen, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	67 (100.0%)	72 (100.0%)	139 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Creatinine, Unit:UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	67 (100.0%)	72 (100.0%)	139 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Aspartate Aminotransferase, Unit:IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	67 (100.0%)	72 (100.0%)	139 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Alanine Aminotransferase, Unit:IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	67 (100.0%)	72 (100.0%)	139 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Total Bilirubin, Unit:UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	67 (100.0%)	72 (100.0%)	139 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Children
Parameter:Thyroid Stimulating Hormone, Unit:MU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (1.4%)	1 (0.7%)
Number of Patients with Assessment	67 (100.0%)	72 (100.0%)	139 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Hemoglobin, Unit:G/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Hematocrit, Unit:%

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	5 (7.4%)	4 (6.9%)	9 (7.1%)
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Red Blood Cell Count, Unit:10^12/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:White Blood Cell Count, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Platelets, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Basophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
	Paroxetine	Placebo	Total
Flag			
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Eosinophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (1.7%)	1 (0.8%)
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Lymphocytes Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Monocytes Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (1.7%)	1 (0.8%)
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Neutrophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	1 (1.5%)	0 .	1 (0.8%)
Low (Extended)	2 (2.9%)	2 (3.4%)	4 (3.2%)
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Sodium, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Potassium, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Blood Urea Nitrogen, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Creatinine, Unit:UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Aspartate Aminotransferase, Unit:IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Alanine Aminotransferase, Unit:IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Total Bilirubin, Unit:UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	68 (100.0%)	58 (100.0%)	126 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Adolescents
Parameter:Thyroid Stimulating Hormone, Unit:MU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	1 (1.5%)	0 .	1 (0.8%)
Number of Patients with Assessment	66 (100.0%)	58 (100.0%)	124 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Hemoglobin, Unit:G/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	0 .	1 (0.8%)	1 (0.4%)
Number of Patients with Assessment	134 (100.0%)	130 (100.0%)	264 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Hematocrit, Unit:%

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	10 (7.5%)	10 (7.7%)	20 (7.6%)
Number of Patients with Assessment	134 (100.0%)	130 (100.0%)	264 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Red Blood Cell Count, Unit:10^12/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	134 (100.0%)	130 (100.0%)	264 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:White Blood Cell Count, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	134 (100.0%)	130 (100.0%)	264 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Platelets, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	134 (100.0%)	130 (100.0%)	264 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Basophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	134 (100.0%)	130 (100.0%)	264 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Eosinophils Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	4 (3.0%)	3 (2.3%)	7 (2.7%)
Number of Patients with Assessment	134 (100.0%)	130 (100.0%)	264 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Lymphocytes Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	2 (1.5%)	1 (0.8%)	3 (1.1%)
Number of Patients with Assessment	134 (100.0%)	130 (100.0%)	264 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Monocytes Absolute, Unit:10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (0.8%)	1 (0.4%)
Number of Patients with Assessment	134 (100.0%)	130 (100.0%)	264 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Neutrophils Absolute, Unit:10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	1 (0.7%)	1 (0.8%)	2 (0.8%)
Low (Extended)	4 (3.0%)	4 (3.1%)	8 (3.0%)
Number of Patients with Assessment	134 (100.0%)	130 (100.0%)	264 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Sodium, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	135 (100.0%)	130 (100.0%)	265 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Potassium, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (0.8%)	1 (0.4%)
Number of Patients with Assessment	135 (100.0%)	130 (100.0%)	265 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Blood Urea Nitrogen, Unit:MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	135 (100.0%)	130 (100.0%)	265 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Creatinine, Unit:UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	135 (100.0%)	130 (100.0%)	265 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Aspartate Aminotransferase, Unit:IU/L

	Acute Study Treatment Group		
	Paroxetine	Placebo	Total
Flag			
Number of Patients with Assessment	135 (100.0%)	130 (100.0%)	265 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Alanine Aminotransferase, Unit:IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	135 (100.0%)	130 (100.0%)	265 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Total Bilirubin, Unit:UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	135 (100.0%)	130 (100.0%)	265 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern at Acute Study Baseline
by Acute Study Treatment Group
All Patients
Age Group:Total
Parameter:Thyroid Stimulating Hormone, Unit:MU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	1 (0.8%)	1 (0.8%)	2 (0.8%)
Number of Patients with Assessment	133 (100.0%)	130 (100.0%)	263 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Hemoglobin, Unit : G/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	2 (3.3%)	5 (8.3%)	7 (5.8%)
Number of Patients with Assessment	60 (100.0%)	60 (100.0%)	120 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Hematocrit, Unit : %

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	12 (20.0%)	11 (18.3%)	23 (19.2%)
Number of Patients with Assessment	60 (100.0%)	60 (100.0%)	120 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Red Blood Cell Count, Unit : 10^12/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	60 (100.0%)	60 (100.0%)	120 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : White Blood Cell Count, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	60 (100.0%)	60 (100.0%)	120 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Platelets, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	0 .	1 (1.7%)	1 (0.8%)
Number of Patients with Assessment	60 (100.0%)	60 (100.0%)	120 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Basophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	60 (100.0%)	60 (100.0%)	120 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Eosinophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	1 (1.7%)	2 (3.3%)	3 (2.5%)
Number of Patients with Assessment	60 (100.0%)	60 (100.0%)	120 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	5 (8.3%)	0 .	5 (4.2%)
Number of Patients with Assessment	60 (100.0%)	60 (100.0%)	120 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Monocytes Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	60 (100.0%)	60 (100.0%)	120 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	2 (3.3%)	1 (1.7%)	3 (2.5%)
Low (Extended)	1 (1.7%)	2 (3.3%)	3 (2.5%)
Number of Patients with Assessment	60 (100.0%)	60 (100.0%)	120 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Sodium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	61 (100.0%)	60 (100.0%)	121 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Potassium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	1 (1.6%)	0 .	1 (0.8%)
Number of Patients with Assessment	61 (100.0%)	60 (100.0%)	121 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	61 (100.0%)	60 (100.0%)	121 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Creatinine, Unit : UMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	61 (100.0%)	60 (100.0%)	121 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Aspartate Aminotransferase, Unit : IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	61 (100.0%)	60 (100.0%)	121 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	61 (100.0%)	60 (100.0%)	121 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Total Bilirubin, Unit : UMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	61 (100.0%)	60 (100.0%)	121 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Hemoglobin, Unit : G/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	0 .	2 (4.1%)	2 (1.8%)
Number of Patients with Assessment	60 (100.0%)	49 (100.0%)	109 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Hematocrit, Unit : %

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	11 (18.3%)	9 (18.4%)	20 (18.3%)
Number of Patients with Assessment	60 (100.0%)	49 (100.0%)	109 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Red Blood Cell Count, Unit : 10^12/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	60 (100.0%)	49 (100.0%)	109 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : White Blood Cell Count, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	60 (100.0%)	49 (100.0%)	109 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Platelets, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	60 (100.0%)	49 (100.0%)	109 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Basophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	60 (100.0%)	49 (100.0%)	109 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Eosinophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	1 (1.7%)	3 (6.1%)	4 (3.7%)
Number of Patients with Assessment	60 (100.0%)	49 (100.0%)	109 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Lymphocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (2.0%)	1 (0.9%)
Number of Patients with Assessment	60 (100.0%)	49 (100.0%)	109 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Monocytes Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	0 .	1 (2.0%)	1 (0.9%)
Number of Patients with Assessment	60 (100.0%)	49 (100.0%)	109 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	1 (1.7%)	1 (2.0%)	2 (1.8%)
Low (Extended)	2 (3.3%)	1 (2.0%)	3 (2.8%)
Number of Patients with Assessment	60 (100.0%)	49 (100.0%)	109 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Sodium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	60 (100.0%)	50 (100.0%)	110 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Potassium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	1 (1.7%)	0 .	1 (0.9%)
Number of Patients with Assessment	60 (100.0%)	50 (100.0%)	110 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	60 (100.0%)	50 (100.0%)	110 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Creatinine, Unit : UMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	60 (100.0%)	50 (100.0%)	110 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Aspartate Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	60 (100.0%)	50 (100.0%)	110 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	60 (100.0%)	50 (100.0%)	110 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Total Bilirubin, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	60 (100.0%)	50 (100.0%)	110 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Hemoglobin, Unit : G/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	2 (1.7%)	7 (6.4%)	9 (3.9%)
Number of Patients with Assessment	120 (100.0%)	109 (100.0%)	229 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Hematocrit, Unit : %

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	23 (19.2%)	20 (18.3%)	43 (18.8%)
Number of Patients with Assessment	120 (100.0%)	109 (100.0%)	229 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Red Blood Cell Count, Unit : 10^12/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	120 (100.0%)	109 (100.0%)	229 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : White Blood Cell Count, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	120 (100.0%)	109 (100.0%)	229 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Platelets, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	0 .	1 (0.9%)	1 (0.4%)
Number of Patients with Assessment	120 (100.0%)	109 (100.0%)	229 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Basophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	120 (100.0%)	109 (100.0%)	229 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Eosinophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	2 (1.7%)	5 (4.6%)	7 (3.1%)
Number of Patients with Assessment	120 (100.0%)	109 (100.0%)	229 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	5 (4.2%)	1 (0.9%)	6 (2.6%)
Number of Patients with Assessment	120 (100.0%)	109 (100.0%)	229 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Monocytes Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	0 .	1 (0.9%)	1 (0.4%)
Number of Patients with Assessment	120 (100.0%)	109 (100.0%)	229 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	3 (2.5%)	2 (1.8%)	5 (2.2%)
Low (Extended)	3 (2.5%)	3 (2.8%)	6 (2.6%)
Number of Patients with Assessment	120 (100.0%)	109 (100.0%)	229 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Sodium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	121 (100.0%)	110 (100.0%)	231 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Potassium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	2 (1.7%)	0 .	2 (0.9%)
Number of Patients with Assessment	121 (100.0%)	110 (100.0%)	231 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Number of Patients with Assessment	121	(100.0%)	110	(100.0%)	231	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Creatinine, Unit : UMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	121 (100.0%)	110 (100.0%)	231 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Aspartate Aminotransferase, Unit : IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	121 (100.0%)	110 (100.0%)	231 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	121 (100.0%)	110 (100.0%)	231 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase (including Taper)
by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Total Bilirubin, Unit : UMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	121 (100.0%)	110 (100.0%)	231 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Hemoglobin, Unit : G/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	13 (100.0%)	10 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Hematocrit, Unit : %

	Acute Study Treatment Group		
	Paroxetine	Placebo	Total
Flag			
Low (Extended)	1 (7.7%)	1 (10.0%)	2 (8.7%)
Number of Patients with Assessment	13 (100.0%)	10 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Red Blood Cell Count, Unit : 10^12/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	13 (100.0%)	10 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : White Blood Cell Count, Unit : 10^9/L

	Acute Study Treatment Group		
	Paroxetine	Placebo	Total
Flag			
Low (Extended)	0 .	1 (10.0%)	1 (4.3%)
Number of Patients with Assessment	13 (100.0%)	10 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Platelets, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	13 (100.0%)	10 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Basophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	13 (100.0%)	10 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Eosinophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	13 (100.0%)	10 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Lymphocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	13 (100.0%)	10 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Monocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	13 (100.0%)	10 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Neutrophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	1 (7.7%)	1 (10.0%)	2 (8.7%)
Number of Patients with Assessment	13 (100.0%)	10 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Sodium, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	12 (100.0%)	11 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Potassium, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	12 (100.0%)	11 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	12 (100.0%)	11 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Creatinine, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	12 (100.0%)	11 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Aspartate Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	12 (100.0%)	11 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Alanine Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	1 (9.1%)	1 (4.3%)
Number of Patients with Assessment	12 (100.0%)	11 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Total Bilirubin, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	12 (100.0%)	11 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Hemoglobin, Unit : G/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	11 (100.0%)	7 (100.0%)	18 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Hematocrit, Unit : %

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	1 (9.1%)	1 (14.3%)	2 (11.1%)
Number of Patients with Assessment	11 (100.0%)	7 (100.0%)	18 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Red Blood Cell Count, Unit : 10^12/L

