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Paroxetine

BRL-029060

A 16 Week Double-Blind, Placebo Controlled Study to Investigate the Efficacy and Tolerability of Paroxetine in the Treatment of Children and Adolescents with Social Anxiety Disorder/Social Phobia

676

Final Clinical Report

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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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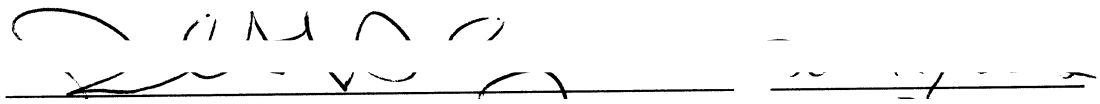

Report Synopsis

Study Title: A 16 Week Double-Blind, Placebo Controlled Study to Investigate the Efficacy and Tolerability of Paroxetine in the Treatment of Children and Adolescents with Social Anxiety Disorder/Social Phobia (29060/676)

Investigators and Centers: Psychiatrist investigators from 22 centers in the US, 10 in South Africa, 4 in Canada and 2 in Belgium participated.

Publication: None published as of the date of this report.

Study Dates: The first dose of randomized study medication was administered on 30 November 1999 and the last dose of study medication (including taper) was taken on 19 October 2001.

Objectives: The primary objective was to investigate the efficacy of paroxetine compared to placebo in the treatment of children and adolescents with Social Anxiety Disorder / Social Phobia as measured by the proportion of responders based on the Clinical Global Impression Global Improvement item at the Week 16 last observation carried forward (LOCF) endpoint.

The secondary objective was to investigate the safety and tolerability of paroxetine in the treatment of children and adolescents with Social Anxiety Disorder/Social Phobia.

Study Design: This was a 16-week, multicenter, randomized double-blind placebo-controlled parallel-group, flexible-dose trial in children (8–11 years) and adolescents (12–17 years).

After screening, eligible patients entered the Treatment Phase and received paroxetine or placebo for 16 weeks. There were 9 post-baseline visits, which occurred at Weeks 1, 2, 3, 4, 6, 8, 10, 12 and 16. Upon completion of the Treatment Phase or upon early withdrawal, study medication was gradually reduced over a maximum of four weeks during the Taper Phase. A safety follow-up visit was performed 14 days ± 3 days after the last dose of taper medication.

Study Population: Male and female outpatients, 8-17 years of age, who met Diagnostic and Statistical Manual Version IV (DSM-IV) criteria for Social Anxiety Disorder (300.23) and also met all other entrance criteria.

Treatment and Administration: Paroxetine was supplied as blue, size 1, hard gelatin capsules. Batch numbers for paroxetine were N99194 (5 mg); N98187 (10 mg); N98080 (15 mg); N98189 (20 mg); or N98058 (25 mg). The placebo capsules (Batch no. N99102) were identical in appearance. All bottles contained sufficient medication for one week of treatment plus an overage of 3 days medication (20 capsules/bottle). Therefore, one bottle was dispensed for Weeks 1, 2, 3 and 4, two bottles for Weeks 5-6, 7-8, 9-10 and 11-12 and four bottles for Weeks 13-16. The Taper Phase medication (Weeks 17, 18, 19 and 20) was also supplied as single bottles, each bottle containing sufficient medication for one week.

Eligible patients were randomly assigned (1:1) to paroxetine or placebo and were instructed to take 2 capsules each morning, with food. For the first week, all patients received dose level (DL) 1 (10 mg/day) of paroxetine or matching placebo. The dose could then be up-titrated in single dose level (10 mg/day) increments no more frequently than every seven days, up to a maximum of DL 5 (50 mg/day on paroxetine), according to clinical response and tolerability. Dose escalation was permitted only at the clinic visit. One dose reduction to the next lower dose level consequent to an AE was permitted. Patients who were unable to tolerate DL 1 or who required more than one dose reduction were withdrawn from the study. A gradual reduction of study medication was required for all patients on DL 2 or higher at the end of the study.

Evaluation Criteria

Efficacy Parameters: The primary efficacy parameter was the proportion of responders based on a Clinical Global Impression (CGI) Global Improvement score of 1 or 2 at the Week 16 LOCF endpoint. All other efficacy parameters were assessed as the change from baseline at the Week 16 LOCF endpoint.

The secondary efficacy parameters included change from baseline on the CGI Severity of Illness, the Liebowitz Social Anxiety Scale for Children and Adolescents (LSAS–CA), the Dalhousie Generalized Social Anxiety Disorder Scale for Adolescents (D–GSADS–A: ages 11 to 18 only); the Social Phobia Anxiety Inventory (SPAI–C: ages 8 years to 13 years 11 months; SPAI: ages 14 years to 17 years 11 months); and the Global Assessment of Functioning Scale (GAF).

An additional variable of interest was the Children's Depression Rating Scale–Revised (CDRS–R).

Safety Parameters: Safety was assessed through routine adverse event (AE) monitoring, vital sign (including body weight) determinations, and clinical laboratory evaluations. In addition, physical examinations were performed at Screening and Week 16/Early Withdrawal.

Pharmacokinetic Parameters: Pharmacokinetic (PK) blood samples were drawn from consenting patients at Weeks 4 and 16 (or at early withdrawal from the study, if applicable) for paroxetine assay. These results will be reported separately, combined with similar data from studies 701 (Major Depressive Disorder) and 704 (Obsessive Compulsive Disorder) to examine the effects of dose and selected demographic characteristics on paroxetine steady-state plasma concentrations in the pediatric population.

Statistical Methods: All patients who were randomized to double-blind medication, received at least one dose of randomized study medication and had at least one post-baseline safety (including AEs) or efficacy assessment were included in the intention-to-treat (ITT) population. Statistical conclusions concerning the efficacy of paroxetine were made using the last observation carried forward (LOCF), the observed cases (OC) and the 70% LOCF datasets, based on the ITT population. All hypothesis tests were two-sided. The effect of interactions was assessed at the 10% level of significance. All other statistical tests were performed at the 5% level of significance. Binary data were analyzed using logistic regression with results presented as odds ratios, 95% confidence intervals around the odds ratios, and associated p-values. The change from Baseline in CGI Severity of Illness was analyzed using the Wilcoxon rank sum test with results presented as the median difference and p-value for the difference. Continuous efficacy variables were analyzed by analysis of variance techniques with results presented as point estimates, 95% confidence intervals for the differences, and associated p-values.

Analysis of the primary efficacy variable was performed in the ITT population with and without data from patients at Center 001 because the investigator broke the blind at the end of the study. Removal of these data did not change the findings or conclusions from the study. Results presented in this report include the data from this center.

Patient Disposition and Key Demographic Data: A total of 425 patients were screened and 322 were randomized, 165 (51.2%) to paroxetine and 157 (48.8%) placebo. Of these, 319 patients were included in the ITT population. Three randomized patients were not included in the ITT population: one paroxetine patient and one placebo patient had no post-baseline assessment or AE; one paroxetine patient who was randomized in error at the Screening Visit had no baseline assessment and the post-baseline assessment was after the last dose of medication. The percentage of randomized patients withdrawn from the study was slightly higher for the placebo group (34.4%, 54/157) than for the paroxetine group (25.5%, 42/165). The primary reasons for withdrawal in the ITT population were protocol deviation (6.7%, 11/163) in the paroxetine group and lack of efficacy (14.1%, 22/156) in the placebo group.

Patient Disposition

Study Stage/Population	Treatment Group		Total
	Paroxetine n (%)	**Placebo n (%)**	**n (%)**
Screened	–	–	425
Randomized	165 (100.0)	157 (100.0)	322 (100.0)
Withdrawn	42 (25.5)	54 (34.4)	96 (29.8)
Completed the study	123 (74.5)	103 (65.6)	226 (70.2)
Intention-to-Treat*	163 (98.8)	156 (99.4)	319 (99.1)
Per-Protocol**	124 (75.2)	110 (70.1)	234 (72.7)

* Randomized patients who received at least one dose of double-blind medication and who had at least one post-baseline efficacy or safety assessment

** Patients in the ITT population not identified as protocol violators during blind review

The ITT population comprised 28.5% children and 71.5% adolescents. There were no marked imbalances between the treatment groups in any of the patient characteristics, although there was a greater proportion of females in the paroxetine group and a greater proportion of males in the placebo group. The percentage of patients with comorbid psychiatric illness was slightly greater in the paroxetine group (56.4%, 92/163) than in the placebo group (48.7%, 76/156).

The proportion of patients in each severity rating for Social Anxiety Disorder based on the ADIS for DSM-IV:C was similar between the two treatment groups at Screening. Baseline severity scores for CGI–S and LSAS were also similar between the two treatment groups.

Demography and Baseline Characteristics (ITT Population)

	Treatment Group		
	Paroxetine	**Placebo**	**Total**
Age Group: Total			
Males: Females	71:92	89:67	160:159
Mean age (SD): years	13.0 (2.81)	13.3 (2.73)	13.1 (2.77)
Caucasian: n (%)	139 (85.3)	131 (84.0)	270 (84.6)
Baseline LSAS mean (SD)	77.6 (28.72)	77.7 (7.05)	77.6 (27.87)
Baseline CGI-S: Mildly ill, n (%)	4 (2.5)	6 (3.8)	10 (3.1)
Moderately ill, n (%)	74 (45.4)	69 (44.2)	143 (44.8)
Markedly ill, n (%)	61 (37.4)	61 (39.1)	122 (38.2)
Severely/among the most extremely ill, n (%)	23 (14.1)	19 (12.2)	42 (13.2)
Age Group: Children			
Males: Females	25:21	23:22	48:43
Mean age (SD): years	9.3 (1.26)	9.8 (1.15)	9.5 (1.22)
Caucasian: n (%)	38 (82.6)	41 (91.1)	79 (86.8)
Baseline LSAS	70.7 (31.00)	71.2 (28.65)	70.9 (29.66)
Baseline CGI-S: Mildly ill, n (%)	1 (2.2)	3 (6.7)	4 (4.4)
Moderately ill, n (%)	25 (54.3)	20 (44.4)	45 (49.5)
Markedly ill, n (%)	16 (34.8)	20 (44.4)	36 (39.6)
Severely/among the most extremely ill, n (%)	3 (6.5)	2 (4.4)	5 (5.5)
Age Group: Adolescents			
Males: Females	46:71	66:45	112:116
Mean age (SD): years	14.5 (1.67)	14.7 (1.71)	14.6 (1.69)
Caucasian: n (%)	101 (86.3)	90 (81.1)	191 (83.8)
Baseline LSAS	80.3 (27.49)	80.3 (26.04)	80.3 (26.74)
Baseline CGI-S: Mildly ill, n (%)	3 (2.6)	3 (2.7)	6 (2.6)
Moderately ill, n (%)	49 (41.9)	49 (44.1)	98 (43.0)
Markedly ill, n (%)	45 (38.5)	41 (36.9)	86 (37.7)
Severely/among the most extremely ill, n (%)	20 (17.1)	17 (15.3)	37 (16.2)

Efficacy Results

Datasets: Primary inferences from efficacy analyses were based on the ITT population at Week 16 LOCF. In addition, the primary efficacy variable was analyzed using the per-protocol (PP) population. The Week 16 OC and the 70% LOCF datasets were used to assess the robustness of the conclusions from the primary analysis.

Primary Efficacy Variable: Analysis of the primary endpoint provided statistically significant evidence that paroxetine was more efficacious than placebo in the treatment of Social Anxiety Disorder in the population under study. The proportion of patients treated with paroxetine who were CGI Global Improvement responders at Week 16 LOCF endpoint was 77.6% (125/161) and the proportion of placebo-treated patients was 38.3% (59/154). The odds of being a CGI Global Improvement responder on paroxetine compared to placebo at Week 16 LOCF for the intention-to-treat population were 7.02 (95% CI: [4.07, 12.11], $p < 0.001$), showing a statistically significant benefit of paroxetine over placebo. This conclusion was supported by the Week 16 LOCF analysis in the PP population (odds ratio 8.41, 95% CI: [4.36, 16.21], $p < 0.001$) and by the Week 16 OC and 70% LOCF analyses in both populations. There was no evidence of any statistically significant treatment by covariate interactions for age group, gender, CGI Severity of Illness baseline scores, or country grouping.

Secondary Efficacy Parameters: Statistically significant differences favoring paroxetine over placebo were achieved in all secondary parameters in both the LOCF and OC datasets.

Safety Results

Adverse Events: In the ITT population, 144 (88.3%) patients in the paroxetine group and 125 (80.1%) in the placebo group reported gender-non-specific, Treatment Phase-emergent AEs. The most common (>10%) gender-non-specific AEs on paroxetine were headache, infection, respiratory disorder, abdominal pain, asthenia, insomnia, somnolence, rhinitis, and nausea, while the most common AEs on placebo were headache, infection, respiratory disorder, and rhinitis

The only gender-specific AEs reported were dysmenorrhea in 5 female patients on paroxetine and 4 female patients on placebo, amenorrhea in one female patient on paroxetine, and abnormal ejaculation in one male patient on paroxetine. Insomnia, decreased appetite, and vomiting occurred at an incidence ≥5% and at least twice as frequently in patients receiving paroxetine than in those receiving placebo. In the paroxetine group, the overall incidence of AEs was approximately the same in children and adolescents (84.6% vs. 83.5%, respectively).

Most AEs were mild to moderate in intensity. The most frequent (>10%) AEs reported as related or possibly related to study medication in the paroxetine group were headache, asthenia, insomnia, and somnolence. These AEs, with the exception of headache, had a related or possibly related incidence in the paroxetine group that approached or exceeded twice that in the placebo group. During the Treatment Phase, 17.2% of patients in the paroxetine group (28/163) and 38.0% of patients in the placebo group (6/156) had AEs that led to dose reductions.

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

Three patients in the paroxetine group and one in the placebo group reported a serious adverse event after the first dose of randomized medication, including the 30-day period following the last dose of study medication. All of the SAEs were considered unrelated to study medication, except for unintentional overdose in the one placebo patient. Anemia, which also led to withdrawal from the Treatment Phase, occurred in the paroxetine group. Serious adverse events for the other 2 patients in the paroxetine group occurred post-treatment: fear and depression related to Social Anxiety Disorder (14 days post-treatment) and injury (broken arm) (20 days post-treatment).

Withdrawals Due to Adverse Events: In total, 5.5% (9/163 of patients receiving paroxetine, including 2 children) and 1.3% (2/156, both children) of patients receiving placebo were withdrawn during the Treatment Phase due to an AE. The only AE leading to withdrawal that occurred in more than 1 patient in the same treatment group was manic reaction, experienced by 2 patients in the paroxetine group. One adolescent in each treatment group withdrew due to an AE during the Taper Phase.

Vital Signs: Twenty-two patients on paroxetine and 17 patients on placebo had an on-therapy absolute value and change in value in one or more of the vital signs that met the criteria for potential clinical concern. Three paroxetine patients and one placebo patient had vital sign values of concern that were reported as AEs by the investigator, all for increased body weight. Mean changes in all vital sign parameters were very small and generally comparable between groups.

Laboratory Tests: Twenty-five patients on paroxetine and 15 patients on placebo had an on-therapy value in one or more of the laboratory parameters that met the criteria for potential clinical concern. The most common value of concern was low hematocrit (13 paroxetine patients and 6 placebo patients). One patient had a laboratory value of concern that was reported as an AE by the investigator, a patient in the paroxetine group with high neutrophils and AEs of leukocytosis and leukopenia, considered probably unrelated to study medication. There were no substantial differences between the paroxetine and the placebo groups in any mean laboratory values at Week 16, at endpoint, or in the change from Baseline at endpoint.

Conclusions: Assessment of the primary efficacy variable, the proportion of responders based on the Clinical Global Impression–Global Improvement item at the Week 16 last observation carried forward (LOCF) endpoint, provided statistically significant and clinically relevant evidence that paroxetine was more efficacious than placebo in treating children and adolescents with Social Anxiety Disorder. This conclusion was supported by statistically significant results favoring paroxetine over placebo for all secondary efficacy variables. This conclusion was further supported by statistically significant results from analysis of all efficacy variables using the Week 16 Observed Cases (OC) dataset and the 70% LOCF dataset.

Data from this study demonstrated that paroxetine was safe and generally well tolerated compared to placebo when used in children and adolescents with Social Anxiety Disorder over a period of up to 16 weeks over the dosage range of 10-50 mg/day. There were no serious unexpected adverse events or findings in laboratory tests or vital signs. There was some indication that the AE profile in children may differ slightly from that in adolescents.

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List of Abbreviations & Definitions

Abbreviation	Unabridged Term
ADECS	Adverse Drug Experience Coding System (based on COSTART system)
ADHD	Attention-Deficit/Hyperactivity Disorder
ADIS for DSM-IV:C	Anxiety Disorders Interview Schedule for DSM-IV–Child and Parent
AE	adverse event
Ag	Agoraphobia
ALT	alanine aminotransferase (SGPT)
ART	Adverse Reaction Terminology
AST	aspartate aminotransferase (SGOT)
ATC	Anatomical Therapeutic Chemical Code
BMI	body mass index
BP	blood pressure
bpm	beats per minute
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
CI	confidence interval
CNS	central nervous system
CRF	Case Report Form
CSR	clinician's severity rating
CV	curriculum vitae
D–GSADS–A	Dalhousie Generalized Social Anxiety Disorder Scale for Adolescents
DL	dose level
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, fourth edition
ECDEU	Early Clinical Drug Evaluation Unit
ECG	electrocardiogram
eCRF	Electronic Case Report Form

Abbreviation	Unabridged Term
ECT	electroconvulsive therapy
FDA	Food and Drug Administration
g	gram
GAD	Generalized Anxiety Disorder
GAF	Global Assessment of Functioning scale
GCP	Good Clinical Practice
HDPE	high density polyethylene
IRB	Institutional Review Board
ITT	intention-to-treat
L	liter
LOCF	last observation carried forward
LOE	lack of efficacy
LSAS–CA	Liebowitz Social Anxiety Scale for Children and Adolescents
MAOI	monoamine oxidase inhibitor
MDD	Major Depressive Disorder
MEDRA	Medical Dictionary for Regulatory Affairs
mmHg	millimeters mercury
NEC	Not else classified
NOS	Not otherwise specified
NSRI	noradrenergic serotonin reuptake inhibitor
OC	observed cases
OCD	Obsessive Compulsive Disorder
OR	Odds Ratio
pmol	picomole
PP	Per Protocol
PTSD	Post Traumatic Stress Disorder
RDE	Remote Data Entry
SAE	serious adverse event
SAS	Statistical Analysis System
SD	Standard Deviation
SE	standard error
SGOT	serum glutamic oxaloacetic transaminase
SGPT	serum glutamic pyruvic transaminase

Abbreviation	Unabridged Term
SOPs	Standard Operating Procedures
SPAI	Social Phobia and Anxiety Inventory
SPAI–C	Social Phobia and Anxiety Inventory for Children
SSRI	selective serotonin reuptake inhibitor
TCA	tricyclic antidepressant
TSH	thyroid stimulating hormone
WBC	white blood cell count
WHO	World Health Organization
WRC	Worldwide Regulatory Compliance

Term	Definition
Baseline	The last available value before administration of active study treatment

1 Introduction

Paroxetine (Paxil®, Seroxat®, Deroxat®, Aropax®), a phenylpiperidine compound, is a selective serotonin reuptake inhibitor (SSRI) approved for use in adults in the treatment of Major Depressive Disorder (MDD), Obsessive Compulsive Disorder (OCD), Panic Disorder, Social Anxiety Disorder, Generalized Anxiety Disorder (GAD), and Post-Traumatic Stress Disorder (PTSD). Due to the success of paroxetine in the treatment of mood and anxiety disorders in adults, a series of studies in pediatric patients with depression, OCD, or Social Anxiety Disorder were also undertaken. This clinical study report presents the results of a multicenter, randomized, double-blind, placebo-controlled study that was conducted to evaluate the efficacy and safety of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

Social Anxiety Disorder has been established as a distinct anxiety disorder, both in the psychiatric literature and in the fourth edition of the Diagnostic and Statistical Manual (DSM-IV). Social Anxiety Disorder is recognized as having an early age of onset [1], and although reports have estimated prevalence of 1-2% in children and adolescents according to DSM-III criteria [2], the prevalence of Social Anxiety Disorder in children and adolescents is considerably higher when assessed according to DSM-IV criteria. Social isolation in children and adolescents and its resulting detrimental effects have often been reported [3][4]. The similarity between the clinical manifestations of Social Anxiety Disorder in children, adolescents and adults clearly demonstrates that this disorder can persist throughout childhood and adolescence and into adulthood. Indeed, many adults with Social Anxiety Disorder report that they have been socially anxious “all their lives” [5]. Adults with social anxiety suffer significant emotional, social and occupational maladjustment, and their incidence of comorbid depression, substance abuse and suicidal ideation is greatly increased. It is clear, therefore, that a safe and effective treatment of Social Anxiety Disorder in children/adolescents would be of considerable benefit.

Paroxetine has been approved for the treatment of Social Anxiety Disorder in adults in 74 countries worldwide, including the USA, Canada, Australia, Germany and Sweden. Although the effectiveness of pharmacologic treatment of Social Anxiety Disorders in adults is well established, very few investigations into its pharmacological treatment in pediatric patients have been conducted. A study of fluoxetine in children with selective mutism (considered to be a severe manifestation of Social Anxiety Disorder) did not show clear efficacy over placebo [6]. In small open-label studies, both sertraline and fluoxetine were

reported to improve symptoms of social anxiety in pediatric patients [7] [8] [9], and fluvoxamine has been reported to be effective in pediatric patients with mixed anxiety disorders (including Social Anxiety Disorder) [10]. However, there have been no placebo-controlled trials published to date that studied only children or adolescents with Social Anxiety Disorder as their predominant psychiatric illness.

One of the consequences of the fact that this disorder has only recently received much recognition and attention in children and adolescents is that there are no validated, clinician-rated scales available to assess children and adolescents with Social Anxiety Disorder. For that reason, the primary endpoint selected for this study was the Clinical Global Impression–Global Improvement item. However, several disorder-specific scales have been included in this study as secondary endpoints. Two of these scales, the Liebowitz Social Anxiety Scale for Children and Adolescents (LSAS–CA) and the Dalhousie Generalized Social Anxiety Disorder Scale for Adolescents (D-GSADS-A), are currently in the process of being validated.

Paroxetine has previously demonstrated an acceptable safety and tolerability profile in pediatric patients with depression or OCD in four double-blind, placebo-controlled, multicenter studies (three studies in the treatment of Major Depression [11] [12] [13] and one in the treatment of Obsessive Compulsive Disorder [14]). The pooled intention-to-treat (ITT) population from these four studies consisted of 861 patients who received either paroxetine or placebo. Of these, 474 patients were randomized to paroxetine (10-50 mg/day). In all four studies paroxetine was well tolerated, with no unexpected findings regarding adverse events (AEs), vital signs, or laboratory parameters. Paroxetine is expected to be similarly well tolerated in pediatric patients with social anxiety disorder.

2 Objectives

2.1 Primary Objective

The primary objective was to investigate the efficacy of paroxetine compared to placebo in the treatment of children and adolescents with Social Anxiety Disorder/Social Phobia as measured by the proportion of responders based on the Clinical Global Impression–Global Improvement (CGI-I) item at the Week 16 last observation carried forward (LOCF) endpoint.

2.2 Secondary Objective

The secondary objective was to investigate the safety and tolerability of paroxetine in the treatment of children and adolescents with Social Anxiety Disorder / Social Phobia.

3 Methodology

3.1 Study Design

This was a multicenter, randomized, double-blind, placebo-controlled, trial with a 16-week Treatment Phase. Children (ages 8-11) and adolescents (ages 12-17) who met DSM-IV diagnostic criteria for Social Anxiety Disorder (300.23) and who fulfilled the entrance criteria entered a 1-week Screening Phase. At the end of this period, Baseline evaluations were performed to determine eligibility for randomization to the Treatment Phase of the study.

Eligible patients were randomly assigned (1:1) to paroxetine or placebo and entered the Treatment Phase. The nine possible post-baseline Treatment Phase visits were to occur at Weeks 1, 2, 3, 4, 6, 8, 10, 12 and 16. Upon completion of the Treatment Phase or upon early withdrawal, study medication was gradually reduced over a maximum of four weeks during the Taper Phase. A safety follow-up visit was performed 14 days ± 3 days after the last dose of study medication (including taper medication). The total maximum duration of the study was 23 weeks (1 week Screening Phase, 16-week Treatment Phase, maximum 4-week Taper Phase, and a safety follow-up visit 2 weeks after the Taper Phase).

The dose of active medication ranged from 10 to 50 mg daily. Blinding of study medication was maintained by referring to the daily medication dose as dose levels. All patients in the Treatment Phase initiated therapy at Dose Level (DL) 1 (10 mg/day paroxetine or matching placebo) for Week 1 of the Treatment Phase. The dosage could thereafter be increased at each visit by 10 mg/day (1 dose level) increments no more frequently than every 7 days. This increase in dose was at the discretion of the investigator, based on clinical response and tolerability. The maximum dose allowed was 50 mg/day. Dose escalation was permitted only at the clinic visit. A dose reduction to the next lower dose level consequent to an AE was permitted after Week 2. Treatment occurred over a period of 16 weeks followed by a Taper Phase of up to 4 weeks. See Section 3.5.1, Study Medication, and Section 3.5.3, Dosage and Administration, for more details.

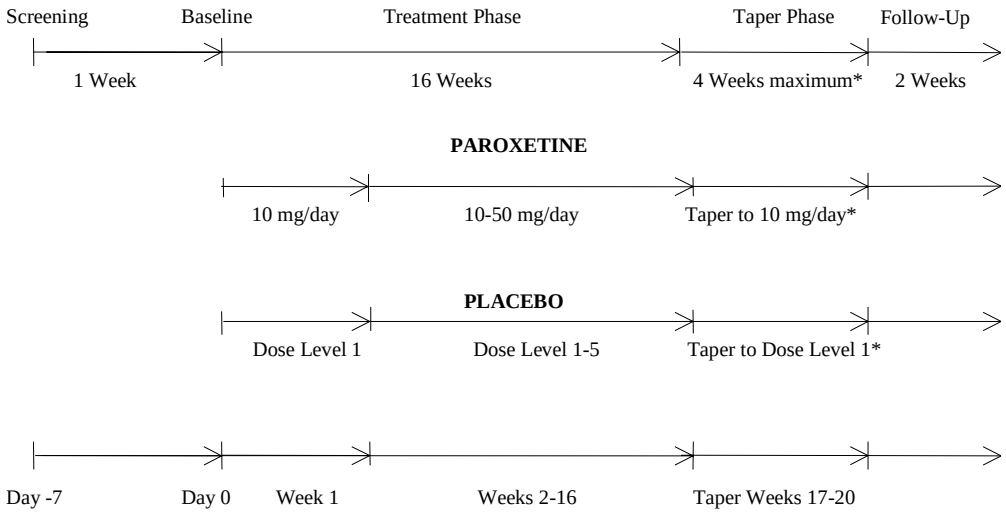
A gradual reduction of dosing at the conclusion of the Treatment Phase (for treatment completers as well as early withdrawals) was required for all patients except for those who completed the 16-week Treatment Phase at DL 1 (10 mg/day paroxetine or matching placebo) or who were withdrawn from the study while at DL 1. All patients who completed the Treatment Phase (or who were withdrawn

from the study) while at DL 2, 3, 4, or 5 (i. e., 20, 30, 40, or 50 mg/day, respectively) were dispensed double-blind Taper Phase medication and were down-titrated at the rate of 10 mg/day per week until they finished one week of Taper Phase dosing at DL 1.

Children and adolescents participating in the study and their parents received psychoeducational material regarding the nature and course of the disorder and offered suggestions for self-help [15] [16] [17]. Extended discussions or more specific cognitive or behavioral interventions were not permitted.

The study design is depicted in Figure 1:

Figure 1 Study Design for 676



* The Taper Phase duration is dependent on ending Dosage Level at Week 16 or Early Withdrawal.

3.1.1 Protocol Amendments

Protocol 29060/676 was finalized on 24 August 1999. The protocol was subsequently amended twice over the course of the trial and modified three times.[1] Both amendments and all three modifications were relatively minor in scope and/or administrative in nature.

Amendment 1, dated 3 September 1999, was issued to modify the Taper Phase so that patients who titrated down to 10 mg could be removed from the study after they had been maintained on the 10 mg dose for just one week.

[1] Appendix A contains the protocol amendments and modifications.

Amendment 2, dated 3 April 2000 was issued to stipulate a minimum 5-week washout period for patients who took fluoxetine prior to study start (4 weeks prior to the Screening Visit). It also stipulated washout periods for any medications with known sedative-like side effects (e. g., some antihistamines), for any CNS-active herbal/natural supplements, and for MAOIs.

Modification 1, dated 24 August 1999, was issued to modify the Sample Informed Consent to gain consent from both the child and the child's parent or guardian. It also added to the consent form the information that the patient would be tested for drugs of abuse during the screening visit.

Modification 2, dated 25 January 2000, corrected the age ranges for the use of the Social Phobia and Anxiety Inventory (SPAI) and of the Social Phobia and Anxiety Inventory for Children (SPAI–C).

Modification 3, dated 3 April 2000, clarified the second "Comparisons of Interest" paragraph in the Data Evaluation Section so that it applied to all data comparisons. It also clarified the statement in the section on "Covariates for Adjustment in the Efficacy Analyses" that if the variable is not linearly associated with response it would not be included. In addition, it clarified the definition of the intention-to-treat (ITT) population and clarified how the variables of blood pressure, heart rate and weight would be evaluated.

3.2 Investigators

It was planned that 328 patients in the United States, Canada, South Africa and Belgium would be randomized (164 patients per treatment arm with 130 evaluable patients per treatment arm). Each center aimed to enroll a minimum of 10-20 patients; therefore, approximately 20-25 centers minimum in the United States, Canada, South Africa and Belgium were expected to participate. However, 38 centers (22 centers in the US, 4 in Canada, 10 in South Africa and 2 in Belgium) participated in this study. Center 16 in the United States screened but did not randomize patients.

Table 1 presents a list of the principal investigators, their center numbers, their affiliated institution and their geographic location. (Centers 8, 18 and 25 in the United States are excluded because they discontinued before enrolling any patients.) These investigators were selected based on their experience with the patient population, their ability to conduct the study according to Good Clinical Practice (GCP) standards, and their ability to enter eligible patients. Appendix A

contains copies of curricula vitae (CVs) of all principal investigators providing details of the investigators' qualifications and experience.

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

Investigators	Center	Affiliated Institution	City	State
United States				
xxxxxx, xxxxxx, M.D.; xxxxxxx, xxxxx,M.D.; xxxxxx, xxxxxxx, Ph.D.	001	xxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxx xxxxxx	xxxxxxx xxxxxx	xx
xxxxxxx, xxxxx, M.D.; xxxxxxxxxxx, xxxxx, M.D.	002	xxxxxxxxxxxxxxx xxxxx	xxxxxxx	xx
xxxxxx, xxxxx, M.D.	003	xxxxxxxxxxxxxxxxxxxxx xxxxxxxxx	xxxxxxxx	xx
xxxxx, xxxxx, M.D.	004	xxxxxxxxxx xxxxxxxx xxxxxxxxxxx xxxxx xxxxxx	xxxxx	xx
xxxxx, xxxxx, M.D.; xxxxx, xxxxx, M.D.	005	xxxxx xx xxxxxxxxxx xxxxxxxxx xxxxx xxxxxx	xxxxxxxx	xx
xxxxxxxx, xxxx, M.D., MPH	006	xxxxxxxx xxxxx xxxxx, xxxx. xx xxxxxxxx	xxxxxxx	xx
xxxx, xxxxxx, M.D., MPH	007	xxx xxxxxxx xxxxxx, xxx.	xxxx xxxxxx	xx
xxxxx, xxxxx, M.D.	009	xxxxxx xxxxxx xxxxxxxx, Inc.	xxxxxxxx	xx

* Center 016 Screened but did not enroll any patients

(Table continues)

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

Investigators	Center	Affiliated Institution	City	State
	010	Medicine	Atlanta	GA
	011		New York	NY
	012	Investigations, Inc.	Lake Oswego	OR
	013	Behavioral Health	St. Paul	MN
		Health	Seattle	WA
		Dept. of Psychiatry	Phoenix	AZ
	016	College of Medicine	Cincinnati	OH
	017	Psychiatric Center	Tampa	FL
MBA	019		Galveston	TX
Ph.D.	020	Philadelphia	Philadelphia	PA
M.D.	022	Johns Hopkins Medical Institutions	Baltimore	MD
	023	Massachusetts General Hospital	Boston	MA
M.D.		Corporation	Houston	TX
Canada				
	101		Vancouver	BC

* Center 016 Screened but did not enroll any patients

(Table continues)

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

Investigators	Center	Affiliated Institution	City
Canada (continued)			
	102	Centre	Hamilton ON
Belgium			
	300		Yvoir
M.D.			
South Africa			
	200		
M.Med.			
	203		
M.Med.			
	204		
	205		
Prof.			fontein
	206		
M.Med.			
	208	l	Johannes-burg
			fontein

* Center 016 Screened but did not enroll any patients

3.3 Ethics

The study was conducted in accordance with Good Clinical Practice Guidelines[2], 21 CFR Parts 50 and 56, and the Declaration of Helsinki as amended in Somerset

[2] As stated in EU CPMP (European Union Committee for Proprietary Medicinal Products) for European multi-national studies and 21 CFR (Code of Federal Regulations) for studies filed to the US IND.

West, Republic of South Africa (October 1996). The protocol and statement of informed consent[3] were approved by an Institutional Review Board (or Ethics Committee) prior to each center's initiation. Written informed consent from each patient's parent or legal guardian and patient assent to participate were obtained prior to entry into the study. Electronic Case Report Forms (eCRFs) were provided for each patient's data to be recorded.

The IRBs were informed by the investigators of the protocol amendments and modifications. The IRBs were also informed 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.

3.4 Eligibility Criteria

This study enrolled male and female outpatients (8 to 17 years of age) who met DSM-IV criteria for Social Anxiety Disorder (DSM-IV 300.23) as their predominant psychiatric diagnosis. Patients were screened for the presence of Social Anxiety Disorder using the Anxiety Disorders Interview Schedule for DSM-IV (ADIS for DSM-IV:C) semi-structured clinical interview. The complete list of entrance criteria are provided below.

3.4.1 Inclusion Criteria

Patients were to be included in the study if they satisfied all of the following inclusion criteria:

1. Male or female outpatients with a primary diagnosis of Social Anxiety Disorder according to DSM-IV (300.23), confirmed by the ADIS for DSM-IV:C semi-structured clinical interview.