	Acute Study Treatment Group		
	Paroxetine	Placebo	Total
Flag			
Number of Patients with Assessment	11 (100.0%)	7 (100.0%)	18 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : White Blood Cell Count, Unit : 10^9/L

	Acute Study Treatment Group		
	Paroxetine	Placebo	Total
Flag			
Low (Extended)	0 .	1 (14.3%)	1 (5.6%)
Number of Patients with Assessment	11 (100.0%)	7 (100.0%)	18 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Platelets, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	11 (100.0%)	7 (100.0%)	18 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Basophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	11 (100.0%)	7 (100.0%)	18 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Eosinophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
	Paroxetine	Placebo	Total
Flag			
Number of Patients with Assessment	11 (100.0%)	7 (100.0%)	18 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Lymphocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	11 (100.0%)	7 (100.0%)	18 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Monocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	11 (100.0%)	7 (100.0%)	18 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Neutrophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group					
	Paroxetine		Placebo		Total	
Flag						
Low (Extended)	0	.	2	(28.6%)	2	(11.1%)
Number of Patients with Assessment	11	(100.0%)	7	(100.0%)	18	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Sodium, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	10 (100.0%)	8 (100.0%)	18 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Potassium, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	11 (100.0%)	8 (100.0%)	19 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Acute Study Treatment Group		
	Paroxetine	Placebo	Total
Flag			
Number of Patients with Assessment	11 (100.0%)	8 (100.0%)	19 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Creatinine, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	11 (100.0%)	8 (100.0%)	19 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Aspartate Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	11 (100.0%)	8 (100.0%)	19 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Alanine Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
	Paroxetine	Placebo	Total
Flag			
High (Extended)	0 .	1 (12.5%)	1 (5.3%)
Number of Patients with Assessment	11 (100.0%)	8 (100.0%)	19 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Total Bilirubin, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	11 (100.0%)	8 (100.0%)	19 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Hemoglobin, Unit : G/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	24 (100.0%)	17 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Hematocrit, Unit : %

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	2 (8.3%)	2 (11.8%)	4 (9.8%)
Number of Patients with Assessment	24 (100.0%)	17 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Red Blood Cell Count, Unit : 10^12/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	24 (100.0%)	17 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : White Blood Cell Count, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	0 .	2 (11.8%)	2 (4.9%)
Number of Patients with Assessment	24 (100.0%)	17 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Platelets, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	24 (100.0%)	17 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Basophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
	Paroxetine	Placebo	Total
Flag			
Number of Patients with Assessment	24 (100.0%)	17 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Eosinophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	24 (100.0%)	17 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Lymphocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	24 (100.0%)	17 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Monocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	24 (100.0%)	17 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Neutrophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	1 (4.2%)	3 (17.6%)	4 (9.8%)
Number of Patients with Assessment	24 (100.0%)	17 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Sodium, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	22 (100.0%)	19 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Potassium, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	23 (100.0%)	19 (100.0%)	42 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	23 (100.0%)	19 (100.0%)	42 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Creatinine, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	23 (100.0%)	19 (100.0%)	42 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Aspartate Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	23 (100.0%)	19 (100.0%)	42 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Alanine Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	2 (10.5%)	2 (4.8%)
Number of Patients with Assessment	23 (100.0%)	19 (100.0%)	42 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Follow-Up Phase
by Acute Study Treatment Group
Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Total Bilirubin, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	23 (100.0%)	19 (100.0%)	42 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Hemoglobin, Unit : G/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	2 (3.2%)	5 (7.9%)	7 (5.6%)
Number of Patients with Assessment	62 (100.0%)	63 (100.0%)	125 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Hematocrit, Unit : %

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	12 (19.4%)	12 (19.0%)	24 (19.2%)
Number of Patients with Assessment	62 (100.0%)	63 (100.0%)	125 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Red Blood Cell Count, Unit : 10^12/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	62 (100.0%)	63 (100.0%)	125 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : White Blood Cell Count, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	0 .	1 (1.6%)	1 (0.8%)
Number of Patients with Assessment	62 (100.0%)	63 (100.0%)	125 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Platelets, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	0 .	1 (1.6%)	1 (0.8%)
Number of Patients with Assessment	62 (100.0%)	63 (100.0%)	125 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Basophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	62 (100.0%)	63 (100.0%)	125 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Eosinophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	1 (1.6%)	2 (3.2%)	3 (2.4%)
Number of Patients with Assessment	62 (100.0%)	63 (100.0%)	125 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	5 (8.1%)	0 .	5 (4.0%)
Number of Patients with Assessment	62 (100.0%)	63 (100.0%)	125 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Monocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	62 (100.0%)	63 (100.0%)	125 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Neutrophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	2 (3.2%)	1 (1.6%)	3 (2.4%)
Low (Extended)	2 (3.2%)	2 (3.2%)	4 (3.2%)
Number of Patients with Assessment	62 (100.0%)	63 (100.0%)	125 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Sodium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	63 (100.0%)	64 (100.0%)	127 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Potassium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	1 (1.6%)	0 .	1 (0.8%)
Number of Patients with Assessment	63 (100.0%)	64 (100.0%)	127 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	63 (100.0%)	64 (100.0%)	127 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Creatinine, Unit : UMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	63 (100.0%)	64 (100.0%)	127 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Aspartate Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	63 (100.0%)	64 (100.0%)	127 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	0 .	1 (1.6%)	1 (0.8%)
Number of Patients with Assessment	63 (100.0%)	64 (100.0%)	127 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Children
Parameter : Total Bilirubin, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	63 (100.0%)	64 (100.0%)	127 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Hemoglobin, Unit : G/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	0 .	2 (3.8%)	2 (1.8%)
Number of Patients with Assessment	61 (100.0%)	52 (100.0%)	113 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Hematocrit, Unit : %

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Low (Extended)	11 (18.0%)	10 (19.2%)	21 (18.6%)
Number of Patients with Assessment	61 (100.0%)	52 (100.0%)	113 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Red Blood Cell Count, Unit : 10^12/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	61 (100.0%)	52 (100.0%)	113 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : White Blood Cell Count, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	0 .	1 (1.9%)	1 (0.9%)
Number of Patients with Assessment	61 (100.0%)	52 (100.0%)	113 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Platelets, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	61 (100.0%)	52 (100.0%)	113 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Basophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	61 (100.0%)	52 (100.0%)	113 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Eosinophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	1 (1.6%)	3 (5.8%)	4 (3.5%)
Number of Patients with Assessment	61 (100.0%)	52 (100.0%)	113 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	0 .	1 (1.9%)	1 (0.9%)
Number of Patients with Assessment	61 (100.0%)	52 (100.0%)	113 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Monocytes Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	0 .	1 (1.9%)	1 (0.9%)
Number of Patients with Assessment	61 (100.0%)	52 (100.0%)	113 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	1 (1.6%)	1 (1.9%)	2 (1.8%)
Low (Extended)	2 (3.3%)	3 (5.8%)	5 (4.4%)
Number of Patients with Assessment	61 (100.0%)	52 (100.0%)	113 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Sodium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	61 (100.0%)	53 (100.0%)	114 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Potassium, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	1 (1.6%)	0 .	1 (0.9%)
Number of Patients with Assessment	61 (100.0%)	53 (100.0%)	114 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	61 (100.0%)	53 (100.0%)	114 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Creatinine, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	61 (100.0%)	53 (100.0%)	114 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Aspartate Aminotransferase, Unit : IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	61 (100.0%)	53 (100.0%)	114 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	0 .	1 (1.9%)	1 (0.9%)
Number of Patients with Assessment	61 (100.0%)	53 (100.0%)	114 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Total Bilirubin, Unit : UMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	61 (100.0%)	53 (100.0%)	114 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Hemoglobin, Unit : G/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	2 (1.6%)	7 (6.1%)	9 (3.8%)
Number of Patients with Assessment	123 (100.0%)	115 (100.0%)	238 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Hematocrit, Unit : %

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	23 (18.7%)	22 (19.1%)	45 (18.9%)
Number of Patients with Assessment	123 (100.0%)	115 (100.0%)	238 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Red Blood Cell Count, Unit : 10^12/L

	Acute Study Treatment Group		
	Paroxetine	Placebo	Total
Flag			
Number of Patients with Assessment	123 (100.0%)	115 (100.0%)	238 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : White Blood Cell Count, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	0 .	2 (1.7%)	2 (0.8%)
Number of Patients with Assessment	123 (100.0%)	115 (100.0%)	238 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Platelets, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Low (Extended)	0 .	1 (0.9%)	1 (0.4%)
Number of Patients with Assessment	123 (100.0%)	115 (100.0%)	238 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Basophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	123 (100.0%)	115 (100.0%)	238 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Eosinophils Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	2 (1.6%)	5 (4.3%)	7 (2.9%)
Number of Patients with Assessment	123 (100.0%)	115 (100.0%)	238 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Lymphocytes Absolute, Unit : 10^9/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	5 (4.1%)	1 (0.9%)	6 (2.5%)
Number of Patients with Assessment	123 (100.0%)	115 (100.0%)	238 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Monocytes Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	0 .	1 (0.9%)	1 (0.4%)
Number of Patients with Assessment	123 (100.0%)	115 (100.0%)	238 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
High (Extended)	3 (2.4%)	2 (1.7%)	5 (2.1%)
Low (Extended)	4 (3.3%)	5 (4.3%)	9 (3.8%)
Number of Patients with Assessment	123 (100.0%)	115 (100.0%)	238 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Sodium, Unit : MMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	124 (100.0%)	117 (100.0%)	241 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Potassium, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	2 (1.6%)	0 .	2 (0.8%)
Number of Patients with Assessment	124 (100.0%)	117 (100.0%)	241 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
Number of Patients with Assessment	124 (100.0%)	117 (100.0%)	241 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Creatinine, Unit : UMOL/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	124 (100.0%)	117 (100.0%)	241 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Aspartate Aminotransferase, Unit : IU/L

Flag	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	124 (100.0%)	117 (100.0%)	241 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Alanine Aminotransferase, Unit : IU/L

	Acute Study Treatment Group		
Flag	Paroxetine	Placebo	Total
High (Extended)	0 .	2 (1.7%)	2 (0.8%)
Number of Patients with Assessment	124 (100.0%)	117 (100.0%)	241 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

BRL 29060 - 716

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern during the Open-Label Treatment Phase, Taper Phase or Follow-Up Phase by Acute Study Treatment Group
Intention-To-Treat Population
Age Group : Total
Parameter : Total Bilirubin, Unit : UMOL/L

	Acute Study Treatment Group		
	Paroxetine	Placebo	Total
Flag			
Number of Patients with Assessment	124 (100.0%)	117 (100.0%)	241 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.2

Criteria for Clinical Concern Flagging of Laboratory Parameters

Parameter	Gender	Age(Years)	Clinical Concern Low Value	Clinical Concern High Value	Unit
Hemoglobin	Female		95.00		G/L
	Male		115.00		G/L
Hematocrit	Both	12-17	36.00		%
		6-11	35.00		%
	Female	18-64	35.00		%
	Male	18-64	41.00		%
Red Blood Cell Count	Female			10.00	10^12/L
	Male			8.00	10^12/L
White Blood Cell Count	Both		2.80	16.00	10^9/L
Platelets	Both		75.00	700.00	10^9/L
Basophils Absolute	Both			0.40	10^9/L
Eosinophils Absolute	Both			0.79	10^9/L
Lymphocytes Absolute	Both		0.53	4.43	10^9/L
Monocytes Absolute	Both			1.38	10^9/L
Neutrophils Absolute	Both		1.58	8.64	10^9/L
Sodium	Both		126.00	156.00	MMOL/L
Potassium	Both		3.00	6.00	MMOL/L
Blood Urea Nitrogen	Both			10.71	MMOL/L
Creatinine	Both			176.80	UMOL/L
Aspartate Aminotransferase	Both			150.00	IU/L
Alanine Aminotransferase	Both			165.00	IU/L
Total Bilirubin	Both			34.20	UMOL/L
Thyroid Stimulating Hormone	Both			10.00	MU/L

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BRL-029060

Narratives for Patients with Laboratory Parameters Associated with an Adverse Event and Meeting the Criteria for Clinical Concern

716

Table 15.3.3

SB Document Number: BRL-029060/RSD-101TD0/1

Issue Date: 16 September 2002

PID 716.167.25696

Treatment Group: Placebo (Protocol 701), paroxetine (Protocol 716)

Laboratory Value of Clinical Concern: Low absolute neutrophils

Adverse Event Reported: Leukopenia (low eosinophils, low neutrophils, low white cell count)

This 8-year-old white male, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 6-week study Protocol 715 (OCD/MDD), the 8-week study Protocol 701 (MDD), or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.167.25696), and had received treatment with placebo in that study.

Concomitant medications included Rhinocort® nasal spray (budesonide) for nasal congestion, Benadryl® (diphenhydramine HCl) for skin rash, Motrin® (ibuprofen) for headache, and intramuscular penicillin for Strep throat.

The patient received the first dose of study medication on 07 October 2000 at a dose of 10 mg/day and was titrated up to 30 mg/day by 21 October 2000 (Day 15). The dose of study medication was reduced temporarily to 20 mg/day on 24 January 2001 due to mild urinary incontinence (enuresis), which started on 09 January 2001 (Day 95). The investigator considered the enuresis to be possibly related to treatment with study medication. The enuresis continued without treatment for 75 days. On 27 January 2001 (Days 110-112), dosing was resumed at 30 mg/day. The patient completed the study as planned and took the final dose of study medication on 23 March 2001 (Day 168).

Laboratory values assessed at Screening of the previous acute protocol (Day -86) were within normal limits with the exception of a low blood urea nitrogen (BUN) level of 1.428 mmol/L (reference range: 2.856 to 7.497 mmol/L). Laboratory values assessed at Weeks 4 (Day 26) and 12 (Day 88) of Protocol 716 were all within normal limits.

On Week 24 (Day 168), the patient had a low white blood count of 3.0 x 10^9/L (reference range 4.5 to 13.5 x 10^9/L), low absolute eosinophils of 0.0 x 10^9/L (reference range 0.05 to 0.55 x 10^9/L), and low absolute neutrophils of 1.44 x 10^9/L (reference range 1.8 to 8.0 x 10^9/L). The absolute neutrophil count was at the level of potential clinical concern (<1.58 x 10^9/L). The investigator reported an adverse event of moderately severe leukopenia (low eosinophils, low neutrophils, and low white blood cell count). No corrective therapy was given and the investigator reported that the event resolved in 20 days. The investigator considered the leukopenia to be possibly related to treatment with study medication.

Two weeks after the final dose of study medication was taken (Day 182), follow-up laboratory assessments were performed. The patient had a white blood count of 2.0 x 10^9/L, an absolute eosinophil count of 0.02 x 109/L, an absolute monocyte count of 0.18 x 10^9/L (reference range 0.2 to 1.1 x 10^9/L), and an absolute neutrophil count of 0.9 x 10^9/L. The white blood cell count and the absolute neutrophil count were at the level of potential clinical concern (<2.8 x 10^9/L for white blood cell count; <1.58 x 10^9/L for neutrophils).

Several other non-serious adverse events were reported during the study. On 13 October 2000 (Day 7) and on 20 October 2000 (Day 5), the patient experienced mild headaches, which each resolved with treatment in one day. The investigator considered the headaches to be unrelated to treatment with study medication.

On 11 October 2000 (Day 5), mild pharyngitis (sore throat) was reported, which resolved with treatment in one day. The investigator considered the pharyngitis to be unrelated to treatment with study medication.

Mild albuminuria (urine dipstick positive for protein) was reported as an adverse event on 01 November 2000 (Day 26). This resolved without treatment in 3 days and was considered by the investigator to be unrelated to treatment with study medication.

On 13 November 2000 (Day 38), the patient reported mild rhinitis (nasal congestion), which resolved with treatment in 6 days. Rhinitis was considered by the investigator to be unrelated to treatment with study medication.

On 30 December (Day 85), mild maculopapular rash (macular skin rash, left cheek and forearms) and pruritus were reported. Corrective therapy was given for

rash only, and each resolved in 35 days. The investigator considered both to be unrelated to treatment with study medication.

On 15 January 2001 (Day 101), the patient reported mild abdominal pain (stomach ache), which resolved without treatment in 3 days.

On 28 January 2001 (Day 114), the patient experienced moderately severe infection (Strep throat), which resolved with treatment in 8 days. The investigator considered this event to be unrelated to treatment with study medication.

On 20 February 2001 (Day 137), the patient reported moderately severe respiratory disorder (cold symptoms), which resolved without treatment in 11 days. The investigator considered the event to be unrelated to treatment with study medication.

Following cessation of study medication, on 03 April 2001 (Day 179), the patient reportedly experienced mild diarrhea and mild nausea, both of which resolved in 2 days without treatment. Both of these events were considered by the investigator to be unrelated to treatment with study medication.

No other adverse events were reported.

PID 716.169.25781

Treatment Group: Placebo (Protocol 701), paroxetine (Protocol 716)

Laboratory Value of Clinical Concern: Low hematocrit

Adverse Event Reported: Anemia (abnormal laboratory results); leukopenia (abnormal laboratory results)

This 10-year-old white female, with a primary diagnosis of major depressive disorder (MDD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 6-week study Protocol 715 (OCD/MDD), the 8-week study Protocol 701 (MDD), or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.169.25781), and had received treatment with placebo in that study.

Concomitant medications included Vicks VapoRub® (camphor, eucalyptus oil, menthol, turpentine oil) for chest congestion; Clonidine® (clonidine), Remeron® (mirtazapine) and diphenhydramine for sleepless nights; and children's aspirin (acetylsalicylic acid) and Motrin® (ibuprofen) for flu symptoms.

The patient received the first dose of study medication on 10 November 2000 at a dose of 10 mg/day and remained at that dose throughout the study. The patient completed the study as planned and took the final dose of study medication on 09 April 2001 (Day 151).

Laboratory values assessed at screening of the previous acute protocol (Day -64) were within normal limits with the exception of a low hemoglobin of 111 g/L (reference range 115 to 155 g/L), low hematocrit of 33.1% (reference range 35.0 to 45.0 %), and low red blood cell count (RBC) of 3.7 x 10^9/L (reference range 4.0 to 5.2 x 10^9/L). Hematocrit values were at the level of potential clinical concern (<35.0%). These values and subsequent laboratory test values are tabulated below. All other laboratory results were within normal limits.

	Hemoglobin g/L	Hematocrit %	RBCs (x 10^9/L)	WBCs (x 10^9/L)	Monocytes (x 10^9/L)
Reference range	115 to 155	35.0 to 45.0	4.0 to 5.2	4.5 to 13.5	0.2 to 1.1
Acute Screening (Day -64)	111*	33.1 **	3.7*	6.3	0.27
Week 4	116	34.6 **	3.9*	8.1	0.29
Week 12	108*	32.7 **	3.7*	4.1*	0.06*
Post-Week 24 (Day 211)	114*	34.8 **	3.8*	7.5	0.38

* Outside reference range

** Met the level of potential clinical concern (<35%)

On 02 February 2001 (Day 85), the investigator reported an adverse event of mild anemia (abnormal laboratory results) and mild leukopenia (abnormal laboratory results). These conditions resolved without treatment in 127 days. The investigator considered these events to be unrelated to treatment with study medication.

On 14 November 2000 (Day 5), the patient reported mild insomnia (sleeplessness), which continued despite treatment. On 13 March 2001 (Day 124), moderately severe insomnia was reported, which resolved with treatment in 47 days. The insomnia reported on Day 5 was considered to be probably unrelated to treatment with study medication; the episode on reported on Day 134 was considered to be unrelated to treatment with study medication.

On 27 November 2000 (Day 18), the patient experienced a moderately severe infection (gastrointestinal upset, flu symptoms), which resolved with treatment in 6 days. The investigator considered the event to be unrelated to treatment with study medication.

On 19 December 2000 (Day 40), the patient reported a mild respiratory disorder (chest congestion), which resolved with treatment in 4 days. The investigator considered the event to be unrelated to treatment with study medication.

No other adverse events were reported.

PID 716.176.27164

Treatment Group: Paroxetine (Protocol 704), paroxetine (Protocol 716)

Laboratory Value of Clinical Concern: Low hematocrit

Adverse Event Reported: Anemia (low hemoglobin, low hematocrit)

This 11-year-old white male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 6-week study Protocol 715 (OCD/MDD), the 8-week study Protocol 701 (MDD), or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.048.27164), and had received treatment with paroxetine in that study.

The patient received the first dose of study medication on 04 April 2001 at a dose of 10 mg/day and was titrated up to 30 mg/day by 18 April 2001 (Day 15). The dose of study medication remained at 30 mg/day throughout the rest of the study. The patient completed the study as planned and took the last dose of study medication during the Treatment Phase on 17 September 2001 (Day 167). The last dose of taper phase study medication was taken on 01 October 2001 (Day 181).

Concomitant medications included Rhinocort® inhaler (budesonide), Allegra® (fexofenadine HCl), and Ventolin® inhaler (salbutamol) for perennial allergic rhinitis; multivitamins with iron and Tums® (calcium carbonate) for dietary supplementation; simethicone (dimethicone activated) for flatulence; and topical Silvadene® cream (sulfadiazine) silver for sunburn.

Laboratory values assessed at acute screening of Protocol 704 and at the first assessment in Protocol 716 (Week 4; Day 28) were within normal limits with the exception of low hematocrit of 33.7% and 33.9%, respectively (reference range 35% to 45%). At Week 12 (Day 84), hemoglobin of 112 g/L (reference range 115 to 155 g/L) was decreased, and hematocrit was decreased to 33.2%. Hemoglobin and hematocrit values met the level of potential clinical concern (<115 g/L). The investigator reported an adverse event of mild anemia (low

hematocrit, low hemoglobin) on Day 84, which was treated and resolved in 102 days. The investigator considered the anemia to be unrelated to treatment with study medication. At Week 24 (Day 168), low hemoglobin (109 g/L), hematocrit (31.8%), and red blood cell count (3.9 [reference range 4.0 to 5.2 x 10^9/L) were noted. Hemoglobin and hematocrit values at Week 24 again met the level of potential clinical concern. At Week 24+ (Day 184), all laboratory values were within normal limits with the exception of low hematocrit of 34.5%. Hematocrit values throughout the study were at a level of potential clinical concern (<35%).

Moderately severe flatulence and mild rhinitis continued into the Protocol 716 extension study from the double-blind acute study and continued throughout the study. Corrective therapy was given for both. The investigator considered the flatulence to be probably unrelated to treatment with study medication and the rhinitis to be unrelated to treatment with study medication.

On 12 April 2001 (Day 9), the patient reported moderately severe somnolence (drowsiness), which resolved without treatment in 8 days. The investigator considered the drowsiness to be related to treatment with study medication.

On 23 June 2001 (Day 81), the patient reported moderately severe trauma (sunburn), which resolved with treatment in 10 days. The investigator considered the sunburn to be unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID 716.176.27172

Treatment Group: Placebo (Protocol 704), paroxetine (Protocol 716)

Laboratory Value of Clinical Concern: Elevated absolute eosinophils, elevated absolute monocytes

Adverse Event Reported: Eosinophilia (elevated eosinophils), monocytosis (elevated monocytes)

This 16-year-old American Indian male, with a primary diagnosis of obsessive-compulsive disorder (OCD), was a participant in the trial of BRL-29060/716. The patient was 15 years old at entry into acute Study 704. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 6-week study Protocol 715 (OCD/MDD), the 8-week study Protocol 701 (MDD), or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 704 (Patient 704.048.27172), and had received treatment with placebo in that study.

The patient received the first dose of study medication on 15 June 2001 at a dose of 10 mg/day and was titrated up to 40 mg/day by 27 July 2001 (Day 43). The last dose of study medication was on 09 October 2001 (Day 117). The patient withdrew from the study at Week 16 for protocol violation.

Concomitant medications included Robitussin® (guaifenesin) and pseudoephedrine HCl (Sudafed®) for upper respiratory infection and Tylenol® (paracetamol) and Motrin® (ibuprofen) for headaches/intermittent sinus headaches.