2. The patient must have been greater than or equal to 8 years old and less than 18 years old at the Screening Visit.

3. The patient (and parent/guardian where appropriate) must have given written informed consent/assent.

[3] Appendix A contains the protocol; the sample informed consent is an appendix to the protocol.

3.4.2 Exclusion Criteria

Patients meeting any of the following exclusion criteria were to be excluded from the study:

1. Patients with a clinically predominant Axis I disorder (other than Social Anxiety Disorder), such as dysthymia, simple phobia, OCD, Panic Disorder, body dysmorphic disorder, or Attention-Deficit/Hyperactivity Disorder (ADHD)

2. Patients having a concurrent major depressive episode

3. Patients with any history of a psychotic episode, including schizophrenia and bipolar disorder, or a pervasive developmental disorder

4. Patients diagnosed with substance abuse or dependence in the 3 months prior to the screening visit

5. Patients with hypersensitivity to SSRIs

6. Patients who were pregnant or lactating, confirmed by positive pregnancy test where appropriate

7. Patients who had electroconvulsive therapy (ECT) within 3 months of screening

8. Patients who were a serious suicidal or homicidal risk

9. Patients taking concurrent MAOIs or who had taken MAOIs within 4 weeks prior to the Screening Visit

10. Patients taking concurrent psychoactive medications, or who had taken psychoactive medications within the time frames specified below prior to the Screening Visit:

    - Depot neuroleptics–at least 12 weeks

    - Fluoxetine–at least 4 weeks

    - Antidepressants other than MAOIs or fluoxetine (e. g., TCAs, SSRIs, noradrenergic serotonin reuptake inhibitors [NSRIs]), lithium, and oral antipsychotics–at least 14 days

- Hypnotics, benzodiazepines, and all other sedatives (including sedating antihistamines)–5 half-lives or at least 14 days, whichever is longer

- Any CNS-active herbal/natural supplement or preparation known or thought to have any psychoactive effects–at least 14 days

11. Patients requiring concurrent psychotherapy. Patient/physician interactions were to be restricted to the psychoeducation detailed in Appendix O of the Protocol, Guidelines for Psychoeducation

12. Clinically significant abnormal laboratory or electrocardiogram (ECG) findings

13. Patients who tested positive for illicit drug use

14. Use of an investigational drug within 30 days or 5 half-lives (whichever is longer) preceding the first dose of study medication

15. Patients who in the investigator's opinion had a serious medical condition that would preclude the administration of paroxetine

3.5 Study Medication and Administration

3.5.1 Study Medication

Paroxetine was supplied as blue, size 1, hard gelatin capsules containing 5 mg paroxetine, 10 mg paroxetine, 15 mg paroxetine, 20 mg paroxetine, or 25 mg paroxetine. The placebo capsules were identical in appearance. The appearance, formulation, dose strength, and batch numbers of the study medication used are presented in Table 2.

Table 2 The Appearance, Formulation and Dosage Strength of Drugs Used in this Study (with Batch Numbers)

Study Drug	Appearance and Formulation	Dose Units	Batch / Lot Numbers
Paroxetine	Blue, size 1, hard gelatin capsules	5 mg	N99194 / 97P70173FF
Paroxetine	Blue, size 1, hard gelatin capsules	10 mg	N98187 / 98P70229FF
Paroxetine	Blue, size 1, hard gelatin capsules	15 mg	N98080 / 97P70173FF
Paroxetine	Blue, size 1, hard gelatin capsules	20 mg	N98189 / 98P70383FF
Paroxetine	Blue, size 1, hard gelatin capsules	25 mg	N98058 / 97P70173FF
Placebo	Blue, size 1, hard gelatin capsules	–	N99102

Source: Appendix A contains the batch numbers for GSK manufactured product, lot numbers, and Certificates of Analyses.

All bottles contained 20 capsules, i. e., sufficient medication for one week of treatment and overage of 3 days worth of study medication. Therefore, one bottle was dispensed for Weeks 1, 2, 3 and 4, two bottles were dispensed for Weeks 5–6, 7–8, 9-10 and 11-12, and four bottles were dispensed for Weeks 13–16. The Taper Phase medication (Weeks 17, 18, 19 and 20) was also supplied as single bottles, each bottle containing 20 capsules.

For the purpose of blinding during the study, daily doses were referred to as dose levels. Dose levels 1, 2, 3, 4 and 5 corresponded to daily medication doses of 10, 20, 30, 40 and 50 mg of paroxetine (Table 3). Investigators and patients were not blinded as to dose level.

Table 3 Treatment Medication

Dose Level	Study Medication	Paroxetine Dosage	Placebo Dosage
1	2 x 5 mg capsules	10 mg/day	2 placebo capsules
2	2 x 10 mg capsules	20 mg/day	2 placebo capsules
3	2 x 15 mg capsules	30 mg/day	2 placebo capsules
4	2 x 20 mg capsules	40 mg/day	2 placebo capsules
5	2 x 25 mg capsules	50 mg/day	2 placebo capsules

3.5.2 Storage and Drug Accountability

Study medication was required to be stored in secure (locked) areas at controlled room temperature (15° to 30° C) and dispensed according to protocol under the supervision of the investigator or his/her designee.

Records of all study drug shipped to the centers, dispensed to the patients, returned by patients, and returned to the sponsor were to be maintained at the study centers. At the end of the study all unused supplies were to be returned to GlaxoSmithKline or destroyed locally by suitable personnel.

3.5.3 Dosage and Administration

Randomized patients, under parental supervision, were instructed to take 2 capsules each morning, with food, throughout the double-blind Treatment Phase of the study (Weeks 1-16) and the Taper Phase (Weeks 17-20). For the first week of the Treatment Phase, all patients received DL 1 (10 mg/day paroxetine or matching placebo). The dose could then be up-titrated in 10 mg/day increments (one dose level) no more frequently than every seven days, up to a maximum of 50 mg/day (DL 5), according to clinical response and tolerability. Dose escalation was permitted only at the clinic visit. Tapering of study medication was recommended for all patients on DL 2 (20 mg/day paroxetine or matching placebo) or higher at the end of the study.

A dose reduction to the next lower dose level consequent to an AE was permitted once a patient had reached DL 2 (20 mg/day paroxetine or matching placebo) and was brought in for a visit. The patient could return to the original dose level upon resolution of the AE. Patients who were unable to tolerate DL 1 (10 mg/day paroxetine or matching placebo) were withdrawn from the study. Patients who required more than one dose reduction were also withdrawn from the study.

Patients who completed the 16-week Treatment Phase (or those who withdrew prematurely at DL 2 or higher) were required to enter the Taper Phase, commencing Taper Phase dosing at one level below the level of their final therapy. The duration of the Taper Phase was 1-4 weeks and was dependent on the dose level achieved during the Treatment Phase (Table 4). No medication was supplied after the Taper Phase.

Table 4 Study Medication (Taper Phase)

Dose Level* at End of Treatment	Week 17**	Week 18**	Week 19**	Week 20**
DL 1 = 10 mg	**No taper medication**			
DL 2 = 20 mg	DL 1 = 10 mg	**No further taper medication**		
DL 3 = 30 mg	DL 2 = 20 mg	DL 1 = 10 mg	**No further taper medication**	
DL 4 = 40 mg	DL 3 = 30 mg	DL 2 = 20 mg	DL 1 = 10 mg	**No further taper medication**
DL 5 = 50 mg	DL 4 = 40 mg	DL 3 = 30 mg	DL 2 = 20 mg	DL 1 = 10 mg

* Paroxetine or matching placebo

** Or corresponding Weeks 1, 2, 3 or 4 following early withdrawal

Taper Phase medication was dispensed at Week 16 or Early Withdrawal Visit, with each bottle of taper medication being for one week only (+ 3 days' extra medication supply). Patients were reminded that the weekly taper medication bottles were to be used in strict sequential order and that study medication was to be taken for one week only before patients started dosing from the next bottle.

3.5.4 Methods of Blinding

Blinding of study medication was maintained by referring to the daily medication dose as dose levels, i. e., paroxetine dose (or matching placebo) as DL 1 to 5 (10 mg = DL 1, 20 mg = DL 2, 30 mg = DL 3, 40 mg = DL 4, and 50 mg = DL 5). Placebo capsules were identical in appearance to active study medication capsules. Labels on the packaging identified the randomization number.

A computer-generated randomization list was generated using a 1:1 ratio of paroxetine (10 to 50 mg flexible dose) to placebo. The randomization number corresponded to the blinded medication and was recorded in the e-CRF. Appendix A contains a copy of the randomization code. The master randomization list was held by the sponsor.

Individual sealed code envelopes indicating the treatment assigned to each patient were lodged with the investigator/pharmacist. Only in the event of a serious adverse event (SAE) that the investigator felt could not be adequately treated without knowing the identity of the study medication could the medication code be broken for a particular patient. Every effort had to have been made to contact a GlaxoSmithKline Medical Monitor prior to breaking the code. If this was not

possible and the situation was an emergency, the investigator could have broken the code and contacted the Medical Monitor as soon as possible thereafter.

3.6 Compliance with Study Medication

Every effort was made to encourage patient compliance with the dosage regimen as per protocol. Patients were encouraged to return their medication bottles with any unused drug when they returned for each visit. A record of the medication dispensed and returned was made in the eCRF at each visit. At each visit, adherence to the dosing regimen was assessed by study site staff by counts of returned capsules.

Patients who missed more than three consecutive days of study medication were to have been withdrawn from the study. Likewise, if, in the investigator's judgment, there were any significant irregularities in compliance, the patient was to be withdrawn from the study.

3.7 Prior and Concomitant Medication

All psychoactive medication taken during the year prior to the Screening Visit was recorded in the eCRF with a pharmacotherapy class identification (SSRI, MAOI, TCA, benzodiazepine or other), drug name (trade name preferred), indication, and dates taken. In order to be eligible for the study, patients were required to meet specific discontinuation time periods from the Screening Visit for psychoactive medications. The use of psychoactive medications other than study medication was also prohibited during the study (see Section 3.4, Eligibility Criteria)

All non-psychoactive medication taken during the 1 month prior to Screening and all concomitant medication taken during the study were likewise to be recorded in the eCRF, along with dosage information and dates taken.

Behavioral therapy (i. e., exposure and response prevention) or psychotherapy (except for the structured psychoeducation pamphlet defined in Appendix O of the Protocol, Guidelines for Psychoeducation) was not permitted during the conduct of the study.

3.8 Study Procedures

3.8.1 Schedule of Assessments

A schedule of study assessments and procedures is presented in Table 5. Efficacy assessment tools are described in Section 3.11, Efficacy Assessments.

The Screening Phase of the study consisted of the time period between the Screening Visit (Day -7) and the Baseline Visit (Day 0), inclusive. The double-blind Treatment Phase began on the first day that study medication was taken, Day 1, and continued through completion of the Week 16 Visit (or Early Withdrawal Visit, if applicable). The double-blind Taper Phase was the time period after the Week 16 Visit or the Early Withdrawal Visit, continuing for up to a maximum of 4 weeks thereafter. The length of the Taper Phase was dependent on the ending dose level at the Week 16 or Early Withdrawal Visit. The Follow-up Visit was scheduled for 14 days after the last dose of study medication (including Taper Phase dosing) for all patients. The study design is depicted in Figure 1.

Table 5 Schedule of Assessments for 29060/676

Visit	Screening	Baseline	Week 1	2	3	4	6	8	10	12	16	Early Withdrawal	Taper End	Follow-up
Patient demography	X													
ECG	X	X *												
Medical surgical history	X													
Pregnancy test **	X													
ADIS for DSM-IV:C	X													
Inclusion/Exclusion	X	X												
Pharmacotherapy history	X													
Drug screening	X													
Randomization		X												
CGI–Severity of Illness		X	X	X	X	X	X	X	X	X	X	X		
CGI–Global Improvement			X	X	X	X	X	X	X	X	X	X		
SPAI / SPAI–C		X				X		X		X	X	X		
LSAS–CA and GAF		X				X		X		X	X	X		
D–GSADS–A (age 11-18)		X				X		X		X	X	X		
CDRS		X									X	X		
Vital signs	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Baseline signs/symptoms		X												
AE monitoring			X	X	X	X	X	X	X	X	X	X	X	X
Medical Procedures		X	X	X	X	X	X	X	X	X	X	X		
Laboratory evaluation	X	X *									X	X		X *
PK sampling						X					X	X		
Physical examination	X										X	X		X*
Height/weight	X										X	X		
Concomitant medication	X †	X	X	X	X	X	X	X	X	X	X	X	X	X
Medication dispensed		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	
Study conclusion module											X	X		

* To be performed only if abnormal values were noted at Screening Visit or at study termination evaluation

** Only if appropriate/required

† Prior medications recorded at Screening Visit

3.8.2 Screening Visit (Day –7)

All patients underwent an initial screening visit (Visit 1, Day -7) one week prior to the Baseline Visit in order to determine eligibility for entry. At this visit the following evaluations were to be performed:

- Anxiety Disorders Interview Schedule for DSM-IV (ADIS for DSM-IV:C)
- Patient demography
- Inclusion/Exclusion criteria
- Vital signs (sitting blood pressure and pulse)
- Body weight and height determination
- ECG
- Physical examination
- Pregnancy test for female patients where appropriate
- Laboratory assessments consisting of hematology (hemoglobin, hematocrit, white blood cell (WBC) count with differential and platelet count); blood chemistry (urea, creatinine, total bilirubin, alkaline phosphatase, serum glutamic pyruvic transaminase (SGPT; alanine aminotransferase [ALT]), serum glutamic oxaloacetic transaminase (SGOT; aspartate aminotransferase [AST]) and electrolytes); thyroid function tests (thyroid stimulating hormone [TSH], Free T3 and Free T4); and dipstick urinalysis (if dipstick method was positive for blood or protein, full microscopy was performed)
- Drug screening (opiates, cocaine, benzodiazepines, cannabinoids, amphetamines, barbiturates and methadone)
- Medical and surgical history
- Prior and concomitant medications
- Pharmacotherapy history

Patients who satisfied the criteria for eligibility at the Screening Visit entered a 1-week Screening Phase. The Screening Phase of the study was the time period between the Screening Visit (Day -7) and the Baseline Visit (Day 0), inclusive.

A patient log was to be kept at each site listing all patients considered for the study, including those not entering the trial. The reasons for excluding patients from the study were to be recorded.

3.8.3 Baseline Visit (Day 0)

At the end of the Screening Phase, a Baseline Visit was conducted to determine eligibility to enter the Treatment Phase. The following procedures/assessments were to be performed at the Baseline Visit (Visit 2, Day 0):

- Clinical Global Impression–Severity of Illness (CGI–S)
- Laboratory assessments (performed only if abnormal values were noted at the screening visit)
- ECG (performed only if abnormal values were noted at the screening visit)
- Study medication dispensed
- Vital signs (sitting blood pressure and pulse)
- Concomitant medications
- Baseline signs and symptoms
- Medical procedures record
- Liebowitz Social Anxiety Scale for Children and Adolescents (LSAS–CA)
- Dalhousie Generalized Social Anxiety Disorder Scale for Adolescents (D–GSADS–A) (patients ≥11 years only)
- Social Phobia and Anxiety Inventory (SPAI or SPAI–C)
- Global Assessment of Functioning Scale (GAF)
- Children’s Depression Rating Scale–Revised (CDRS–R)
- Inclusion/Exclusion criteria

Patients who continued to satisfy all criteria for eligibility at the Baseline Visit were randomized to double-blind medication and instructed to take two capsules per day during the 16-week Treatment Phase.

3.8.4 Double-Blind Treatment Phase (Weeks 1-16)

Study assessments during the Treatment Phase were scheduled at the end of Weeks 1, 2, 3, 4, 6, 8, 10, 12 and 16 or upon early withdrawal. Each study assessment included the following evaluations unless otherwise specified:

- Vital signs (sitting blood pressure and pulse)
- Adverse events
- Medical procedures record
- Concomitant medications
- Study medication record
- CGI–S
- Clinical Global Impression–Global Improvement (CGI-I)
- LSAS–CA (Weeks 4, 8, 12, and 16 or Early Withdrawal)
- D–GSADS–A (Weeks 4, 8, 12, and 16 or Early Withdrawal)
- SPAI or SPAI–C (Weeks 4, 8, 12, and 16 or Early Withdrawal)
- GAF (Weeks 4, 8, 12, and 16 or Early Withdrawal)
- Pharmacokinetic sampling (optional)–Weeks 4 and 16 (or Early Withdrawal, if applicable) for consenting patients only
- Laboratory assessments (Week 16 or Early Withdrawal)
- Height and weight measured (Week 16 or Early Withdrawal)
- Physical examination (Week 16 or Early Withdrawal)
- CDRS–R (Week 16 or Early Withdrawal)
- Medication dispensed (taper medication at Week 16 or Early Withdrawal, if applicable)

- Study conclusion module completed (Week 16 or Early Withdrawal)

3.8.5 Taper Phase (Weeks 17-20)

Tapering of medication was recommended for all patients upon conclusion of the study, either upon premature termination or study completion (DL 2 or higher). Patients discontinuing the study at DL 1 (10 mg/day paroxetine or matching placebo) did not enter the Taper Phase. The duration of the Taper Phase was 1-4 weeks and was dependent on dose level achieved during the Treatment Phase. Medication was to be reduced in single dose level (10 mg/day or matching placebo) increments per week. Thus, for patients taking DL 5 as their final dose in the study, it was recommended that the dose be tapered over the next 4 weeks (i. e., DL 4 for one week, DL 3 for one week, DL 2 for one week, and DL 1 for the final week).

3.8.6 Taper End Visit

Following completion of the Taper Phase, patients returned to the clinic for the Taper End Visit. Patients returned all double-blind taper medication and underwent a safety evaluation. The following evaluations were to be performed at this visit:

- Vital signs
- Adverse events
- Concomitant medication
- Taper medication record

3.8.7 Follow-up Visit

All patients were to return for a post-study safety Follow-up Visit. Follow-up was to occur 14 days (± 3 days) after the patient's last dose of study medication, including Taper Phase. The following evaluations were performed at this visit:

- Vital signs
- Concomitant medications
- Adverse events
- Repeat laboratory evaluation if clinically significantly abnormal values were noted at previous visit

- Medical procedures record

3.9 Patient Completion and Early Withdrawal

3.9.1 Definition

Patients were considered to have completed the study if they participated in the full 16-week double-blind Treatment Phase of the study. Patients were considered to have prematurely withdrawn if they discontinued participation for any reason prior to the Week 16 visit.

3.9.2 Reasons for Withdrawal

A patient could withdraw (or be withdrawn) from the study prematurely for any of the following reasons:

- Adverse event
- Lack of efficacy
- Protocol deviation (including non-compliance)
- Lost to follow-up
- Other

The reason for termination was to be recorded in the Study Conclusion section of the eCRF. If the patient withdrew, every attempt was made to carry out the assessments at the patient's last visit that were scheduled for the Week 16 visit.

3.10 Diagnostic Assessment

3.10.1 Anxiety Disorders Interview Schedule for DSM-IV: Child Version

To be eligible for participation in the study, patients had to meet DSM-IV criteria for Social Anxiety Disorder, according to the ADIS for DSM-IV:C. The ADIS for DSM-IV:C, a clinician-based, semi-structured diagnostic interview of both the parent and child, was written in accordance with the current diagnostic classification (DSM-IV) of the American Psychiatric Association. The Child and Parent Interview Schedules for the ADIS for DSM-IV:C are organized diagnostically to permit differential diagnoses among all of the DSM-IV anxiety disorders [18][19][20]. Based on information obtained from the Child and Parent

Interview, the clinician uses his or her clinical judgment to determine the principal diagnoses as well as the degree of interference (severity rating).

The clinician's severity rating is based on the following 9-point scale (0-8) and is guided by the information obtained from both the parent and child interview interference ratings, the total number of symptoms endorsed, and the clinician's impression for each diagnostic category:

0	=	absent (none)
1-3	=	mild (slightly disturbing/not really disturbing)
4-5	=	moderate (definitely disturbing/disabling)
6-7	=	severe (markedly disturbing/disabling)
8	=	very severe (very severely disturbing/disabling)

3.11 Efficacy Assessments

All the efficacy assessments were to be conducted by a Psychiatrist or 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 throughout the study.

A copy of the efficacy instruments may be found in the protocol:

- Clinical Global Impression–Global Improvement (CGI–I) (protocol Appendix G)
- Clinical Global Impression–Severity of Illness (CGI–S) (protocol Appendix G)
- Social Phobia and Anxiety Inventory for Children (SPAI-C) (protocol Appendix H)
- Social Phobia and Anxiety Inventory (SPAI) (protocol Appendix I)
- Liebowitz Social Anxiety Scale for Children and Adolescents (LSAS–CA) (protocol Appendix J)
- Dalhousie Generalized Social Anxiety Disorder Scale for Adolescents (D-GSADS–A) (protocol Appendix K)
- Global Assessment of Functioning Scale (GAF) (protocol Appendix L)

- Children's Depression Rating Scale–Revised (CDRS–R) (protocol Appendix M)

3.11.1 Clinical Global Impression (CGI) Improvement and Severity Items

The CGI Global Improvement (CGI–I) and Severity of Illness (CGI–S) 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 [21].

The CGI–I is a widely accepted measure of clinical improvement in a variety of psychiatric disorders. The CGI–I is based 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 study, whether or not that improvement or worsening is judged to be due to drug treatment, 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 were categorized as responders if they were rated either as 1 (very much improved) or 2 (much improved) compared to Baseline.

For the CGI–S item, clinicians indicate their assessment of the patients' severity of illness considering their total clinical experience with the particular 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

3.11.2 Liebowitz Social Anxiety Scale for Children and Adolescents (LSAS-CA)

The LSAS-CA, a clinician-rated scale (not yet validated), was designed to assess the range of social interaction and performance situations that children and adolescents with social phobia may fear and/or avoid. The scale consists of 24 items that are divided into two subscales that address social interactional (12 items) and performance (12 items) situations. Patient's are asked to rate both their "Fear and Anxiety" and "Avoidance" during the past week. Thus there are a total of 48 sub-scores, 24 "Fear or Anxiety" and 24 "Avoidance." The fear ratings range from 0 = None to 3 = Severe, while the avoidance ratings range from 0 = 0% to 3 = 68-100%. The maximum score (most severe) is 144.

3.11.3 Dalhousie Generalized Social Anxiety Disorder Scale for Adolescents (D–GSADS–A)

The D–GSADS–A, a clinician-rated scale (not yet validated), was designed to assess social anxiety disorder in adolescents. This scale was used only in the subgroup of patients aged 11-17 years.

The scale consists of three parts:

A) 18 items, each rated on a scale of 0-3, representing None-Severe, for "discomfort/anxiety distress" and for "avoidance"

B) 3 items, each rated on a scale of 0-3, representing None-Extreme, for the most feared social situations and how strong is the fear/avoidance of each. These items are not included in the total score.

C) 11 distress quotient items, rated on a scale of 0-3, representing Never / Mild / Moderate / Severe.

The maximum score (most severe) is 141.

3.11.4 Social Phobia Anxiety Inventory for Children (SPAI–C)

The SPAI–C is a self-report scale developed for screening purposes and for use as a treatment outcome measure specifically for children/early adolescents with social anxiety/social phobia. The SPAI-C was developed for children between the ages of 8 and 14; it is recommended, however, that patients 14 years or older complete the SPAI.

The SPAI-C assesses somatic, cognitive and behavioral aspects of social anxiety across a broad range of social encounters and settings. The scale consists of 26 questions, some of which require multiple responses. Questions are answered on a 3-point Likert-type scale to quantify frequency, ranging from 0 (never, or hardly ever) to 2 (most of the time, or always). A cut-off score of 18 or higher is most appropriate for determining the presence of Social Anxiety Disorder [22]. The maximum score (most severe) is 52.

3.11.5 The Social Phobia Anxiety Inventory (SPAI)

The SPAI, a self-report scale, was developed for screening purposes and for use as a treatment outcome measure for adolescents and adults with social anxiety/social phobia. This scale is validated for use only in the subgroup of patients aged 14 years and older.

The scale consists of 45 questions, some of which require multiple responses. Questions are answered on a 7-point Likert-type scale ranging from 0 (never) to 6 (always). The SPAI assesses the somatic, cognitive, and behavioral aspects of social anxiety across a wide range of social situations and settings. It is divided into two subscales: Social Phobia (SP) and Agoraphobia (Ag). The maximum score for the SP subscale is 192 and for the Ag subscale 78. A difference score is derived by subtracting the Ag subscale from the SP subscale, providing a purer measure of social anxiety by distinguishing the symptoms from those of Panic Disorder with Agoraphobia. It is this difference score that is considered in the analysis, not the sum of the two subscales. A difference score of 80 or above is

likely to confirm the presence of Social Anxiety Disorder [23]. The maximum possible difference score (most severe) is 192.

3.11.6 Global Assessment of Functioning Scale (GAF)

The GAF is an investigator-rated scale for assessing a patient's overall level of functioning. The GAF assesses psychological, social and occupational functioning only and does not include impairment due to physical or environmental limitations. The scale ranges from 0 (inadequate information) or 1 (lowest level of functioning / persistent danger of severely hurting self or others) (most severe) to a maximum of 100 (superior functioning in a wide range of activities / no symptoms).

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

The CDRS–R is a clinician-rated instrument designed to measure the severity of depression in children, although it has also been used successfully in adolescents. The CDRS–R assesses 17 symptom areas, including those that serve as the criteria in the DSM-IV for the diagnosis of depressive disorders. The first 14 items of the scale are rated on the basis of the child's verbal responses to interview questions. The remaining 3 symptom areas (Depressed Facial Affect, Listless Speech and Hypoactivity) of the CDRS–R are rated by the clinician on the basis of the child's non-verbal behavior for signs of depression. Each symptom is graded on a 5- or 7-point scale. The maximum (most severe) score is 113.

The CDRS-R Total Score may be interpreted as follows:

39 or lower:	A score this low is extremely rare. May be associated with pervasive denial
40-54:	A depressive disorder is unlikely
55-64:	A depressive disorder might be confirmed in a comprehensive diagnostic evaluation.
65-74:	A depressive disorder is likely to be confirmed.
75-84:	A depressive disorder is very likely to be confirmed
85 or higher:	A depressive disorder is almost certain to be confirmed.

3.12 Safety Assessments

Safety was assessed primarily through AE monitoring, vital sign (including body weight and height) determinations, physical examinations and clinical laboratory evaluations. In addition, a pregnancy test (females of child-bearing potential only) and electrocardiogram (ECG) were performed at the Screening Visit (described below).

3.12.1 Adverse Events

All adverse events (AEs), serious and non-serious, whether observed by the investigator or reported by the patient or parent/guardian, were evaluated by the investigator and recorded in the adverse event section of the patient's eCRF. Adverse events were to be elicited by the investigator asking the patient a non-leading question such as "Have you felt different in any way since starting the new treatment?" If the patient responded "Yes," details of the AE and its intensity, including any change in study drug administration, investigator attribution to study drug, any corrective therapy given, and outcome status, were documented in the eCRF. Investigators were instructed to follow patients with AEs until the event had subsided (disappeared) or until the condition had stabilized. Attribution or relationship to study drug was judged by the investigator to be unrelated, probably unrelated, possibly related, or related.

A serious adverse event (SAE) was defined as any event that was fatal, life threatening, disabling/incapacitating or resulted in hospitalization,[4] prolonged a hospital stay, or was associated with congenital abnormality, cancer or overdose (either accidental or intentional). In addition, any experience that the investigator regarded as serious or that suggested any significant hazard, contraindication, side effect or precaution that may have been associated with the use of the drug was documented as a serious event. Important medical events that may not result in death, be life-threatening, or require hospitalization could be considered an SAE when, based upon appropriate medical judgment, they jeopardized the patient or patients and required medical or surgical intervention to prevent one of the outcomes listed in this definition.

The definitions for AEs and serious AEs, as well as the instructions provided to the study sites for assessing AE severity and causality, for reporting serious AEs, and how overdosages, on-study pregnancies, and breaking the study blind should be handled may be found in the protocol (Appendix A of this report).

All AEs in the database for this report were coded from the verbatim term according to the World Health Organization (WHO) Adverse Reaction (ART) dictionary and then mapped by body system and preferred term according to the COSTART-based Adverse Drug Experiences Coding System (ADECS), for

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[4] 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 AEs and were to be recorded on the medical procedures page of the CRF.

consistency with other pediatric studies of paroxetine. In the separate clinical safety database for reporting serious adverse events (SAEs), the events were coded by the Medical Dictionary for Regulatory Affairs (MEDRA), but not mapped by ADECS. Therefore, body system and preferred terms for SAEs will differ between the two databases. Both MEDRA and ADECS terms are provided in Table 15.1.2.2, Section 13, Narratives for Patients with Serious Emergent Adverse Events, and in Section 6.4, Serious Adverse Events.

3.12.2 Physical Examinations and Vital Signs

Complete physical examinations were required at the Screening Visit and at the end of study (Week 16 or Early Withdrawal Visit). Any adverse changes in the physical examination were to be recorded in the adverse event section of the eCRF. Vital signs, consisting of systolic and diastolic blood pressure and heart rate after 3 minutes of sitting, were conducted at each visit. Body height and weight were measured at the Screening Visit and at the end of study (Week 16 or Early Withdrawal Visit). Likewise, any clinically significant adverse change in any of these parameters was to be recorded as an adverse event.

3.12.3 Laboratory Monitoring

Clinical laboratory evaluations were performed on samples drawn at the Screening Visit and Week 16/Early Withdrawal Visit. Repeat laboratory evaluations were required for any abnormal laboratory parameters noted at the Screening or Week 16 or Early Withdrawal Visit. Clinical laboratory evaluations consisted of hematology (hemoglobin, hematocrit, WBC with differential, platelet count and red blood cell count); blood chemistry (sodium, potassium, creatinine, total bilirubin, aspartate aminotransferase (AST), alanine amino transferase (ALT), and alkaline phosphatase); and dipstick urinalysis (if feasible). The urine dipstick assessed protein, glucose and occult blood. Other findings were reported only if observed under microscopic examination. Thyroid function tests (TSH, FT3 and FT4), urine drug screen (opiates, cocaine, benzodiazepines, cannabinoids, amphetamines, barbiturates and methadone) and a urine dipstick pregnancy test in females of child-bearing potential were performed at the Screening Visit only.

Any laboratory abnormalities considered clinically significant were to be recorded in the Significant Medical/Surgical History or the Adverse Event section of the eCRF, as appropriate. Patients testing positive for illegal drugs were excluded from the study.

3.13 Pharmacokinetic Assessments

The collection of pharmacokinetic (PK) samples was optional (i. e., it was not required by the protocol) and only patients consenting to this additional assessment had samples obtained. The PK data from this study will be combined with data from other relevant studies, studies 704 (10-week study of children and adolescents with OCD) [14] and 701 (8-week study of children and adolescents with major depressive disorder) [13]. The results will be reported separately at a later time.

3.13.1 Sampling Times

Venous blood samples were drawn from consenting patients at Weeks 4 and 16 (or early withdrawal from the study) for paroxetine assay. The samples were to be drawn pre-dose, if possible. Otherwise, both samples were to be collected at approximately the same time of day for each patient. Sampling had to occur at least one week after the last dose adjustment (i. e., the patient must have been receiving a constant daily dose for at least the preceding 7 days).

3.13.2 Specimen Preparation

Within one hour of collection, the blood samples were centrifuged to separate the plasma, which was frozen and transported for analysis by Quest Diagnostics. Full details of all these procedures were provided by Quest Diagnostics before the start of the study.

3.13.3 Assay Methods and Pharmacokinetic Analysis

Plasma concentrations of paroxetine were determined by HPLC/MS/MS [24] under the direction of the Department of Drug Metabolism and Pharmacokinetics of GlaxoSmithKline.

3.14 Data Quality Assurance

To ensure that the protocol-stipulated study procedures were well understood and performed as consistently as possible across all investigator sites, the protocol, eCRF, and safety reporting were reviewed with the investigators and their personnel responsible for the conduct of the study by the sponsor representatives at the investigator sites prior to initiation of the study at each center. In addition, prior to initiation of the study, multicenter investigators' meetings were held on 13-14 October 1999 in Philadelphia, Pennsylvania, for North American

investigators; on 23 October 1999 in Cape Town, South Africa, for South African investigators; and on 26 November 1999 in Hertfordshire, UK, for European investigators.

Electronic case report forms were provided by means of laptop computers and used as part of a remote data entry (RDE) system. Each site received a laptop computer, and all site staff participated in specialized training on the use of the RDE system. Each investigator and authorized staff member received a unique password to log on to the system. As with traditional "paper" CRFs, sites were required to retain source documentation to support all remote entries. A Patient Workbook, which was a paper copy resembling the electronic case report form (eCRF), was also distributed to the sites to facilitate RDE and maintenance of source documentation.

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

This study was subject to audit by GlaxoSmithKline's department of Worldwide Regulatory Compliance-GCP (WRC-GCP). A list of audited sites can be found in Appendix A.

3.15 Statistical Evaluation

All efficacy measures over the course of the study are presented and summarized in graphs and tables: continuous data by means, standard deviations, medians, maxima, minima and numbers of patients, and categorical data by counts and percentages.

Minor modifications were made from the analyses specified in the protocol and those specified in the Reporting and Analysis Plan (RAP). The changes to the RAP were made following Food and Drug Administration (FDA) comments (letter received 26 June 26 2000) on the statistical section of the previously completed pediatric protocol 701 [13]. Since protocol 701 was a study of similar design, the FDA comments were applied to this study as well. Specifically, where

additional analyses were conducted in the situation where assumptions did not hold for the analyses of continuous variables, they were for assessing robustness of conclusions and did not replace primary inferences. Further, reference to checking for linearity of covariates was removed. Additionally, it was clarified that investigation of interactions was limited to the primary variable at the primary timepoint of interest for the primary dataset, and was to assess robustness of conclusions from the primary analysis.

A potential issue was discovered at one of the centers (Center 001), whereby the blind was broken for all 4 randomized patients upon their completion of the double-blind Treatment Phase of the study. This situation was investigated and the principal investigator confirmed that the unblinding was carried out at the request of the patients' parents. It was also confirmed that the physicians who made the efficacy and safety assessments remained blinded to treatment assignment. As a conservative approach in analyzing the efficacy data, it was decided, prior to breaking the treatment blind, that all patients from this center would be excluded from the Per-Protocol population. Additionally, a supplementary analysis of the ITT population for the primary efficacy variable was performed with Center 001 excluded, in order to assess the overall impact of this center; if any differences were found, it was agreed that further analysis could be performed. However, the ITT population including patients from Center 001 is considered to be the primary dataset of interest. For purposes of this report, the results are presented including Center 001 patients, except for additional Table 14.1.2bZ, Section 12, Summary of Analysis for CGI Global Improvement–Proportion of Responders, which presents the analyses of the primary outcome measure in the ITT population without these patients (see Section 5.2.3, CGI Global Improvement–ITT Population Excluding Center 001).