Laboratory values assessed at acute screening in Protocol 704 (Day -105) and at baseline of Protocol 716 were all within normal limits. At Week 2 (Day 12), all absolute eosinophils were 1.12 x 10^9/L (reference range 0.05 to 0.55 x 10^9/L) and absolute monocytes were 1.6 x 10^9/L (reference range 0.2 to 1.1 x 10^9/L). Both of these elevated values met the level of potential clinical concern (>0.79 x 10^9/L for eosinophils and >1.38 x 10^9/L for monocytes). The investigator reported an adverse event of moderately severe eosinophilia (elevated eosinophils), and moderately severe monocytosis (elevated monocytes). These conditions resolved without treatment in 17 days and the investigator considered

these events to be unrelated to treatment with study medication. All laboratory values were within normal limits at Week 4 (Day 28). At last assessment, Week 12 (Day 84), all laboratory values were within normal limits with the exception of a slightly low absolute eosinophil count of 0.02 x 10^9/L.

On 19 June 2001 (Day 5) the patient reported mild respiratory disorder (upper respiratory infection), which resolved with treatment in 12 days. The URI was considered by the investigator to be related to treatment with study medication.

On 25 June 2001 (Day 11), the patient reported mild epistaxis (epistaxis), which resolved without treatment in one day. The investigator considered the epistaxis to be probably unrelated to treatment with study medication.

On 26 June 2001 (Day 12), the patient reported mild allergic reaction, which continued through the end of the study. No corrective therapy was given for this event, which was considered to be unrelated to treatment with study medication.

On 04 August 2001 (Day 51, the patient reported moderately severe abdominal pain (abdominal pains), headaches, diarrhea, and nausea. Corrective therapy was given for headaches, but for none of the other events. Abdominal pain and nausea resolved within 4 days. Headaches and diarrhea continued through the end of the study. The investigator considered all these adverse events to be unrelated to study medication.

On 31 August 2001 (Day 78), the patient experienced moderately severe fever that resolved without treatment in 3 days. The investigator considered this event to be unrelated to treatment with study medication.

On 02 September 2001 (D80), the patient experienced moderately severe respiratory disorder (upper respiratory infection) that resolved with treatment in 8 days. This event was considered to be unrelated to treatment with study medication by the investigator.

No other adverse events were reported during the study.

PID 716.192.25868

Treatment Group: Paroxetine (Protocol 701), paroxetine (Protocol 716)

Laboratory Value of Clinical Concern: Low absolute neutrophils,

Adverse Event Reported: Leukopenia (low absolute neutrophils, low white blood cell count)

This 16-year-old white male, with a primary diagnosis of major-depressive disorder (MDD), was a participant in the trial of BRL-29060/716. The patient was 15 years old at entry into acute Protocol 701. Protocol 716 is a 6-month open-label extension study to assess the long-term safety of paroxetine in children and adolescents with major depressive disorder (MDD) or obsessive-compulsive disorder (OCD) who had previously completed the 6-week study Protocol 715 (OCD/MDD), the 8-week study Protocol 701 (MDD), or the 10-week study Protocol 704 (OCD). This patient previously completed Protocol 701 (Patient 701.192.25868), and had received treatment with paroxetine in that study.

The patient received the first dose of study medication on 25 October 2000 at a dose of 10 mg/day and was titrated up to 30 mg/day by 18 November 2000 (Day 25). The 30 mg/day dose was reduced to 20 mg/day on 24 November 2000 (Day 31), and the patient remained at this dose until the end of the active study phase, 29 January 2001 (Week 12; Day 97). The patient was withdrawn from the study at Week 12 (Day 97) because of protocol violations. The dose of study medication was tapered to 10 mg/day on Day 98 and the last dose of study medication was taken on 07 February 2001 (Day 105).

Concomitant medications included Pulmocort® (budesonide) for asthma.

Laboratory values assessed at acute screening in Protocol 701 (Day -90) were all within normal limits with the exception of a slightly elevated hemoglobin of 164 g/L (reference range 120 to 160 g/L) and hematocrit of 52.5% (reference range 36.0% to 49.0%). At baseline of extension Protocol 716, only urine dipstick was assessed, and was within normal limits. At Week 8 (Day 70), all laboratory values were within normal limits with the exception of low white blood cell count of 3.0 x 10^9/L (reference range 4.5 to 13.0 x 10^9/L), and low absolute neutrophils of 1.0 x 10^9/L (reference range 1.8 to 8.0 x 10^9/L). The low absolute neutrophil value at Week 8 met the level of potential clinical concern

(<1.58 x 10^9/L), but not the WBC count (<2.8 x 10^9/L). The investigator reported an adverse event of mild leukopenia (low absolute neutrophils, low white blood cell count), which continued through the end of the study. No corrective therapy was given and the investigator considered the leukopenia to be possibly related to treatment with study medication.

All laboratory values were within normal limits at Week 12 (Day 83) with the exception of a low white blood cell count of 2.8 x 10^9/L, and low absolute neutrophil count of 1.2 x 10^9/L. The low absolute neutrophil value at Week 12 again met the level of potential clinical concern. At the last assessment, Week 16 (Day 99, 111), all laboratory values were within normal limits with the exception of a slightly elevated alanine aminotransferase on Day 99 (56 IU/L; reference range 0 to 48 IU/L). The white blood cell count at Week 16 (Day 111) was 4.8 x 10^9/L , and the absolute neutrophil count was 2.1 x 10^9/L, both within reference range.

Mild headaches were reported on 31 October 2000 (Day 7) and 01 November 2000 (Day 8), both of which resolved without treatment in one day. The investigator considered both headaches to be unrelated to treatment with study medication.

On 19 January 2001 (Day 87), the patient reported severe infection (intestinal infection), which resolved without treatment in 15 days. The investigator considered this event to be unrelated to treatment with study medication.

On 16 February 2001 (Day 115), the patient experienced moderately severe asthma that continued, despite treatment, through the end of the study period. The investigator considered the asthma to be unrelated to treatment with study medication.

No other adverse events were reported.

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Hemoglobin Unit : Grams per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	1	0	0	1
I	n	0	0	107	4	2	113	0	0	21	0	0	21
L	n	0	0	2	3	0	5	0	0	1	1	0	2
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	100	0	0	100
I	%	0	0	95	4	2	100	0	0	100	0	0	100
L	%	0	0	40	60	0	100	0	0	50	50	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Hemoglobin Unit : Grams per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	2	0	0	2	0	0	0	0	0	0
I	n	0	1	93	4	3	101	0	0	16	1	0	17
L	n	0	0	2	2	1	5	0	0	0	0	0	0
-	n	0	0	1	0	0	1	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	1	92	4	3	100	0	0	94	6	0	100
L	%	0	0	40	40	20	100	0	0	0	0	0	0
-	%	0	0	100	0	0	100	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Hematocrit Unit : Percentage
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	1	0	0	1
I	n	0	0	99	0	9	108	0	0	20	0	0	20
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	2	0	8	10	0	0	1	0	2	3
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	100	0	0	100
I	%	0	0	92	0	8	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	20	0	80	100	0	0	33	0	67	100

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Hematocrit Unit : Percentage
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	0	0	0	0
I	n	0	0	92	0	7	99	0	0	15	0	1	16
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	4	0	5	9	0	0	0	0	1	1
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	0	93	0	7	100	0	0	94	0	6	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	44	0	56	100	0	0	0	0	100	100

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Red Blood Cell Count Unit : 10^12 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	1	0	0	0	1	0	0	1	0	0	1
I	n	0	1	107	6	0	114	0	0	22	0	0	22
L	n	0	0	0	4	0	4	0	0	0	1	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	100	0	0	0	100	0	0	100	0	0	100
I	%	0	1	94	5	0	100	0	0	100	0	0	100
L	%	0	0	0	100	0	100	0	0	0	100	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Red Blood Cell Count Unit : 10^12 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	1	1	0	0	2	0	0	0	0	0	0
I	n	0	1	95	4	0	100	0	0	16	0	0	16
L	n	0	0	3	4	0	7	0	0	0	1	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	50	50	0	0	100	0	0	0	0	0	0
I	%	0	1	95	4	0	100	0	0	100	0	0	100
L	%	0	0	43	57	0	100	0	0	0	100	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : White Blood Cell Count Unit : 10^9 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	0	0	0	0
I	n	0	0	103	7	0	110	0	0	22	1	0	23
L	n	0	0	6	2	0	8	0	0	1	0	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	0	94	6	0	100	0	0	96	4	0	100
L	%	0	0	75	25	0	100	0	0	100	0	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

BRL 29060 - 716

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : White Blood Cell Count Unit : 10^9 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	1	90	10	0	101	0	0	11	1	2	14
L	n	0	0	7	1	0	8	0	0	1	2	0	3
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	1	89	10	0	100	0	0	79	7	14	100
L	%	0	0	88	13	0	100	0	0	33	67	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Platelets Unit : 10^9 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	2	2	0	0	4	0	0	0	0	0	0
I	n	0	3	112	0	0	115	0	1	23	0	0	24
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	50	50	0	0	100	0	0	0	0	0	0
I	%	0	3	97	0	0	100	0	4	96	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Platelets Unit : 10^9 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	1	4	0	0	5	0	1	0	0	0	1
I	n	0	3	100	0	0	103	0	1	15	0	0	16
L	n	0	0	1	0	0	1	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	20	80	0	0	100	0	100	0	0	0	100
I	%	0	3	97	0	0	100	0	6	94	0	0	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Basophils Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	0	119	0	0	119	0	0	24	0	0	24
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	100	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Basophils Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	0	109	0	0	109	0	0	17	0	0	17
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	100	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Eosinophils Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	1	2	0	0	3	0	1	0	0	0	1
H	n	0	0	7	2	0	9	0	0	2	0	0	2
I	n	0	4	93	2	0	99	0	1	17	0	0	18
L	n	0	0	8	0	0	8	0	0	3	0	0	3
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	33	67	0	0	100	0	100	0	0	0	100
H	%	0	0	78	22	0	100	0	0	100	0	0	100
I	%	0	4	94	2	0	100	0	6	94	0	0	100
L	%	0	0	100	0	0	100	0	0	100	0	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Eosinophils Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	2	0	1	0	0	3	0	0	0	0	0	0
H	n	0	1	6	0	0	7	0	0	0	0	0	0
I	n	2	3	85	3	0	93	0	0	15	1	0	16
L	n	0	0	3	3	0	6	0	0	0	1	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	67	0	33	0	0	100	0	0	0	0	0	0
H	%	0	14	86	0	0	100	0	0	0	0	0	0
I	%	2	3	91	3	0	100	0	0	94	6	0	100
L	%	0	0	50	50	0	100	0	0	0	100	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Lymphocytes Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	2	0	0	0	0	2	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	2	1	114	0	0	117	0	0	24	0	0	24
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	100	0	0	0	0	100	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	2	1	97	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Lymphocytes Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	1	0	0	1	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	0	106	1	0	107	0	0	16	0	0	16
L	n	0	0	1	0	0	1	0	0	1	0	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	100	0	0	100	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	99	1	0	100	0	0	100	0	0	100
L	%	0	0	100	0	0	100	0	0	100	0	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Monocytes Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	0	96	14	0	110	0	0	17	3	0	20
L	n	0	0	8	1	0	9	0	0	4	0	0	4
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	87	13	0	100	0	0	85	15	0	100
L	%	0	0	89	11	0	100	0	0	100	0	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Monocytes Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	1	0	0	1	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	0	83	10	0	93	0	0	15	1	0	16
L	n	0	0	10	5	0	15	0	0	1	0	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	100	0	0	100	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	89	11	0	100	0	0	94	6	0	100
L	%	0	0	67	33	0	100	0	0	100	0	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Neutrophils Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	1	0	0	1	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	0	0	0	0
I	n	2	0	102	3	3	110	0	0	22	0	1	23
L	n	0	0	4	0	0	4	0	0	1	0	0	1
-	n	0	0	2	1	0	3	0	0	0	0	0	0
+	%	0	0	100	0	0	100	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	2	0	93	3	3	100	0	0	96	0	4	100
L	%	0	0	100	0	0	100	0	0	100	0	0	100
-	%	0	0	67	33	0	100	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Neutrophils Absolute Unit : 10^9 per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	1	0	0	1
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	2	0	98	2	1	103	0	0	12	1	3	16
L	n	0	0	2	0	0	2	0	0	0	0	0	0
-	n	0	0	4	0	0	4	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	100	0	0	100
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	2	0	95	2	1	100	0	0	75	6	19	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	100	0	0	100	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Sodium Unit : Millimoles per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	2	0	0	2	0	0	0	0	0	0
I	n	0	2	117	0	0	119	0	0	22	0	0	22
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	2	98	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Sodium Unit : Millimoles per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	2	0	0	2	0	0	0	0	0	0
I	n	0	0	107	1	0	108	0	0	19	0	0	19
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	0	99	1	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Potassium Unit : Millimoles per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	0	0	0	0
I	n	0	1	119	0	0	120	0	0	23	0	0	23
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	1	99	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Potassium Unit : Millimoles per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	1	0	0	1	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	3	105	0	0	108	0	0	19	0	0	19
L	n	0	0	1	0	0	1	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	100	0	0	100	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	3	97	0	0	100	0	0	100	0	0	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Blood Urea Nitrogen Unit : Millimoles per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	3	0	0	3	0	0	0	0	0	0
I	n	0	0	117	1	0	118	0	1	22	0	0	23
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	0	99	1	0	100	0	4	96	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Blood Urea Nitrogen Unit : Millimoles per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	5	102	1	0	108	0	1	18	0	0	19
L	n	0	0	2	0	0	2	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	5	94	1	0	100	0	5	95	0	0	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Creatinine Unit : Micromoles per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	0	119	1	0	120	0	0	23	0	0	23
L	n	0	0	1	0	0	1	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	99	1	0	100	0	0	100	0	0	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Creatinine Unit : Micromoles per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	1	0	0	1
I	n	0	0	108	0	0	108	0	0	18	0	0	18
L	n	0	0	1	0	0	1	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	100	0	0	100
I	%	0	0	100	0	0	100	0	0	100	0	0	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Alkaline Phosphatase Unit : International Units per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	3	0	0	3	0	0	0	0	0	0
I	n	0	1	117	0	0	118	0	0	23	0	0	23
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	1	99	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Alkaline Phosphatase Unit : International Units per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	3	1	0	0	4	0	0	1	0	0	1
I	n	0	1	105	0	0	106	0	1	17	0	0	18
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	75	25	0	0	100	0	0	100	0	0	100
I	%	0	1	99	0	0	100	0	6	94	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Aspartate Aminotransferase Unit : International Units per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	2	119	0	0	121	0	0	23	0	0	23
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	2	98	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Aspartate Aminotransferase Unit : International Units per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	1	0	0	0	1	0	1	0	0	0	1
I	n	0	2	107	0	0	109	0	2	16	0	0	18
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	100	0	0	0	100	0	100	0	0	0	100
I	%	0	2	98	0	0	100	0	11	89	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Alanine Aminotransferase Unit : International Units per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	0	0	0	0
I	n	0	3	117	0	0	120	0	0	23	0	0	23
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	3	98	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Alanine Aminotransferase Unit : International Units per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	1	1	0	0	2	1	0	0	0	0	1
I	n	0	1	107	0	0	108	1	1	16	0	0	18
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	50	50	0	0	100	100	0	0	0	0	100
I	%	0	1	99	0	0	100	6	6	89	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Total Bilirubin Unit : Micromoles per Litre
Acute Study Treatment Group : Paroxetine

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	1	120	0	0	121	0	0	23	0	0	23
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	1	99	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Acute Study Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Total Bilirubin Unit : Micromoles per Litre
Acute Study Treatment Group : Placebo

ACUTE STUDY BASELINE		Endpoint (incl. Taper) +	H	I	L	-	T	Follow Up +	H	I	L	-	T
+	n	0	0	0	0	0	0	0	0	0	0	0	0
H	n	0	0	2	0	0	2	0	0	1	0	0	1
I	n	0	0	108	0	0	108	0	0	18	0	0	18
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	100	0	0	100
I	%	0	0	100	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline

Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Glucose - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	60 (100.0%)	47 (100.0%)	107 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Blood - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
1+	0	1 (2.1%)	1 (0.9%)
2+	3 (4.9%)	0	3 (2.8%)
3+	4 (6.6%)	1 (2.1%)	5 (4.6%)
Trace	3 (4.9%)	4 (8.5%)	7 (6.5%)
Number of Patients with Assessment	61 (100.0%)	47 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Red Blood Cells/HPF

	Acute Study Treatment Group		
Result	Paroxetine	Placebo	Total
0-1	8 (13.1%)	6 (12.8%)	14 (13.0%)
1-3	1 (1.6%)	1 (2.1%)	2 (1.9%)
10-15	2 (3.3%)	1 (2.1%)	3 (2.8%)
25-50	1 (1.6%)	0	1 (0.9%)
5-10	2 (3.3%)	1 (2.1%)	3 (2.8%)
INNUMERABLE	1 (1.6%)	0	1 (0.9%)
NONE SEEN	55 (90.2%)	44 (93.6%)	99 (91.7%)
Number of Patients with Assessment	61 (100.0%)	47 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine White Blood Cells/HPF

	Acute Study Treatment Group		
	Paroxetine	Placebo	Total
Result			
0-1	28 (45.9%)	21 (44.7%)	49 (45.4%)
1-3	4 (6.6%)	7 (14.9%)	11 (10.2%)
10-15	2 (3.3%)	0	2 (1.9%)
15-25	2 (3.3%)	2 (4.3%)	4 (3.7%)
3-5	1 (1.6%)	1 (2.1%)	2 (1.9%)
5-10	6 (9.8%)	1 (2.1%)	7 (6.5%)
NONE SEEN	38 (62.3%)	26 (55.3%)	64 (59.3%)
Number of Patients with Assessment	61 (100.0%)	47 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Bacteria

	Acute Study Treatment Group		
Result	Paroxetine	Placebo	Total
Few	14 (93.3%)	9 (81.8%)	23 (88.5%)
Many	1 (6.7%)	0	1 (3.8%)
MODERATE	2 (13.3%)	1 (9.1%)	3 (11.5%)
OCCASIONAL	0	1 (9.1%)	1 (3.8%)
Number of Patients with Assessment	15 (100.0%)	11 (100.0%)	26 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Protein - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
1+	8 (13.1%)	2 (4.3%)	10 (9.3%)
3+	0	1 (2.1%)	1 (0.9%)
Trace	8 (13.1%)	6 (12.8%)	14 (13.0%)
Number of Patients with Assessment	61 (100.0%)	47 (100.0%)	108 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Calcium Oxalate Crystals

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Few	11 (78.6%)	7 (70.0%)	18 (75.0%)
Many	1 (7.1%)	0	1 (4.2%)
MODERATE	2 (14.3%)	3 (30.0%)	5 (20.8%)
Number of Patients with Assessment	14 (100.0%)	10 (100.0%)	24 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Uric Acid Crystals

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Few	0	3 (75.0%)	3 (60.0%)
Many	1 (100.0%)	1 (25.0%)	2 (40.0%)
Number of Patients with Assessment	1 (100.0%)	4 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Amorphous Sediment

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Few	30 (68.2%)	26 (78.8%)	56 (72.7%)
Many	17 (38.6%)	5 (15.2%)	22 (28.6%)
MODERATE	4 (9.1%)	5 (15.2%)	9 (11.7%)
Number of Patients with Assessment	44 (100.0%)	33 (100.0%)	77 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Generic - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
1	21 (18.1%)	10 (9.1%)	31 (13.7%)
2	107 (92.2%)	108 (98.2%)	215 (95.1%)
Number of Patients with Assessment	116 (100.0%)	110 (100.0%)	226 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Hyaline Casts

Result	Acute Study Treatment Group: Placebo	Total
3-5	1 (100.0%)	1 (100.0%)
Number of Patients with Assessment	1 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Mucous Threads

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Few	31 (83.8%)	32 (100.0%)	63 (91.3%)
Many	1 (2.7%)	0	1 (1.4%)
MODERATE	8 (21.6%)	0	8 (11.6%)
Number of Patients with Assessment	37 (100.0%)	32 (100.0%)	69 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Squamous Epithelial Cells

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
FEW (1-5)	27 (81.8%)	17 (85.0%)	44 (83.0%)
MANY (21 OR GREATER)	8 (24.2%)	1 (5.0%)	9 (17.0%)
MODERATE (6-20)	7 (21.2%)	3 (15.0%)	10 (18.9%)
OCCASIONAL	2 (6.1%)	1 (5.0%)	3 (5.7%)
Number of Patients with Assessment	33 (100.0%)	20 (100.0%)	53 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716

Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis findings during the Open-Label Treatment Phase (including Taper) by Acute Study Treatment Group
Intention-To-Treat Population
Parameter : Urine Yeast

	Acute Study Treatment Group	
	Placebo	Total
Result		
Few	1 (100.0%)	1 (100.0%)
Number of Patients with Assessment	1 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Glucose - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Number of Patients with Assessment	6 (100.0%)	11 (100.0%)	17 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Blood - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
3+	0	1 (9.1%)	1 (5.9%)
Number of Patients with Assessment	6 (100.0%)	11 (100.0%)	17 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Red Blood Cells/HPF

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
25-50	0	1 (9.1%)	1 (5.9%)
3-5	0	1 (9.1%)	1 (5.9%)
NONE SEEN	6 (100.0%)	9 (81.8%)	15 (88.2%)
Number of Patients with Assessment	6 (100.0%)	11 (100.0%)	17 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine White Blood Cells/HPF

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
0-1	0	5 (45.5%)	5 (29.4%)
NONE SEEN	6 (100.0%)	6 (54.5%)	12 (70.6%)
Number of Patients with Assessment	6 (100.0%)	11 (100.0%)	17 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Bacteria

Result	Acute Study Treatment Group: Placebo	Total
Few	1 (100.0%)	1 (100.0%)
Number of Patients with Assessment	1 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Protein - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
1+	0	2 (18.2%)	2 (11.8%)
TRACE	1 (16.7%)	0	1 (5.9%)
Number of Patients with Assessment	6 (100.0%)	11 (100.0%)	17 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Amorphous Sediment

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Few	3 (75.0%)	3 (50.0%)	6 (60.0%)
MANY	1 (25.0%)	1 (16.7%)	2 (20.0%)
MODERATE	0	2 (33.3%)	2 (20.0%)
Number of Patients with Assessment	4 (100.0%)	6 (100.0%)	10 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Generic - Dipstick

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
1	1 (4.8%)	2 (10.0%)	3 (7.3%)
2	20 (95.2%)	18 (90.0%)	38 (92.7%)
Number of Patients with Assessment	21 (100.0%)	20 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Mucous Threads

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
Few	2 (100.0%)	5 (100.0%)	7 (100.0%)
Number of Patients with Assessment	2 (100.0%)	5 (100.0%)	7 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 716

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis findings during the Follow-Up Phase by Acute Study Treatment Group

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Squamous Epithelial Cells

Result	Acute Study Treatment Group: Paroxetine	Placebo	Total
FEW (1-5)	3 (75.0%)	6 (100.0%)	9 (90.0%)
MANY (21 OR GREATER)	1 (25.0%)	0	1 (10.0%)
Number of Patients with Assessment	4 (100.0%)	6 (100.0%)	10 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Paroxetine