3.15.1 Target Sample Size

A total of 130 evaluable patients per treatment group were deemed to be sufficient to detect a difference of 20 percentage points between paroxetine and placebo in the proportion of patients who had a CGI–I score of 1 or 2 at the Week 16 LOCF endpoint. The number of evaluable patients was based on a placebo response rate of 40%. This difference is detectable with a power of 90%, given a significance level of 5% and using a two-sided significance test.

Assuming a 20% attrition rate between randomization and first post-dose assessment, it was planned to randomize 328 patients (164 per treatment group) into the study.

3.15.2 Method of Randomization

A computer-generated randomization list was used to balance assignment of patients to each treatment group. The randomization was generated using a 1:1 ratio of paroxetine to placebo. Eligible patients were identified throughout the study by their study/patient number, allocated at the baseline visit. Each center was expected to randomize a minimum of 8 patients to facilitate robust statistical analyses.

The master randomization list was held by the sponsor. Individual sealed code envelopes indicating the treatment received by each patient was lodged with the investigator (Appendix A contains a copy of the randomization code).

3.15.3 Planned Efficacy Evaluations

Primary inference was based on the last observation carried forward (LOCF) dataset at the protocol-defined Week 16 endpoint (see Section 9.3.6 of the protocol). Data were collected at each visit for CGI-S, at each visit except baseline for CGI-I, at baseline and Weeks 4, 8, 12 and 16 or Early Withdrawal for the LSAS–CA, D–GSADS–A, SPAI-C/SPAI and GAF, and at baseline and Week 16 or Early Withdrawal for the CDRS–R

The primary measure of efficacy was the following:

- Proportion of responders based on the CGI–I item, where response is defined as a score of 1 (“very much improved”) or 2 (“much improved”) on the scale at the Week 16 LOCF endpoint.

The secondary measures of efficacy were as follows:

- Change from baseline to Week 16 LOCF endpoint in CGI–S
- Change from baseline to Week 16 LOCF endpoint in LSAS–CA total score
- Change from baseline to Week 16 LOCF endpoint in D–GSADS–A total score
- Change from baseline to Week 16 LOCF endpoint in SPAI difference score or SPAI–C total score
- Change from baseline to Week 16 LOCF endpoint in GAF score.

The SPAI-C scale is validated for use in patients aged 8-14 years; it is recommended, however, that patients 14 years or older complete the SPAI. The protocol specified that the scale was intended to be used in this study for children aged 8-13. However, for the analysis, an exception was made to the protocol requirements such that patients aged 14 or 15 years who inadvertently completed the SPAI-C were included in the analyses of this endpoint. Patients aged 16 years and above who inadvertently completed the SPAI-C were excluded from the analyses of this endpoint (see Appendix H, Statistical Appendix).

Similarly, the SPAI scale is validated for use only in the subgroup of patients aged 14 years and older, and the protocol specified that the scale was intended to be used in this study for adolescents aged 14-17. However, for the analysis, an exception was made to the protocol requirements such that patients aged 13 years who inadvertently completed the SPAI were included in the analyses of this endpoint. Patients aged 12 years and younger who inadvertently completed the SPAI were excluded from the analyses of this endpoint (see Appendix H, Statistical Appendix).

3.15.4 Other Variables of Interest

- Change from baseline to Week 16 LOCF endpoint in the CDRS–R total score

3.15.5 Methods of Analysis

3.15.5.1 Comparisons of Interest

The primary comparison of interest is paroxetine versus placebo. Differences between paroxetine and placebo were estimated as "paroxetine minus placebo."

In all cases, changes from baseline were calculated as "treatment assessment minus baseline assessment."

3.15.5.2 Tests of Significance

All hypothesis tests were two sided.

The effect of interactions was assessed during the model building process at the 10% level of significance.

All other statistical tests were performed at the 5% level of significance. Each difference between paroxetine and placebo was estimated and 95% confidence intervals were constructed around the estimated differences. The primary

endpoint must have achieved statistical significance at the 5% level for the study to be considered a success.

The null hypothesis for this study was: There is no difference between paroxetine and placebo in the proportion of responders based on CGI-I at the Week 16 LOCF endpoint in the ITT population.

The alternate hypothesis for this study was: There is a difference between paroxetine and placebo in the proportion of responders based on CGI-I at the Week 16 LOCF endpoint in the ITT population.

3.15.5.3 Covariates for Adjustment in the Efficacy Analysis

Social Anxiety Disorder in Children and Adolescents is a relatively new area of research. Therefore there is limited information on the variables that affect response. It was thought that the following variables may be considered to affect response:

- Age group (according to the FDA definitions of children (8–11) and adolescents (≥ 12 years old)
- Gender
- Baseline efficacy scores
- Center

The method of grouping centers is described in Appendix H, Statistical Appendix.

3.15.5.4 Categorical Efficacy Variables

Categorical efficacy variables (i. e., proportion of patients scoring 1 or 2 on the CGI–I scale) were analyzed by logistic regression. The statistical model on which the primary inference was based included terms for each of the covariates, center and treatment group.

The robustness of the conclusions from the primary analysis described above was then assessed by the investigation of interactions. The effect of adding the treatment-by-center interaction term into the model was considered, with all main effects in the model. The treatment-by-center interaction term was used in order to assess the uniformity of effects across centers. If the interaction term was found not to be significant ($p > 0.10$), it was to be dropped from the model and the data pooled across centers. If the treatment-by-center interaction was found to be

significant ($p \leq 0.10$) the reason was to be explored. Results may then be presented by center (or center group) or excluding a particular center (or center group) depending on the reason for the interaction. In the latter case, the results were to be presented with and without the excluded center (or center group). Interactions between treatment and each of the covariates were also investigated in turn. Any interaction terms found to be significant ($p \leq 0.10$) were to be explored and if necessary results were to be reported for each level of the covariate. Investigation of interactions were confined to the primary variable using the Week 16 LOCF dataset.

For each treatment group, there is an odds of a patient being classed as a responder. The results were presented in terms of odds ratios, i. e., the odds of a patient responding on paroxetine relative to the odds of a patient responding on placebo; 95% confidence intervals for the odds ratios and the p-values for the treatment effect were also provided.

Adequacy of the model fit was explored by inspecting the half normal probability plot with a simulated envelope and plots of standardized deviance residuals against the continuous covariates. Observations with large residuals or that strongly influenced the fit of the model to the data were investigated by examining the change in effect size on exclusion of these observations. However, influential outliers were to be included in the final model.

The change from baseline in the CGI–S item was analyzed using the non-parametric Wilcoxon rank sum test to compare the treatment groups, because it is expected that in an analysis of the difference between the two categorical variables there will be a limited range of discrete values. Results were presented as the median difference and p-value for the difference between the treatment groups. The median difference is not related to the p-value from the Wilcoxon rank sum test. No adjustment was made for center or covariates.

3.15.5.5 Continuous Efficacy Variables

Continuous efficacy variables (e.g. change from baseline on the LSAS-CA) were analyzed using parametric analysis of variance. As for the categorical efficacy variables, the statistical model on which inference was based included terms for each of the covariates, center and treatment.

Results were presented as the mean, 95% confidence interval, and p-value for the difference between the paroxetine and the placebo group. The assumptions of normality and homogeneity of variance were assessed by inspection of normal probability plots, plots of standardized residuals against predicted values, and

plots of standardized residuals against continuous covariates. Observations with large residuals or that strongly influenced the fit of the model to the data were investigated by examining the change in effect size on exclusion of these observations. However, influential outliers were to be included in the final model.

Where the assumptions of normality and homogeneity of variance were not met, appropriate non-parametric methods were to be used (i.e., the Wilcoxon Rank Sum test) in order to assess the robustness of the conclusions from the parametric analysis.

3.15.5.6 Treatment of Missing Values

For the individual items of each scale, the raw data values were listed. Any subtotals or total scores that were listed and/or used in the analyses were adjusted to include the relevant imputations. See Appendix H, Statistical Appendix, for a full description of the treatment of missing values.

3.15.6 Populations/Data Sets To Be Evaluated

Two patient populations were evaluated; primary inferences were based on the ITT population. An analysis was also performed on the primary efficacy variable using the per-protocol (PP) population to assess robustness of conclusions from the primary analysis.

3.15.6.1 Intention-to-Treat (ITT) Population

The intention-to-treat (ITT) population is defined as consisting of all patients who were randomized into the study, who received at least one dose of randomized double-blind medication, and for whom at least one valid post-baseline evaluation (including any adverse event) is available. The primary inferences concerning the efficacy of paroxetine were made using the ITT population.

3.15.6.2 Per-Protocol (PP) Population

The Per-Protocol population consisted of all patients who were included in the ITT population and who also met the following criteria:

- no major protocol violation with regard to inclusion or exclusion criteria
- no major protocol violation during the course of the study (Weeks 1-16)
- no break in study medication for more than 3 consecutive days during the study (Weeks 1-16)

- minimum treatment duration of 4 weeks

Additional to the criteria given above, which were specified in the protocol, all patients from Center 001 were excluded from the PP population (see Section 3.15, Statistical Evaluation).

Only the primary efficacy variable was analyzed using the Per-Protocol population. The Per-Protocol population was not to be analyzed if this population comprised more than 95% or less than 50% of the ITT population. Patients excluded from the PP efficacy analysis were identified before the randomization code was broken.

For both of the defined populations, primary inference was based on the last observation carried forward (LOCF) dataset at the protocol defined Week 16 endpoint. Unless the patient numbers were similar, two additional datasets were to be analyzed for primary and secondary variables to ensure the robustness of the results. These are the LOCF dataset at the latest timepoint where at least 70% of the patients remain in the study (70% LOCF endpoint) and an observed cases (OC) dataset at the Week 16 endpoint. A decision on whether to analyze these datasets was to be agreed between Biometrics and the Neurosciences Clinical Group prior to breaking the study blind, when the total number of patients in the datasets was known.

In the LOCF dataset, the last available on-therapy observation for a patient was used to estimate missing data points. In the OC dataset, efficacy data were evaluated only at the timepoint when they were collected; no data were carried forward to estimate missing data points. In both datasets, data for patients who withdrew prematurely were excluded from visits where the patient had discontinued study medication 7 or more days prior to the visit. All efficacy variables were summarized using the LOCF and OC datasets.

3.15.7 Safety Evaluations

All patients who were randomized into the study, who received at least one dose of randomized, double-blind medication, and who had at least one valid post-baseline evaluation (including any AEs) were assessed for clinical safety and tolerability. The safety population was thus the same as the ITT population.

3.15.7.1 Adverse Events

All AEs were coded from the verbatim term according to the World Health Organization (WHO) Adverse Reaction (ART) dictionary and then mapped by

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

Adverse events were summarized into four phases:

1. **Pre-Treatment Phase:** All AEs where onset date is prior to the first day of randomized treatment.

2. **Treatment Phase:** All AEs where onset date is on or after the first day of treatment and before or on the last day of treatment (excluding taper medication).

3. **Taper Phase:** All AEs where onset date is on or after the first day of taper medication and on or prior to last day of taper medication. Some patients may not have this phase.

4. **Follow-up Phase:** AEs where onset date is after the last date of randomized treatment (or taper medication if the patient down titrated) but less than 14 days (or 30 days if a Serious AE) after this date. Some patients may not have this phase.

Definition of Emergent AEs:

Adverse events were categorized as emergent according to 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 study is divided into 4 phases, "Pre-treatment," "Treatment," "Taper" and "Follow-up." Hence the definition of a treatment-emergent event has been modified to the following:

" An event that emerges during the phase, having been absent pre-treatment, or worsens relative to the pre-treatment state."

The following are examples of how the definition was applied:

- If the same AE was reported as starting and ending during each of the Treatment, Taper and Follow-up Phases but was not reported Pre-treatment, this AE was counted as emergent in the Treatment Phase, Taper Phase and Follow-up Phase.

- If the same AE was reported as starting during the Treatment Phase and ending during the Taper Phase but was not reported Pre-treatment, this AE was counted as emergent in the Treatment Phase only.

- If the same AE was reported as starting and ending during all phases (including Pre-treatment), each time with the same intensity, this AE was not counted as emergent during the Treatment, Taper, or Follow-up Phase because the AE was present prior to treatment; it was counted in the Pre-treatment AE table only.

- If the same AE was reported as starting and ending during all phases (including Pre-treatment), but the AE during Treatment, Taper or Follow-up was of a higher intensity than at Pre-treatment, the AE was counted as emergent during the Pre-treatment Phase at the intensity at which it occurred and was counted as emergent in the phases in which the AE worsened relative to the Pre-treatment state.

- If the same AE was reported as starting and ending during all phases (including Pre-treatment), but the AE during the Pre-treatment Phase was of a higher intensity than at any other phase, the AE was counted during the Pre-treatment Phase at the intensity at which it occurred but was not counted as emergent during any other phase as the AE was of a same or lower intensity than at Pre-treatment.

- If the same AE was reported as starting and ending twice at Pre-treatment with different intensities, then at varying intensities later in the study, the AE was counted during the Pre-treatment Phase at both intensity levels and was not counted as emergent during subsequent phases where the intensity was the same or lower than the maximum Pre-treatment intensity. However, it was counted as emergent during any subsequent phases where the AE intensity was higher than the maximum intensity at Pre-treatment.

In addition, a Post-Follow-up Phase was defined for the listing of SAEs where the onset date was >30 days after the last date of randomized treatment (or taper medication if the patient down-titrated).

3.15.7.2 Withdrawals

Withdrawals were summarized by reason for withdrawal. The incidence of withdrawals due to AEs are presented.

3.15.7.3 Vital Signs and Laboratory Values of Potential Clinical Concern

The number of patients in each treatment group with values of BP, heart rate, and weight of potential clinical concern pre-defined by the sponsor and with increases or decreases from baseline by more than a specified amount were tabulated. A patient with the same variable above and below the normal range at different timepoints was counted twice. In addition, summary statistics for changes from baseline for BP, heart rate, weight, height and body mass index (BMI) are presented by treatment group. Sponsor-defined criteria for clinical concern values may be found in Table 6.

Table 6 Sponsor-Defined Vital Sign and Body Weight Values and Changes in Value of Clinical Concern

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

bpm = beats per minute; BP = blood pressure

* For weight, the last pre-treatment value was considered the Baseline value

Laboratory data (hematology, blood chemistry and urinalysis) were evaluated by tabulating the number (%) of patients in each treatment group with values outside normal and clinical concern ranges. A listing of sponsor-defined values of potential clinical concern is provided in Listing 15.3.1, Appendix F, and Table 7.

Summary statistics for the changes from baseline in laboratory values are presented by parameter. 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 treatment group. Baseline for laboratory data was defined as the last valid laboratory assessment prior to treatment. Endpoint was defined as the last on-treatment laboratory assessment, including the Taper Phase.

Patients who had an abnormal value at Screening and were retested at Baseline and no longer had an abnormal value were not considered to have an abnormal value at Baseline.

Table 7 Laboratory Values of Potential Clinical Concern

Laboratory Tests Groupings		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
RBC	male	$x10^{12}$/L	>8
	female	$x10^{12}$/L	>10
WBC		$x10^{9}$/L	<2.8 or >16
Lymphocytes		$x10^{9}$/L	<0.53 or >4.43
Monocytes		$x10^{9}$/L	>1.38
Basophils		$x10^{9}$/L	>0.4
Eosinophils		$x10^{9}$/L	>0.79
Neutrophils, Absolute		$x10^{9}$/L	<1.58 or >8.64
Platelet Count		$x10^{9}$/L	<75 or >700
Liver Function			
ASAT (SGOT)		IU/L	>150
ALAT (SGPT)		IU/L	>165
Total Bilirubin		micromol/L	≥34.2
Renal Function			
Creatinine		micromol/L	>176.8
Other			
Sodium		mmol/L	<126 or >156
Potassium		mmol/L	<3 or >6
Thyroid Stimulating Hormone (TSH)		mu/L	>10

Source: Table 15.3.2, Section 13; Listing 15.3.1, Appendix F

3.15.7.4 Defined Visit Timepoints

The protocol stipulated that patients' visits during the Treatment Phase were to occur at specific timepoints. However, because of schedule problems, patient visits could not always occur on the exact day in question. 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 study medication.

Visit	Proposed Day Relative to First Dose of Study Medication	Visit Window
Screening (Visit 1)	-7	–
Baseline (Visit 2)	0	–
Week 1 (Visit 3)	7	Days 1 * to 10
Week 2 (Visit 4)	14	Days 11 to 17
Week 3 (Visit 5)	21	Days 18 to 24
Week 4 (Visit 6)	28	Days 25 to 35
Week 6 (Visit 7)	42	Days 36 to 49
Week 8 (Visit 8)	56	Days 50 to 63
Week 10 (Visit 9)	70	Days 64 to 77
Week 12 (Visit 10)	84	Days 78 to 98
Week 16 (Visit 11)	112	Days 99 to 140
Post-Week 16	–	Greater than 140 days

* Day 1 was included as baseline (Visit 2) if data were recorded before study medication was taken; however, Day 1 was included as Week 1 (Visit 3) if data were recorded after study medication was taken.

Screening (Visit 1) data are all data that were collected on the Screening page of the eCRF, if this was prior to the first dose of study medication. Similarly, Baseline (Visit 2) data are all data that were collected on the Baseline page of the eCRF, if this was prior to the first dose of study medication.

For data recorded at specific visits only (i. e., SPAI /SPAI–C, LSAS–CA, D–GSADS–A, GAF, CDRS–R), data 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 SPAI/SPAI–C assessments that fell into baseline, and Week 4, 8, 12 and 16 intervals were tabulated, while only CDRS–R assessments that fell into baseline and Week 16 intervals were tabulated. However, unscheduled assessments contributed to the LOCF analysis if they were the last on-treatment assessment.

Efficacy assessments performed more than 7 days after the last dose of randomized 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 last dose of randomized medication if the patient didn't enter the Taper Phase, were excluded from the summary tables and analyses. However, all data are listed. Efficacy data slotted as Post-Week 16 did not contribute to the LOCF analysis.

If more than one assessment occurred in the same time window (or at the same visit for non-slotted data) then the latest assessment was used in the data summaries and analyses; 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.

3.15.8 Phases of the Study

3.15.8.1 Pre-Treatment Phase

The pre-Treatment Phase was defined as the period of time prior to the first dose of study medication. This phase, therefore, included all data collected at Screening and Baseline visits.

Baseline was defined as Visit 1 (Screening) for the laboratory data, height, weight and body mass index, and Visit 2 (Baseline) for the remaining data. If more than one assessment was recorded at these visits, then the latest assessment prior to randomized medication was regarded as Baseline. For patients who had abnormal laboratory values at Screening and had a repeat laboratory assessment at Baseline, the last recorded laboratory values prior to randomized medication for those parameters were regarded as Baseline.

3.15.8.2 Treatment Phase

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

- the date of the last dose of study medication, if no taper medication was taken.
- the day prior to the date of first taper medication taken.

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

3.15.8.3 Taper Phase

The Taper Phase was defined as the period of time from the first dose date of taper medication until the last dose date of taper medication. No efficacy assessments were made during the Taper Phase.

3.15.8.4 Follow-up Phase

The Follow-up Phase collected safety information after the last dose of study medication (including taper). No efficacy assessments were made during the Follow-up Phase.

3.15.9 Interim Analysis

No interim analysis was planned or conducted for this study.

3.15.10 Data Irregularities

One patient, 676.004.24089, was screened as patient 676.004.24086 and failed, then was screened and randomized at a later date. This patient is therefore counted twice, both as a randomized patient in the paroxetine group and a screened-only patient.

In South Africa, some laboratory samples were sent to local laboratories. Only absolute values were tabulated. Samples were sent to local laboratories by Centers 202, 203, 206 and 209 for 37 patients, which produced 1344 results. Values of concern were flagged before entry into the database.

Also in South Africa, SPAI question 26c was omitted from the first translation of the Afrikaans version (the question is, "What will I do if no one speaks to me?"). The centers affected are 201, 202, 203, 205, 206, 207, and 209. A total of 18 patients had this question missing, 16 of whom were from the centers that could have used the Afrikaans SPAI.

4 Study Population

4.1 Study Dates

The first dose of double-blind study medication was administered on 30 November 1999, and the last dose (including taper) was administered on 19 October 2001 (Listing 13.17.1, Appendix B). The last study visit for the last patient to complete participation occurred on 30 October 2001.

4.2 Patient Disposition

4.2.1 Number and Distribution of Patients

A total of 425 patients completed the Screening Visit and 322 were randomized to double-blind treatment[5]. Among the 103 patients not randomized (66 adolescents [64.1%] and 37 children [35.9%]), the primary reason for pre-randomization withdrawal was failure to meet one or more of the entrance criteria (Table 8 and Table 9). Reasons for all pre-randomization withdrawals are shown in Table 8, which provides data for both age groups combined (Age Group: Total).

Table 8 Number (%) of Patients Who Were Withdrawn Pre-Randomization by the Reason for Withdrawal–Age Group: Total (Screening-only Population)

Total Withdrawn	**(N = 103)**
Reason for Pre-randomization Withdrawal	**n (%)**
Baseline AE	0
Did not meet entrance criteria	64 (62.1)
Protocol deviation (including non-compliance)	4 (3.9)
Lost to follow-up	7 (6.8)
Other *	28 (27.2)

* Other includes unknown and non-study-related personal reasons
Source: Table 13.3.1a, Section 11; Listing 13.3.1a, Appendix B

A total of 322 patients were randomized to treatment, 92 children (29%) and 230 adolescents (71%) (Table 13.1.1, Section 11, and Listing 13.1.1, Appendix B). The numbers of patients in each treatment group and in each age subgroup are presented in Table 9. Fewer patients needed to be randomized than was initially

[5] Appendix A contains the randomization code.

planned due to a lower-than-expected attrition rate between randomization and the first post-dose assessment. The required number of evaluable patients was still reached.

Three randomized patients were not included in the ITT population (Listing 13.1.1, Appendix B). Patient 676.004.24089 (paroxetine) and patient 676.003.24068 (placebo) did not have a post-baseline assessment or AE. Patient 676.300.25009 (paroxetine) was randomized in error at the screening visit. This patient has no baseline assessment, and the post-baseline assessment is after the last dose of medication. The denominator for percentages in Table 9 is the number of patients randomized.

One patient, 676.004.24089, was screened as 676.004.24086 and failed, then was screened and randomized at a later date. This patient is therefore counted twice, both as a randomized patient in the paroxetine group and a screened-only patient.

The ITT population, therefore, consisted of 319 patients (163 paroxetine patients and 156 placebo patients). Of the 156 placebo patients, one adolescent patient (676.015.24401) was randomized and dispensed medication, but was unable to swallow the study medication capsules. Therefore, this patient is included erroneously in the ITT population, both total and adolescents, and is included in the total Ns (including the denominator for efficacy and safety assessments) for the ITT population at all visits except Baseline (see Section 15, Errata). At Week 16 LOCF, the patient is categorized as missing. Post-baseline efficacy assessments were completed but are not tabulated, and the patient is not included in the summary statistics. The patient is included in dosing tables but is not included in the calculation of overall duration of exposure to study medication.

The PP population consisted of those patients who had no major protocol violation with regard to inclusion or exclusion criteria, no major protocol violation during the Treatment Phase, no break in study medication for more than 3 consecutive days during the Treatment Phase (as recorded by the investigator), and exposure to a minimum duration of 4 weeks of randomized study medication (see Section 4.3, Protocol Violations). Additionally, all 4 patients from Center 001 were excluded from the PP population (see Section 3.15, Statistical Evaluation). The PP population consisted of 124 paroxetine patients and 110 placebo patients.

Overall, of all patients randomized, more patients in the paroxetine group (74.5%, 123/165) completed the study than in the placebo group (65.6%, 103/157). The difference was more pronounced in the adolescents

subgroup, in which 78.0% (92/118) of paroxetine patients completed the study, compared to 66.1% of placebo patients (74/112). Among children, the proportion of completers was similar in both treatment groups (paroxetine 66.0%, 31/47; placebo 64.4%, 29/45).

Table 9 The Number (%) of Patients by Population–Age Group: Total/Children/Adolescents (All Randomized)

	Treatment Group		
Number of Patients	**Paroxetine n (%)**	**Placebo n (%)**	**Total * n (%)**
Age Group: Total	**(N = 165)**	**(N = 157)**	**(N = 425)**
Screened only	–	–	103 **
Randomized	165 (100.0) **	157 (100.0)	322 (100.0)
Completed study †	123 (74.5)	103 (65.6)	226 (70.2)
Early withdrawal	42 (25.5)	54 (34.4)	96 (29.8)
ITT Population	163 (98.8)	156 (99.4) ††	319 (99.1)
PP Population	124 (75.2)	110 (70.1)	234 (72.7)
Age Group: Children	**(N = 47)**	**(N = 45)**	**(N = 129)**
Screened only	–	–	37 **
Randomized	47 (100.0) **	45 (100.0)	92 (100.0)
Completed study †	31 (66.0)	29 (64.4)	60 (65.2)
Early withdrawal	16 (34.0)	16 (35.6)	32 (34.8)
ITT Population	46 (97.9)	45 (100.0)	91 (98.9)
PP Population	32 (68.1)	32 (71.1)	64 (69.6)
Age Group: Adolescents	**(N = 118)**	**(N = 112)**	**(N = 296)**
Screened only	–	–	66
Randomized	118 (100.0)	112 (100.0)	230 (100.0)
Completed study †	92 (78.0)	74 (66.1) ††	166 (72.2)
Early withdrawal	26 (22.0)	38 (33.9)	64 (27.8)
ITT Population	117 (99.2)	111 (99.1)	228 (99.1)
PP Population	92 (78.0)	78 (69.6)	170 (73.9)

Note: Denominator for percentages is the number of patients randomized.
* Total N includes Screened Only patients, hence is greater than paroxetine N + placebo N
** Three randomized patients were not included in the ITT population. Patients 676.004.24089 (paroxetine) and 676.003.24068 (placebo) had no post-baseline assessment or AE. Patient 676.300.25009 (paroxetine) was randomized in error at the screening visit and has no baseline assessment; the post-baseline assessment is after the last dose of medication. The denominator for percentages in this table is the number of patients randomized. One patient was screened and failed, then was screened and randomized as patient 676.004.24089 at a later date. This patient is therefore counted twice, both as a randomized patient in the paroxetine group and a screened-only patient (see Section 3.15.10, Data Irregularities).
† Completed = patients who completed a Week 16 visit eCRF.
†† Patient 676.015.24401 was randomized and dispensed medication, but was unable to swallow the study medication capsules. Therefore, this patient is included erroneously in the ITT population. See Section 15, Errata.
Source: Table 13.1.1, Section 11; Listings 13.1.1, 13.3.1a, and 13.3.1b, Appendix B

Table 10 presents the number of patients by country. This study was conducted in 38 centers (22 centers in the USA, 4 in Canada, 10 in South Africa and 2 in

Belgium) (Table 11). Centers in the USA and South Africa enrolled the majority of patients, 182 (57.1%) and 100 (31.3%), respectively.

Table 10 The Number (%) of Patients by Country

Number of Patients	Paroxetine	Placebo	Total *
Country = USA	**(N = 94)**	**(N = 88)**	**(N = 247)**
Screened only	–	–	65 **
Randomized	94 (100.0) **	88 (100.0)	182 (100.0)
Completed †	67 (71.3)	52 (59.1)	119 (65.4)
Early withdrawal	27 (28.7)	36 (40.9)	63 (34.6)
ITT Population	93 (98.9)	87 (98.9)	180 (98.9)
Per-Protocol Population	68 (72.3)	60 (68.2)	128 (70.3)
Country = South Africa	**(N = 50)**	**(N = 50)**	**(N = 125)**
Screened only	–	–	25
Randomized	50 (100.0)	50 (100.0)	100 (100.0)
Completed †	40 (80.0)	37 (74.0)	77 (77.0)
Early withdrawal	10 (20.0)	13 (26.0)	23 (23.0)
ITT Population	50 (100.0)	50 (100.0)	100 (100.0)
Per-Protocol Population	41 (82.0)	37 (74.0)	78 (78.0)
Country = Canada	**(N = 15)**	**(N = 14)**	**(N = 42)**
Screened only	–	–	13
Randomized	15 (100.0)	14 (100.0)	29 (100.0)
Completed †	11 (73.3)	12 (85.7)	23 (79.3)
Early withdrawal	4 (26.7)	2 (14.3)	6 (20.7)
ITT Population	15 (100.0)	14 (100.0)	29 (100.0)
Per-Protocol Population	11 (73.3)	11 (78.6)	22 (75.9)
Country = Belgium	**(N = 6)**	**(N = 5)**	**(N = 11)**
Screened only	–	–	0
Randomized	6 (100.0)	5 (100.0)	11 (100.0)
Completed †	5 (83.3)	2 (40.0)	7 (63.6)
Early withdrawal	1 (16.7)	3 (60.0)	4 (36.4)
ITT Population	5 (83.3)	5 (100.0)	10 (90.9)
Per-Protocol Population	4 (66.7)	2 (40.0)	6 (54.5)

* Total N includes Screened Only patients, hence is greater than Paroxetine N + Placebo N
** PID 676.004.24086 was screened and failed, then was screened and randomized as 676.004.24089 at a later date. This patient is therefore counted twice, both as a randomized patient in the paroxetine group and a screened-only patient. The patient subsequently had no post-baseline assessment and is not included in the ITT population.
† Completed = patients who completed a Week 16 Visit eCRF.
Source: Table 13.1.2, Section 11; Listings 13.1.1, 13.3.1a, and 13.3.1b, Appendix B

There were some differences in the relative proportions of children and adolescents in the USA, Canada, and South Africa. However, it is considered that

these small imbalances do not affect the interpretation of the data. The number of patients by country by age group may be found in Table 13.1.2, Section 11.

Of the 38 participating centers, one center (016) screened, but did not randomize any patients. Table 11 presents the number of patients randomized and completed by center. Investigator names at each center and their affiliations may be found in Table 1, Section 3.2, Investigators. The number of patients enrolled per center ranged from a single patient at Center 208 to 21 patients at Center 007. A total of 15 centers each randomized at least 10 patients. The number of patients by center by age group may be found in Table 13.4.1, Section 11.

Table 11 The Number (%) of Patients Randomized and Completed by Center–Age Group: Total (ITT Population)

	Paroxetine (N = 163)		Placebo (N = 156)		Total (N = 319)	
	R	C	R	C	R	C
No.*	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
001	2 (2.2)	2 (2.2)	2 (2.3)	2 (2.3)	4 (2.2)	4 (2.2)
002	7 (7.5)	4 (4.3)	7 (8.0)	7 (8.0)	14 (7.8)	11 (6.1)
003	8 (8.6)	7 (7.5)	6 (6.9)	5 (5.7)	14 (7.8)	12 (6.7)
004	1 (1.1)	1 (1.1)	1 (1.1)	0	2 (1.1)	1 (0.6)
005	8 (8.6)	5 (5.4)	8 (9.2)	5 (5.7)	16 (8.9)	10 (5.6)
006	3 (3.2)	3 (3.2)	2 (2.3)	2 (2.3)	5 (2.8)	5 (2.8)
007	11 (11.8)	9 (9.7)	10 (11.5)	6 (6.9)	21 (11.7)	15 (8.3)
009	3 (3.2)	2 (2.2)	4 (4.6)	3 (3.4)	7 (3.9)	5 (2.8)
010	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.1)	2 (1.1)	2 (1.1)
011	2 (2.2)	1 (1.1)	1 (1.1)	0	3 (1.7)	1 (0.6)
012	3 (3.2)	2 (2.2)	4 (4.6)	4 (4.6)	7 (3.9)	6 (3.3)
013	5 (5.4)	5 (5.4)	5 (5.7)	2 (2.3)	10 (5.6)	7 (3.9)
014	7 (7.5)	4 (4.3)	6 (6.9)	3 (3.4)	13 (7.2)	7 (3.9)
015	9 (9.7)	6 (6.5)	9 (10.3)	3 (3.4)	18 (10.0)	9 (5.0)
016	0	0	0	0	0	0
017	3 (3.2)	2 (2.2)	3 (3.4)	2 (2.3)	6 (3.3)	4 (2.2)
019	6 (6.5)	5 (5.4)	6 (6.9)	2 (2.3)	12 (6.7)	7 (3.9)
020	3 (3.2)	3 (3.2)	3 (3.4)	2 (2.3)	6 (3.3)	5 (2.8)
021	2 (2.2)	2 (2.2)	2 (2.3)	1 (1.1)	4 (2.2)	3 (1.7)
022	3 (3.2)	2 (2.2)	3 (3.4)	2 (2.3)	6 (3.3)	4 (2.2)
023	2 (2.2)	1 (1.1)	1 (1.1)	0	3 (1.7)	1 (0.6)
024	4 (4.3)	0	3 (3.4)	0	7 (3.9)	0
100	5 (33.3)	3 (20.0)	5 (35.7)	5 (35.7)	10 (34.5)	8 (27.6)
101	5 (33.3)	4 (26.7)	4 (28.6)	3 (21.4)	9 (31.0)	7 (24.1)
102	2 (13.3)	1 (6.7)	2 (14.3)	1 (7.1)	4 (13.8)	2 (6.9)
103	3 (20.0)	3 (20.0)	3 (21.4)	3 (21.4)	6 (20.7)	6 (20.7)
200	8 (16.0)	6 (12.0)	7 (14.0)	7 (14.0)	15 (15.0)	13 (13.0)
201	3 (6.0)	3 (6.0)	2 (4.0)	1 (2.0)	5 (5.0)	4 (4.0)
202	6 (12.0)	5 (10.0)	6 (12.0)	3 (6.0)	12 (12.0)	8 (8.0)
203	2 (4.0)	1 (2.0)	3 (6.0)	1 (2.0)	5 (5.0)	2 (2.0)
204	5 (10.0)	4 (8.0)	6 (12.0)	4 (8.0)	11 (11.0)	8 (8.0)
205	4 (8.0)	3 (6.0)	5 (10.0)	4 (8.0)	9 (9.0)	7 (7.0)
206	6 (12.0)	6 (12.0)	6 (12.0)	5 (10.0)	12 (12.0)	11 (11.0)

R = Randomized; C = Completed (Completed = patients who completed a Week 16 Visit eCRF)
* Centers 001-024, USA; Centers 100-103, Canada; Centers 200-209, South Africa; Centers 300-301, Belgium
Source: Table 13.4.1, Section 11; Listings 13.1.1, 13.3.1a, and 13.3.1b, Appendix B

(Table continues)

Table 11 (Continued) The Number (%) of Patients Randomized and Completed by Center–Age Group: Total (ITT Population)

	Paroxetine (N = 163)		Placebo (N = 156)		Total (N = 319)	
	R	C	R	C	R	C
No.*	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
207	7 (14.0)	5 (10.0)	6 (12.0)	5 (10.0)	13 (13.0)	10 (10.0)
208	0	0	1 (2.0)	1 (2.0)	1 (1.0)	1 (1.0)
209	9 (18.0)	7 (14.0)	8 (16.0)	6 (12.0)	17 (17.0)	13 (13.0)
300	2 (40.0)	2 (40.0)	3 (60.0)	1 (20.0)	5 (50.0)	3 (30.0)
301	3 (60.0)	3 (60.0)	2 (40.0)	1 (20.0)	5 (50.0)	4 (40.0)

R = Randomized; C = Completed (Completed = patients who completed a Week 16 Visit eCRF)
* Centers 001-024, USA; Centers 100-103, Canada; Centers 200-209, South Africa; Centers 300-301, Belgium
Source: Table 13.4.1, Section 11; Listings 13.1.1, 13.3.1a, and 13.3.1b, Appendix B

4.2.2 Number of Patients Present at Each Visit

Table 12 presents the number and percentage of patients remaining in the study at the conclusion of each study visit. The percentages shown in this table are based upon the numbers of patients in the ITT Population. A total of 70.8% (226/319) of patients completed the study (i. e., completed the Week 16 visit assessments). Due to visit windowing (see Section 3.15.7.4, Defined Visit Timepoints), two of these patients were slotted as completing the study at visits other than the Week 16 visit. One paroxetine patient (676.020.24534) was slotted to Post-Week 16 (>140 days). One placebo patient (676.014.24370) was slotted to Week 12 (78-98 days) as the patient had stopped taking study medication on Day 98 relative to start of study medication but completed the Week 16 visit and entered the Taper Phase.