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Alanine Aminotransferase	IU/L	Acute Baseline	133	15.96992	6.613737	15.00000	6.0000	47.0000
		Week 24	59	18.28814	11.522169	14.00000	7.0000	84.0000
		Change to Week 24	59	2.83051	11.275779	1.00000	-23.0000	69.0000
		Endpoint	121	18.19008	10.814584	15.00000	7.0000	84.0000
		Change to Endpoint	121	2.19008	10.765929	1.00000	-23.0000	69.0000
Alkaline Phosphatase	IU/L	Acute Baseline	133	220.03759	89.552541	227.00000	51.0000	452.0000
		Week 24	59	196.45763	72.723928	204.00000	69.0000	367.0000
		Change to Week 24	59	-15.33898	36.500642	-22.00000	-158.0000	72.0000
		Endpoint	121	203.96694	86.144543	215.00000	63.0000	453.0000
		Change to Endpoint	121	-16.90083	38.635348	-14.00000	-158.0000	80.0000
Aspartate Aminotransferase	IU/L	Acute Baseline	133	22.69925	5.756400	22.00000	12.0000	38.0000
		Week 24	59	23.62712	8.880234	22.00000	13.0000	69.0000
		Change to Week 24	59	1.28814	8.529969	0.00000	-10.0000	49.0000
		Endpoint	121	24.44628	7.704923	23.00000	13.0000	69.0000
		Change to Endpoint	121	1.51240	6.893373	1.00000	-10.0000	49.0000
Basophils Absolute	10^9/L	Acute Baseline	132	0.02061	0.014607	0.02000	0.0000	0.1100
		Week 24	59	0.01881	0.011757	0.02000	0.0000	0.0500
		Change to Week 24	58	-0.00345	0.020737	0.00000	-0.0900	0.0300
		Endpoint	120	0.01708	0.011182	0.02000	0.0000	0.0500
		Change to Endpoint	119	-0.00403	0.017482	0.00000	-0.0900	0.0300
Blood Urea Nitrogen	MMOL/L	Acute Baseline	133	4.60611	1.136489	4.28400	2.8560	7.8540
		Week 24	59	4.49578	1.220801	4.28400	2.1420	7.4970
		Change to Week 24	59	0.00605	1.288021	0.35700	-3.5700	2.4990
		Endpoint	121	4.57904	1.144516	4.28400	2.1420	7.4970
		Change to Endpoint	121	0.00885	1.265935	0.00000	-3.5700	2.8560
Creatinine	UMOL/L	Acute Baseline	133	51.97654	14.105339	53.04000	26.5200	88.4000
		Week 24	59	55.13763	15.075351	53.04000	26.5200	97.2400
		Change to Week 24	59	2.09763	11.053229	0.00000	-26.5200	35.3600
		Endpoint	121	53.69752	15.017826	53.04000	26.5200	97.2400
		Change to Endpoint	121	2.11868	10.523239	0.00000	-26.5200	35.3600
Eosinophils Absolute	10^9/L	Acute Baseline	132	0.26742	0.198462	0.23500	0.0000	0.9600
		Week 24	59	0.22593	0.127172	0.21000	0.0500	0.5800
		Change to Week 24	58	-0.04534	0.200615	-0.00500	-0.6200	0.2800
		Endpoint	120	0.23842	0.153601	0.21500	0.0000	0.7900
		Change to Endpoint	119	-0.02672	0.192583	0.00000	-0.6000	0.4300

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Paroxetine

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Free T3	PMOL/L	Acute Baseline	130	5.68994	0.772327	5.59790	4.1118	10.7646
Hematocrit	%	Acute Baseline	132	39.46742	3.284999	39.15000	32.5000	52.5000
		Week 24	59	39.70847	3.254349	39.30000	31.8000	47.0000
		Change to Week 24	58	-0.47069	2.337040	-0.30000	-5.0000	6.1000
		Endpoint	120	38.73500	3.339191	38.45000	31.5000	47.2000
		Change to Endpoint	119	-0.68403	2.395511	-0.50000	-8.1000	6.1000
Hemoglobin	G/L	Acute Baseline	132	133.35606	10.739904	133.00000	106.0000	164.0000
		Week 24	59	134.50847	10.622638	134.00000	109.0000	162.0000
		Change to Week 24	58	-1.03448	6.800324	0.00000	-16.0000	14.0000
		Endpoint	120	130.99167	11.207362	130.50000	101.0000	162.0000
		Change to Endpoint	119	-2.15126	6.914292	-2.00000	-19.0000	16.0000
Lymphocytes Absolute	10^9/L	Acute Baseline	132	2.46924	0.784787	2.29000	1.0200	5.8000
		Week 24	59	2.36695	0.776926	2.19000	1.1200	5.0600
		Change to Week 24	58	-0.07603	0.662263	-0.12000	-1.3500	1.6100
		Endpoint	120	2.40467	0.770700	2.23000	1.0100	5.0600
		Change to Endpoint	119	-0.08084	0.690283	-0.11000	-2.4400	1.7300
Monocytes Absolute	10^9/L	Acute Baseline	132	0.41250	0.191045	0.37000	0.0600	0.9200
		Week 24	59	0.38678	0.183852	0.34000	0.0400	0.8900
		Change to Week 24	58	-0.03793	0.190776	-0.04000	-0.7300	0.4300
		Endpoint	120	0.37092	0.181140	0.34000	0.0100	0.8900
		Change to Endpoint	119	-0.05496	0.188648	-0.05000	-0.7300	0.4400
Neutrophils Absolute	10^9/L	Acute Baseline	132	3.76886	1.554524	3.53500	0.7400	9.0000
		Week 24	59	3.69051	1.569904	3.31000	1.4700	9.3700
		Change to Week 24	58	-0.10828	1.535299	-0.02000	-3.8400	3.8900
		Endpoint	120	3.80683	1.569773	3.63500	1.1500	9.3700
		Change to Endpoint	119	-0.07588	1.636041	-0.02000	-4.5300	5.5400
Platelets	10^9/L	Acute Baseline	132	287.07576	61.381005	284.00000	154.0000	469.0000
		Week 24	59	283.20339	63.677739	284.00000	172.0000	439.0000
		Change to Week 24	58	-6.17241	47.914814	-5.50000	-142.0000	171.0000
		Endpoint	120	278.83333	59.683385	281.50000	135.0000	439.0000
		Change to Endpoint	119	-11.10084	45.361896	-13.00000	-145.0000	171.0000
Potassium	MMOL/L	Acute Baseline	133	4.29774	0.336980	4.20000	3.6000	5.6000
		Week 24	58	4.31552	0.341720	4.30000	3.7000	5.3000
		Change to Week 24	58	0.02241	0.440113	0.00000	-1.8000	1.2000
		Endpoint	121	4.28760	0.346066	4.30000	3.6000	5.9000

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Paroxetine

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Potassium	MMOL/L	Change to Endpoint	121	0.00083	0.437702	0.00000	-1.8000	1.4000
Red Blood Cell Count	10^12/L	Acute Baseline	132	4.61970	0.338258	4.60000	3.8000	5.6000
		Week 24	59	4.62881	0.359142	4.60000	3.9000	5.4000
		Change to Week 24	58	-0.03448	0.244628	0.00000	-0.5000	0.7000
		Endpoint	120	4.53583	0.357347	4.50000	3.7000	5.4000
		Change to Endpoint	119	-0.07143	0.253499	-0.10000	-0.8000	0.7000
Sodium	MMOL/L	Acute Baseline	133	141.70677	2.088141	142.00000	137.0000	149.0000
		Week 24	59	141.15254	2.032610	141.00000	137.0000	147.0000
		Change to Week 24	59	-0.74576	2.886313	-1.00000	-7.0000	8.0000
		Endpoint	121	141.35537	1.995242	141.00000	137.0000	147.0000
		Change to Endpoint	121	-0.30579	2.866016	-1.00000	-7.0000	9.0000
Thyroid Stimulating Hormone	MU/L	Acute Baseline	131	2.27634	1.604697	2.00000	0.1000	17.0000
Total Bilirubin	UMOL/L	Acute Baseline	133	7.77857	3.866689	6.84000	0.0000	22.2300
		Week 24	58	6.92845	3.685992	5.13000	3.4200	23.9400
		Change to Week 24	58	-0.85500	3.468407	-0.85500	-11.9700	6.8400
		Endpoint	121	7.00959	3.630177	5.13000	3.4200	23.9400
		Change to Endpoint	121	-0.57942	3.118533	0.00000	-11.9700	6.8400
Total Free Thyroxine	PMOL/L	Acute Baseline	93	13.60742	1.944475	12.90000	10.3200	20.6400
White Blood Cell Count	10^9/L	Acute Baseline	132	6.93333	2.078816	6.80000	3.0000	14.9000
		Week 24	59	6.68814	1.942278	6.40000	3.4000	12.6000
		Change to Week 24	58	-0.26207	1.841798	-0.30000	-4.3000	5.2000
		Endpoint	120	6.83667	2.012396	6.65000	2.8000	13.3000
		Change to Endpoint	119	-0.23782	2.004402	-0.20000	-6.5000	5.2000

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Placebo

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Alanine Aminotransferase	IU/L	Acute Baseline	130	16.76923	8.267372	14.00000	7.0000	59.0000
		Week 24	40	18.82500	9.256702	16.00000	8.0000	47.0000
		Change to Week 24	40	2.62500	6.815094	1.50000	-12.0000	27.0000
		Endpoint	110	18.64545	9.777888	16.00000	6.0000	79.0000
		Change to Endpoint	110	2.06364	7.366272	2.00000	-20.0000	33.0000
Alkaline Phosphatase	IU/L	Acute Baseline	130	236.55385	93.389910	236.00000	49.0000	512.0000
		Week 24	40	206.00000	92.580111	213.50000	74.0000	528.0000
		Change to Week 24	40	-19.90000	36.724756	-13.00000	-112.0000	64.0000
		Endpoint	110	215.35455	92.508922	217.00000	61.0000	528.0000
		Change to Endpoint	110	-19.30909	42.070876	-15.50000	-170.0000	106.0000
Aspartate Aminotransferase	IU/L	Acute Baseline	130	24.41538	6.496015	24.00000	12.0000	47.0000
		Week 24	40	24.50000	6.898532	23.00000	15.0000	53.0000
		Change to Week 24	40	1.62500	6.635907	1.00000	-16.0000	28.0000
		Endpoint	110	26.18182	7.987584	26.00000	13.0000	59.0000
		Change to Endpoint	110	1.96364	6.034955	1.00000	-16.0000	28.0000
Basophils Absolute	10^9/L	Acute Baseline	130	0.02031	0.012694	0.02000	0.0000	0.0700
		Week 24	41	0.01634	0.012198	0.01000	0.0000	0.0700
		Change to Week 24	41	-0.00220	0.015085	0.00000	-0.0300	0.0300
		Endpoint	109	0.02064	0.023145	0.02000	0.0000	0.1800
		Change to Endpoint	109	0.00037	0.026420	0.00000	-0.0600	0.1700
Blood Urea Nitrogen	MMOL/L	Acute Baseline	130	4.38286	1.292937	4.28400	1.4280	8.9250
		Week 24	40	4.52497	1.266418	4.28400	2.1420	8.5680
		Change to Week 24	40	0.33915	1.143172	0.35700	-2.8560	2.4990
		Endpoint	110	4.75784	1.384015	4.64100	2.1420	8.5680
		Change to Endpoint	110	0.32130	1.265609	0.35700	-2.8560	4.2840
Creatinine	UMOL/L	Acute Baseline	130	51.95200	14.603190	53.04000	26.5200	132.6000
		Week 24	40	55.91300	10.086603	53.04000	35.3600	79.5600
		Change to Week 24	40	4.64100	8.723060	0.00000	-17.6800	26.5200
		Endpoint	110	53.12036	12.643945	53.04000	26.5200	88.4000
		Change to Endpoint	110	1.12509	11.677907	0.00000	-79.5600	26.5200
Eosinophils Absolute	10^9/L	Acute Baseline	130	0.24569	0.201198	0.18000	0.0000	1.3300
		Week 24	41	0.21366	0.141134	0.19000	0.0000	0.6300
		Change to Week 24	41	-0.01902	0.178533	-0.01000	-0.5400	0.4600
		Endpoint	109	0.26569	0.212343	0.20000	0.0000	1.2800
		Change to Endpoint	109	0.01394	0.204532	0.00000	-0.5400	0.8200