Overall, a slightly higher percentage of patients withdrew at Week 8 (6.5% total, 3.4% paroxetine, 9.9% placebo) than at other weeks during the study.

Table 12 Number (%) of Patients Remaining in the Study, Withdrawn, or Completed at Each Visit–Age Group: Total (ITT Population)

Visit	Status	Paroxetine (N = 163) n (%)	Placebo (N = 156) n (%)	Total (N = 319) n (%)
Baseline	Entered	163 (100.0)	156 (100.0)	319 (100.0)
Week 1	Still in Study	160 (98.2)	151 (96.8)	311 (97.5)
	Withdrew	3 (1.8)	5 (3.2)	8 (2.5)
Week 2	Still in Study	158 (96.9)	149 (95.5)	307 (96.2)
	Withdrew	2 (1.3)	2 (1.3)	4 (1.3)
Week 3	Still in Study	157 (96.3)	147 (94.2)	304 (95.3)
	Withdrew	1 (0.6)	2 (1.3)	3 (1.0)
Week 4	Still in Study	149 (91.4)	141 (90.4)	290 (90.9)
	Withdrew	8 (5.1)	6 (4.1)	14 (4.6)
Week 6	Still in Study	145 (89.0)	131 (84.0)	276 (86.5)
	Withdrew	4 (2.7)	10 (7.1)	14 (4.8)
Week 8	Still in Study	140 (85.9)	118 (75.6)	258 (80.9)
	Withdrew	5 (3.4)	13 (9.9)	18 (6.5)
Week 10	Still in Study	134 (82.2)	113 (72.4)	247 (77.4)
	Withdrew	6 (4.3)	5 (4.2)	11 (4.3)
Week 12	Still in Study	128 (78.5)	105 (67.3)	233 (73.0)
	Withdrew	6 (4.5)	7 (6.2)	13 (5.3)
	Completed *	0	1 (0.6)	1 (0.3)
Week 16	Still in Study	1 (0.6)	0	1 (0.3)
	Withdrew	5 (3.9)	3 (2.9)	8 (3.4)
	Completed**	122 (74.8)	102 (65.4)	224 (70.2)
Post-Week 16	Completed *	1 (0.6)	0	1 (0.3)

Note: Percentages for patients still in the study or completed at each visit are based on the total number of patients at Baseline. Percentages for patients withdrawing at each visit are based on the total number of patients at each visit.
Date of withdrawal = date of last dose of study medication (excluding Taper). Efficacy assessments up to 7 days after this date are considered evaluable.
* Due to visit windowing, two patients were slotted as completing the study at visits other than the Week 16 visit. One paroxetine patient (676.020.24534) was slotted to Post-Week 16 (>140 days), and one placebo patient (676.014.24370) was slotted to Week 12 (78-98 days).
** Completed = These numbers represent patients who completed the study between the Week 16 visit window (99-140 days).
Source: Table 13.3.2, Section 11; Listing 13.3.1b, Appendix B

4.2.3 Withdrawal Reasons

Table 13 presents a summary of the number and percentage of patients in the ITT population not completing the study and the reason for withdrawal.

A total of 29.2% (93/319) of patients in the ITT population were withdrawn during the Treatment Phase. Overall, the percentage of patients who withdrew prematurely was higher in the placebo group (34.0%, 53/156) than in the paroxetine group (24.5%, 40/163). The primary reason for withdrawal in the paroxetine group was protocol deviation (6.7%, 11/163), followed by AE (5.5%, 9/163 for paroxetine compared to 1.9%, 3/156 for placebo) and "other" (5.5%, 9/163 for paroxetine compared to 4.5%, 7/156). In the placebo group, the number of patients withdrawn due to protocol deviation (7.1%, 11/156) was similar to that in the paroxetine group. However, in the placebo group, the primary reason for withdrawal was lack of efficacy (14.1%, 22/156, compared to 3.7%, 6/163 in the paroxetine group).

The overall withdrawal rates were slightly higher for children (34.1%, 31/91) than for adolescents (27.2%, 62/228). Among children, withdrawal rates were similar for both paroxetine and placebo-treated patients, 32.6% (15/46) and 35.6% (16/45), respectively. The primary reason for withdrawal in the paroxetine group among children was protocol deviation (13.0%, 6/46), compared to 8.9% (4/45) in the placebo group; the primary reason for withdrawal in the placebo group was lack of efficacy (15.6%, 7/45).

Among adolescents, more placebo patients were withdrawn (33.3%, 37/111) than paroxetine-treated patients (21.4%, 25/117). Among adolescents in the paroxetine group, the primary reason for withdrawal was AE (6.8%, 8/117, compared to 0.9%, 1/111, in the placebo group, according to Table 13.3.1b, Section 11). However, 1 adolescent in each treatment group was actually withdrawn during the Taper Phase (see Section 15, Errata). Therefore, the number of AE withdrawals among adolescents in the paroxetine group was 7/117 (6.0%) and the number of AE withdrawals among adolescents in the placebo group was none. The primary reason for withdrawal in the placebo group among adolescents was lack of efficacy (13.5%, 15/111), compared to 4.3% (5/117) in the paroxetine group.

Table 13.3.1c, Section 11, presents a summary of the number and percentage of patients in the PP population not completing the study and the reason for withdrawal. Withdrawal rates and reasons for withdrawal were similar in the PP population to those in the ITT population.

Table 13 Number (%) of Patients Completing the Study or Withdrawing from Study by Reason for Withdrawal–Age Group: Total/Children/Adolescents (ITT Population)

	Age Group: Total			Age Subgroups			
				Age Group: Children		Age Group: Adolescents	
Reason for Study Conclusion	**Paroxetine (N = 163) n (%)**	**Placebo (N = 156) n (%)**	**Total (N = 319) n (%)**	**Paroxetine (N = 46) n (%)**	**Placebo (N = 45) n (%)**	**Paroxetine (N = 117) n (%)**	**Placebo (N = 111) n (%)**
Adverse event	10 (6.1) *	3 (1.9) *	13 (4.1) *	2 (4.3)	2 (4.4)	8 (6.8) *	1 (0.9) *
Lack of efficacy	6 (3.7)	22 (14.1)	28 (8.8)	1 (2.2)	7 (15.6)	5 (4.3)	15 (13.5)
Protocol deviation (including non-compliance)	11 (6.7)	11 (7.1)	22 (6.9)	6 (13.0)	4 (8.9)	5 (4.3)	7 (6.3)
Lost to follow-up	4 (2.5)	10 (6.4)	14 (4.4)	1 (2.2)	3 (6.7)	3 (2.6)	7 (6.3)
Other **	9 (5.5)	7 (4.5)	16 (5.0)	5 (10.9)	0	4 (3.4)	7 (6.3)
Total withdrawn	40 (24.5)	53 (34.0)	93 (29.2)	15 (32.6)	16 (35.6)	25 (21.4)	37 (33.3)
Completed study †	123 (75.5)	103 (66.0)	226 (70.8)	31 (67.4)	29 (64.4)	92 (78.6)	74 (66.7)

* 1 adolescent in each treatment group was actually withdrawn during the Taper Phase (see Section 15, Errata). Therefore, the number of AE withdrawals in the overall population should be 9 (5.5%) paroxetine and 2 (1.3%) placebo; among adolescents it should be 7 (6.0%) paroxetine and none placebo.

** Includes unknown and non-study-related personal reasons: withdrew consent (12 patients/parents), treatment needed for ADHD (1 patient), 2-month vacation (1 patient), scheduling conflict (1 patient), psychotherapy needed for witnessing a traumatic event (1 patient).

† Patients were considered to have completed the study if they completed the Week 16 visit. The total of 226 completers includes 1 patient who completed at Week 12 and 1 patient who completed at Post-Week 16.

Source: Table 13.3.1b, Section 11; Listing 13.3.1b, Appendix B

Table 14, Table 15, and Table 16 present cumulative summaries of patients withdrawing from the study by visit and reason for withdrawal for both age groups combined, as well as for children and adolescents separately. The greatest percentage of withdrawals occurred at Week 8 overall; however, approximately half of the patients who withdrew did so before or at Week 6. The predominant reason for withdrawal at Week 8 was “Other” (protocol deviation [including non-compliance], lost to follow-up and non-study related personal reasons) for both the paroxetine and placebo groups.

Table 14 Cumulative Number (%) of Patient Withdrawals by Reason and by Visit–Age Group: Total (ITT Population)

	Treatment Group								
	Paroxetine (N = 163)				Placebo (N = 156)				Total
Visit	AE * n (%)	LOE * n (%)	Other ** n (%)	Total n (%)	AE * n (%)	LOE * n (%)	Other ** n (%)	Total n (%)	(N = 319) n (%)
Week 1	1 (0.6)	1 (0.6)	1 (0.6)	3 (1.8)	1 (0.6)	0	4 (2.6)	5 (3.2)	8 (2.5)
Week 2	1 (0.6)	1 (0.6)	3 (1.8)	5 (3.1)	1 (0.6)	2 (1.3)	4 (2.6)	7 (4.5)	12 (3.8)
Week 3	1 (0.6)	1 (0.6)	4 (2.5)	6 (3.7)	1 (0.6)	4 (2.6)	4 (2.6)	9 (5.8)	15 (4.7)
Week 4	4 (2.5)	1 (0.6)	9 (5.5)	14 (8.6)	1 (0.6)	8 (5.1)	6 (3.8)	15 (9.6)	29 (9.1)
Week 6	7 (4.3)	2 (1.2)	9 (5.5)	18 (11.0)	2 (1.3)	11 (7.1)	12 (7.7)	25 (16.0)	43 (13.5)
Week 8	9 (5.5)	2 (1.2)	12 (7.4)	23 (14.1)	3 (1.9)	16 (10.3)	19 (12.2)	38 (24.4)	61 (19.1)
Week 10	9 (5.5)	4 (2.5)	16 (9.8)	29 (17.8)	3 (1.9)	19 (12.2)	21 (13.5)	43 (27.6)	72 (22.6)
Week 12	9 (5.5)	6 (3.7)	20 (12.3)	35 (21.5)	3 (1.9)	21 (13.5)	26 (16.7)	50 (32.1)	85 (26.6)
Week 16	10 (6.1)	6 (3.7)	24 (14.7)	40 (24.5)	3 (1.9)	22 (14.1)	28 (17.9)	53 (34.0)	93 (29.2)

* AE = adverse event; LOE = lack of efficacy

** Other includes protocol deviation (including non-compliance), lost to follow-up, and non-study related personal reasons

Source: Table 13.3.3, Section 11; Listing 13.3.1b, Appendix B

Table 15 Cumulative Number (%) of Patient Withdrawals by Reason and by Visit–Age Group: Children (ITT Population)

	Treatment Group								
	Paroxetine (N = 46)				Placebo (N = 45)				Total
Visit	AE * n (%)	LOE * n (%)	Other ** n (%)	Total n (%)	AE * n (%)	LOE * n (%)	Other ** n (%)	Total n (%)	(N = 91) n (%)
Week 1	0	0	0	0	0	0	0	0	0
Week 2	0	0	2 (4.3)	2 (4.3)	0	0	0	0	2 (2.2)
Week 3	0	0	3 (6.5)	3 (6.5)	0	0	0	0	3 (3.3)
Week 4	0	0	4 (8.7)	4 (8.7)	0	3 (6.7)	0	3 (6.7)	7 (7.7)
Week 6	0	0	4 (8.7)	4 (8.7)	1 (2.2)	4 (8.9)	2 (4.4)	7 (15.6)	11 (12.1)
Week 8	2 (4.3)	0	5 (10.9)	7 (15.2)	2 (4.4)	6 (13.3)	3 (6.7)	11 (24.4)	18 (19.8)
Week 10	2 (4.3)	1 (2.2)	8 (17.4)	11 (23.9)	2 (4.4)	6 (13.3)	4 (8.9)	12 (26.7)	23 (25.3)
Week 12	2 (4.3)	1 (2.2)	10 (21.7)	13 (28.3)	2 (4.4)	7 (15.6)	6 (13.3)	15 (33.3)	28 (30.8)
Week 16	2 (4.3)	1 (2.2)	12 (26.1)	15 (32.6)	2 (4.4)	7 (15.6)	7 (15.6)	16 (35.6)	31 (34.1)

* AE = adverse event; LOE = lack of efficacy

** Other includes protocol deviation (including non-compliance), lost to follow-up, and non-study related personal reasons

Source: Table 13.3.3, Section 11; Listing 13.3.1b, Appendix B

Table 16 Cumulative Number (%) of Patient Withdrawals by Reason and by Visit–Age Group: Adolescents (ITT Population)

	Treatment Group								
	Paroxetine (N = 117)				Placebo (N = 111)				Total
Visit	AE * n (%)	LOE * n (%)	Other ** n (%)	Total n (%)	AE * n (%)	LOE * n (%)	Other ** n (%)	Total n (%)	(N = 228) n (%)
Week 1	1 (0.9)	1 (0.9)	1 (0.9)	3 (2.6)	1 (0.9)	0	4 (3.6)	5 (4.5)	8 (3.5)
Week 2	1 (0.9)	1 (0.9)	1 (0.9)	3 (2.6)	1 (0.9)	2 (1.8)	4 (3.6)	7 (6.3)	10 (4.4)
Week 3	1 (0.9)	1 (0.9)	1 (0.9)	3 (2.6)	1 (0.9)	4 (3.6)	4 (3.6)	9 (8.1)	12 (5.3)
Week 4	4 (3.4)	1 (0.9)	5 (4.3)	10 (8.5)	1 (0.9)	5 (4.5)	6 (5.4)	12 (10.8)	22 (9.6)
Week 6	7 (6.0)	2 (1.7)	5 (4.3)	14 (12.0)	1 (0.9)	7 (6.3)	10 (9.0)	18 (16.2)	32 (14.0)
Week 8	7 (6.0)	2 (1.7)	7 (6.0)	16 (13.7)	1 (0.9)	10 (9.0)	16 (14.4)	27 (24.3)	43 (18.9)
Week 10	7 (6.0)	3 (2.6)	8 (6.8)	18 (15.4)	1 (0.9)	13 (11.7)	17 (15.3)	31 (27.9)	49 (21.5)
Week 12	7 (6.0)	5 (4.3)	10 (8.5)	22 (18.8)	1 (0.9)	14 (12.6)	20 (18.0)	35 (31.5)	57 (25.0)
Week 16	8 (6.8)	5 (4.3)	12 (10.3)	25 (21.4)	1 (0.9)	15 (13.5)	21 (18.9)	37 (33.3)	62 (27.2)

* AE = adverse event; LOE = lack of efficacy

** Other includes protocol deviation (including non-compliance), lost to follow-up, and non-study related personal reasons

Source: Table 13.3.3, Section 11; Listing 13.3.1b, Appendix B

4.3 Protocol Violations

Protocol violations were defined as any significant variation from the protocol-defined inclusion/exclusion criteria or conduct of the study that could potentially impact treatment efficacy. All patients in the ITT population failing to meet one or more of the protocol-defined entrance criteria and/or who met criteria for non-compliance were assessed by the sponsor prior to unblinding of the data for classification as major protocol violators and exclusion from the PP population.

4.3.1 Patients Excluded from the Per-Protocol Population

Table 17 summarizes the number (%) of patients excluded from the PP population for protocol violations by the reason leading to the exclusion. The total number of patients identified as having at least one major protocol violation warranting exclusion from the PP population was 82 (25.7%). The percentage of major protocol violators was slightly higher in the placebo group (28.8%, 45/156) than in the paroxetine group (22.7%, 37/163). The most frequent violation in the overall population in each treatment group (9.8%, 16/163 paroxetine; 16.0%, 25/156 placebo) and in both age subgroups was missing more than 3 consecutive days of study medication. A slightly greater proportion of the children (28.6%, 26/91) were major protocol violators than were adolescents (24.6%, 56/228).

The significant violations identified before unblinding of the data were the following:

- **Patient had concurrent major depressive episode.** Four paroxetine patients (676.023.17879, 676.103.24654, 676.103.24648, and 676.209.24955) and one placebo patient (676.009.24230) were so identified before unblinding (Listings 13.2.1, 13.7.1, and PV2.5, Appendix B). A diagnosis of major depression was not recorded on the ADIS for DSM-IV:C for one of the four paroxetine patients (676.209.24955); however, documentation received from the primary investigator indicated that the patient had a current major depressive episode at the time of study entry. In addition, one paroxetine patient (676.101.24622), and four placebo patients (676.205.24989, 676.014.24365, 676.203.24817, 676.300.25011) were reported as having major depression on the ADIS for DSM-IV:C (Listing 13.7.1, Appendix B); however, per site confirmation none of the major depressive episodes were current at the time of study entry and the patients were not considered protocol violators.

- **Patient was taking or took a prohibited psychoactive medication.** Fifteen patients, 9 in the paroxetine group and 6 in the placebo group, were so identified before unblinding (Listing 13.2.1, Appendix B).

- **Patient required more than 1 dose reduction.** One patient (676.003.24071) in the paroxetine group and one patient (676.204.24843) in the placebo group were so identified before unblinding (Listings 13.2.1 and PV8, Appendix B).

- **Patient missed more than 3 consecutive days of study medication as recorded by the investigator.** Forty-one patients were so identified before unblinding, 16 in the paroxetine group and 25 in the placebo group. Per protocol, these patients were to have withdrawn from the study due to protocol violation. However, only 16 of these patients withdrew for that reason. Three of these patients withdrew due to adverse events, 3 for lack of efficacy, 2 withdrew consent, and 6 were lost to follow-up. Eleven of these patients completed the study (Listing 13.3.1b Appendix B). Two of these patients missed more than 3 consecutive days of study medication on more than one occasion as recorded by the investigator (Listings 13.2.1 and PV9, Appendix B).

- **Patient took less than 4 weeks of study medication.** Twenty-one patients, 9 patients in the paroxetine group and 12 patients in the placebo group, were so identified before unblinding (Listings 13.2.1 and PV10, Appendix B).

- **Study medication non-compliance.** In addition to patients who missed >3 consecutive days study medication, 5 patients (2 paroxetine, 3 placebo) were non-compliant for other reasons. Patient 676.003.24073 (child paroxetine): study medication was dispensed to the patient at the Screening Visit in error and was started prior to the Baseline date. Patient 676.204.24847 (adolescent placebo) and patient 676.019.24509 (adolescent paroxetine): patient was dispensed the wrong bottle of study medication in error. Patient 676.005.24120 (child placebo): uncertainty about compliance with study medication. Patient 676.209.24958 (child placebo): study medication capsules were opened and damaged.

Additional to the criteria above that were specified in the protocol, all four patients from Center 001 were excluded from the PP population (see Section 3.15, Statistical Evaluation). One of these patients (676.001.24012), in the placebo group, missed more than 3 consecutive days of study medication and appears in Table 17 as a protocol violator. The other 3 patients (676.001.24008 and 676.001.24003, both on paroxetine, and 676.001.24004, placebo) completed the

study with no pre-defined major protocol violations and are not counted in Table 17. Therefore, the total number of patients excluded from the PP population was 39 paroxetine and 46 placebo. The number of patients included in the PP population was 124 paroxetine and 110 placebo.

Table 17 Number (%) of Patients with Protocol Violations–Age Group: Total/Children/Adolescents (ITT Population)

	Total		Age Subgroup			
			Age Group: Children		Age Group: Adolescents	
Number of Patients, n (%)	**Paroxetine (N = 163)**	**Placebo (N = 156)**	**Paroxetine (N = 46)**	**Placebo (N = 45)**	**Paroxetine (N = 117)**	**Placebo (N = 111)**
	n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Total number of patients excluded *	37 (22.7)	45 (28.8)	13 (28.3)	13 (28.9)	24 (20.5)	32 (28.8)
Patient took prohibited medication	9 (5.5)	6 (3.8)	3 (6.5)	3 (6.7)	6 (5.1)	3 (2.7)
Patient required more than one dose reduction	1 (0.6)	1 (0.6)	1 (2.2)	0	0	1 (0.9)
Patient missed >3 consecutive days study medication	16 (9.8)	25 (16.0)	5 (10.9)	7 (15.6)	11 (9.4)	18 (16.2)
Patient took <4 weeks study medication	9 (5.5)	12 (7.7)	4 (8.7)	1 (2.2)	5 (4.3)	11 (9.9)
Study medication non-compliance **	2 (1.2)	3 (1.9)	1 (2.2)	2 (4.4)	1 (0.9)	1 (0.9)
Patients had concurrent major depressive episode	4 (2.5)	1 (0.6)	0	0	4 (3.4)	1 (0.9)
Total number of patients with no protocol violations	126 (77.3)	111 (71.2)	33 (71.7)	32 (71.1)	93 (79.5)	79 (71.2)

* A patient could have more than one protocol violation leading to exclusion.

** In addition to patients who missed >3 consecutive days study medication, 5 patients were non-compliant for other reasons.

Source: Table 13.2.1, Section 11; Listing 13.2.1, Appendix B

4.3.2 Protocol Deviations Included in the Per-Protocol Population

Table 13.2.2, Section 11, presents a summary of the number and percentage of patients included in the Per-Protocol (PP) population who had protocol deviations only. Deviations are failures of protocol requirements that are not considered to adversely affect the efficacy evaluation.

Two children, one in each treatment group, were considered to have a protocol deviation. Patient 676.013.24344, in the paroxetine group, had active thyroid disease at screening that was not treated with medication (Listing PV6, Appendix B). It was considered a serious illness that contraindicated the use of paroxetine (exclusion criterion 15). The condition should have been considered a protocol violation since the condition could adversely affect the efficacy evaluation. However, it was categorized as a protocol deviation in error and the patient is included in the PP population (see Errata, Section 15). Patient 676.011.24281, in the placebo group, had an abnormal ECG at Screening and at Baseline (Listing PV7, Appendix B). The patient was admitted into the study after consultation with a cardiologist indicated that the abnormality was not serious and that an SSRI would not have an effect. The patient had previously taken fluoxetine and tolerated it well. This patient is included in the PP population.

No patients were considered protocol violators or deviators for any of the following reasons: patients with inclusion criteria not ticked “yes” or exclusion criteria not ticked “no”; no overall diagnosis for Social Anxiety Disorder from the ADIS for DSM-IV:C; outside permitted age range; additional psychiatric conditions from the ADIS for DSM-IV:C; positive test for illicit drugs at Screening; or patients with a positive pregnancy test (Listings PV1, PV1.5, PV2, PV3, PV4, and PV5, Appendix B).

4.4 Demographic and Baseline Characteristics

4.4.1 Demographic Characteristics

The demographic characteristics of the overall ITT population are summarized in Table 18. Table 19 summarizes the demographic data by age subgroup. There was no marked imbalance between the treatment groups in any demographic characteristics, although the percentage of males in the paroxetine group (43.6%, 71/163) was lower than in the placebo group (57.1%, 89/156). This same pattern was observed in the adolescent subgroup (39.3%, 46/117 males in the paroxetine group, compared to 59.5%, 66/111 males in the placebo group), while there was no such imbalance in gender for children.

The mean patient age was similar in both treatment groups (13.0 years [SD 2.81] and 13.3 years [SD 2.73] in the paroxetine and placebo groups, respectively). The mean ages of children in both treatment subgroups were also similar (9.3 years [SD 1.26] and 9.8 years [SD 1.15] in the paroxetine and placebo groups, respectively), as were mean ages of adolescents (14.5 years [SD 1.67] and 14.7 years [SD 1.71] in the paroxetine and placebo groups, respectively). Overall, 84.6% (270/319) of the patients were white, 3.1% (10/319) were black, 1.3% (4/319) were oriental, and 11.0% (35/319) were “other” (16 biracial/mixed, 10 Hispanic patients, 5 Asian, 2 Eurasian, 1 Middle Eastern, 1 Latino). The proportions of races were evenly divided between the treatment groups. Mean height, weight, and body mass index (BMI) were similar in both treatment groups, as were mean height, weight, and BMI between treatment groups in the child and adolescent age subgroups.

There was a higher proportion of adolescents in the overall population (71.5%, 228/319) than children (28.5%, 91/319). The proportions were similar in both treatment groups.

Table 18 Demographic Characteristics–Age Group: Total (ITT Population)

Demographic Characteristics	Paroxetine (N = 163)	Placebo (N = 156)	Total (N = 319)
Gender n (%)			
Male	71 (43.6)	89 (57.1)	160 (50.2)
Female	92 (56.4)	67 (42.9)	159 (49.8)
Age (yrs)			
Mean (SD)	13.0 (2.81)	13.3 (2.73)	13.1 (2.77)
Range*	7-17	7-17	7-17
Race n (%)			
White	139 (85.3)	131 (84.0)	270 (84.6)
Black	4 (2.5)	6 (3.8)	10 (3.1)
Oriental	2 (1.2)	2 (1.3)	4 (1.3)
Other **	18 (11.0)	17 (10.9)	35 (11.0)
Height (cm) †			
Mean (SD)	156.71 (16.81)	159.91 (14.87)	158.26 (15.95)
Range	70.0-183.0	114.3-193.0	70.0-193.0
Weight (kg) †, ††			
Mean (SD)	55.12 (20.14)	58.79 (20.24)	56.91 (20.24)
Range	20.5-115.5	24.1-140.7	20.5-140.7
BMI (kg/m^2) †			
Mean (SD)	22.10 (6.57)	22.62 (6.50)	22.35 (6.53)
Range	14.1-57.1	13.7-59.6	13.7-59.6

* Five patients were under 8 years old, three paroxetine (676.003.24059, 676. 015.24397, and 676.023.17877) and two placebo patients (676.007.24175 and 676.007.24185). All were more than 7 years 6 months old at study entry.
** Other race includes 16 biracial/mixed, 10 Hispanic patients, 5 Asian, 2 Eurasian, 1 Middle Eastern, and 1 Latino.
† Two values for height, one for weight and two for body mass index (BMI) are missing (all adolescents in the placebo group).
†† Weight measured in pounds was converted to kilograms using the conversion 1 lb. = 0.454 kg.
Source: Tables 13.5.1b and 13.5.2b, Section 11; Listing 13.5.1, Appendix B; Listing 15.2.1, Appendix E; Appendix H, Statistical Appendix

Table 19 Demographic Characteristics–Age Group: Children/Adolescents (ITT Population)

Demographic Characteristics	Age Group: Children			Age Group: Adolescents		
	Paroxetine (N = 46)	Placebo (N = 45)	Total (N = 91)	Paroxetine (N = 117)	Placebo (N = 111)	Total (N = 228)
Gender n (%)						
Male	25 (54.3)	23 (51.1)	48 (52.7)	46 (39.3)	66 (59.5)	112 (49.1)
Female	21 (45.7)	22 (48.9)	43 (47.3)	71 (60.7)	45 (40.5)	116 (50.9)
Age (yrs)						
Mean (SD)	9.3 (1.26)	9.8 (1.15)	9.5 (1.22)	14.5 (1.67)	14.7 (1.71)	14.6 (1.69)
Range	7-11 *	7-11 *	7-11 *	12-17	12-17	12-17
Race n (%)						
White	38 (82.6)	41 (91.1)	79 (86.8)	101 (86.3)	90 (81.1)	191 (83.8)
Black	2 (4.3)	0	2 (2.2)	2 (1.7)	6 (5.4)	8 (3.5)
Oriental	1 (2.2)	1 (2.2)	2 (2.2)	1 (0.9)	1 (0.9)	2 (0.9)
Other **	5 (10.9)	3 (6.7)	8 (8.8)	13 (11.1)	14 (12.6)	27 (11.8)
Height (cm) †						
Mean (SD)	137.65 (15.17)	142.99 (10.99)	140.29 (13.47)	164.21 (10.22)	166.89 (9.77)	165.50 (10.07)
Range	70.0-167.6	114.3-163.0	70.0-167.6	134.0-183.0	127.0-193.0	127.0-193.0

* Five patients were under 8 years old, three paroxetine (676.003.24059, 676. 015.24397, and 676.023.17877) and two placebo patients (676.007.24175 and 676.007.24185). All were more than 7 years 6 months old at study entry.

** Other race includes 16 biracial/mixed, 10 Hispanic patients, 5 Asian, 2 Eurasian, 1 Middle Eastern, 1 Latino.

† Two values for height, one for weight and two for body mass index (BMI) are missing (all adolescents in the placebo group).

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

Source: Tables 13.5.1b and 13.5.2b, Section 11; Listing 13.5.1, Appendix B; Listing 15.2.1, Appendix E; Appendix H, Statistical Appendix

(Table continues)

Table 19 (Continued) Demographic Characteristics–Age Group: Children/Adolescents (ITT Population)

Demographic Characteristics	Age Group: Children			Age Group: Adolescents		
	Paroxetine (N = 46)	Placebo (N = 45)	Total (N = 91)	Paroxetine (N = 117)	Placebo (N = 111)	Total (N = 228)
Weight (kg) †, ††						
Mean (SD)	37.95 (11.55)	42.44 (14.51)	40.17 (13.22)	61.87 (18.76)	65.48 (18.40)	63.62 (18.63)
Range	20.5-64.5	24.1-90.5	20.5-90.5	27.2-115.5	30.6-140.7	27.2-140.7
BMI (kg/m^2) †						
Mean (SD)	20.40 (7.58)	20.38 (5.03)	20.39 (6.41)	22.76 (6.03)	23.55 (6.83)	23.14 (6.44)
Range	14.1-57.1	13.7-34.5	13.7-57.1	14.5-43.7	14.6-59.6	14.5-59.6

* Five patients were under 8 years old, three paroxetine (676.003.24059, 676. 015.24397, and 676.023.17877) and two placebo patients (676.007.24175 and 676.007.24185). All were more than 7 years 6 months old at study entry.

** Other race includes 16 biracial/mixed, 10 Hispanic patients, 5 Asian, 2 Eurasian, 1 Middle Eastern, 1 Latino.

† Two values for height, one for weight and two for body mass index (BMI) are missing (all adolescents in the placebo group).

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

Source: Tables 13.5.1b and 13.5.2b, Section 11; Listing 13.5.1, Appendix B; Listing 15.2.1, Appendix E; Appendix H, Statistical Appendix

The distribution of demographic data for the PP population was similar to that of the ITT population. Demographics of the PP population may be found in Tables 13.5.1c and 13.5.2c, Section 11.

4.4.2 Baseline Characteristics

The two treatment groups, both overall and by age subgroup, were similar with respect to their mean baseline scores in the efficacy rating scales, indicating comparable levels of Social Anxiety Disorder severity.

Table 20 summarizes the mean Baseline scores by treatment group and by age subgroup for the LSAS–CA, GAF scale, D-GSADS-A, SPAI-C, SPAI, and CDRS-R. Mean Baseline scores for all efficacy parameters were similar in the two treatment groups. The mean LSAS–CA total score was 77.6 among paroxetine patients and 77.7 among placebo patients. The mean GAF score was 53.0 among paroxetine patients and 53.5 among placebo patients. The mean D-GSADS-A was 84.4 among paroxetine patients and 81.9 among placebo patients.

The mean SPAI-C total scores were similar among children in both treatment groups: 28.1 among paroxetine patients and 29.5 among placebo patients. A score of 18 or higher is likely to confirm the presence of social anxiety disorder.

Similarly, among adolescents, mean SPAI difference scores were similar in both treatment groups: 98.7 among paroxetine patients and 90.9 among placebo patients. A score of 80 or higher is likely to confirm the presence of social anxiety disorder.

The CDRS–R baseline scores were essentially “normal,” i. e., indicative of a very low level of depressive symptoms: 29.4 and 29.6 among paroxetine children and adolescents, respectively, and 29.5 and 31.3 among placebo children and adolescents, respectively.

Table 20 Mean Baseline Efficacy Parameter Scores–Age Group: Total/Children/Adolescents (ITT Population)

		Treatment Group								
		Paroxetine (N = 163)			Placebo (N = 156)			Total (N = 319)		
Instrument	**Age Group**	**n**	**Mean**	**SD**	**n**	**Mean**	**SD**	**n**	**Mean**	**SD**
LSAS–CA Total Score	Total	161	77.6	28.72	155	77.7	27.05	316	77.6	27.87
	Children	44	70.7	31.00	45	71.2	28.65	89	70.9	29.66
	Adolescents	117	80.3	27.49	110	80.3	26.04	227	80.3	26.74
GAF Score	Total	162	53.0	6.85	155	53.5	7.51	317	53.2	7.17
	Children	45	53.0	6.30	45	55.0	7.70	90	54.0	7.07
	Adolescents	117	52.9	7.07	110	52.8	7.38	227	52.9	7.20
D–GSADS–A Total Score *	Adolescents	126	84.4	25.42	125	81.9	26.25	251	83.2	25.82
SPAI–C Total Score*	Children	71	28.1	11.71	66	29.5	11.06	137	28.8	11.39
SPAI Difference Score *	Adolescents	81	98.7	31.56	84	90.9	32.23	165	94.8	32.04
CDRS–R Total Score	Total	162	29.5	10.43	155	30.8	11.90	317	30.1	11.17
	Children	45	29.4	10.05	45	29.5	10.58	90	29.4	10.26
	Adolescents	117	29.6	10.62	110	31.3	12.41	227	30.4	11.53

* Adolescents were aged ≥ 12 years per protocol except for the following: D–GSADS–A was administered to patients aged ≥11 years; SPAI was to be assessed in patients 14 years or older; however, it also included some patients 13 years old; SPAI-C was to be assessed in patients 13 years or younger; however, it also included some patients aged 14 and 15 years old (see Section 3.15.3, Planned Efficacy Evaluations).

Source: Tables 13.10.1, 13.11.1, 13.12.1, 13.13.1, 13.14.1, and 13.15.1, Section 11; Listings 14.2.1, 14.3.1.1, 14.3.1.2, 14.4.1.1, 14.4.1.2, 14.4.1.3, 14.4.1.4, 14.5.1, 14.6.1.1, 14.6.1.2, 14.7.1, and 14.8.1, Appendix C

Table 21 summarizes the proportion of patients in each category of CGI–S item at Baseline by treatment group. The majority of patients (83.0%, 265/319) were moderately to markedly ill at Baseline. Overall, the proportions of patients in each category (in the combined population and in each age subgroup) were generally similar between treatment groups, although among children there was a slightly greater percentage of moderately ill patients in the paroxetine treatment group (54.3%, 25/46) than in the placebo group (44.4%, 20/45) and a slightly lesser percentage of markedly ill patients (34.8%, 16/46) in the paroxetine group than in the placebo group (44.4%, 20/45). A total of 13.2% (42/319) of all patients in the ITT population, mostly adolescent patients (37 of the 42), were rated severely ill or among the most extremely ill. These 42 severely/among the most extremely ill patients were evenly distributed between the two treatment groups.

Table 21 Number (%) of Patients in Each Category of the CGI Severity of Illness Item Score at Baseline–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group		
CGI Severity of Illness	**Paroxetine n (%)**	**Placebo n (%)**	**Total n (%)**
Age Group: Total	**(N = 163)**	**(N = 156)**	**(N = 319)**
Not Assessed (0)	0	0	0
Normal, Not Ill (1)	0	0	0
Borderline Ill (2)	0	0	0
Mildly Ill (3)	4 (2.5)	6 (3.8)	10 (3.1)
Moderately Ill (4)	74 (45.4)	69 (44.2)	143 (44.8)
Markedly Ill (5)	61 (37.4)	61 (39.1)	122 (38.2)
Severely Ill (6)	21 (12.9)	17 (10.9)	38 (11.9)
Among the Most Extremely Ill (7)	2 (1.2)	2 (1.3)	4 (1.3)
Age Group: Children	**(N = 46)**	**(N = 45)**	**(N = 91)**
Not Assessed (0)	0	0	0
Normal, Not Ill (1)	0	0	0
Borderline Ill (2)	0	0	0
Mildly Ill (3)	1 (2.2)	3 (6.7)	4 (4.4)
Moderately Ill (4)	25 (54.3)	20 (44.4)	45 (49.5)
Markedly Ill (5)	16 (34.8)	20 (44.4)	36 (39.6)
Severely Ill (6)	3 (6.5)	2 (4.4)	5 (5.5)
Among the Most Extremely Ill (7)	0	0	0
Age Group: Adolescents	**(N = 117)**	**(N = 111)**	**(N = 228)**
Not Assessed (0)	0	0	0
Normal, Not Ill (1)	0	0	0
Borderline Ill (2)	0	0	0
Mildly Ill (3)	3 (2.6)	3 (2.7)	6 (2.6)
Moderately Ill (4)	49 (41.9)	49 (44.1)	98 (43.0)
Markedly Ill (5)	45 (38.5)	41 (36.9)	86 (37.7)
Severely Ill (6)	18 (15.4)	15 (13.5)	33 (14.5)
Among the Most Extremely Ill (7)	2 (1.7)	2 (1.8)	4 (1.8)

Source: Table 13.9.1, Section 11; Listing 14.2.1, Appendix C

Median baseline scores for CGI-S were similar in the two treatment groups. For children, median scores were 4.0 in both treatment groups, with a range of 3 to 6. For adolescents, median scores were 5.0 in both treatment groups, with a range of 3 to 7 (Table 14.2.3, Section 12; Listings 14.2.1 and 14.2.3, Appendix C).

4.5 Presenting Conditions and Medical History

4.5.1 General Medical and Surgical History

Overall, there were no meaningful differences between the treatment groups with respect to general medical/surgical history, either in terms of total number of patients in each treatment group with past or current medical conditions, or in the type of past or current conditions reported.

The proportions of patients reporting a prior medical or surgical problem (excluding psychiatric disorders) were similar in both treatment groups: 58.3% (95/163) of patients in the paroxetine group and 54.5% (85/156) of patients in the placebo group. Most of the reported prior medical conditions were benign. The only past medical condition reported for 10% or more of patients in either treatment group was asthma, occurring in 8.0% (13/163) of patients in the paroxetine group and 10.3% (16/156) of patients in the placebo group.

The only surgical procedure reported for 10% or more of patients in either treatment group was nose/mouth operation, reported for 11.0% (18/163) of patients in the paroxetine group and 12.2% (19/156) of patients in the placebo group). Consistent with these numbers, the body system with the highest proportion of patients having a medical history was the Respiratory System (27.0% [44/163] of paroxetine-treated patients and 27.6% [43/156] of placebo patients). A complete tabulation of prior significant medical and surgical history may be found in Tables 13.6.1.1 and 13.6.1.2, Section 11, by body system and by decreasing frequency, respectively. Per-patient information may be found in Listing 13.6.1, Appendix B.

The proportions of patients reporting active medical conditions at Screening (excluding psychiatric disorders) were also similar in both treatment groups: 57.1% (93/163) in the paroxetine group and 53.2% (83/156) in the placebo group (Table 22). The only active medical conditions reported for 10% or more of patients in either treatment group were allergic rhinitis, reported for 13.5% (22/163) of patients in the paroxetine group and 15.4% (24/156) of patients in the placebo group) and headache, reported for 11.0% (18/163) of patients in the paroxetine group and 12.8% (20/156) of patients in the placebo group).

Consistent with these findings, the body system with the highest proportion of patients having an active medical condition was Respiratory (22.7% [37/163] of paroxetine-treated patients and 24.4% [38 /156] of placebo patients), followed by General Body or Unspecified (17.2% [28/163] of paroxetine-treated patients and

19.2% [30/156] of placebo patients). A complete tabulation of active medical conditions at Screening may be found in Tables 13.6.2.1 and 13.6.2.2, Section 11, by body system and by decreasing frequency, respectively, and Listing 13.6.1, Appendix B.

Patient 676.013.24344 had current elevated free T3 (preferred term: abnormal thyroid function) at Screening. The condition should have precluded the patient's entering the study. However, the patient was randomized to paroxetine and included in the PP population (see Section 4.3.2, Protocol Deviations Included in the Per-Protocol Population, and Section 15, Errata).

Table 22 Number and Percentage of Patients with Active Medical Conditions at Screening (Occurring in ≥5% of Patients in Either Treatment Group) (ITT Population)

	Treatment Group		
Active Condition	**Paroxetine (N = 163) n (%)**	**Placebo (N = 156) n (%)**	**Total (N = 319) n (%)**
Total Number of Patients with at Least One Active Condition	93 (57.1)	83 (53.2)	176 (55.2)
Rhinitis, allergic	22 (13.5)	24 (15.4)	46 (14.4)
Headache	18 (11.0)	20 (12.8)	38 (11.9)
Skin/subcut disorder, other	15 (9.2)	13 (8.3)	28 (8.8)
Asthma	10 (6.1)	12 (7.7)	22 (6.9)
Obesity	9 (5.5)	8 (5.1)	17 (5.3)
Allergy, NEC	6 (3.7)	8 (5.1)	14 (4.4)

Source: Table 13.6.2.2, Section 11; Listing 13.6.1, Appendix B

4.5.2 Current Psychiatric History

Table 23, Table 24 and Table 25 summarize the current history of Social Anxiety Disorder and other psychiatric conditions for both age groups combined and for children and for adolescents separately by treatment group. The psychiatric conditions presented here are based on information obtained using the Anxiety Disorders Interview Schedule for DSM-IV (ADIS for DSM-IV:C). The ADIS for DSM-IV:C Child and Parent Interview schedules are each semi-structured interviews organized diagnostically to permit differential diagnoses among all of the DSM-IV anxiety disorders. The diagnosis of any psychiatric disorder, including Social Anxiety Disorder, was to be made solely by the psychiatrist.

For the purposes of this study, the ADIS for DSM-IV:C was intended to capture current diagnoses for the purpose of determining the number of patients with

comorbid conditions. However, it is possible that in some cases past conditions were included as current conditions, and that the number of patients with these conditions is overestimated.

The proportions of patients with a current history of each psychiatric illness other than Social Anxiety Disorder were similar in both treatment groups, except that more patients in the paroxetine group (14.7%, 24/163) had a current history of an Additional Psychiatric Condition than in the placebo group (5.8%, 9/156) (Table 23). The most common conditions of patients in both treatment groups were Specific Phobia (24.8%, 79/319) and Generalized Anxiety Disorder (23.5%, 75/319), followed by Separation Anxiety Disorder (16.3%, 52/319).

Among children, there were small differences between treatment groups in the history of specific psychiatric disorders. There was a higher percentage of paroxetine patients with Additional Psychiatric Conditions (17.4%, 8/46) than placebo patients (6.7%, 3/45) and a higher percentage of paroxetine patients with Externalizing Disorders (13.0%, 6/46 paroxetine vs. 2.2%, 1/45 placebo). Conversely, there was a higher percentage of placebo patients with Generalized Anxiety Disorder (28.9%, 13/45) than paroxetine patients (15.2%, 7/46).

Among adolescents, there were no marked differences between treatment groups except for Additional Psychiatric Conditions (13.7%, 16/117 paroxetine vs. 5.4%, 6/111 placebo).

There was a higher percentage of children (28/91, 30.8%) with separation anxiety disorder compared to adolescents (24/228, 10.5%). Other conditions were generally comparable between the age groups.

Table 23 Summary of Psychiatric Conditions from ADIS for DSM-IV:C at Baseline–Age Group: Total (ITT Population)

	Paroxetine (N = 163)		Placebo (N = 156)		Total N = (319)	
Psychiatric Condition *	**Yes n (%)**	**No n (%)**	**Yes n (%)**	**No n (%)**	**Yes n (%)**	**No n (%)**
Social Anxiety Disorder (Social Phobia)	163 (100.0)	0	156 (100.0)	0	319 (100.0)	0
Specific Phobia	39 (23.9)	124 (76.1)	40 (25.6)	116 (74.4)	79 (24.8)	240 (75.2)
Generalized Anxiety Disorder	37 (22.7)	126 (77.3)	38 (24.4)	118 (75.6)	75 (23.5)	244 (76.5)
Separation Anxiety Disorder	28 (17.2)	135 (82.8)	24 (15.4)	132 (84.6)	52 (16.3)	267 (83.7)
Additional Psychiatric Conditions **	24 (14.7)	6 (3.7)	9 (5.8)	5 (3.2)	33 (10.3)	11 (3.4)
Dysthymia	13 (8.0)	150 (92.0)	13 (8.3)	143 (91.7)	26 (8.2)	293 (91.8)
Externalizing Disorders	13 (8.0)	150 (92.0)	8 (5.1)	148 (94.9)	21 (6.6)	298 (93.4)
Agoraphobia (with or without Panic Disorder)	4 (2.5)	159 (97.5)	5 (3.2)	151 (96.8)	9 (2.8)	310 (97.2)
Major Depressive Disorder	4 (2.5)	159 (97.5)	5 (3.2)	151 (96.8)	9 (2.8)	310 (97.2)
Post-traumatic Stress Disorder (PTSD) /Acute Stress Disorder	2 (1.2)	161 (98.8)	4 (2.6)	152 (97.4)	6 (1.9)	313 (98.1)
Panic Disorder	2 (1.2)	161 (98.8)	1 (0.6)	155 (99.4)	3 (0.9)	316 (99.1)
Obsessive Compulsive Disorder	1 (0.6)	162 (99.4)	2 (1.3)	154 (98.7)	3 (0.9)	316 (99.1)

Note: Sorted by paroxetine patients with a psychiatric condition

* Based on Anxiety Disorders Interview Schedule C/P conducted by a psychiatrist

** Additional Psychiatric Conditions include Oppositional Defiant Disorder, Enuresis, Selective Mutism, ADHD, Trichotillomania, Learning Disorder, Disorder of Written Expression, Reading Disorder, Conduct Disorder, History of Expressive Language Disorder, Drug Abuse, History of Alcohol Abuse and Chronic Motor Disorder.

Source: Table 13.7.1, Section 11; Listing 13.7.1, Appendix B

Table 24 Summary of Psychiatric Conditions from ADIS for DSM-IV:C at Baseline–Age Group: Children (ITT Population)

	Paroxetine (N = 46)		Placebo (N = 45)		Total (N = 91)	
Psychiatric Condition *	**Yes n (%)**	**No n (%)**	**Yes n (%)**	**No n (%)**	**Yes n (%)**	**No n (%)**
Social Anxiety Disorder (Social Phobia)	46 (100.0)	0	45 (100.0)	0	91 (100.0)	0
Separation Anxiety Disorder	15 (32.6)	31 (67.4)	13 (28.9)	32 (71.1)	28 (30.8)	63 (69.2)
Specific Phobia	12 (26.1)	34 (73.9)	13 (28.9)	32 (71.1)	25 (27.5)	66 (72.5)
Additional Psychiatric Conditions **	8 (17.4)	2 (4.3)	3 (6.7)	2 (4.4)	11 (12.1)	4 (4.4)
Generalized Anxiety Disorder	7 (15.2)	39 (84.8)	13 (28.9)	32 (71.1)	20 (22.0)	71 (78.0)
Externalizing Disorders	6 (13.0)	40 (87.0)	1 (2.2)	44 (97.8)	7 (7.7)	84 (92.3)
Agoraphobia (with or without Panic Disorder)	2 (4.3)	44 (95.7)	0	45 (100.0)	2 (2.2)	89 (97.8)
Dysthymia	2 (4.3)	44 (95.7)	4 (8.9)	41 (91.1)	6 (6.6)	85 (93.4)
Major Depressive Disorder	1 (2.2)	45 (97.8)	1 (2.2)	44 (97.8)	2 (2.2)	89 (97.8)
Panic Disorder	0	46 (100.0)	0	45 (100.0)	0	91 (100.0)
Obsessive Compulsive Disorder	0	46 (100.0)	1 (2.2)	44 (97.8)	1 (1.1)	90 (98.9)
Post-traumatic Stress Disorder (PTSD) / Acute Stress Disorder	0	46 (100.0)	0	45 (100.0)	0	91 (100.0)

Note: Sorted by paroxetine patients with a psychiatric condition

* Based on Anxiety Disorders Interview Schedule C/P conducted by a psychiatrist

** Additional Psychiatric Conditions include Oppositional Defiant Disorder, Enuresis, Selective Mutism, ADHD, Conduct Disorder, History of Expressive Language Disorder.

Source: Table 13.7.1, Section 11; Listing 13.7.1, Appendix B

Table 25 Summary of Psychiatric Conditions from ADIS for DSM-IV:C at Baseline–Age Group: Adolescents (ITT Population)

	Paroxetine (N = 117)		Placebo (N = 111)		Total (N = 228)	
Psychiatric Condition *	**Yes n (%)**	**No n (%)**	**Yes n (%)**	**No n (%)**	**Yes n (%)**	**No n (%)**
Social Anxiety Disorder (Social Phobia)	117 (100.0)	0	111 (100.0)	0	228 (100.0)	0
Generalized Anxiety Disorder	30 (25.6)	87 (74.4)	25 (22.5)	86 (77.5)	55 (24.1)	173 (75.9)
Specific Phobia	27 (23.1)	90 (76.9)	27 (24.3)	84 (75.7)	54 (23.7)	174 (76.3)
Additional Psychiatric Conditions **	16 (13.7)	4 (3.4)	6 (5.4)	3 (2.7)	22 (9.6)	7 (3.1)
Separation Anxiety Disorder	13 (11.1)	104 (88.9)	11 (9.9)	100 (90.1)	24 (10.5)	204 (89.5
Dysthymia	11 (9.4)	106 (90.6)	9 (8.1)	102 (91.9)	20 (8.8)	208 (91.2)
Externalizing Disorders	7 (6.0)	110 (94.0)	7 (6.3)	104 (93.7)	14 (6.1)	214 (93.9)
Major Depressive Disorder	3 (2.6)	114 (97.4)	4 (3.6)	107 (96.4)	7 (3.1)	221 (96.9)
Panic Disorder	2 (1.7)	115 (98.3)	1 (0.9)	110 (99.1)	3 (1.3)	225 (98.7)
Agoraphobia (with or without Panic Disorder)	2 (1.7)	115 (98.3)	5 (4.5)	106 (95.5)	7 (3.1)	221 (96.9)
Post-traumatic Stress Disorder (PTSD) / Acute Stress Disorder	2 (1.7)	115 (98.3)	4 (3.6)	107 (96.4)	6 (2.6)	222 (97.4)
Obsessive Compulsive Disorder	1 (0.9)	116 (99.1)	1 (0.9)	110 (99.1)	2 (0.9)	226 (99.1)

Note: Sorted by paroxetine patients with a psychiatric condition

* Based on Anxiety Disorders Interview Schedule C/P conducted by a psychiatrist

**Additional Psychiatric Conditions include Oppositional Defiant Disorder, Enuresis, Selective Mutism, ADHD, Trichotillomania, Learning Disorder, Disorder of Written Expression, Reading Disorder, Drug Abuse, History of Alcohol Abuse, Conduct Disorder, and Chronic Motor Disorder.

Source: Table 13.7.1, Section 11; Listing 13.7.1, Appendix B

According to results from the ADIS, the percentage of patients with comorbid psychiatric illness was slightly greater in the paroxetine group (56.4%, 92/163) than in the placebo group (48.7%, 76/156) (Appendix H, Statistical Appendix). The same pattern was observed in the child and adolescent subgroups (53.8%, 63/117 paroxetine vs. 45.0%, 50/111 placebo; and 64.4%, 29/45 paroxetine vs. 56.5%, 26/46 placebo, respectively).

Table 26 summarizes the DSM-IV clinician diagnosis and clinician severity ratings at Baseline for each condition based on the ADIS for DSM-IV:C. Section 3.10.1, Anxiety Disorders Interview Schedule (ADIS) for DSM-IV: Child Version, gives details of the symptom rating scale.

Overall, the proportion of patients in each severity rating for Social Anxiety Disorder was similar between the two treatment groups at Baseline. The majority of patients in the overall population were assessed with a Social Anxiety Disorder severity rating of Moderate (4-5) (paroxetine 27.6%, 45/163; placebo 31.4%, 49/156) or Severe (6-7) (paroxetine 58.3%, 95/163; placebo 55.8%, 87/156). The total of the two ratings is 87.2%, 140/163 of patients in the paroxetine group and 87.2%, 136/156 of patients in the placebo group at Baseline.

In the paroxetine group, 12.9% (21/163) of patients had a severity rating of Very Severe at Baseline, compared to 10.9% (17/156) of placebo patients. All patients in the study were diagnosed with Social Anxiety Disorder, but 3 adolescents, 2 randomized to paroxetine and 1 to placebo, were not assigned a severity rating and are not counted in Table 26.

Although there are more assessment categories in the CGI Severity of Illness item than in the ADIS for DSM-IV:C, the severity of Social Anxiety Disorder as determined by the ADIS for DSM-IV:C correlates well with the overall severity of illness as determined by the CGI-S in both treatment groups at Baseline in that over 95% of patients had a severity rating of moderately ill or worse according to both scales (Table 21 for CGI–S and Table 26 for ADIS for DSM-IV:C).

More than 15% of patients in each treatment group had an additional diagnosis of Separation Anxiety Disorder, Specific Phobia, or Generalized Anxiety Disorder. Among these disorders, the greatest percentage of patients in each treatment group were rated as having illness of moderate severity. Few patients had a severity rating of severe for Separation Anxiety Disorder or Specific Phobia; however, for GAD, 7.4% (12/163) of the paroxetine patients had a rating of severe, compared to 3.2% (5/156) of placebo patients.

Table 26 Number (%) of Patients in Each Diagnostic Category of the ADIS for DSM-IV:C by Overall Clinician Severity Rating at Baseline–Age Group: Total/Children/Adolescents (ITT Population)

	Paroxetine			Placebo		
Principal Diagnosis Severity *	**Children (N = 46) n (%)**	**Adolescents (N = 117) n (%)**	**Total (N = 163) n (%)**	**Children (N = 45) n (%)**	**Adolescents (N = 111) n (%)**	**Total (N = 156) n (%)**
Social Anxiety Disorder	46 (100.0)	115 (98.3)	161 (98.8)	45 (100.0)	110 (99.1)	155 (99.4)
Mild (1-3)	0	0	0	1 (2.2)	1 (0.9)	2 (1.3)
Moderate (4-5)	14 (30.4)	31 (26.5)	45 (27.6)	14 (31.1)	35 (31.5)	49 (31.4)
Severe (6-7)	26 (56.5)	69 (59.0)	95 (58.3)	22 (48.9)	65 (58.6)	87 (55.8)
Very Severe (8)	6 (13.0)	15 (12.8)	21 (12.9)	8 (17.8)	9 (8.1)	17 (10.9)
Separation Anxiety Disorder	15 (32.6)	13 (11.1)	28 (17.2)	13 (28.9)	11 (9.9)	24 (15.4)
Mild (1-3)	4 (8.7)	3 (2.6)	7 (4.3)	1 (2.2)	3 (2.7)	4 (2.6)
Moderate (4-5)	10 (21.7)	7 (6.0)	17 (10.4)	9 (20.0)	6 (5.4)	15 (9.6)
Severe (6-7)	1 (2.2)	2 (1.7)	3 (1.8)	3 (6.7)	1 (0.9)	4 (2.6)
Very Severe (8)	0	1 (0.9)	1 (0.6)	0	1 (0.9)	1 (0.6)

Note: Totals for each diagnosis are the number of patients with a severity rating, not necessarily the number of patients diagnosed

* Based on Anxiety Disorders Interview Schedule C/P conducted by a psychiatrist

** Other psychiatric conditions include Oppositional Defiant Disorder, Enuresis, Selective Mutism, ADHD, Trichotillomania, Learning Disorder, Disorder of Written Expression, Reading Disorder, Conduct Disorder, History of Expressive Language Disorder, Drug Abuse, History of Alcohol Abuse and Chronic Motor Disorder.

† The denominator used for the percentages of patients with "Other" psychiatric conditions in the data source table was the number of patients who had an additional condition listed; the percentages have been changed in this table so that the denominator is the ITT population (see Section 15, Errata).

Source: Table 13.7.2, Section 11; Listing 13.7.1, Appendix B

(Table continues)

Table 26 (Continued) Number (%) of Patients in Each Diagnostic Category of the ADIS for DSM-IV:C by Overall Clinician Severity Rating at Baseline–Age Group: Total/Children/Adolescents (ITT Population)

	Paroxetine			Placebo		
Principal Diagnosis Severity *	**Children (N = 46) n (%)**	**Adolescents (N = 117) n (%)**	**Total (N = 163) n (%)**	**Children (N = 45) n (%)**	**Adolescents (N = 111) n (%)**	**Total (N = 156) n (%)**
Specific Phobia	12 (26.1)	26 (22.2)	38 (23.3)	13 (28.9)	27 (24.3)	40 (25.6)
Mild (1-3)	4 (8.7)	9 (7.7)	13 (8.0)	6 (13.3)	10 (9.0)	16 (10.3)
Moderate (4-5)	7 (15.2)	14 (12.0)	21 (12.9)	6 (13.3)	15 (13.5)	21 (13.5)
Severe (6-7)	1 (2.2)	2 (1.7)	3 (1.8)	0	2 (1.8)	2 (1.3)
Very Severe (8)	0	1 (0.9)	1 (0.6)	1 (2.2)	0	1 (0.6)
Panic Disorder	0	2 (1.7)	2 (1.2)	0	1 (0.9)	1 (0.6)
Mild (1-3)	0	1 (0.9)	1 (0.6)	0	1 (0.9)	1 (0.6)
Moderate (4-5)	0	1 (0.9)	1 (0.6)	0	0	0
Severe (6-7)	0	0	0	0	0	0
Very Severe (8)	0	0	0	0	0	0

Note: Totals for each diagnosis are the number of patients with a severity rating, not necessarily the number of patients diagnosed

* Based on Anxiety Disorders Interview Schedule C/P conducted by a psychiatrist

** Other psychiatric conditions include Oppositional Defiant Disorder, Enuresis, Selective Mutism, ADHD, Trichotillomania, Learning Disorder, Disorder of Written Expression, Reading Disorder, Conduct Disorder, History of Expressive Language Disorder, Drug Abuse, History of Alcohol Abuse and Chronic Motor Disorder.

† The denominator used for the percentages of patients with "Other" psychiatric conditions in the data source table was the number of patients who had an additional condition listed; the percentages have been changed in this table so that the denominator is the ITT population (see Section 15, Errata).

Source: Table 13.7.2, Section 11; Listing 13.7.1, Appendix B

(Table continues)

Table 26 (Continued) Number (%) of Patients in Each Diagnostic Category of the ADIS for DSM-IV:C by Overall Clinician Severity Rating at Baseline–Age Group: Total/Children/Adolescents (ITT Population)

	Paroxetine			Placebo		
Principal Diagnosis Severity *	**Children (N = 46) n (%)**	**Adolescents (N = 117) n (%)**	**Total (N = 163) n (%)**	**Children (N = 45) n (%)**	**Adolescents (N = 111) n (%)**	**Total (N = 156) n (%)**
Agoraphobia (with or without Panic Disorder)	2 (4.3)	2 (1.7)	4 (2.5)	0	5 (4.5)	5 (3.2)
Mild (1-3)	1 (2.2)	1 (0.9)	2 (1.2)	0	2 (1.8)	2 (1.3)
Moderate (4-5)	1 (2.2)	1 (0.9)	2 (1.2)	0	1 (0.9)	1 (0.6)
Severe (6-7)	0	0	0	0	2 (1.8)	2 (1.3)
Very Severe (8)	0	0	0	0	0	0
GAD	7 (15.2)	30 (25.6)	37 (22.7)	13 (28.9)	25 (22.5)	38 (24.4)
Mild (1-3)	1 (2.2)	3 (2.6)	4 (2.5)	0	4 (3.6)	4 (2.6)
Moderate (4-5)	4 (8.7)	17 (14.5)	21 (12.9)	10 (22.2)	19 (17.1)	29 (18.6)
Severe (6-7)	2 (4.3)	10 (8.5)	12 (7.4)	3 (6.7)	2 (1.8)	5 (3.2)
Very Severe (8)	0	0	0	0	0	0

Note: Totals for each diagnosis are the number of patients with a severity rating, not necessarily the number of patients diagnosed

* Based on Anxiety Disorders Interview Schedule C/P conducted by a psychiatrist

** Other psychiatric conditions include Oppositional Defiant Disorder, Enuresis, Selective Mutism, ADHD, Trichotillomania, Learning Disorder, Disorder of Written Expression, Reading Disorder, Conduct Disorder, History of Expressive Language Disorder, Drug Abuse, History of Alcohol Abuse and Chronic Motor Disorder.

† The denominator used for the percentages of patients with "Other" psychiatric conditions in the data source table was the number of patients who had an additional condition listed; the percentages have been changed in this table so that the denominator is the ITT population (see Section 15, Errata).

Source: Table 13.7.2, Section 11; Listing 13.7.1, Appendix B

(Table continues)

Table 26 (Continued) Number (%) of Patients in Each Diagnostic Category of the ADIS for DSM-IV:C by Overall Clinician Severity Rating at Baseline–Age Group: Total/Children/Adolescents (ITT Population)

	Paroxetine			Placebo		
Principal Diagnosis Severity *	**Children (N = 46) n (%)**	**Adolescents (N = 117) n (%)**	**Total (N = 163) n (%)**	**Children (N = 45) n (%)**	**Adolescents (N = 111) n (%)**	**Total (N = 156) n (%)**
OCD	0	1 (0.9)	1 (0.6)	1 (2.2)	1 (0.9)	2 (1.3)
Mild (1-3)	0	0	0	1 (2.2)	0	1 (0.6)
Moderate (4-5)	0	0	0	0	1 (0.9)	1 (0.6)
Severe (6-7)	0	1 (0.9)	1 (0.6)	0	0	0
Very Severe (8)	0	0	0	0	0	0
Post Traumatic Stress	0	2 (1.7)	2 (1.2)	0	4 (3.6)	4 (2.6)
Mild (1-3)	0	1 (0.9)	1 (0.6)	0	0	0
Moderate (4-5)	0	1 (0.9)	1 (0.6)	0	4 (3.6)	4 (2.6)
Severe (6-7)	0	0	0	0	0	0
Very Severe (8)	0	0	0	0	0	0

Note: Totals for each diagnosis are the number of patients with a severity rating, not necessarily the number of patients diagnosed

* Based on Anxiety Disorders Interview Schedule C/P conducted by a psychiatrist

** Other psychiatric conditions include Oppositional Defiant Disorder, Enuresis, Selective Mutism, ADHD, Trichotillomania, Learning Disorder, Disorder of Written Expression, Reading Disorder, Conduct Disorder, History of Expressive Language Disorder, Drug Abuse, History of Alcohol Abuse and Chronic Motor Disorder.

† The denominator used for the percentages of patients with "Other" psychiatric conditions in the data source table was the number of patients who had an additional condition listed; the percentages have been changed in this table so that the denominator is the ITT population (see Section 15, Errata).

Source: Table 13.7.2, Section 11; Listing 13.7.1, Appendix B

(Table continues)

Table 26 (Continued) Number (%) of Patients in Each Diagnostic Category of the ADIS for DSM-IV:C by Overall Clinician Severity Rating at Baseline–Age Group: Total/Children/Adolescents (ITT Population)

	Paroxetine			Placebo		
Principal Diagnosis Severity *	**Children (N = 46) n (%)**	**Adolescents (N = 117) n (%)**	**Total (N = 163) n (%)**	**Children (N = 45) n (%)**	**Adolescents (N = 111) n (%)**	**Total (N = 156) n (%)**
Dysthymia	2 (4.3)	11 (9.4)	13 (8.0)	4 (8.9)	9 (8.1)	13 (8.3)
Mild (1-3)	1 (2.2)	1 (0.9)	2 (1.2)	2 (4.4)	2 (1.8)	4 (2.6)
Moderate (4-5)	1 (2.2)	7 (6.0)	8 (4.9)	1 (2.2)	7 (6.3)	8 (5.1)
Severe (6-7)	0	3 (2.6)	3 (1.8)	1 (2.2)	0	1 (0.6)
Very Severe (8)	0	0	0	0	0	0
Major Depressive Disorder	1 (2.2)	3 (2.6)	4 (2.5)	1 (2.2)	4 (3.6)	5 (3.2)
Mild (1-3)	0	1 (0.9)	1 (0.6)	1 (2.2)	1 (0.9)	2 (1.3)
Moderate (4-5)	1 (2.2)	0	1 (0.6)	0	2 (1.8)	2 (1.3)
Severe (6-7)	0	2 (1.7)	2 (1.2)	0	1 (0.9)	1 (0.6)
Very Severe (8)	0	0	0	0	0	0

Note: Totals for each diagnosis are the number of patients with a severity rating, not necessarily the number of patients diagnosed

* Based on Anxiety Disorders Interview Schedule C/P conducted by a psychiatrist

** Other psychiatric conditions include Oppositional Defiant Disorder, Enuresis, Selective Mutism, ADHD, Trichotillomania, Learning Disorder, Disorder of Written Expression, Reading Disorder, Conduct Disorder, History of Expressive Language Disorder, Drug Abuse, History of Alcohol Abuse and Chronic Motor Disorder.

† The denominator used for the percentages of patients with "Other" psychiatric conditions in the data source table was the number of patients who had an additional condition listed; the percentages have been changed in this table so that the denominator is the ITT population (see Section 15, Errata).

Source: Table 13.7.2, Section 11; Listing 13.7.1, Appendix B

(Table continues)

Table 26 (Continued) Number (%) of Patients in Each Diagnostic Category of the ADIS for DSM-IV:C by Overall Clinician Severity Rating at Baseline–Age Group: Total/Children/Adolescents (ITT Population)

	Paroxetine			Placebo		
Principal Diagnosis Severity *	**Children (N = 46) n (%)**	**Adolescents (N = 117) n (%)**	**Total (N = 163) n (%)**	**Children (N = 45) n (%)**	**Adolescents (N = 111) n (%)**	**Total (N = 156) n (%)**
Externalizing Disorders	6 (13.0)	7 (6.0)	13 (8.0)	1 (2.2)	7 (6.3)	8 (5.1)
Mild (1-3)	1 (2.2)	0	1 (0.6)	0	2 (1.8)	2 (1.3)
Moderate (4-5)	4 (8.7)	6 (5.1)	10 (6.1)	0	5 (4.5)	5 (3.2)
Severe (6-7)	1 (2.2)	1 (0.9)	2 (1.2)	1 (2.2)	0	1 (0.6)
Very Severe (8)	0	0	0	0	0	0
Other ** †	9 (19.6)	16 (13.7)	25 (15.3)	3 (6.6)	6 (5.4)	9 (5.8)
Mild (1-3)	2 (4.3)	5 (4.3)	7 (4.3)	2 (4.4)	3 (2.7)	5 (3.2)
Moderate (4-5)	4 (8.7)	8 (6.8)	12 (7.4)	0	2 (1.8)	2 (1.3)
Severe (6-7)	3 (6.5)	3 (2.6)	6 (3.7)	0	1 (0.9)	1 (0.6)
Very Severe (8)	0	0	0	1 (2.2)	0	1 (0.6)

Note: Totals for each diagnosis are the number of patients with a severity rating, not necessarily the number of patients diagnosed

* Based on Anxiety Disorders Interview Schedule C/P conducted by a psychiatrist

** Other psychiatric conditions include Oppositional Defiant Disorder, Enuresis, Selective Mutism, ADHD, Trichotillomania, Learning Disorder, Disorder of Written Expression, Reading Disorder, Conduct Disorder, History of Expressive Language Disorder, Drug Abuse, History of Alcohol Abuse and Chronic Motor Disorder.

† The denominator used for the percentages of patients with "Other" psychiatric conditions in the data source table was the number of patients who had an additional condition listed; the percentages have been changed in this table so that the denominator is the ITT population (see Section 15, Errata).

Source: Table 13.7.2, Section 11; Listing 13.7.1, Appendix B

4.6 Baseline Signs and Symptoms

Data Source Table 15.1.1.0, Section 13, summarizes the baseline signs and symptoms (baseline AEs) reported prior to the start of randomized treatment using ADECS body system and preferred term. Listing 15.1.1, Appendix D, presents the baseline signs and symptoms for each patient by treatment group and provide details on the onset, severity and duration of the events.