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Placebo

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Free T3	PMOL/L	Acute Baseline	127	5.66247	0.656260	5.66720	3.7422	8.0388
Hematocrit	%	Acute Baseline	130	39.27462	3.415975	38.95000	31.8000	48.8000
		Week 24	41	38.78049	3.645080	38.50000	29.0000	47.2000
		Change to Week 24	41	-1.00732	2.740930	-1.10000	-7.8000	4.7000
		Endpoint	109	38.61927	3.244553	38.30000	29.0000	47.2000
		Change to Endpoint	109	-0.51560	2.498487	-0.40000	-7.8000	6.2000
Hemoglobin	G/L	Acute Baseline	130	132.27692	11.381350	131.00000	104.0000	163.0000
		Week 24	41	131.14634	13.995644	129.00000	86.0000	162.0000
		Change to Week 24	41	-2.58537	9.672062	-3.00000	-22.0000	20.0000
		Endpoint	109	130.41284	11.369396	129.00000	86.0000	162.0000
		Change to Endpoint	109	-1.54128	7.607905	-1.00000	-22.0000	20.0000
Lymphocytes Absolute	10^9/L	Acute Baseline	130	2.37369	0.669167	2.31000	0.8000	4.8700
		Week 24	41	2.24634	0.619773	2.14000	1.1400	3.4500
		Change to Week 24	41	-0.01122	0.441482	-0.05000	-1.0300	1.0500
		Endpoint	109	2.24697	0.619183	2.15000	0.7000	4.0800
		Change to Endpoint	109	-0.07009	0.539603	-0.09000	-2.4600	1.3300
Monocytes Absolute	10^9/L	Acute Baseline	130	0.35392	0.188567	0.34000	0.0000	1.4000
		Week 24	41	0.34537	0.148814	0.32000	0.0600	0.9100
		Change to Week 24	41	0.01805	0.172427	-0.01000	-0.4100	0.5200
		Endpoint	109	0.35339	0.153546	0.35000	0.0400	0.9100
		Change to Endpoint	109	-0.00165	0.195256	-0.01000	-0.9700	0.5400
Neutrophils Absolute	10^9/L	Acute Baseline	130	3.80431	1.396433	3.71000	1.4600	8.6500
		Week 24	41	3.71390	1.420750	3.32000	1.4400	7.0700
		Change to Week 24	41	-0.09561	1.697347	-0.07000	-3.7500	3.5100
		Endpoint	109	3.89248	1.518257	3.56000	1.4400	9.7900
		Change to Endpoint	109	0.18028	1.596051	0.23000	-3.7500	4.8000
Platelets	10^9/L	Acute Baseline	130	293.74615	63.314193	281.50000	115.0000	468.0000
		Week 24	41	290.90244	51.217089	275.00000	216.0000	415.0000
		Change to Week 24	41	5.92683	43.922881	3.00000	-92.0000	130.0000
		Endpoint	109	288.16514	60.212358	290.00000	154.0000	450.0000
		Change to Endpoint	109	-3.94495	46.894648	-4.00000	-154.0000	130.0000
Potassium	MMOL/L	Acute Baseline	130	4.40077	0.378798	4.40000	3.3000	6.1000
		Week 24	40	4.36500	0.344592	4.30000	3.9000	5.1000
		Change to Week 24	40	-0.07250	0.355172	0.00000	-0.9000	0.8000
		Endpoint	110	4.35909	0.390553	4.20000	3.9000	5.9000

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Placebo

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Potassium	MMOL/L	Change to Endpoint	110	-0.06364	0.414801	-0.10000	-1.6000	1.4000
Red Blood Cell Count	10^12/L	Acute Baseline	130	4.57538	0.376450	4.60000	3.7000	5.4000
		Week 24	41	4.50000	0.400625	4.40000	3.9000	5.5000
		Change to Week 24	41	-0.10732	0.322017	-0.10000	-1.0000	0.5000
		Endpoint	109	4.50917	0.364270	4.50000	3.7000	5.5000
		Change to Endpoint	109	-0.05321	0.266864	0.00000	-1.0000	0.5000
Sodium	MMOL/L	Acute Baseline	130	141.75385	2.203104	142.00000	137.0000	149.0000
		Week 24	40	141.00000	1.987138	141.00000	137.0000	145.0000
		Change to Week 24	40	-0.77500	3.125474	-1.00000	-8.0000	5.0000
		Endpoint	110	141.10000	2.071874	141.00000	134.0000	145.0000
		Change to Endpoint	110	-0.62727	2.929944	-1.00000	-8.0000	5.0000
Thyroid Stimulating Hormone	MU/L	Acute Baseline	130	2.31231	1.258892	2.00000	0.5000	11.7000
Total Bilirubin	UMOL/L	Acute Baseline	130	7.32669	3.990386	6.84000	3.4200	34.2000
		Week 24	40	7.78050	3.505527	6.84000	3.4200	18.8100
		Change to Week 24	40	-0.04275	3.386679	0.00000	-15.3900	5.1300
		Endpoint	110	7.04209	2.815366	6.84000	3.4200	18.8100
		Change to Endpoint	110	-0.21764	3.405135	0.00000	-18.8100	5.1300
Total Free Thyroxine	PMOL/L	Acute Baseline	128	13.72641	1.913615	13.54500	9.0300	19.3500
White Blood Cell Count	10^9/L	Acute Baseline	130	6.79692	1.771214	6.50000	3.5000	13.2000
		Week 24	41	6.53659	1.727391	6.30000	3.0000	10.2000
		Change to Week 24	41	-0.10732	1.982724	-0.10000	-4.1000	4.2000
		Endpoint	109	6.77890	1.892484	6.60000	3.0000	13.8000
		Change to Endpoint	109	0.12385	1.825382	0.10000	-4.1000	5.8000

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Total

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Alanine Aminotransferase	IU/L	Acute Baseline	263	16.36502	7.473352	15.00000	6.0000	59.0000
		Week 24	99	18.50505	10.618019	15.00000	7.0000	84.0000
		Change to Week 24	99	2.74747	9.682030	1.00000	-23.0000	69.0000
		Endpoint	231	18.40693	10.314142	16.00000	6.0000	84.0000
		Change to Endpoint	231	2.12987	9.283952	1.00000	-23.0000	69.0000
Alkaline Phosphatase	IU/L	Acute Baseline	263	228.20152	91.668677	231.00000	49.0000	512.0000
		Week 24	99	200.31313	81.013434	204.00000	69.0000	528.0000
		Change to Week 24	99	-17.18182	36.473184	-15.00000	-158.0000	72.0000
		Endpoint	231	209.38961	89.218562	216.00000	61.0000	528.0000
		Change to Endpoint	231	-18.04762	40.237473	-15.00000	-170.0000	106.0000
Aspartate Aminotransferase	IU/L	Acute Baseline	263	23.54753	6.181466	23.00000	12.0000	47.0000
		Week 24	99	23.97980	8.111443	22.00000	13.0000	69.0000
		Change to Week 24	99	1.42424	7.785506	0.00000	-16.0000	49.0000
		Endpoint	231	25.27273	7.871749	24.00000	13.0000	69.0000
		Change to Endpoint	231	1.72727	6.488725	1.00000	-16.0000	49.0000
Basophils Absolute	10^9/L	Acute Baseline	262	0.02046	0.013666	0.02000	0.0000	0.1100
		Week 24	100	0.01780	0.011941	0.02000	0.0000	0.0700
		Change to Week 24	99	-0.00293	0.018530	0.00000	-0.0900	0.0300
		Endpoint	229	0.01878	0.017949	0.02000	0.0000	0.1800
		Change to Endpoint	228	-0.00193	0.022267	0.00000	-0.0900	0.1700
Blood Urea Nitrogen	MMOL/L	Acute Baseline	263	4.49576	1.219148	4.28400	1.4280	8.9250
		Week 24	99	4.50758	1.233089	4.28400	2.1420	8.5680
		Change to Week 24	99	0.14064	1.236493	0.35700	-3.5700	2.4990
		Endpoint	231	4.66418	1.264604	4.28400	2.1420	8.5680
		Change to Endpoint	231	0.15764	1.272670	0.35700	-3.5700	4.2840
Creatinine	UMOL/L	Acute Baseline	263	51.96441	14.326148	53.04000	26.5200	132.6000
		Week 24	99	55.45091	13.234007	53.04000	26.5200	97.2400
		Change to Week 24	99	3.12525	10.205974	0.00000	-26.5200	35.3600
		Endpoint	231	53.42268	13.911078	53.04000	26.5200	97.2400
		Change to Endpoint	231	1.64554	11.074888	0.00000	-79.5600	35.3600
Eosinophils Absolute	10^9/L	Acute Baseline	262	0.25664	0.199738	0.20000	0.0000	1.3300
		Week 24	100	0.22090	0.132513	0.19000	0.0000	0.6300
		Change to Week 24	99	-0.03444	0.191280	-0.01000	-0.6200	0.4600
		Endpoint	229	0.25140	0.184007	0.20000	0.0000	1.2800
		Change to Endpoint	228	-0.00728	0.198990	0.00000	-0.6000	0.8200

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Total

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Free T3	PMOL/L	Acute Baseline	257	5.67637	0.716057	5.63640	3.7422	10.7646
Hematocrit	%	Acute Baseline	262	39.37176	3.345593	39.10000	31.8000	52.5000
		Week 24	100	39.32800	3.432703	39.05000	29.0000	47.2000
		Change to Week 24	99	-0.69293	2.512713	-0.50000	-7.8000	6.1000
		Endpoint	229	38.67991	3.287781	38.40000	29.0000	47.2000
		Change to Endpoint	228	-0.60351	2.441327	-0.50000	-8.1000	6.2000
Hemoglobin	G/L	Acute Baseline	262	132.82061	11.054821	132.00000	104.0000	164.0000
		Week 24	100	133.13000	12.166069	131.50000	86.0000	162.0000
		Change to Week 24	99	-1.67677	8.103701	-1.00000	-22.0000	20.0000
		Endpoint	229	130.71616	11.263695	130.00000	86.0000	162.0000
		Change to Endpoint	228	-1.85965	7.244475	-1.50000	-22.0000	20.0000
Lymphocytes Absolute	10^9/L	Acute Baseline	262	2.42183	0.729887	2.30000	0.8000	5.8000
		Week 24	100	2.31750	0.715812	2.16500	1.1200	5.0600
		Change to Week 24	99	-0.04919	0.579382	-0.10000	-1.3500	1.6100
		Endpoint	229	2.32961	0.705584	2.20000	0.7000	5.0600
		Change to Endpoint	228	-0.07570	0.621491	-0.10000	-2.4600	1.7300
Monocytes Absolute	10^9/L	Acute Baseline	262	0.38344	0.191714	0.35000	0.0000	1.4000
		Week 24	100	0.36980	0.170791	0.33000	0.0400	0.9100
		Change to Week 24	99	-0.01475	0.184586	-0.02000	-0.7300	0.5200
		Endpoint	229	0.36258	0.168434	0.34000	0.0100	0.9100
		Change to Endpoint	228	-0.02947	0.193262	-0.03000	-0.9700	0.5400
Neutrophils Absolute	10^9/L	Acute Baseline	262	3.78645	1.475474	3.58500	0.7400	9.0000
		Week 24	100	3.70010	1.503199	3.31500	1.4400	9.3700
		Change to Week 24	99	-0.10303	1.595915	-0.02000	-3.8400	3.8900
		Endpoint	229	3.84760	1.542680	3.60000	1.1500	9.7900
		Change to Endpoint	228	0.04658	1.618576	0.05000	-4.5300	5.5400
Platelets	10^9/L	Acute Baseline	262	290.38550	62.317752	282.50000	115.0000	469.0000
		Week 24	100	286.36000	58.736102	280.50000	172.0000	439.0000
		Change to Week 24	99	-1.16162	46.461243	-4.00000	-142.0000	171.0000
		Endpoint	229	283.27511	59.986170	284.00000	135.0000	450.0000
		Change to Endpoint	228	-7.67982	46.138349	-8.00000	-154.0000	171.0000
Potassium	MMOL/L	Acute Baseline	263	4.34867	0.361280	4.30000	3.3000	6.1000
		Week 24	98	4.33571	0.341992	4.30000	3.7000	5.3000
		Change to Week 24	98	-0.01633	0.408339	0.00000	-1.8000	1.2000
		Endpoint	231	4.32165	0.368851	4.20000	3.6000	5.9000

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

Table 15.3.6

Summary Statistics For Acute Study Baseline and Change From Acute Study Baseline to Endpoint for Laboratory Parameters
By Acute Study Treatment Group
Intention-To-Treat Population