A total of 12.3% (20/163) of ITT patients randomized to paroxetine and 15.4% (24/156) of patients in the placebo group reported one or more non-gender-specific baseline signs or symptoms. No patients reported gender-specific baseline signs or symptoms. The nature and incidence of baseline signs and symptoms were comparable between the treatment groups. The most frequent baseline sign or symptom was headache, which occurred in 3.1%(5/163) of paroxetine patients and 5.1% (8/156) of placebo patients. There were no other baseline signs or symptoms that occurred in more than 3% of patients in either treatment group.

4.6.1 Electrocardiographic Data

A 12-lead ECG was carried out at Screening on all patients; a repeat ECG was performed at Baseline if clinically significant abnormalities were identified at the previous visit. If clinically significant abnormalities were identified at Baseline, the patient was not to be entered into the study. Table 13.8.1, Section 11, presents summary data for all patients with ECG assessments during the study. Individual patient results may be found in Listing 13.8.1, Appendix B.

Patient 676.002.24043 had an abnormal ECG at Screening and was not randomized. Patient 676.015.24406, an adolescent randomized to paroxetine, had an abnormal ECG at Screening and a normal ECG at Baseline. The patient discontinued due to an AE of nausea/vomiting at Week 1. Patient 676.020.24536, an adolescent randomized to paroxetine, had an abnormal ECG at Screening and a normal ECG on Day 17. The patient completed the study with no ECG-related adverse events. Patient 676.011.24281, a child randomized to placebo, had an abnormal ECG at Screening and at Baseline. The patient was admitted into the study after consultation with a cardiologist indicated that the abnormality was not serious and that an SSRI would not have an effect. The patient had previously taken fluoxetine and tolerated it well (see Section 4.3.2, Protocol Deviations Included in the Per-Protocol Population). The patient did not experience any adverse events on therapy. Patient 676.101.24617, an adolescent randomized to

placebo, had an abnormal ECG at Screening and a normal ECG at Baseline. The patient completed the study with no ECG-related adverse events.

All other ECGs at Screening were normal (Listing 13.8.1, Appendix B). No additional ECGs were scheduled per protocol.

4.7 Prior and Concomitant Medications

4.7.1 Prior Medications

4.7.1.1 Prior Psychoactive Medications

Table 27 summarizes prior psychoactive medication taken during the past year prior to Screening by psychoactive class. Psychoactive medication history may be found in Table 13.16.1.1, presented by therapeutic class, and Table 13.16.1.2, in order of decreasing frequency, both in Section 11, and Listing 13.16.1, Appendix B. Most patients had not previously taken any psychoactive medications. The proportion of patients who had taken prior psychoactive medications was similar between the two treatment groups (18.4% [30/163] and 19.2% [30/156] for the paroxetine and placebo groups, respectively).

The most frequent prior psychoactive medication was methylphenidate HCl (Ritalin®), taken by 7.4% (12/163) of paroxetine patients and 6.4% (10/156) placebo patients. Adderall® (amphetamine aspartate, amphetamine sulfate, dextroamphetamine saccharate, and dextroamphetamine sulfate) was taken by 1.2% of paroxetine patients (2/163) and 2.6% of placebo patients (4/156). Paroxetine was previously taken by 2.5% (4/163) of paroxetine patients and 3.8% (6/156) placebo patients. Other prior psychoactive medications used by >1 patient in either treatment group were the SSRIs sertraline, citalopram, and fluoxetine; the tricyclic antidepressant imipramine; and the benzodiazepine lorazepam. None was taken by more than 4 patients in either treatment group and no other psychoactive medication was taken by more than one person in either treatment group (Table 13.16.1.2, Section 11).

Table 27 Psychoactive Medication History–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group		
Previous Psychoactive Medication *	**Paroxetine**	**Placebo**	**Total**
Therapeutic Class and Medication **	**n (%)**	**n (%)**	**n (%)**
Age Group: Total	**(N = 163)**	**(N = 156)**	**(N = 319)**
Total Patients Taking Prior Psychoactive Medication †	30 (18.4)	30 (19.2)	60 (18.8)
SSRI	10 (6.1)	12 (7.7)	22 (6.9)
TCA	5 (3.1)	1 (0.6)	6 (1.9)
Benzodiazepines	3 (1.8)	4 (2.6)	7 (2.2)
Other psychoactive medications ††	20 (12.3)	16 (10.3)	36 (11.3)
None	133 (81.6)	126 (80.8)	259 (81.2)
Age Group: Children	**(N = 46)**	**(N = 45)**	**(N = 91)**
Total Patients Taking Prior Psychoactive Medication	4 (8.7)	8 (17.8)	12 (13.2)
SSRI	0	2 (4.4)	2 (2.2)
TCA	1 (2.2)	0	1 (1.1)
Benzodiazepines	0	1 (2.2)	1 (1.1)
Other psychoactive medications ††	3 (6.5)	5 (11.1)	8 (8.8)
None	42 (91.3)	37 (82.2)	79 (86.8)
Age Group: Adolescents	**(N = 117)**	**(N = 111)**	**(N = 228)**
Total Patients Taking Prior Psychoactive Medication †	26 (22.2)	22 (19.8)	48 (21.1)
SSRI	10 (8.5)	10 (9.0)	20 (8.8)
TCA	4 (3.4)	1 (0.9)	5 (2.2)
Benzodiazepines	3 (2.6)	3 (2.7)	6 (2.6)
Other psychoactive medications ††	17 (14.5)	11 (9.9)	28 (12.3)
None	91 (77.8)	89 (80.2)	180 (78.9)

SSRI = selective serotonin reuptake inhibitor, TCA = tricyclic antidepressant

* Taken during the one year prior to Screening.

** No patient took an MAOI in the year prior to Screening

† Some patients took more than one prior medication

†† "Other" includes amfebutamone hydrochloride, amphetamine aspartate, amphetamine sulfate, carbamazepine, clonidine, dexamphetamine sulfate, dextroamphetamine saccharate, dextroamphetamine sulfate, flupentixol dihydrochloride, hydroxyzine hydrochloride, hypericum extract, methylphenidate hydrochloride, mirtazapine, nefazodone, oxybutynin, pemoline magnesium, propranolol hydrochloride, risperidone, thioridazine hydrochloride, and trazodone hydrochloride.

Source: Table 13.16.1.1, Section 11; Listing 13.16.1, Appendix B

4.7.1.2 Prior Non-psychoactive Medications

Non-psychoactive medications that were taken within the month prior to entry into the trial are summarized in Table 13.16.2.1, Section 11. The medications are summarized using the WHO ATC (Anatomical Therapeutic Chemical) Code generic names and the Level I drug classification system. In the ATC Level I classification system, medications that are part of combination products may be counted in more than one ATC level. For example, acetylsalicylic acid is represented in both the central nervous system category and the respiratory category. A complete summary by generic name in order of decreasing frequency may be found in Table 13.16.2.2, Section 11, in which components are counted only once. Per-patient details, including dosage, route, indication, and starting and ending days relative to start and end of randomized study medication may be found in Listings 13.16.2.1 and 13.16.2.2, Appendix B.

A total of 44.8% (73/163) of paroxetine patients and 39.7% (62/156) of placebo patients had used non-psychoactive medication within the month prior to Screening. The therapeutic classes with the greatest number of prior medications in both treatment groups were Central Nervous System, Dermatological, and Respiratory (Table 13.16.2.1, Section 11; Listings 13.16.2.1 and 13.16.2.2, Appendix B).

The most frequent single medications used were over-the-counter (OTC) analgesics, primarily paracetamol (7.4%, 12/163, in the paroxetine group and 10.3%, 16/156, in the placebo group) and ibuprofen (6.7%, 11/163 in the paroxetine group and 5.1%, 8/156 in the placebo group). There were no substantial differences between treatment groups relative to medication use prior to study entry (Table 13.16.2.2, Section 11; Listings 13.16.2.1 and 13.16.2.2, Appendix B).

4.7.2 Concomitant Medication

Table 28 presents a summary of the most frequently reported (≥5% in either treatment group) concomitant medications taken during the Treatment Phase by therapeutic class. A total of 75.2% of the ITT population (240/319) were reported to have taken at least one concomitant medication, 79.1% of patients (129/163) in the paroxetine group and 71.2% of patients (111/156) in the placebo group. The proportion of patients taking each medication by therapeutic class was generally similar between treatment groups.

As was the case for prior medications, the most frequently reported concomitant medications by therapeutic class in both treatment groups were central nervous system agents (primarily OTC analgesics, most frequently paracetamol and ibuprofen), taken by 54.0% of the patients (88/163) in the paroxetine group and 46.2% of patients (72/156) in the placebo group (Table 13.16.2.4, Section 11). There were no important differences between treatment groups with respect to specific medication intake. The most frequent single medication used was paracetamol, taken by 41.1% of patients (67/163) in the paroxetine group and 35.3% of patients (55/156) in the placebo group.

If during the Treatment Phase a patient took any psychoactive medication for a psychiatric indication, or took a psychoactive medication for any indication other than a psychiatric indication for more than 7 days, the patient was excluded from the PP population (see Section 4.3, Protocol Violations). Patients 676.002.24031, 676.003.24058, 676.010.24254 (all children in the paroxetine group), and 676.015.24414 (an adolescent on paroxetine) all took medication containing diphenhydramine for ≥ 7 days and were considered protocol violators (Listing 13.2.1, Appendix B).

According to Table 13.16.2.3, Section 11, 4 patients in the paroxetine group and 2 patients in the placebo group took paroxetine during the Treatment Phase in addition to or instead of blinded medication. However, 4 of these patients (676.005.24124 and 676.007.24184 in the paroxetine group and 676.007.24175 and 676.007.24185 in the placebo group) were prescribed paroxetine at the end of the study by the investigator in order to continue the treatment of Social Anxiety Disorder, and patient 676.100.24705, in the paroxetine group was prescribed paroxetine at the end of the study by the investigator for worsening depression. Because of the way data were reported, it appeared in each case that there was a one-day overlap of study medication with the prescribed paroxetine. However, only patient 676.209.24961, in the paroxetine group, was prescribed paroxetine (Aropax®) before the last dose of study medication (in this case on Day 52 of the study, 31 days before the last dose of study medication). This patient was considered a protocol violator (Listing 13.2.1, Appendix B).

A complete summary by WHO ATC generic names and the Level I drug classification system may be found in Table 13.16.2.3, Section 11, 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 13.16.2.4, Section 11, in which components are counted only once. Per-patient details, including dosage, indication, and starting

and ending days relative to start and end of randomized study medication may be found in Listings 13.16.2.1 and 13.16.2.2, Appendix B.

Table 28 Frequently Reported (≥5% in Either Treatment Group) Concomitant Medications During the Treatment Phase (Excluding Taper Phase) by Therapeutic Classes and Drug–Age Group: Total (ITT Population)

	Treatment Group	
	Paroxetine	**Placebo**
Total Number of Patients	**(N = 163)**	**(N = 156)**
Total Patients with a Concomitant Medication *	**129 (79.1)**	**111 (71.2)**
Therapeutic Class and Medication	**n (%)**	**n (%)**
Alimentary Tract/Metabolic	48 (29.4)	31 (19.9)
Acetylsalicylic acid	11 (6.7)	9 (5.8)
Vitamins NOS	10 (6.1)	5 (3.2)
Anti-infectives, Systemic	45 (27.6)	48 (30.8)
Amoxicillin Trihydrate	9 (5.5)	12 (7.7)
Blood/Blood Forming Organs	13 (8.0)	10 (6.4)
Acetylsalicylic acid	11 (6.7)	8 (5.1)
Central Nervous System	88 (54.0)	72 (46.2)
Paracetamol	64 (39.3)	52 (33.3)
Ibuprofen	34 (20.9)	22 (14.1)
Acetylsalicylic acid	16 (9.8)	15 (9.6)
Caffeine	8 (4.9)	8 (5.1)
Pseudoephedrine HCl	7 (4.3)	8 (5.1)
Dermatologicals	39 (23.9)	36 (23.1)
Diphenhydramine HCl	10 (6.1)	3 (1.9)
Musculoskeletal	40 (24.5)	30 (19.2)
Ibuprofen	32 (19.6)	23 (14.7)
Respiratory	68 (41.7)	68 (43.6)
Pseudoephedrine HCl	18 (11.0)	17 (10.9)
Chlorphenamine Maleate	16 (9.8)	12 (7.7)
Paracetamol	13 (8.0)	16 (10.3)
Diphenhydramine HCl	13 (8.0)	7 (4.5)
Phenylpropanolamine HCl	10 (6.1)	12 (7.7)
Phenylephrine HCl	9 (5.5)	8 (5.1)
Loratadine	8 (4.9)	8 (5.1)
Guaifenesin	3 (1.8)	12 (7.7)

Note: Sorted by medications taken by paroxetine patients by descending frequency within each therapeutic class
NOS = Not otherwise specified
* Patients taking multiple concomitant medications are counted only once.
Source: Tables 13.16.2.3 and 13.16.2.4, Section 11; Listing 13.16.2.1 and 13.16.2.2, Appendix B

During the combined Taper and Follow-up Phases, concomitant medication usage was reported for 67.4% (97/144) and 64.3% (83/129) of the paroxetine and placebo patients, respectively (Tables 13.16.2.5 and 13.16.2.6, by Level I classification and by generic name in order of decreasing frequency, respectively) Section 11; Listings 13.16.2.1 and 13.16.2.2, Appendix B). The most frequently used medication during the Taper and Follow-up Phases in both treatment groups was paracetamol, taken by 16.0% (23/144) of the paroxetine patients and 16.3% (21/129) of the placebo patients. Other medications taken by >5% of patients were ibuprofen (11.8%, 17/144 paroxetine group; 10.1%, 13/129 placebo group); ethinylestradiol (6.3%, 9/144 paroxetine group; 0.8%, 1/129 placebo group); loratadine (5.6%, 8/144 paroxetine group; 5.4%, 7/129 placebo group); and vitamins NOS (5.6%, 8/144 paroxetine group; 3.1%, 4/129 placebo group).

4.8 Treatment Compliance and Titration

4.8.1 Treatment Compliance

Table 29 (both age groups combined) and Table 30 (children and adolescents) present summaries of the patients who missed more than 3 consecutive days study medication at any time during the study and by each visit interval. The percentage of patients who missed more than 3 consecutive days study medication at any time was greater in the placebo group, 17.4% (27/156), than in the paroxetine group, 11.7% (19/163) (Table 13.17.1, Section 11; Listing 13.17.1, Appendix B). This imbalance occurred similarly among children (10.9% paroxetine, 5/46, vs. 17.8% placebo, 8/45) and among adolescents (12.1% paroxetine, 14/117, vs. 17.3% placebo, 19/111).

Table 13.17.1, Section 11, counts patients with unknown compliance at a visit and duration of study medication >3 days at that visit as non-compliant for that visit. Therefore, it contains 5 more patients as having missed more than 3 consecutive days medication than Listing 13.2.1, Appendix B (Protocol Violators), which is based solely on the investigators' reporting of patients who missed more than 3 consecutive days study medication and does not account for patients with unknown compliance (see Section 4.3.1, Patients Excluded from the Per-Protocol Population).

Patients missing >3 consecutive days of dosing were to be withdrawn from the study. Of the total of 19 paroxetine patients and 27 placebo patients who missed >3 consecutive days of dosing according to the study medication record completed by the investigator, only 6 paroxetine and 10 placebo patients were withdrawn from the study for a protocol violation. Six of the remaining

paroxetine patients and 8 of the placebo patients completed the study, and the rest were withdrawn prematurely for other reasons. All patients who missed more than 3 consecutive days of study medication, even if on only one occasion, were excluded from the PP population.

Table 29 Summary of Patients Missing >3 Consecutive Days Study Medication, Excluding Taper Phase–Age Group: Total (ITT Population)

	Treatment Group			
	Paroxetine		Placebo	
Missed >3 Consecutive Days	No n (%) *	Yes n (%) *	No n (%) *	Yes n (%) *
Week 1	159 (98.1)	3 (1.9)	154 (99.4)	1 (0.6)
Week 2	160 (100.0)	0	151 (100.0)	0
Week 3	158 (99.4)	1 (0.6)	149 (100.0)	0
Week 4	155 (100.0)	0	141 (99.3)	1 (0.7)
Week 6	148 (96.7)	5 (3.3)	137 (97.2)	4 (2.8)
Week 8	140 (97.9)	3 (2.1)	124 (94.7)	7 (5.3)
Week 10	134 (96.4)	5 (3.6)	111 (94.9)	6 (5.1)
Week 12	131 (100.0)	0	108 (98.2)	2 (1.8)
Week 16	124 (96.1)	5 (3.9)	98 (90.7)	10 (9.3)
Overall **	143 (88.3)	19 (11.7)	128 (82.6)	27 (17.4)

Note: Data for PID 676.021.24565, an adolescent in the paroxetine group, are not included in this table due to irreconcilable dosing data. This patient is included in Listing 13.17.1, Appendix B (see Section 15, Errata)

* Percentages are based on the number of patients in each treatment group who have this study medication information on the relevant eCRF panel. Patients with unknown compliance and duration of study medication >3 days at that visit were considered non-compliant.

** Number of patients who missed >3 consecutive days of study medication at any time during the study. Patients missing >3 consecutive days on more than one occasion are only counted once.

Source: Table 13.17.1, Section 11; Listing 13.17.1, Appendix B

Table 30 Summary of Patients Missing >3 Consecutive Days Study Medication, Excluding Taper Phase–Age Group: Children/Adolescents (ITT Population)

	Treatment Group			
	Paroxetine		Placebo	
Missed >3 Consecutive Days	No n (%) *	Yes n (%) *	No n (%) *	Yes n (%) *
Age Group: Children				
Week 1	46 (100.0)	0	45 (100.0)	0
Week 2	46 (100.0)	0	45 (100.0)	0
Week 3	45 (97.8)	1 (2.2)	45 (100.0)	0
Week 4	43 (100.0)	0	43 (100.0)	0
Week 6	42 (100.0)	0	39 (95.1)	2 (4.9%)
Week 8	39 (95.1)	2 (4.9)	37 (97.4)	1 (2.6)
Week 10	38 (97.4)	1 (2.6)	33 (97.1)	1 (2.9)
Week 12	35 (100.0)	0	31 (100.0)	0
Week 16	32 (94.1)	2 (5.9)	27 (87.1)	4 (12.9)
Overall **	41 (89.1)	5 (10.9)	37 (82.2)	8 (17.8)
Age Group: Adolescents				
Week 1	113 (97.4)	3 (2.6)	109 (99.1)	1 (0.9)
Week 2	114 (100.0)	0	106 (100.0)	0
Week 3	113 (100.0)	0	104 (100.0)	0
Week 4	112 (100.0)	0	98 (99.0)	1 (1.0)
Week 6	106 (95.5)	5 (4.5)	98 (98.0)	2 (2.0)
Week 8	101 (99.0)	1 (1.0)	87 (93.5)	6 (6.5)
Week 10	96 (96.0)	4 (4.0)	78 (94.0)	5 (6.0)
Week 12	96 (100.0)	0	77 (97.5)	2 (2.5)
Week 16	92 (96.8)	3 (3.2)	71 (92.2)	6 (7.8)
Overall **	102 (87.9)	14 (12.1)	91 (82.7)	19 (17.3)

Note: Data for PID 676.021.24565, an adolescent in the paroxetine group, are not included in this table due to irreconcilable dosing data. This patient is included in Listing 13.17.1, Appendix B (see Section 15, Errata).

* Percentages are based on the number of patients in each treatment group who have this study medication information on the relevant eCRF panel. Patients with unknown compliance and duration of study medication >3 days at that visit were considered non-compliant.

** Number of patients who missed >3 consecutive days study medication at any time during the study. Patients missing >3 consecutive days on more than one occasion are only counted once.

Source: Table 13.17.1, Section 11; Listing 13.17.1, Appendix B

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

$$\left(\frac{No.\,of\ \ Capsules\ Dispensed - No.\,of\ \ Capsules\ Returned}{No.\,of\ \ Days * 2} \right) * 100$$

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

Between 77.5% and 93.1% of paroxetine patients and between 83.5% and 91.4% of placebo patients in the overall population fell within the range of 80% to 120% accountability at each visit (Table 31, Table 32, and Table 33). The pattern of accountability was similar among placebo patients and paroxetine patients in both age groups, with one exception: Accountability at Week 8 fell to 77.5% (31/46 patients) among children receiving paroxetine compared to 89.5% (34/45 patients) for children receiving placebo.

Table 31 Capsule Accountability (Number (%) of Patients) at Each Visit–Age Group: Total (ITT Population)

	Treatment Group					
	Paroxetine		Placebo		Total	
Accountability *	Accountable n (%)	Non-accountable n (%)	Accountable n (%)	Non-accountable n (%)	Accountable n (%)	Non-accountable n (%)
Week 1	143 (89.4)	17 (10.6)	136 (88.3)	18 (11.7)	279 (88.9)	35 (11.1)
Week 2	149 (93.1)	11 (6.9)	134 (88.7)	17 (11.3)	283 (91.0)	28 (9.0)
Week 3	147 (92.5)	12 (7.5)	134 (90.5)	14 (9.5)	281 (91.5)	26 (8.5)
Week 4	137 (89.0)	17 (11.0)	120 (85.1)	21 (14.9)	257 (87.1)	38 (12.9)
Week 6	117 (77.5)	34 (22.5)	116 (83.5)	23 (16.5)	233 (80.3)	57 (19.7)
Week 8	123 (86.0)	20 (14.0)	115 (89.8)	13 (10.2)	238 (87.8)	33 (12.2)
Week 10	116 (84.1)	22 (15.9)	94 (83.9)	18 (16.1)	210 (84.0)	40 (16.0)
Week 12	112 (85.5)	19 (14.5)	95 (88.0)	13 (12.0)	207 (86.6)	32 (13.4)
Week 16	112 (86.2)	18 (13.8)	96 (91.4)	9 (8.6)	208 (88.5)	27 (11.5)
Overall	143 (91.7)	13 (8.3)	134 (94.4)	8 (5.6)	277 (93.0)	21 (7.0)

Note: Data for PID 676.021.24565, an adolescent in the paroxetine group, are not included in this table due to irreconcilable dosing data. This patient is included in Listing 13.17.1, Appendix B (see Section 15, Errata).

* Accountable is defined as the result of the following calculation falling within the 80%-120% band: [(No. of Capsules Dispensed - No. of Capsules Returned) / (No. of Days* 2)] x 100. Accountability was calculated only if all data needed were present. Percentages at each visit are based on the number of patients with study medication information for that visit.

Source: Table 13.17.2, Section 11; Listing 13.17.1, Appendix B

Table 32 Capsule Accountability (Number (%) of Patients) at Each Visit–Age Group: Children (ITT Population)

	Treatment Group					
	Paroxetine		Placebo		Total	
Accountability *	Accountable n (%)	Non-accountable n (%)	Accountable n (%)	Non-accountable n (%)	Accountable n (%)	Non-accountable n (%)
Week 1	40 (87.0)	6 (13.0)	40 (88.9)	5 (11.1)	80 (87.9)	11 (12.1)
Week 2	42 (91.3)	4 (8.7)	39 (86.7)	6 (13.3)	81 (89.0)	10 (11.0)
Week 3	43 (93.5)	4 (6.5)	40 (88.9)	5 (11.1)	83 (91.2)	8 (8.8)
Week 4	37 (86.0)	6 (14.0)	36 (83.7)	7 (16.3)	73 (84.9)	13 (15.1)
Week 6	29 (69.0)	13 (31.0)	31 (77.5)	9 (22.5)	60 (73.2)	22 (26.8)
Week 8	31 (77.5)	9 (22.5)	34 (89.5)	4 (10.5)	65 (83.3)	13 (16.7)
Week 10	32 (82.1)	7 (17.9)	26 (76.5)	8 (23.5)	58 (79.5)	15 (20.5)
Week 12	29 (82.9)	6 (17.1)	26 (83.9)	5 (16.1)	55 (83.3)	11 (16.7)
Week 16	28 (80.0)	7 (20.0)	28 (90.3)	3 (9.7)	56 (84.8)	10 (15.2)
Overall	43 (95.6)	2 (4.4)	41 (93.2)	3 (6.8)	84 (94.4)	5 (5.6)

* Accountable is defined as the result of the following calculation falling within the 80%-120% band: [(No. of Capsules Dispensed - No. of Capsules Returned) / (No. of Days * 2)] x 100. Accountability was calculated only if all data needed were present. Percentages at each visit are based on the number of patients with study medication information for that visit.

Source: Table 13.17.2, Section 11; Listing 13.17.1, Appendix B

Table 33 Capsule Accountability (Number (%) of Patients) at Each Visit–Age Group: Adolescents (ITT Population)

	Treatment Group					
	Paroxetine		Placebo		Total	
Accountability *	Accountable n (%)	Non-accountable n (%)	Accountable n (%)	Non-accountable n (%)	Accountable n (%)	Non-accountable n (%)
Week 1	103 (90.4)	11 (9.6)	96 (88.1)	13 (11.9)	199 (89.2)	24 (10.8)
Week 2	107 (93.9)	7 (6.1)	95 (89.6)	11 (10.4)	202 (91.8)	18 (8.2)
Week 3	104 (92.0)	9 (8.0)	94 (91.3)	9 (8.7)	198 (91.7)	18 (8.3)
Week 4	100 (90.1)	11 (9.9)	84 (85.7)	14 (14.3)	184 (88.0)	25 (12.0)
Week 6	88 (80.7)	21 (19.3)	85 (85.9)	14 (14.1)	173 (83.2)	35 (16.8)
Week 8	92 (89.3)	11 (10.7)	81 (90.0)	9 (10.0)	173 (89.6)	20 (10.4)
Week 10	84 (84.8)	15 (15.2)	68 (87.2)	10 (12.8)	152 (85.9)	25 (14.1)
Week 12	83 (86.5)	13 (13.5)	69 (89.6)	8 (10.4)	152 (87.9)	21 (12.1)
Week 16	84 (88.4)	11 (11.6)	68 (91.9)	6 (8.1)	152 (89.9)	17 (10.1)
Overall	100 (90.1)	11 (9.9)	93 (94.9)	5 (5.1)	193 (92.3)	16 (7.7)

Note: Data for PID 676.021.24565, an adolescent in the paroxetine group, are not included in this table due to irreconcilable dosing data. This patient is included in Listing 13.17.1, Appendix B (see Section 15, Errata).

* Accountable is defined as the result of the following calculation falling within the 80%-120% band: [(No. of Capsules Dispensed - No. of Capsules Returned) / (No. of Days * 2)] x 100. Accountability was calculated only if all data needed were present. Percentages at each visit are based on the number of patients with study medication information for that visit.

Source: Table 13.17.2, Section 11; Listing 13.17.1, Appendix B

4.8.2 Titration of Dose

Dosing was initiated at DL 1 (10 mg/day paroxetine or matching placebo). If necessary, the dose could be titrated upward in increments of one dose level at weekly intervals to a maximum daily dose of 50 mg (or matching placebo). Dose escalation was to be based on therapeutic response and tolerability of the medication, according to the judgment of the investigator.

Table 34 presents the number of patients exposed to each daily dose of study medication both overall and by age subgroup. In the overall population, 26.5% of paroxetine patients (43/162) took a maximum dose of 50 mg/day, compared to 49.4% (77/156) of patients in the placebo group who took placebo at the maximum level, DL 5. More adolescents than children were exposed to all daily doses of paroxetine >10 mg/day and dose levels >DL 1. Among children, 13.0% (6/46) paroxetine patients took a maximum dose of paroxetine (50 mg/day) for at least one dosing period compared to 37.8% (17/45) of placebo patients dosed at DL 5. Among adolescents, 31.9% (37/116) of paroxetine patients took a maximum dose of paroxetine (50 mg/day) for at least one dosing period compared to 54.1% (60/111) of placebo patients dosed at DL 5.

Table 34 Number (%) of Patients Exposed to Each Daily Dose of Study Medication–Age Group: Total/Children/Adolescents (ITT Population)

	Age Group: Total	Age Group: Children	Age Group: Adolescents
Titration Doses	**n (%)**	**n (%)**	**n (%)**
Paroxetine			
10 mg/day	162 (100.0)	46 (100.0)	116 (100.0)
20 mg/day	151 (93.2)	40 (87.0)	111 (95.7)
30 mg/day	117 (72.2)	26 (56.5)	91 (78.4)
40 mg/day	84 (51.9)	16 (35.0)	68 (58.6)
50 mg/day	43 (26.5)	6 (13.0)	37 (31.9)
Placebo			
DL 1	156 (100.0)	45 (100.0)	111 (100.0)
DL 2	147 (94.2)	42 (93.3)	105 (94.6)
DL 3	124 (79.5)	33 (73.3)	91 (82.0)
DL 4	110 (70.5)	27 (60.0)	83 (74.8)
DL 5	77 (49.4)	17 (37.8)	60 (54.1)

Note: Data for PID 676.021.24565, an adolescent in the paroxetine group, are not included in this table due to irreconcilable dosing data. This patient is included in Listing 13.17.1, Appendix B (see Section 15, Errata).
Source: Table 13.17.4, Section 11; Listing 13.17.1, Appendix B

Table 35 presents summaries of patient dosing by visit (excluding Taper Phase) and also maximum dose for the paroxetine group; Table 36 presents the same summary for the placebo group. Patients in the placebo group reached higher dose levels earlier in the study compared to patients in the paroxetine group.

A total of 72.2% (117/162) of patients in the paroxetine group received a dose higher than 20 mg/day. Slightly more than half the children (56.5%, 26/46) took a dose higher than 20 mg/day, compared to 78.4% (91/116) of the adolescents.

Table 35 Summary of the Number (%) of Patients Exposed to Each Dose of Paroxetine by Visit–Age Group: Total/Children/Adolescents (ITT Population)

Daily Dose	N*	10 mg n (%)	20 mg n (%)	30 mg n (%)	40 mg n (%)	50 mg n (%)
Age Group: Total						
Week 1	162	162 (100.0)	0	0	0	0
Week 2	160	62 (38.8)	98 (61.3)	0	0	0
Week 3	159	30 (18.9)	84 (52.8)	45 (28.3)	0	0
Week 4	155	20 (12.9)	61 (39.4)	47 (30.3)	27 (17.4)	0
Week 6	154	18 (11.7)	40 (26.0)	49 (31.8)	28 (18.2)	19 (12.3)
Week 8	144	13 (9.0)	39 (27.1)	32 (22.2)	35 (24.3)	25 (17.4)
Week 10	139	12 (8.6)	32 (23.0)	26 (18.7)	37 (26.6)	32 (23.0)
Week 12	131	11 (8.4)	28 (21.4)	27 (20.6)	33 (25.2)	32 (24.4)
Week 16	130	12 (9.2)	26 (20.0)	25 (19.2)	33 (25.4)	34 (26.2)
Maximum **	162	11 (6.8)	34 (21.0)	33 (20.4)	41 (25.3)	43 (26.5)
Age Group: Children						
Week 1	46	46 (100.0)	0	0	0	0
Week 2	46	23 (50.0)	23 (50.0)	0	0	0
Week 3	46	15 (32.6)	20 (43.5)	11 (23.9)	0	0
Week 4	43	11 (25.6)	15 (34.9)	11 (25.6)	6 (14.0)	0
Week 6	42	10 (23.8)	13 (31.0)	9 (21.4)	6 (14.3)	4 (9.5)
Week 8	41	7 (17.1)	16 (39.0)	6 (14.6)	8 (19.5)	4 (9.8)
Week 10	39	6 (15.4)	13 (33.3)	6 (15.4)	8 (20.5)	6 (15.4)
Week 12	35	4 (11.4)	12 (34.3)	8 (22.9)	5 (14.3)	6 (17.1)
Week 16	35	5 (14.3)	10 (28.6)	9 (25.7)	5 (14.3)	6 (17.1)
Maximum **	46	6 (13.0)	14 (30.4)	10 (21.7)	10 (21.7)	6 (13.0)
Age Group: Adolescents						
Week 1	116	116 (100.0)	0	0	0	0
Week 2	114	39 (34.2)	75 (65.8)	0	0	0
Week 3	113	15 (13.3)	64 (56.6)	34 (30.1)	0	0
Week 4	112	9 (8.0)	46 (41.1)	36 (32.1)	21 (18.8)	0
Week 6	112	8 (7.1)	27 (24.1)	40 (35.7)	22 (19.6)	15 (13.4)
Week 8	103	6 (5.8)	23 (22.3)	26 (25.2)	27 (26.2)	21 (20.4)
Week 10	100	6 (6.0)	19 (19.0)	20 (20.0)	29 (29.0)	26 (26.0)
Week 12	96	7 (7.3)	16 (16.7)	19 (19.8)	28 (29.2)	26 (27.1)
Week 16	95	7 (7.4)	16 (16.8)	16 (16.8)	28 (29.5)	28 (29.5)
Maximum **	116	5 (4.3)	20 (17.2)	23 (19.8)	31 (26.7)	37 (31.9)

Note: Data for PID 676.021.24565, an adolescent in the paroxetine group, are not included in this table due to irreconcilable dosing data. This patient is included in Listing 13.17.1, Appendix B (see Section 15, Errata).

* N = number of patients who were dispensed medication at that visit; percentages are based on N.

**Represents number of patients for whom that dose was the maximum dose during the study.

Source: Tables 13.17.3, 13.17.4, Section 11; Listing 13.17.1, Appendix B

Table 36 presents a summary of patient dosing by visit (excluding Taper Phase) and also maximum dose for the placebo group.

A total of 79.5% of patients in the placebo group (124/156) took a dose higher than DL 2/day, with comparable percentages among children (73.3%, 33/45) and adolescents (82.0%, 91/111).

Table 36 Summary of the Number (%) of Patients Exposed to Each Dose Level of Placebo by Visit–Age Group: Total/Children/Adolescents (ITT Population)

Dose Level		1	2	3	4	5
	N*	n (%)	n (%)	n (%)	n (%)	n (%)
Age Group: Total						
Week 1	156	156 (100.0)	0	0	0	0
Week 2	151	62 (41.1)	89 (58.9)	0	0	0
Week 3	149	23 (15.4)	68 (45.6)	58 (38.9)	0	0
Week 4	143	13 (9.1)	44 (30.8)	41 (28.7)	45 (31.5)	0
Week 6	141	8 (5.7)	30 (21.3)	35 (24.8)	36 (25.5)	32 (22.7)
Week 8	132	7 (5.3)	20 (15.2)	19 (14.4)	43 (32.6)	43 (32.6)
Week 10	118	5 (4.2)	19 (16.1)	13 (11.0)	31 (26.3)	50 (42.4)
Week 12	110	4 (3.6)	17 (15.5)	14 (12.7)	20 (18.2)	55 (50.0)
Week 16	108	4 (3.7)	15 (13.9)	11 (10.2)	20 (18.5)	58 (53.7)
Maximum **	156	9 (5.8)	23 (14.7)	14 (9.0)	33 (21.2)	77 (49.4)
Age Group: Children						
Week 1	45	45 (100.0)	0	0	0	0
Week 2	45	22 (48.9)	23 (51.1)	0	0	0
Week 3	45	11 (24.4)	17 (37.8)	17 (37.8)	0	0
Week 4	43	5 (11.6)	15 (34.9)	9 (20.9)	14 (32.6)	0
Week 6	41	3 (7.3)	13 (31.7)	7 (17.1)	8 (19.5)	10 (24.4)
Week 8	39	3 (7.7)	11 (28.2)	4 (10.3)	8 (20.5)	13 (33.3)
Week 10	34	2 (5.9)	10 (29.4)	4 (11.8)	6 (17.6)	12 (35.3)
Week 12	31	2 (6.5)	9 (29.0)	5 (16.1)	4 (12.9)	11 (35.5)
Week 16	31	2 (6.5)	8 (25.8)	4 (12.9)	6 (19.4)	11 (35.5)
Maximum **	45	3 (6.7)	9 (20.0)	6 (13.3)	10 (22.2)	17 (37.8)
Age Group: Adolescents						
Week 1	111	111 (100.0)	0	0	0	0
Week 2	106	40 (37.7)	66 (62.3)	0	0	0
Week 3	104	12 (11.5)	51 (49.0)	41 (39.4)	0	0
Week 4	100	8 (8.0)	29 (29.0)	32 (32.0)	31 (31.0)	0
Week 6	100	5 (5.0)	17 (17.0)	28 (28.0)	28 (28.0)	22 (22.0)
Week 8	93	4 (4.3)	9 (9.7)	15 (16.1)	35 (37.6)	30 (32.3)
Week 10	84	3 (3.6)	9 (10.7)	9 (10.7)	25 (29.8)	38 (45.2)
Week 12	79	2 (2.5)	8 (10.1)	9 (11.4)	16 (20.3)	44 (55.7)
Week 16	77	2 (2.6)	7 (9.1)	7 (9.1)	15 (18.2)	47 (61.0)
Maximum **	111	6 (5.4)	14 (12.6)	8 (7.2)	23 (20.7)	60 (54.1)

* N = number of patients who were dispensed medication at that visit; percentages are based on N.
**Represents the patients for whom that dose level was the maximum dose during the study.
Source: Tables 13.17.3, 13.17.4, Section 11; Listing 13.17.1, Appendix B

Table 37 presents the mean daily dose of paroxetine by visit and overall for both age groups combined and separately. The overall mean dose of paroxetine to which patients were exposed was 24.8 mg/day for all patients: 21.7 mg/day for children and 26.1 mg/day for adolescents. The mean dose at Week 16 LOCF endpoint was 32.6 mg/day for all patients: 26.5 mg/day for children and 35.0 mg/day for adolescents (Tables 13.17.6 and 13.17.7, Section 11). The mean dose at Week 16 for study completers was 33.9 mg/day for all patients: 29.1 mg/day for children and 35.7 mg/day for adolescents.

The overall mean dose level achieved by patients receiving placebo was DL 2.7: DL 2.6 for children and DL 2.8 for adolescents. The mean placebo dose level at Week 16 LOCF endpoint was DL 3.9 overall: DL 3.6 for children and DL 4.0 for adolescents. The mean placebo dose level for study completers was DL 4.0 overall: DL 3.5 for children and DL 4.3 for adolescents (Tables 13.17.6 and 13.17.7, Section 11).

Table 37 Mean Daily Dose of Paroxetine by Visit and Overall–Age Group: Total/Children/Adolescents (ITT Population)

Visit	N	Mean	SD
Age Group: Total *			
Week 1	162	10.0	0.00
Week 2	160	16.1	4.89
Week 3	159	20.9	6.82
Week 4	155	25.2	9.28
Week 6	154	29.4	11.86
Week 8	144	31.4	12.49
Week 10	139	33.2	12.92
Week 12	131	33.6	12.89
Week 16	130	33.9	13.15
Overall Mean	162	24.8	8.51
Week 16 LOCF **	161	32.6	13.63
Age Group: Children			
Week 1	46	10.0	0.00
Week 2	46	15.0	5.06
Week 3	46	19.1	7.55
Week 4	43	22.8	10.08
Week 6	42	25.5	12.73
Week 8	41	26.6	12.57
Week 10	39	28.7	13.41
Week 12	35	29.1	12.92
Week 16	35	29.1	13.14
Overall Mean	46	21.7	8.85
Week 16 LOCF **	46	26.5	13.20
Age Group: Adolescents *			
Week 1	116	10.0	0.00
Week 2	114	16.6	4.77
Week 3	113	21.7	6.40
Week 4	112	26.2	8.83
Week 6	112	30.8	11.24
Week 8	103	33.3	12.00
Week 10	100	35.0	12.35
Week 12	96	35.2	12.56
Week 16	95	35.7	12.77
Overall Mean	116	26.1	8.09
Week 16 LOCF **	115	35.0	13.07

* Note: Data for PID 676.021.24565, an adolescent in the paroxetine group, are not included in this table due to irreconcilable dosing data (see Section 15, Errata).
** The Week 16 LOCF endpoint corresponds to the visit making up each patient's LOCF assessment for CGI Global Improvement.
Source: Table 13.17.6 and 13.17.7, Section 11; Listing 13.17.1, Appendix B

Duration of exposure to study medication may be found in Table 60, Section 6.1, Extent of Exposure, and Table 13.17.5.1, Section 11.

5 Efficacy Analysis

5.1 Efficacy Evaluation

This section presents the analyses of the efficacy data for all primary and secondary variables using data from the ITT population, which comprised 163 patients in the paroxetine group and 156 patients in the placebo group.

Analysis of efficacy data derived from the PP population, which comprised 124 patients in the paroxetine group and 110 patients in the placebo group, is also described here. Only the primary efficacy variable was analyzed using the PP population. The PP population was analyzed because it contained less than 95% and more than 50% of the total number of patients in the ITT population. Patients excluded from the PP population were identified before the randomization code was broken (see Section 3.15.6.2, Per-Protocol Population).

A potential issue was discovered at one of the centers (Center 001), whereby the blind was broken for all randomized patients upon their completion of the double-blind Treatment Phase of the study. This situation was investigated and the principal investigator confirmed that the unblinding was carried out at the request of the patients' parents. It was also confirmed that the physicians who made the efficacy and safety assessments remained blinded to treatment. As a precaution it was decided, prior to breaking the treatment blind, that all patients from this Center would be excluded from the PP population. Additionally, a supplementary analysis of the primary efficacy variable was to be performed for the ITT population with Center 001 excluded, in order to assess the overall impact of this Center. However, the ITT population including patients from Center 001 is considered primary. Results of the analysis of the primary efficacy variable for the ITT population excluding Center 001 are presented in Section 5.2.3, CGI Global Improvement–ITT Population Excluding Center 001.

Section 3.15.6, Populations/Data Sets To Be Evaluated, and Section 3.15.7.4, Defined Visit Timepoints, provide detailed descriptions of the populations, datasets and conventions used to define time periods. Additional details of the analyses may be found in Appendix H, Statistical Appendix.

Data are presented in the form of data listings and tables of counts, means and standard deviations. These listings and tables were obtained using the SAS statistical package, version 6.12.

5.1.1 Datasets Analyzed

Results are provided for three datasets: the Week 16 LOCF dataset, the Week 16 OC dataset, and the 70% LOCF dataset. Primary inference is based on the Week 16 LOCF dataset for the ITT population. In the LOCF datasets for proportion of responders based on the CGI Global Improvement item, change in CGI Severity of Illness, and change in GAF, the last non-zero post-baseline score for each patient was carried forward to estimate missing data points. In the LOCF datasets for change in LSAS-CA total score, change in D-GSADS-A total score, change in SPAI-C/SPAI, and change in CDRS-R, the last known non-missing post-baseline score for each patient was carried forward to estimate missing data points. The Week 16 LOCF dataset contains all data for the Week 16 visit, plus the last on-treatment assessment prior to that visit for patients who were not assessed at that visit (this includes withdrawals). An additional dataset was specified in the protocol, the 70% LOCF dataset, defined as the latest timepoint where at least 70% of patients in each treatment group remained in the study. This occurred at Week 12; therefore, the 70% LOCF endpoint was analyzed.

Efficacy analyses accounted for the covariates baseline score, country grouping, age group (children, adolescents), and gender. Due to insufficient observations, the observed CGI Severity of Illness baseline scores (included in the CGI Global Improvement analysis) were recatagorized as combined “Mildly or Moderately Ill,” “Markedly Ill,” or combined “Severely or Among the Most Extremely Ill.” Also due to insufficient observations in some of the centers, centers were grouped by country; further, South Africa and Belgium were combined to form one country group. Full details of the algorithm used to group low recruiting centers are presented in Appendix H, Statistical Appendix.

Analysis of the primary efficacy variable was performed in the ITT population with and without data from patients at Center 001. Removal of these data did not change the findings or conclusions from the study. Primary efficacy results presented in this report include the data from this center. Results from the additional analysis may be found in Table 14.1.2bZ, Section 12, and are discussed in Section 5.2.3, CGI Global Improvement–ITT Population Excluding Center 001.

5.2 Primary Efficacy Variable

5.2.1 CGI Global Improvement, Intention-to-Treat Population

The protocol defined the primary efficacy variable as the proportion of responders based on the CGI–I item. A responder was defined as a patient who scored 1 (very much improved) or 2 (much improved) at endpoint compared to Baseline. The Week 16 LOCF ITT dataset for the proportion of responders based on the CGI Global Improvement item contained 161 patients treated with paroxetine and 154 patients treated with placebo. There were four patients in the ITT population that were not included in this primary analysis. Two of these patients (676.015.24401 and 676.021.24562, both placebo patients) had no CGI Global Improvement assessments, one patient (paroxetine patient 676.015.24406) had no CGI Global Improvement assessments that were on treatment (the patient did have a post-treatment CGI Global Improvement assessment) and the other patient (paroxetine patient 676.003.24073) had no CGI Severity of Illness Baseline Score.

Table 38 summarizes the analyses of responders based on the 7-point CGI–I assessment for the Week 16 LOCF and OC datasets and the 70% LOCF dataset, based on the ITT population.

The proportion of patients treated with paroxetine that were CGI Global Improvement responders at Week 16 LOCF was 77.6% (125/161), and the proportion of placebo patients was 38.3% (59/154). The odds of being a CGI Global Improvement responder on paroxetine compared to placebo at Week 16 LOCF were 7.02 (95% CI: [4.07, 12.11], $p < 0.001$), showing a statistically significant benefit of paroxetine over placebo.

The study was powered to detect a clinically meaningful difference of 20 percentage points between paroxetine and placebo.

The OC dataset at Week 16 supports the conclusions drawn from the Week 16 LOCF endpoint, in that there is a statistically significant benefit of paroxetine over placebo.

Analysis of the 70% LOCF dataset also supports these conclusions..

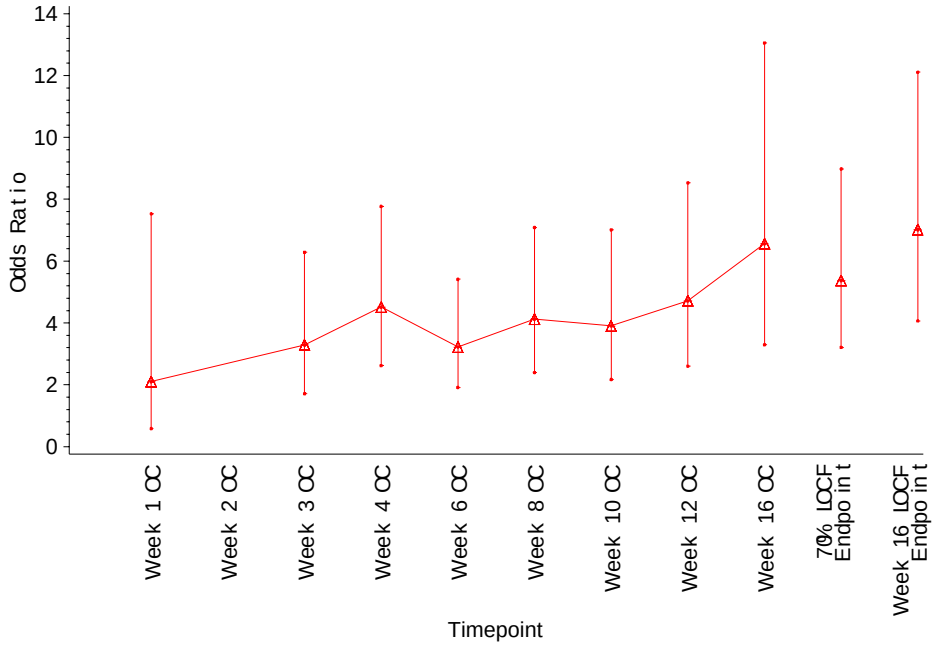
Table 38 Proportion of Responders Based on the CGI Global Improvement Item–Age Group: Total (ITT Population)

	Treatment Groups						Treatment Comparisons		
	Paroxetine			Placebo					
	N *	n **	(%)	N *	n **	(%)	Odds Ratio †	95% CI	p-value
Week 1	157	9	5.7	148	4	2.7	–	–	–
Week 2	154	24	15.6	144	11	7.6	–	–	–
Week 3	143	42	29.4	137	16	11.7	–	–	–
Week 4	154	77	50.0	145	28	19.3	–	–	–
Week 6	143	82	57.3	137	41	29.9	–	–	–
Week 8	139	98	70.5	126	49	38.9	–	–	–
Week 10	129	97	75.2	113	53	46.9	–	–	–
Week 12	132	104	78.8	109	51	46.8	–	–	–
Week 16 OC	124	106	85.5	99	51	51.5	6.56	(3.29, 13.05)	<0.001
Week 16 LOCF	161	125	77.6	154	59	38.3	7.02	(4.07, 12.11)	<0.001
70% LOCF ††	161	118	73.3	154	57	37.0	5.37	(3.21, 8.98)	<0.001

* N = total number of patients at the visit who had a CGI-I assessment and did not have any missing values for any of the covariates
** Responders (n) are defined as patients with a score of 1 (very much improved) or 2 (much improved) on the scale at endpoint.
† The odds ratio represents the odds of improving with paroxetine relative to that with placebo. Percentage of responders is unadjusted; the odds ratio is adjusted for terms in the model (Baseline score [CGI Severity of Illness], age group, gender, and country grouping).
†† 70% LOCF endpoint was Week 12.
Source: Table 14.1.2b, Section 12; Listings 14.1.1 and 14.1.2b, Appendix C

Figure 2 shows the proportion of CGI responders analysis results at each visit based on the ITT population. Results for the analysis at Week 2 are not shown as there were convergence problems fitting the specified model.

Figure 2 Proportion of CGI Responders Analysis Results at Each Visit–Odds Ratio and 95% Confidence Interval



Source: Appendix H, Statistical Appendix

The covariate significance table for the primary model is shown in Table 39.

Table 39 Summary of Analysis for CGI Global Improvement: Proportion of Responders–Covariate Significance, Week 16 LOCF (ITT Population)

Terms in Model	Change in Deviance *	Change in Degrees of Freedom **	P-value †
Country grouping ††	25.53	2	<0.001
Baseline score ††	2.76	2	0.251
Age group	3.29	1	0.070
Gender	0.25	1	0.619

* Increase in deviance from removing the term from the full model
** Increase in degrees of freedom from removing the term from the full model
† By comparison to the chi-squared distribution
†† See Section 5.1.1, Datasets Analyzed, for a description of the covariate groupings
Source: Table 14.1.2.1, Section 12

Table 39 shows that there is a statistically significant difference in response between patients from the different countries (South Africa and Belgium, USA or Canada). These differences are independent of which treatment the patient received. There is no evidence of any variation in response due to varying baseline scores, age group and gender.

Patients in the South Africa / Belgium country group had a greater proportion of responders than those in either USA or Canada, irrespective of treatment group. The odds of being a CGI Global Improvement responder in South Africa / Belgium compared to the USA were 4.38 and the odds of being a CGI Global Improvement responder in Canada compared to the USA were 1.17. These correspond to Week 16 LOCF for the ITT population and are adjusted for the other covariates in the model.

Even though the age group term in the model is not statistically significant, there was some evidence to suggest that there is a difference in response between patients in the different age groups, irrespective of treatment. The odds of being a CGI Global Improvement responder at Week 16 LOCF for the ITT population for an adolescent compared to a child were 0.58 (adjusted estimate).

Interactions between treatment and each of the covariates were investigated in turn for the primary variable, in order to assess the consistency of treatment effect across the covariates. There was no evidence of any statistically significant treatment by covariate interactions at the 10% significance level for the primary endpoint (Appendix H, Statistical Appendix). This indicated that the treatment effect is consistent across Baseline CGI-S score, age group, gender, and country grouping.

Details of the distribution of patient ratings in each global improvement category at Week 16 LOCF and OC are presented by treatment group for both age groups combined and by age subgroup in Table 40 and Table 41. In particular, the difference between paroxetine and placebo with regard to the percentage of patients who were “very much improved” at Week 16 LOCF is most evident, 47.5% (77/162) of paroxetine patients compared to 14.9% (23/154) of placebo patients. Few patients in either treatment group and no children on paroxetine became worse over the course of the study, and no patients were rated very much worse at endpoint.

As indicated above, the treatment effect was consistent across age subgroups. Among children, 80.4% of paroxetine patients (37/46) were rated “much improved” or “very much improved” at endpoint, compared with 46.6% (21/45)

of placebo patients. Among adolescents, 76.7% of paroxetine patients (89/116) were rated "much improved" or "very much improved" at endpoint, compared with 34.9% (38/109) of placebo patients (Table 14.1.1b, Section 12). Results at Week 16 OC were also similar between children and adolescents.

Table 40 Number (%) of Patients in Each Category of the CGI Global Improvement Item Score at Week 16 LOCF and OC–Age Group: Total (ITT Population)

	LOCF		OC	
	Paroxetine	**Placebo**	**Paroxetine**	**Placebo**
	n (%)	**n (%)**	**n (%)**	**n (%)**
Age Group: Total				
Not assessed	0	0	0	2 (2.0)
Very much improved	77 (47.5)	23 (14.9)	69 (55.6)	20 (19.8)
Much improved	49 (30.2)	36 (23.4)	37 (29.8)	31 (30.7)
Minimally improved	19 (11.7)	40 (26.0)	14 (11.3)	24 (23.8)
No change	12 (7.4)	50 (32.5)	3 (2.4)	22 (21.8)
Minimally worse	1 (0.6)	4 (2.6)	0	1 (1.0)
Much worse	4 (2.5)	1 (0.6)	1 (0.8)	1 (1.0)
Very much worse	0	0	0	0
Total	162 (100.0)	154 (100.0)	124 (100.0)	101 (100.0)

Total = number of patients with a Week 16 OC or LOCF assessment
Source: Table 14.1.1b, Section 12; Listing 14.1.1, Appendix C

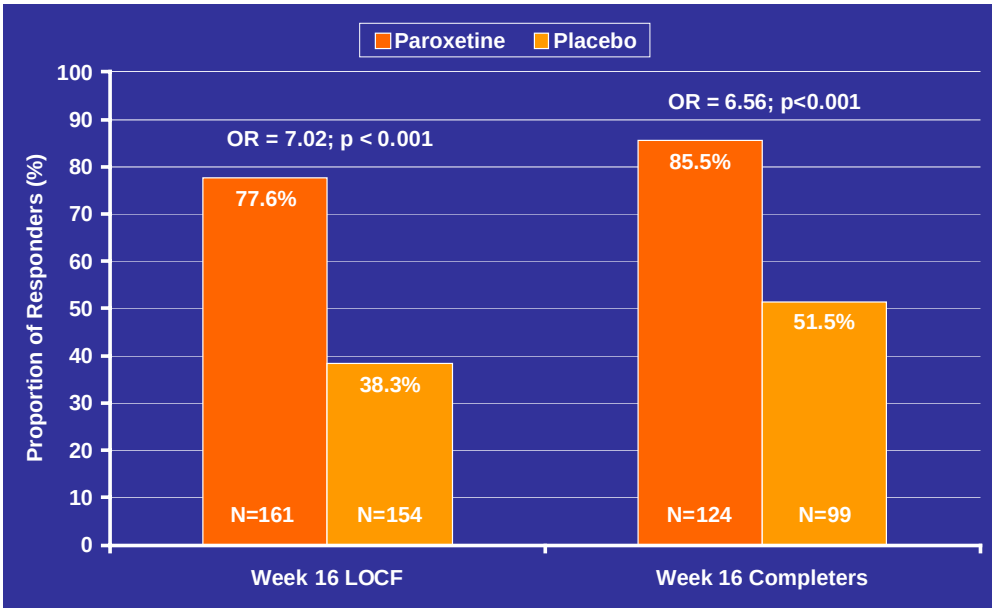
Table 41 Number (%) of Patients in Each Category of the CGI Global Improvement Item Score at Week 16 LOCF and OC–Age Group: Children/Adolescents (ITT Population)

	LOCF		OC	
	Paroxetine	**Placebo**	**Paroxetine**	**Placebo**
	n (%)	**n (%)**	**n (%)**	**n (%)**
Age Group: Children				
Not assessed	0	0	0	0
Very much improved	24 (52.2)	6 (13.3)	18 (56.3)	6 (20.7)
Much improved	13 (28.3)	15 (33.3)	8 (25.0)	12 (41.4)
Minimally improved	5 (10.9)	6 (13.3)	4 (12.5)	3 (10.3)
No change	4 (8.7)	16 (35.6)	2 (6.3)	6 (20.7)
Minimally worse	0	1 (2.2)	0	1 (3.4)
Much worse	0	1 (2.2)	0	1 (3.4)
Very much worse	0	0	0	0
Total	46 (100.0)	45 (100.0)	32 (100.0)	29 (100.0)
Age Group: Adolescents				
Not assessed	0	0	0	2 (2.8)
Very much improved	53 (45.7)	17 (15.6)	51 (55.4)	14 (19.4)
Much improved	36 (31.0)	21 (19.3)	29 (31.5)	19 (26.4)
Minimally improved	14 (12.1)	34 (31.2)	10 (10.9)	21 (29.2)
No change	8 (6.9)	34 (31.2)	1 (1.1)	16 (22.2)
Minimally worse	1 (0.9)	3 (2.8)	0	0
Much worse	4 (3.4)	0	1 (1.1)	0
Very much worse	0	0	0	0
Total	116 (100.0)	109 (100.0)	92 (100.0)	72 (100.0)

Total = number of patients with a Week 16 OC or LOCF assessment
Source: Table 14.1.1b, Section 12; Listing 14.1.1, Appendix C

Figure 3 presents the proportion of CGI responders for both treatment groups at Week 16 LOCF and OC.

Figure 3 Proportion of Responders, CGI Global Improvement–Age Group: Total (ITT)



OR = adjusted odds ratio
Source: Table 14.1.2b, Section 12; Listings 14.1.1 and 14.1.2b, Appendix C

5.2.2 CGI Global Improvement–Per-Protocol Population

The Week 16 LOCF PP dataset for the proportion of CGI Global Improvement responders contained 124 patients treated with paroxetine and 110 patients treated with placebo. Table 42 summarizes the analyses of responders based on the CGI-I assessment for the Week 16 LOCF and OC datasets, and the 70% LOCF dataset, based on the PP population.

The proportion of PP patients treated with paroxetine that were CGI Global Improvement responders at Week 16 LOCF endpoint was 81.5% (101/124), and the proportion of placebo-treated patients responding was 39.1% (43/110). The odds of being a CGI Global Improvement responder on paroxetine compared to placebo at Week 16 LOCF for the Per-Protocol population were 8.41 (95% CI: [4.36, 16.21], p <0.001), showing a statistically significant benefit of paroxetine over placebo.

Therefore, there is statistically significant evidence from the PP analysis that patients treated with paroxetine have a greater response in the CGI Global

Improvement item at Week 16 LOCF endpoint than patients treated with placebo, which is consistent with the ITT analysis.

The OC dataset at Week 16 supports the conclusions drawn from the Week 16 LOCF analysis, in that there is statistically significant evidence that patients treated with paroxetine have a greater response in the CGI–I item than patients treated with placebo.

Analysis of the 70% LOCF dataset also supports the conclusions drawn from the Week 16 LOCF analysis, in that there is statistically significant evidence that patients treated with paroxetine have a greater response in the CGI–I item than patients treated with placebo.

Summaries of the patient ratings for the PP population may be found in Table 14.1.1c, Section 12, and Listing 14.1.1, Appendix C.

Table 42 Proportion of Responders Based on the CGI Global Improvement Item–Age Group: Total (PP Population)

	Paroxetine			Placebo			Treatment Comparisons*		
	N *	n **	(%)	N *	n **	(%)	Odds Ratio †	95% CI	p-value
Week 16 OC	105	91	86.7	85	42	49.4	7.80	(3.60, 16.90)	<0.001
Week 16 LOCF	124	101	81.5	110	43	39.1	8.41	(4.36, 16.21)	<0.001
70% LOCF ††	124	94	75.8	110	42	38.2	5.53	(3.03, 10.07)	<0.001

* N = the 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 endpoint

† The odds ratio represents the odds of improving with paroxetine relative to that with placebo. Percentage of responders is unadjusted; the odds ratio is adjusted for terms in the model (Baseline score [CGI Severity of Illness], age group, gender, and country grouping).

†† 70% LOCF endpoint was Week 12.

Source: Table 14.1.2c, Section 12; Listings 14.1.1 and 14.1.2c, Appendix C

5.2.3 CGI Global Improvement–ITT Population Excluding Center 001

An analysis was conducted for the primary endpoint excluding Center 001, at which the treatment assignments for all four randomized patients were prematurely unblinded by site personnel (see Section 3.15, Statistical Evaluation). The Week 16 LOCF dataset for the ITT population excluding Center 001, for the proportion of CGI-I responders, contained 159 patients treated with paroxetine and 152 patients treated with placebo. Table 43 summarizes the treatment comparisons in the ITT population excluding Center 001.

The proportion of patients treated with paroxetine who were CGI Global Improvement Responders at Week 16 LOCF endpoint was 78.0% (124/159) and the proportion of placebo treated patients was 38.8% (59/152). The odds of being a CGI Global Improvement responder on paroxetine compared to placebo at Week 16 LOCF for the ITT population excluding Center 001 were 7.07 (95% CI: [4.07, 12.29], p <0.001), showing a statistically significant benefit of paroxetine over placebo.

Therefore, there is statistically significant evidence from the analysis of the ITT population excluding Center 001 that patients treated with paroxetine have a greater response in the CGI Global Improvement item at Week 16 LOCF endpoint than patients treated with placebo, which is consistent with the primary ITT analysis.

The OC dataset at Week 16 supports the conclusions drawn from the Week 16 LOCF dataset, in that there is statistically significant evidence that patients treated with paroxetine have a greater response in the CGI–I item than patients treated with placebo.

Analysis of the 70% LOCF dataset also supports the conclusions drawn from the Week 16 LOCF analysis, in that there is statistically significant evidence that patients treated with paroxetine have a greater response in the CGI–I item than patients treated with placebo.

Thus the inclusion of Center 001 does not affect the overall study conclusions.

Table 43 Proportion of Responders Based on the CGI Global Improvement Item–Age Group: Total (ITT Population Excluding Center 001)

	Paroxetine			Placebo			Treatment Comparisons*		
	N *	n **	(%)	N *	n **	(%)	Odds Ratio †	95% CI	p-value
Week 16 OC	122	105	86.1	97	51	52.6	6.67	(3.31, 13.47)	<0.001
Week 16 LOCF	159	124	78.0	152	59	38.8	7.07	(4.07, 12.29)	<0.001
70% LOCF ††	159	117	73.6	152	56	36.8	5.60	(3.32, 9.44)	<0.001

* N = the 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 endpoint

† The odds ratio represents the odds of improving with paroxetine relative to that with placebo. Percentage of responders is unadjusted; the odds ratio is adjusted for terms in the model (Baseline score [CGI Severity of Illness], age group, gender, and country grouping).

†† 70% LOCF endpoint was Week 12.

Source: Table 14.1.2bZ, Section 12; Listing 14.1.1, Appendix C

5.3 Secondary Efficacy Variables

The protocol defined the following secondary efficacy variables to support the primary variable: change from Baseline in LSAS-CA total score, change from baseline in CGI Severity of Illness score, change from baseline in D-GSADS-A total score, change from baseline in SPAI-C total score, change from baseline in SPAI difference score, and change from Baseline in GAF score.

5.3.1 Liebowitz Social Anxiety Scale for Children and Adolescents

The LSAS–CA scale is an investigator-assessed report instrument (not yet validated) for assessing the range of social interaction and performance situations that children and adolescents with social phobia may fear and/or avoid (see Section 3.11.2, Liebowitz Social Anxiety Scale for Children and Adolescents [LSAS-CA]).

Table 44 presents the analysis of change from Baseline in LSAS–CA total score for the Week 16 LOCF, Week 16 OC, and 70% LOCF datasets based on the ITT overall population.

The adjusted mean change from baseline at Week 16 LOCF endpoint in LSAS-CA total score was –48.01 (SE 2.64) for paroxetine patients and –24.25 (SE 2.67) for placebo patients. The adjusted mean difference between paroxetine and placebo at Week 16 LOCF was 23.75 points in favor of paroxetine (95% CI: [-29.77, -17.74], p <0.001) indicating a statistically significant benefit of paroxetine over placebo.

The Week 16 OC and 70% LOCF dataset analyses support the conclusion of the LOCF analysis.

Table 44 Summary of Analysis for Change from Baseline in LSAS–CA Score–Age Group: Total (ITT Population)

	Treatment Groups						Treatment Comparisons		
	Paroxetine			Placebo					
	N	LS Mean *	(SE) *	N	LS Mean *	(SE) *	Difference **	95% CI	p-value
Baseline	161	77.63	28.72	155	77.66	27.05	–	–	–
Change from Baseline to:									
Wk 4	150	–24.76	2.38	140	–12.31	2.41	–	–	–
Wk 8	134	–35.98	2.53	119	–16.55	2.66	–	–	–
Wk 12	129	–43.91	2.78	105	–21.70	2.91	–	–	–
Wk 16 OC	124	–49.03	2.64	101	–25.72	2.75	–23.31	–29.59, –17.03	<0.001
Wk 16 LOCF †	159	–48.01	2.64	150	–24.25	2.67	–23.75	–29.77, –17.74	<0.001
70% LOCF ††	159	–44.31	2.59	150	–22.23	2.63	–22.08	–27.99, –16.16	<0.001

* Least square means. For Baseline, raw means, not least square means, are presented, and standard deviations, not standard errors, are presented.

****** Differences in adjusted (least square) means (paroxetine minus placebo) (adjusted for Baseline score, age group, gender and country grouping).

† LOCF endpoint may have more patients than the first post-Baseline visit, as Early Withdrawal data at unscheduled visits are not tabulated but is carried forward for LOCF endpoint

†† 70% LOCF is Week 12

Source: Table 14.3.2, Section 12; Listings 14.3.1.1, 14.3.1.2, and 14.3.2, Appendix C

Table 45 and Table 46 present summary statistics for LSAS-CA total score at each visit, based on the ITT population, for the overall population and for children and adolescents, respectively, by treatment group. Table 47 and Table 48 present summary statistics for change from Baseline in LSAS-CA total score, based on the ITT population, for the overall population and for children and adolescents, respectively, by treatment group.

Mean LSAS-CA scores decreased (improved) steadily over time in both treatment groups for both age groups combined and separately, but greater improvements were noted at every timepoint among paroxetine patients than among placebo patients. The greatest improvement among paroxetine patients occurred between Baseline and Week 4.

Summary statistics for LSAS–CA total score at each visit, based on the ITT population, may be found in Table 14.3.1, Section 12. Summary statistics for change from Baseline in LSAS-CA total score at each visit, based on the ITT population, may be found in Table 14.3.3, Section 12. Per-patient information may be found in Listings 14.3.1.1, 14.3.1.2, and 14.3.2, Appendix C.

Table 45 Summary Statistics for LSAS–CA Total Score at Each Visit–Age Group: Total (ITT Population)

	Treatment Group							
	Paroxetine (N = 163)				Placebo (N = 156)			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Age Group: Total								
Baseline	161	77.6	28.72	1-133	155	77.7	27.05	9-132
Week 4	150	53.3	31.12	0-138	140	65.7	29.12	11-134
Week 8	134	38.7	27.67	0-112	119	57.4	29.99	4-134
Week 12	129	32.1	26.78	0-126	105	53.9	30.01	2-123
Week 16 OC	124	26.0	23.03	0-94	101	49.5	28.44	0-119
Week 16 LOCF	160	32.0	29.95	0-138	150	55.5	31.09	0-134

Source: Table 14.3.1, Section 12; Listings 14.3.1.1, 14.3.1.2, and 14.3.2, Appendix C

Table 46 Summary Statistics for LSAS–CA Total Score at Each Visit–Age Group: Children/Adolescents (ITT Population)

	Treatment Group							
	Paroxetine				Placebo			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Age Group: Children								
Baseline	44	70.7	31.00	1-127	45	71.2	28.65	9-132
Week 4	41	43.6	30.05	3-114	42	62.5	27.09	14-130
Week 8	39	31.9	25.55	0-112	33	49.7	28.82	6-106
Week 12	35	23.6	27.31	0-126	30	45.5	28.89	2-111
Week 16 OC	32	21.7	23.67	0-94	29	42.0	26.99	0-104
Week 16 LOCF	45	20.5	21.81	0-94	45	49.2	28.53	0-111
Age Group: Adolescents								
Baseline	117	80.3	27.49	22-133	110	80.3	26.04	26-130
Week 4	109	57.0	30.87	0-138	98	67.1	29.97	11-134
Week 8	95	41.5	28.15	0-108	86	60.4	30.06	4-134
Week 12	94	35.2	26.02	0-101	75	57.3	29.98	3-123
Week 16 OC	92	27.5	22.74	0-88	72	52.5	28.63	0-119
Week 16 LOCF	115	36.5	31.55	0-138	105	58.2	31.88	0-134

Source: Table 14.3.1, Section 12; Listings 14.3.1.1, 14.3.1.2, and 14.3.2, Appendix C

Table 47 Summary Statistics for Change from Baseline in LSAS-CA Total Score at Each Visit–Age Group: Total (ITT Population)

	Treatment Group							
	Paroxetine (N = 163)				Placebo (N = 156)			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Baseline	161	77.6	28.72	1 to 133	155	77.7	27.05	9 to 132
Week 4	150	-24.0	26.43	-105 to 50	140	-12.2	22.66	-112 to 48
Week 8	134	-36.8	30.26	-129 to 48	119	-18.0	22.91	-105 to 34
Week 12	129	-42.6	33.93	-127 to 39	105	-20.9	24.77	-88 to 35
Week 16 OC	124	-49.3	32.06	-132 to 36	101	-26.5	29.28	-112 to 33
Week 16 LOCF	159	-45.6	33.87	-132 to 39	150	-21.9	27.63	-112 to 33

Source: Table 14.3.3, Section 12; Listings 14.3.1.1, 14.3.1.2, and 14.3.2, Appendix C

Table 48 Summary Statistics for Change from Baseline in LSAS-CA Total Score at Each Visit–Age Group: Children/Adolescents (ITT Population)

	Treatment Group							
	Paroxetine				Placebo			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Age Group: Children								
Baseline	44	70.7	31.00	1 to 127	45	71.2	28.65	9 to 132
Week 4	41	-27.7	26.69	-105 to 7	42	-7.6	20.36	-53 to 48
Week 8	39	-37.1	28.31	-111 to 7	33	-17.5	19.95	-61 to 10
Week 12	35	-44.7	32.84	-127 to 14	30	-21.3	25.50	-88 to 9
Week 16 OC	32	-46.4	33.83	-126 to 36	29	-25.4	30.83	-91 to 18
Week 16 LOCF	44	-50.2	31.98	-126 to 36	45	-22.0	28.44	-91 to 18
Age Group: Adolescents								
Baseline	117	80.3	27.49	22 to 133	110	80.3	26.04	26 to 130
Week 4	109	-22.6	26.32	-98 to 50	98	-14.2	23.40	-112 to 34
Week 8	95	-36.7	31.17	-129 to 48	86	-18.2	24.05	-105 to 34
Week 12	94	-41.8	34.46	-124 to 139	75	-20.7	24.65	-81 to 35
Week 16 OC	92	-50.4	31.55	-132 to 22	72	-26.9	28.85	-112 to 33
Week 16 LOCF	115	-43.8	34.54	-132 to 39	105	-21.9	27.42	-112 to 33

Source: Table 14.3.3, Section 12; Listings 14.3.1.1, 14.3.1.2, and 14.3.2, Appendix C

5.3.2 CGI Severity of Illness Item

Table 49 and Table 50 present the analyses of the change from Baseline in CGI–S score for the Week 16 LOCF and OC datasets and the 70% LOCF dataset, based on the ITT population, for children and adolescents, respectively. The analysis was performed separately for each age group, and no adjustment was made for covariates.