Acute Study Treatment Group : Total

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Potassium	MMOL/L	Change to Endpoint	231	-0.02987	0.427245	0.00000	-1.8000	1.4000
Red Blood Cell Count	10^12/L	Acute Baseline	262	4.59771	0.357721	4.60000	3.7000	5.6000
		Week 24	100	4.57600	0.380090	4.60000	3.9000	5.5000
		Change to Week 24	99	-0.06465	0.280056	-0.10000	-1.0000	0.7000
		Endpoint	229	4.52314	0.360113	4.50000	3.7000	5.5000
		Change to Endpoint	228	-0.06272	0.259558	-0.10000	-1.0000	0.7000
Sodium	MMOL/L	Acute Baseline	263	141.73004	2.141763	142.00000	137.0000	149.0000
		Week 24	99	141.09091	2.005558	141.00000	137.0000	147.0000
		Change to Week 24	99	-0.75758	2.969542	-1.00000	-8.0000	8.0000
		Endpoint	231	141.23377	2.031680	141.00000	134.0000	147.0000
		Change to Endpoint	231	-0.45887	2.894792	-1.00000	-8.0000	9.0000
Thyroid Stimulating Hormone	MU/L	Acute Baseline	261	2.29425	1.440194	2.00000	0.1000	17.0000
Total Bilirubin	UMOL/L	Acute Baseline	263	7.55521	3.927338	6.84000	0.0000	34.2000
		Week 24	98	7.27622	3.619648	5.98500	3.4200	23.9400
		Change to Week 24	98	-0.52347	3.441161	0.00000	-15.3900	6.8400
		Endpoint	231	7.02506	3.260707	6.84000	3.4200	23.9400
		Change to Endpoint	231	-0.40714	3.256045	0.00000	-18.8100	6.8400
Total Free Thyroxine	PMOL/L	Acute Baseline	221	13.67633	1.923157	12.90000	9.0300	20.6400
White Blood Cell Count	10^9/L	Acute Baseline	262	6.86565	1.929833	6.70000	3.0000	14.9000
		Week 24	100	6.62600	1.849686	6.40000	3.0000	12.6000
		Change to Week 24	99	-0.19798	1.893004	-0.20000	-4.3000	5.2000
		Endpoint	229	6.80917	1.952181	6.60000	2.8000	13.8000
		Change to Endpoint	228	-0.06491	1.925232	-0.10000	-6.5000	5.8000

Note: For laboratory assessments, the last pre-acute study medication assessment is taken to be Acute Study Baseline
Endpoint is the last on treatment assessment (including Taper Phase)
Week 24 includes only assessments that are on-treatment (including taper)

Table 15.4.1

Number (%) of Patients by ECG Assessment by Acute Study Treatment Group

All Patients

Visit		Acute Treatement Group: Paroxetine (N=135)	Placebo (N=130)	Total (N=265)
Acute Study Screening	Abnormal	4 (3.0%)	0	4 (1.5%)
	Normal	131 (97.0%)	129 (100.0%)	260 (98.5%)
	Missing	0	0	0
	Total	135 (100.0%)	129 (100.0%)	264 (100.0%)
Acute Study Baseline	Abnormal	0	0	0
	Normal	1 (2.1%)	0	1 (0.9%)
	Unknown*	0	0	0
	Not Applicable**	46 (97.9%)	64 (100.0%)	110 (99.1%)
	Total	47 (100.0%)	64 (100.0%)	111 (100.0%)
716 Baseline	Abnormal	0	0	0
	Normal	11 (8.3%)	19 (14.6%)	30 (11.4%)
	Unknown*	0	0	0
	Not Applicable**	122 (91.7%)	111 (85.4%)	233 (88.6%)
	Total	133 (100.0%)	130 (100.0%)	263 (100.0%)
Last Study 716 Treatment ECG	Abnormal	0	0	0
	Normal	49 (96.1%)	39 (97.5%)	88 (96.7%)
	Missing	2 (3.9%)	1 (2.5%)	3 (3.3%)
	Total	51 (100.0%)	40 (100.0%)	91 (100.0%)
Early Withdrawals ECG	Abnormal	0	1 (3.2%)	1 (2.2%)
	Normal	7 (50.0%)	26 (83.9%)	33 (73.3%)
	Missing	7 (50.0%)	4 (12.9%)	11 (24.4%)
	Total	14 (100.0%)	31 (100.0%)	45 (100.0%)
Taper End ECG	Abnormal	0	0	0
	Normal	10 (50.0%)	8 (38.1%)	18 (43.9%)
	Missing	1 (5.0%)	1 (4.8%)	2 (4.9%)
	Unknown*	0	0	0
	Not Applicable**	9 (45.0%)	12 (57.1%)	21 (51.2%)
	Total	20 (100.0%)	21 (100.0%)	41 (100.0%)
Follow Up ECG	Abnormal	1 (1.1%)	0	1 (0.6%)

* Abnormal at previous visit, but re-test not done or result of re-test unknown
** Not applicable, Normal at previous visit

(ECGs at timepoints other than Acute Study Screening, Last Study 716 Treatment and Early Withdrawal are performed only on patients who previously had an abnormal ECG)

Note: Percentages are based on number of patients with an assessment at that visit
Note: ECG's at Acute Study Baseline are only taken in Study 704

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Table 15.4.1

Number (%) of Patients by ECG Assessment by Acute Study Treatment Group

All Patients

Visit		Acute Treatement Group: Paroxetine (N=135)	Placebo (N=130)	Total (N=265)
Follow Up ECG	Normal	14 (15.4%)	13 (14.6%)	27 (15.0%)
	Missing	3 (3.3%)	1 (1.1%)	4 (2.2%)
	Unknown*	0	1 (1.1%)	1 (0.6%)
	Not Applicable**	73 (80.2%)	74 (83.1%)	147 (81.7%)
	Total	91 (100.0%)	89 (100.0%)	180 (100.0%)

* Abnormal at previous visit, but re-test not done or result of re-test unknown
** Not applicable, Normal at previous visit

(ECGs at timepoints other than Acute Study Screening, Last Study 716 Treatment and Early Withdrawal are performed only on patients who previously had an abnormal ECG)

Note: Percentages are based on number of patients with an assessment at that visit
Note: ECG's at Acute Study Baseline are only taken in Study 704

13 Errata

Table/Listing	Error
Table 13.10.2, 13.10.3, and 13.10.6, Section 10; Listing 13.10.1, Appendix B	Patient 716.043.27694 received a dose of 15 mg/day between April 18, 2001 and May 25, 2001 (the patient took one-and-a-half 10-mg tablets). The dose was listed in Listing 13.10.1 as 15 mg; and 15 mg was used in the tablet accountability Table 13.10.2. In dosing Table 13.10.3 this 15-mg dose has been excluded from the table and shows no dosing for this patient for Week 20. In Table 13.10.6 the 15-mg dose has been included.
Table 14.4.1b, Section 11	The adolescent patient in the Not Assessed row for week 24 OC has been included in the total row in error. The denominators for the percentages have been based on these totals and are therefore slightly discrepant. The report has been corrected to reflect this (Section 6.3.4.1 and Table 57).
Listing 15.1.2, Appendix D	Patient 716.026.27047 has an AE of dehydration that has a missing intensity.
Listing 13.10.1, Appendix D; Listings 15.1.4, Appendix D	There is a discrepancy in some cases between the dose at onset for an AE and the dosage at the time of the event per the dosing listings. The discrepancy occurred because the dose at the last scheduled visit was used to determine the dose at AE onset, even if the AE occurred after a dose change between visits.
Table 15.4.1, Section 12; Listing 15.4.1, Appendix E	Patients 716.172.25619 and 716.014.25353 had an on-treatment ECG with a baseline page CRF, which cannot be assigned to a visit window. The ECGs for these patients have been listed with a missing visit. They are not included in the summary tables. Patient 716.010.28172 had an on-treatment ECG with a Follow-up page CRF. The ECG was listed as Follow-up and has not been included in the summary tables.

Table/Listing	Error
Listing 15.1.4, Appendix D	Patient 716.028.27685 appears in Listing 15.1.4, AE withdrawals, but no AE is coded STP. In Listing 15.1.1 (AEs on therapy) the patient has no AE with an action of study medication stopped. The patient does not appear in Table 15.1.5.1, AEs leading to withdrawal. However, in Table 13.3.1b (reasons for withdrawal), the patient is coded as having withdrawn due to an adverse event because the investigator indicated that the reason for study conclusion was an adverse event.
Table 15.3.1.3 and 15.3.1.4, Section 12; Listing 15.3.1, Appendix D	Patient 716.167.25696 had an adverse event of moderately severe lymphocytosis (verbatim: high lymphocytes) on Day 182, 14 days after the last dose of open-label study medication. The value of concern (13 x 10^9/L) is not reported in the laboratory tables and listings.
Table 15.1.5.1, Section 12	Patient 716.040.27112 had an adverse event (infection) that occurred on Day 100 with a duration of 2 days with an action of study medication stopped. The patient is therefore included in Table 15.1.5.1 as withdrawing because of an adverse event. However, the investigator did not state that the patient's reason for study conclusion was adverse event, and according to Table 13.3.1b and Listing 13.3.1b, patient 716.040.27112 completed the study.
Table 15.1.5.1, Section 12	Patient 716.019.25753 had an adverse event (vomiting) that occurred on Day 3 with a duration of 4 days, with an action of study medication stopped. The patient is therefore included in Table 15.1.5.1 as withdrawing because of an adverse event. However, the investigator did not state that the patient's reason for study conclusion was adverse event, and according to Table 13.3.1b and Listing 13.3.1b, this patient was withdrawn on Day 29 for "other" reason, given as "did not want to give blood."

Table/Listing	Error
Table 15.1.5.1, Section 12	Patients 716.010.25606 and 716.176.25794 withdrew due to an AE, but their corresponding adverse events with an action of "study medication stopped" occurred during the Taper Phase. Patient 716.010.25606 had an AE of hostility coded STP 25 days after the last dose of study medication. Patient 716.176.25794 had an AE of syncope coded STP 6 days after the last dose of study medication. These patients are not included in the summary table of AE withdrawals.
Listing 15.1.2, Appendix D	Patient 716.159.25798 is listed as having an adverse event of serotonin discontinuation syndrome on Day 351, 176 days after the last day of open-label study medication. Per investigator query, the adverse event started on Day 2 of the open-label study and lasted 3 days.
Table 15.1.1.0.3, Section 12; Listing 15.1.1, Appendix D	Twenty patients (13 in the acute-study paroxetine group and 7 in the acute-study placebo group) had one or more gender-non-specific adverse events during their acute-study Treatment Phase (including taper) that were ongoing at the Study 716 baseline but were not entered into the Study 716 database. The convention was that any unresolved ongoing adverse event was to be transcribed from the acute-study CRF to the applicable baseline 716 CRF page. Adverse events for these patients were not transcribed by the investigators onto the Study 716 CRF from the acute-study CRF and therefore are not included in the table of ongoing AEs or the listing of all AEs.
Tables 15.3.1.2, 15.3.1.3, 15.3.1.4, 15.3.4, Section 12; Listings 15.3.1, 15.3.2, 15.3.3, Appendix D	Some laboratory values should have been flagged as being of clinical concern (but were not flagged) in the Study 716 interim RAP output. They are correct in the final output. The following clinical concern flags were incorrectly omitted from the interim output:

Parameter	Acute-study paroxetine	Acute-study placebo
Low hemoglobin	2	7
Low WBC	0	2
Low Platelets	0	1
High Potassium	1	0
High SGPT	0	2

Table/Listing	Error
Interim Table 15.1.5.1, Section 12; Interim Listing 15.1.4, Appendix D; Interim Table 15.1.8, Section 12; Interim Listings 15.1.1 and 15.1.3.2, Appendix D	Patient 716.020.25458 had a serious adverse event of psychosis that led to withdrawal from the study. reported at Study 716 Baseline. The event was reported in the interim report for this study as having led to a dose reduction.
Listing 13.9.1, Appendix B; Listings 15.1.1 and 15.1.3.2, Appendix D	Patient 716.025.25802 is listed as taking citalopram for an adverse event of homicidal mutilation to self. No corresponding adverse event is listed in the adverse event table.