For children, the median difference between paroxetine and placebo at Week 16 LOCF was -1.0 ($p < 0.001$), indicating a statistically significant benefit of paroxetine over placebo.

Similarly, for adolescents, the median difference between paroxetine and placebo at Week 16 LOCF was –1.0 ($p < 0.001$), again indicating a statistically significant benefit of paroxetine over placebo.

Similar results were observed for the Week 16 OC and 70% LOCF analyses.

Table 49 Summary of Analysis of Change from Baseline in CGI Severity of Illness Score–Age Group: Children (ITT Population)

	Treatment Group								Treatment Comparison	
	Paroxetine				Placebo				Median	
	N	Mean	Median	Range	N	Mean	Median	Range	Difference	p-value *
Baseline	45	4.5	4.0	3 to 6	45	4.5	4.0	3 to 6	–	–
Change from Baseline to:										
Week 1	43	-0.2	-0.0	-3 to 0	43	-0.2	0.0	-2 to 1	–	–
Week 2	44	-0.5	-0.0	-3 to 0	44	-0.4	0.0	-4 to 0	–	–
Week 3	39	-0.8	-1.0	-4 to 0	39	-0.5	0.0	-4 to 0	–	–
Week 4	42	-0.9	-1.0	-4 to 0	44	-0.5	0.0	-3 to 0	–	–
Week 6	41	-1.1	-1.0	-4 to 0	39	-0.7	0.0	-4 to 0	–	–
Week 8	40	-1.1	-1.0	-3 to 0	38	-0.8	-1.0	-4 to 0	–	–
Week 10	32	-1.5	-1.0	-4 to 0	34	-1.1	-1.0	-4 to 0	–	–
Week 12	35	-1.7	-1.0	-4 to 0	31	-1.1	-1.0	-4 to 0	–	–
Week 16 OC	32	-2.0	-2.0	-5 to 0	29	-1.3	-1.0	-4 to 1	-1.0	0.044
Week 16 LOCF	45	-1.9	-2.0	-5 to 0	45	-0.9	-1.0	-4 to 1	-1.0	<0.001
70% LOCF **	45	-1.6	-1.0	-4 to 0	45	-0.8	-1.0	-4 to 0	-1.0	<0.001

* P-value from Wilcoxon Rank Sum Test

** 70% LOCF endpoint was Week 12.

Source: Table 14.2.3, Section 12; Listings 14.2.1 and 14.2.3, Appendix C

Table 50 Summary of Analysis of Change from Baseline in CGI Severity of Illness Score–Age Group: Adolescents (ITT Population)

	Treatment Group								Treatment Comparison	
	Paroxetine				Placebo				Median	
	N	Mean	Median	Range	N	Mean	Median	Range	Difference	p-value *
Baseline	117	4.7	5.0	3 to 7	110	4.7	5.0	3 to 7	–	–
Change from Baseline to:										
Week 1	114	-0.2	0.0	-3 to 1	105	-0.1	0.0	-3 to 1	–	–
Week 2	110	-0.4	0.0	-3 to 1	100	-0.2	0.0	-3 to 0	–	–
Week 3	104	-0.7	-0.5	-4 to 1	98	-0.3	0.0	-3 to 1	–	–
Week 4	112	-1.0	-1.0	-5 to 2	101	-0.5	0.0	-4 to 0	–	–
Week 6	102	-1.2	-1.0	-4 to 0	98	-0.6	0.0	-4 to 1	–	–
Week 8	99	-1.5	-2.0	-5 to 0	88	-0.9	-1.0	-4 to 0	–	–
Week 10	97	-1.7	-2.0	-5 to 1	79	-1.0	-1.0	-4 to 0	–	–
Week 12	97	-2.0	-2.0	-5 to 1	78	-1.1	-1.0	-4 to 0	–	–
Week 16 OC	92	-2.3	-3.0	-5 to 1	71	-1.3	-1.0	-5 to 0	-1.0	<0.001
Week 16 LOCF	116	-2.0	-2.0	-5 to 1	109	-1.0	-1.0	-5 to 0	-1.0	<0.001
70% LOCF **	116	-1.8	-2.0	-5 to 1	109	-0.9	0.0	-4 to 0	-1.0	<0.001

* P-value from Wilcoxon Rank Sum Test

** 70% LOCF endpoint was Week 12.

Source: Table 14.2.3, Section 12; Listings 14.2.1 and 14.2.3, Appendix C

Table 51 summarizes the number and percentage of patients in each treatment group categorized by CGI–S item score at Baseline and at Week 16 LOCF and OC for both age groups combined.

At the Week 16 LOCF endpoint, 47.5% (77/162) of paroxetine patients and 20.8% (32/154) of placebo patients were rated “normal” or “borderline mentally ill,” compared to no patients in either treatment group at Baseline. A total of 22.2% of paroxetine patients (36/162) compared to 7.1% of the placebo patients (11/154) were rated “normal, not at all ill” at the Week 16 LOCF endpoint. In addition, at Week 16 LOCF, no patients in either treatment group were rated “among the most extremely ill,” and only 1.9% (3/162) of paroxetine patients and 5.2% (8/154) of placebo patients were rated “severely ill”; at Baseline, 14.2% (23/162) of paroxetine patients and 12.2% (19/155) of placebo patients had been rated in one of these two categories.

At Week 16 OC, 58.1% (72/124) of paroxetine patients and 29.7% (30/101) of placebo patients were rated “normal” or “borderline mentally ill.” A total of 27.4% of paroxetine patients (34/124) compared to 9.9% of the placebo patients (10/101) were rated “normal, not at all ill” at the Week 16 OC endpoint. In addition, at Week 16 OC, no patients in either treatment group were rated “among the most extremely ill,” and only 0.8% of paroxetine patients (1/124) and 3.0% of placebo patients (3/101) were rated “severely ill.”

Table 51 Number (%) of Patients in Each Category of the CGI Severity of Illness Item Score at Baseline and Week 16 OC and LOCF–Age Group: Total (ITT Population)

	Treatment Group	
	Paroxetine	**Placebo**
	n (%)	**n (%)**
Baseline		
Not assessed	0	0
Normal, not at all ill (1)	0	0
Borderline mentally ill (2)	0	0
Mildly ill (3)	4 (2.5)	6 (3.9)
Moderately ill (4)	74 (45.7)	69 (44.5)
Markedly ill (5)	61 (37.7)	61 (39.4)
Severely ill (6)	21 (13.0)	17 (11.0)
Among the most extremely ill (7)	2 (1.2)	2 (1.3)
Total	162 (100.0)	155 (100.0)
Week 16 OC		
Not assessed	0	1 (1.0)
Normal, not at all ill (1)	34 (27.4)	10 (9.9)
Borderline mentally ill (2)	38 (30.6)	20 (19.8)
Mildly ill (3)	29 (23.4)	22 (21.8)
Moderately ill (4)	17 (13.7)	39 (38.6)
Markedly ill (5)	5 (4.0)	6 (5.9)
Severely ill (6)	1 (0.8)	3 (3.0)
Among the most extremely ill (7)	0	0
Total	124 (100.0)	101 (100.0)
Week 16 LOCF		
Not assessed	0	0
Normal, not at all ill (1)	36 (22.2)	11 (7.1)
Borderline mentally ill (2)	41 (25.3)	21 (13.6)
Mildly ill (3)	42 (25.9)	26 (16.9)
Moderately ill (4)	28 (17.3)	58 (37.7)
Markedly ill (5)	12 (7.4)	30 (19.5)
Severely ill (6)	3 (1.9)	8 (5.2)
Among the most extremely ill (7)	0	0
Total	162 (100.0)	154 (100.0)

Total = number of patients with a Week 16 OC or LOCF assessment
Source: Table 14.2.1, Section 12; Listing 14.2.1, Appendix C

Table 52 and Table 53 summarize the number and percentage of patients in each treatment group categorized by CGI–S item score at Baseline and at Week 16 LOCF and OC for children and adolescents, respectively.

Among children, at the Week 16 LOCF endpoint, 50.0% (23/46) of paroxetine patients and 22.2% (10/45) of placebo patients were rated “normal” or “borderline mentally ill,” compared to no patients in either treatment group at Baseline. In addition, at Week 16 LOCF, no patients in either treatment group were rated “among the most extremely ill,” and no paroxetine patients and 2.2% of placebo patients (1/45) were rated “severely ill”; at Baseline, 6.7% (3/45) of paroxetine patients and 4.4% (2/45) of placebo patients had been rated “severely ill.”

Among children, at Week 16 OC, 59.4% (19/32) of paroxetine patients and 31.0% (9/29) of placebo patients were rated “normal” or “borderline mentally ill,” compared to no patients in either treatment group at Baseline. In addition, at Week 16 OC, no patients in either treatment group were rated “among the most extremely ill” or “severely ill.”

Among adolescents, at the Week 16 LOCF endpoint, 46.6% (54/116) of paroxetine patients and 20.2% (22/109) of placebo patients were rated “normal” or “borderline mentally ill,” compared to no patients in either treatment group at Baseline. This difference was primarily due to the large disparity in the number of patients rated as “normal” between the two treatment groups, 24.1% (28/116) compared to 5.5% (6/109), for paroxetine and placebo, respectively. At Week 16 LOCF, no patients in either treatment group were rated “among the most extremely ill,” and 2.6% (3/116) of paroxetine patients and 6.4% (7/109) of placebo patients were rated “severely ill”; at Baseline, 17.1% (20/117) of paroxetine patients and 15.5% (17/110) of placebo patients had been rated in one of these two categories.

Among adolescents, at Week 16 OC, 57.6% (53/92) of paroxetine patients and 29.2% (21/72) of placebo patients were rated “normal” or “borderline mentally ill,” compared to no patients in either treatment group at Baseline. In addition, at Week 16 OC, no patients in either treatment group were rated “among the most extremely ill,” and only 1.1% (1/92) of paroxetine patients and 4.2% (3/72) of placebo patients were rated “severely ill.”

Table 52 Number (%) of Patients in Each Category of the CGI Severity of Illness Item Score at Baseline and Week 16 OC and LOCF–Age Group: Children (ITT Population)

	Treatment Group	
	Paroxetine n (%)	**Placebo n (%)**
Baseline		
Not assessed	0	0
Normal, not at all ill (1)	0	0
Borderline mentally ill (2)	0	0
Mildly ill (3)	1 (2.2)	3 (6.7)
Moderately ill (4)	25 (55.6)	20 (44.4)
Markedly ill (5)	16 (35.6)	20 (44.4)
Severely ill (6)	3 (6.7)	2 (4.4)
Among the most extremely ill (7)	0	0
Total	45 (100.0)	45 (100.0)
Week 16 OC		
Not assessed	0	0
Normal, not at all ill (1)	6 (18.8)	5 (17.2)
Borderline mentally ill (2)	13 (40.6)	4 (13.8)
Mildly ill (3)	7 (21.9)	8 (27.6)
Moderately ill (4)	3 (9.4)	10 (34.5)
Markedly ill (5)	3 (9.4)	2 (6.9)
Severely ill (6)	0	0
Among the most extremely ill (7)	0	0
Total	32 (100.0)	29 (100.0)
Week 16 LOCF		
Not assessed	0	0
Normal, not at all ill (1)	8 (17.4)	5 (11.1)
Borderline mentally ill (2)	15 (32.6)	5 (11.1)
Mildly ill (3)	13 (28.3)	10 (22.2)
Moderately ill (4)	7 (15.2)	12 (26.7)
Markedly ill (5)	3 (6.5)	12 (26.7)
Severely ill (6)	0	1 (2.2)
Among the most extremely ill (7)	0	0
Total	46 (100.0)	45 (100.0)

Total = number of patients with a Week 16 OC or LOCF assessment
Source: Table 14.2.1, Section 12; Listing 14.2.1, Appendix C

Table 53 Number (%) of Patients in Each Category of the CGI Severity of Illness Item Score at Baseline and Week 16 OC and LOCF–Age Group: Adolescents (ITT Population)

	Treatment Group	
	Paroxetine n (%)	**Placebo n (%)**
Baseline		
Not assessed	0	0
Normal, not at all ill (1)	0	0
Borderline mentally ill (2)	0	0
Mildly ill (3)	3 (2.6)	3 (2.7)
Moderately ill (4)	49 (41.9)	49 (44.5)
Markedly ill (5)	45 (38.5)	41 (37.3)
Severely ill (6)	18 (15.4)	15 (13.6)
Among the most extremely ill (7)	2 (1.7)	2 (1.8)
Total	117 (100.0)	110 (100.0)
Week 16 OC		
Not assessed	0	1 (1.4)
Normal, not at all ill (1)	28 (30.4)	5 (6.9)
Borderline mentally ill (2)	25 (27.2)	16 (22.2)
Mildly ill (3)	22 (23.9)	14 (19.4)
Moderately ill (4)	14 (15.2)	29 (40.3)
Markedly ill (5)	2 (2.2)	4 (5.6)
Severely ill (6)	1 (1.1)	3 (4.2)
Among the most extremely ill (7)	0	0
Total	92 (100.0)	72 (100.0)
Week 16 LOCF		
Not assessed	0	0
Normal, not at all ill (1)	28 (24.1)	6 (5.5)
Borderline mentally ill (2)	26 (22.4)	16 (14.7)
Mildly ill (3)	29 (25.0)	16 (14.7)
Moderately ill (4)	21 (18.1)	46 (42.2)
Markedly ill (5)	9 (7.8)	18 (16.5)
Severely ill (6)	3 (2.6)	7 (6.4)
Among the most extremely ill (7)	0	0
Total	116 (100.0)	109 (100.0)

Total = number of patients with a Week 16 OC or LOCF assessment
Source: Table 14.2.1, Section 12; Listing 14.2.1, Appendix C

Table 54 presents the number and percentage of patients by change in CGI Severity of Illness from Baseline to Week 16 LOCF and OC. At Week 16 LOCF,

63.6% of paroxetine patients (103/162) had a decrease in severity of illness of two or more categories, compared to 27.3% of placebo patients (42/154).

At Week 16 OC, the improvement was greater in both treatment groups: 73.4% of paroxetine patients (91/124) had a decrease in severity of illness of two or more categories, compared to 38.6% of placebo patients (39/101).

The decrease in CGI severity among children was similar to the decrease in the overall population in both datasets. At Week 16 LOCF, 60.9% of children on paroxetine (28/46) had a decrease in severity of illness of two or more categories, compared to 24.4% of children on placebo (11/45). The Week 16 OC dataset showed even greater improvement.

The decrease in CGI severity among adolescents was also similar to the decrease in the overall population in both datasets. At Week 16 LOCF, 64.7% of adolescents on paroxetine (75/116) had a decrease in severity of illness of two or more categories, compared to 28.4% of adolescents on placebo (31/109). The Week 16 OC dataset showed even greater improvement.

Table 54 Number (%) of Patients by Change in CGI Severity of Illness from Baseline to Week 16 OC and LOCF–Age Group: Children/Adolescents/Total (ITT Population)

	Paroxetine			Placebo		
	Children	**Adolescents**	**Total**	**Children**	**Adolescents**	**Total**
Change from Baseline to Week 16 OC						
-5	1 (3.1)	3 (3.3)	4 (3.2)	0	2 (2.8)	2 (2.0)
-4	3 (9.4)	11 (12.0)	14 (11.3)	1 (3.4)	1 (1.4)	2 (2.0)
-3	5 (15.6)	33 (35.9)	38 (30.6)	4 (13.8)	8 (11.1)	12 (11.9)
-2	13 (40.6)	22 (23.9)	35 (28.2)	6 (20.7)	17 (23.6)	23 (22.8)
-1	5 (15.6)	15 (16.3)	20 (16.1)	11 (37.9)	23 (31.9)	34 (33.7)
0	5 (15.6)	6 (6.5)	11 (8.9)	6 (20.7)	20 (27.8)	26 (25.7)
1	0	2 (2.2)	2 (1.6)	1 (3.4)	0	1 (1.0)
Missing	0	0	0	0	1 (1.4)	1 (1.0)
Total	32 (100.0)	92 (100.0)	124 (100.0)	29 (100.0)	72 (100.0)	101 (100.0)
Change from Baseline to Week 16 LOCF						
-5	1 (2.2)	3 (2.6)	4 (2.5)	0	2 (1.8)	2 (1.3)
-4	4 (8.7)	11 (9.5)	15 (9.3)	1 (2.2)	2 (1.8)	3 (1.9)
-3	6 (13.0)	34 (29.3)	40 (24.7)	4 (8.9)	8 (7.3)	12 (7.8)
-2	17 (37.0)	27 (23.3)	44 (27.2)	6 (13.3)	19 (17.4)	25 (16.2)
-1	11 (23.9)	22 (19.0)	33 (20.4)	15 (33.3)	28 (25.7)	43 (27.9)
0	6 (13.0)	15 (12.9)	21 (13.0)	18 (40.0)	50 (45.9)	68 (44.2)
1	0	4 (3.4)	4 (2.5)	1 (2.2)	0	1 (0.6)
Missing	1 (2.2)	0	1 (0.6)	0	0	0)
Total	46 (100.0)	116 (100.0)	162 (100.0)	45 (100.0)	109 (100.0)	154 (100.0)

Source: Table 14.2.2, Section 12; Listing 14.2.1, Appendix C

5.3.3 Dalhousie Generalized Social Anxiety Disorder Scale for Adolescents

The D–GSADS–A scale is a clinician-rated scale (not yet validated) designed to assess of the severity of social anxiety symptoms in adolescents. Table 55 presents the analysis for change from Baseline in D–GSADS–A total score for the Week 16 LOCF, Week 16 OC, and 70% LOCF datasets based on the ITT population for patients aged ≥11 years.

The adjusted mean change from baseline at Week 16 LOCF endpoint in D-GSADS-A total score was –42.94 (SE 2.66) for paroxetine patients and -21.08 (SE 2.71) for placebo patients. The adjusted mean difference between paroxetine and placebo at Week 16 LOCF was 21.86 points in favor of paroxetine (95% CI: [-28.56, -15.16], p <0.001), indicating a statistically significant benefit of paroxetine over placebo.

The Week 16 OC and 70% LOCF dataset analyses support the conclusion of the LOCF analysis.

Summary statistics for D–GSADS–A total score at each visit, based on the ITT population, may be found in Table 14.4.1, Section 12, and Listings 14.4.1.1, 14.4.1.2, 14.4.1.3, 14.4.1.4, and 14.4.2, Appendix C.

Table 55 Summary of Analysis for Change from Baseline in D–GSADS–A Total Score–Age Group: ≥ 11 Years (ITT Population)

	Treatment Groups								
	Paroxetine			Placebo			Treatment Comparisons		
	N	LS Mean *	(SE) *	N	LS Mean *	(SE) *	Difference **	95% CI	p-value
Baseline	126	84.44	25.42	125	81.93	26.25	–	–	–
Change from Baseline to:							–	–	–
Week 4	117	-22.42	2.01	110	-12.66	2.06	–	–	–
Week 8	102	-34.45	2.57	97	-15.00	2.66	–	–	–
Week 12	102	-42.66	2.73	88	-18.83	2.86	–	–	–
Week 16 OC	97	-46.75	2.76	84	-23.49	2.90	-23.26	-30.51, -16.01	<0.001
Week 16 LOCF †	124	-42.94	2.66	120	-21.08	2.71	-21.86	-28.56, -15.16	<0.001
70% LOCF ††	124	-40.06	2.52	120	-18.53	2.57	-21.53	-27.88, -15.17	<0.001

* Least square means. For Baseline, raw means, not least square means, are presented, and standard deviations, not standard errors, are presented.

** Differences in adjusted (least square) means (paroxetine minus placebo) (adjusted for Baseline score, gender and country grouping; not adjusted for age group since, per protocol, only patients aged 11 years and older were administered the D–GSADS–A scale.)

† LOCF endpoint may have more patients than the first post-Baseline visit as Early Withdrawal data at unscheduled visits are not tabulated but is carried forward for LOCF endpoint

†† 70% LOCF is Week 12

Source: Table 14.4.2, Section 12; Listings 14.4.1.1, 14.4.1.2, 14.4.1.3, 14.4.1.4, and 14.4.2, Appendix C

5.3.4 Social Phobia Anxiety Inventory (SPAI–C and SPAI)

The SPAI–C and SPAI scales are self-report instruments for the purpose of diagnosis and assessment of Social Anxiety Disorder in children and adolescents, respectively. For the analysis, an exception was made to the age requirements such that patients aged 14 or 15 years who inadvertently completed the SPAI-C were included in the analyses of the SPAI–C, and patients aged 13 years who inadvertently completed the SPAI were included in the analyses of the SPAI (see Section 3.15.3, Planned Efficacy Evaluations). Patients aged 16 years and older who inadvertently completed the SPAI–C were excluded from the analyses of the SPAI–C; patients aged 12 years and younger who inadvertently completed the SPAI were excluded from the analyses of the SPAI.

Table 56 presents the analysis for change from Baseline in SPAI–C total score for the Week 16 LOCF, Week 16 OC, and 70% LOCF datasets based on the ITT population for patients aged ≤13 years (the analysis could also contain some patients aged 14 or 15). The adjusted mean change from baseline at Week 16 LOCF endpoint in SPAI-C total score was –17.55 (SE 1.59) for paroxetine patients and –8.11 (SE 1.62) for placebo patients. The adjusted mean difference between paroxetine and placebo at Week 16 LOCF was 9.44 points in favor of paroxetine (95% CI: [-13.19, -5.69], p <0.001) indicating a statistically significant benefit of paroxetine over placebo.

The Week 16 OC and 70% LOCF dataset analyses supported the conclusion of the LOCF analysis.

Summary statistics for SPAI-C total score at each visit, based on the ITT population, may be found in Table 14.5.1, Section 12, and Listings 14.5.1 and 14.5.2, Appendix C.

Table 56 Summary of Analysis for Change from Baseline in SPAI–C Total Score–Age Group: ≤13 years (ITT Population)

	Treatment Groups								
	Paroxetine			Placebo			Treatment Comparisons		
	N	LS Mean *	(SE) *	N	LS Mean *	(SE) *	Difference **	95% CI	p-value
Baseline	71	28.06	11.71	66	29.52	11.06	–	–	–
Change from Baseline to:									
Week 4	63	-9.43	1.50	60	-3.23	1.53	–	–	–
Week 8	59	-13.82	1.61	47	-4.44	1.76	–	–	–
Week 12	57	-16.67	1.60	40	-7.96	1.82	–	–	–
Week 16 OC	51	-18.06	1.64	41	-8.69	1.75	-9.36	-13.55, -5.17	<0.001
Week 16 LOCF †	69	-17.55	1.59	66	-8.11	1.62	-9.44	-13.19, -5.69	<0.001
70% LOCF ††	69	-16.79	1.57	66	-8.05	1.60	-8.75	-12.44, -5.05	<0.001

Note: SPAI–C was to include patients 8-13 years old according to protocol; however, it also includes some patients aged 14 and 15 years (see Section 3.15.3, Planned Efficacy Evaluations).

* Least square means. For Baseline, raw means, not least square means, are presented, and standard deviations, not standard errors, are presented.

** Differences in adjusted (least square) means (paroxetine minus placebo) (adjusted for Baseline score, gender and country grouping; not adjusted for age group since only children were administered the SPAI–C.)

† LOCF endpoint may have more patients than first post-Baseline visit as Early Withdrawal data at unscheduled visits are not tabulated but is carried forward for LOCF endpoint.

†† 70% LOCF is Week 12

Source: Table 14.5.2, Section 12; Listings 14.5.1 and 14.5.2, Appendix C

Table 57 presents the analysis for change from Baseline in SPAI difference score for the Week 16 LOCF, Week 16 OC, and 70% LOCF datasets based on the ITT population for patients aged ≥14 years (the analysis could also contain some patients aged 13).

The adjusted mean change from baseline at Week 16 LOCF endpoint in SPAI difference score was –51.85 (SE 4.53) for paroxetine patients and –19.05 (SE 4.40) for placebo patients. The adjusted mean difference between paroxetine and placebo at Week 16 LOCF was 32.80 points in favor of paroxetine (95% CI: [-43.57, -22.03], p <0.001), indicating a statistically significant benefit of paroxetine over placebo.

The Week 16 OC and 70% LOCF dataset analyses supported the conclusion of the LOCF analysis.

Summary statistics for SPAI difference score at each visit, based on the ITT population, may be found in Table 14.6.1, Section 12, and Listings 14.6.1.1, 14.6.1.2, and 14.6.2, Appendix C.

Table 57 Summary of Analysis for Change from Baseline in SPAI Difference Score–Age Group: ≥14 Years of Age (ITT Population)

	Treatment Groups								
	Paroxetine			Placebo			Treatment Comparisons		
	N	LS Mean *	(SE) *	N	LS Mean *	(SE) *	Difference **	95% CI	p-value
Baseline	81	98.70	31.56	84	90.94	32.23	–	–	–
Change from Baseline to:									
Week 4	74	-21.53	3.54	76	-7.36	3.46	–	–	–
Week 8	63	-31.49	4.35	66	-11.33	4.12	–	–	–
Week 12	62	-48.44	4.71	60	-17.73	4.54	–	–	–
Week 16 OC	61	-56.00	4.98	54	-24.63	4.95	-31.37	(-43.62, -19.12)	<0.001
Week 16 LOCF †	77	-51.85	4.53	81	-19.05	4.40	-32.80	(-43.57, -22.03)	<0.001
70% LOCF ††	77	-47.20	4.19	81	-16.85	4.07	-30.35	(-40.30, -20.40)	<0.001

Note: SPAI was to include patients ≥14 years old according to protocol; however, it includes some patients aged 13 years (see Section 3.15.3, Planned Efficacy Evaluations).

* Least square means. For Baseline, raw means, not least square means, are presented, and standard deviations, not standard errors, are presented.

** Differences in adjusted (least square) means (paroxetine minus placebo) (adjusted for Baseline score, gender and country grouping; not adjusted for age group since only adolescents were administered the SPAI)

† LOCF Endpoint may have more patients than first post-Baseline visit as Early Withdrawal data at unscheduled visits are not tabulated but is carried forward for LOCF endpoint.

†† 70% LOCF is Week 12

Source: Table 14.6.2, Section 12; Listings 14.6.1.1, 14.6.1.2, and 14.6.2, Appendix C

5.3.5 Change from Baseline in Global Assessment of Functioning Score

The GAF is an investigator-rated scale for assessing a patient's overall level of psychological, social and occupational functioning. Table 58 presents the analysis for change from Baseline in the GAF score for the Week 16 LOCF, Week 16 OC, and 70% LOCF datasets based on the overall ITT population.

The adjusted mean change from baseline at Week 16 LOCF endpoint in GAF score was 17.11 (SE 1.14) for paroxetine patients and 8.37 (SE 1.15) for placebo patients. The adjusted mean difference between paroxetine and placebo at Week 16 LOCF was 8.74 points in favor of paroxetine (95% CI: [6.15, 11.34)], $p < 0.001$), indicating a statistically significant benefit of paroxetine over placebo.

The Week 16 OC and 70% LOCF dataset analyses supported the conclusion of the Week 16 LOCF analysis.

Summary statistics for GAF score at each visit, based on the ITT population, for children and adolescents separately and combined, may be found in Table 14.7.1, Section 12. Summary statistics for change from Baseline in GAF score at each visit, based on the ITT population, for children and adolescents separately and combined, may be found in Table 14.7.3, Section 12. Per-patient information may be found in Listings 14.7.1, and 14.7.2, Appendix C.

Table 58 Summary of Analysis for Change from Baseline in GAF Score–Age Group: Total (ITT Population)

	Treatment Groups						Treatment Comparisons †		
	Paroxetine			Placebo					
	N	LS Mean*	(SE) *	N	LS Mean *	(SE) *	Difference **	95% CI	p-value
Age Group: Total									
Baseline	162	52.97	6.85	155	53.48	7.51	–	–	–
Change from Baseline to:									
Wk 4	150	7.41	0.71	140	3.88	0.72	–	–	–
Wk 8	134	11.82	0.95	120	6.62	1.00	–	–	–
Wk 12	129	16.25	1.11	106	8.22	1.16	–	–	–
Wk 16 OC	124	19.54	1.24	101	10.37	1.30	9.17	(6.21, 12.13)	<0.001
Wk 16 LOCF †	159	17.11	1.14	151	8.37	1.15	8.74	(6.15, 11.34)	<0.001
70% LOCF ††	159	15.01	1.01	151	7.43	1.02	7.58	(5.28, 9.88)	<0.001

* Least square means. For Baseline, raw means, not least square means, are presented, and standard deviations, not standard errors, are presented.

****** Differences in adjusted (least square) means (paroxetine minus placebo) (adjusted for Baseline score, age group, gender and country grouping)

† LOCF endpoint may have more patients than first post-Baseline visit as Early Withdrawal data at unscheduled visits are not tabulated but is carried forward for LOCF endpoint.

†† 70% LOCF is Week 12

Source: Table 14.7.2, Section 12; Listings 14.7.1 and 14.7.2, Appendix C

5.4 Other Variable of Interest–Children's Depression Rating Scale–Revised (CDRS–R)

The CDRS–R is a clinician-rated instrument designed to measure the severity of depression. Table 59 presents the analysis of the CDRS–R for the Week 16 LOCF and OC datasets based on the ITT population.

The adjusted mean change from baseline at Week 16 LOCF endpoint in CDRS-R total score was –4.75 (SE 0.97) for paroxetine patients and –1.14 (SE 1.00) for placebo patients. The adjusted mean difference between paroxetine and placebo at Week 16 LOCF was 3.61 points in favor of paroxetine (95% CI: [–5.88, -1.34)], p = 0.002). Although this difference indicates a statistically significant benefit of paroxetine over placebo, the benefit is not of clinical relevance because the level of depressive symptomatology was very low at Baseline.

The Week 16 OC dataset analysis supported the conclusion of the Week 16 LOCF analysis.

Summary statistics for CDRS–R total score at each visit, based on the ITT population, may be found in Table 14.8.1, Section 12. Summary statistics for change from Baseline in CDRS–R score by visit, based on the ITT population, may be found in Table 14.8.3, Section 12. Per-patient information may be found in Listings 14.8.1 and 14.8.2, Appendix C.

Table 59 Summary of Analysis for Change from Baseline in CDRS–R Total Score–Age Group: Total (ITT Population)

	Treatment Group								
	Paroxetine			Placebo			Treatment Comparison		
	N	LS Mean *	(SE) *	N	LS Mean *	(SE) *	Difference **	95% CI	p-value
Baseline	162	29.51	10.43	155	30.77	11.90			
Change from Baseline to:									
Week 16 OC	124	-6.16	0.79	100	-2.13	0.83	-4.03	(-5.91, -2.15)	<0.001
Week 16 LOCF †	145	-4.75	0.97	126	-1.14	1.00	-3.61	(-5.88, -1.34)	0.002

Note: 70% LOCF analysis not conducted because CDRS-R only scheduled for assessment at Baseline and Week 16 or Early Withdrawal.

* Least square means. For Baseline, raw means, not least square means, are presented, and standard deviations, not standard errors, are presented.

****** Differences in adjusted (least square) means (paroxetine minus placebo) (adjusted for Baseline score, age group, gender and country grouping)

† LOCF endpoint may have more patients than the first post-Baseline visit as Early Withdrawal data at unscheduled visits are not tabulated but is carried forward for LOCF endpoint

Source: Table 14.8.2, Section 12; Listings 14.8.1 and 14.8.2, Appendix C.

6 Safety Results

This section describes the safety data from the ITT population, which includes all patients who received at least one dose of randomized study medication and for whom at least one post-Baseline assessment (including any adverse events) was available. For this study, the ITT population is identical to the safety population. The safety data summarized include all AEs, vital signs, and laboratory data.

6.1 Extent of Exposure

Table 60 and Table 61 show the mean duration of time in days (excluding Taper Phase) that patients were exposed to paroxetine or placebo by treatment group, as well as overall duration of exposure and the range of exposure, for the overall population and for children and adolescents, respectively.

The overall mean number of days of exposure to study medication (excluding taper) was 101.0 days for all patients who received paroxetine and 93.6 days for all patients who received placebo. The mean duration of exposure in children was similar between the two treatment groups (97.6 and 94.7 days for paroxetine and placebo, respectively). However, among adolescents, the paroxetine group had a higher overall mean duration (paroxetine 102.4 days; placebo 93.1 days); this difference is consistent with the fact that fewer adolescent paroxetine patients (21.4%) withdrew prematurely from the study than adolescent placebo patients (33.3%).

The extent of exposure including Taper Phase is presented in Table 13.17.5.2, Section 11. Consistent with the higher doses received by placebo patients than by paroxetine patients (Table 34), requiring a longer taper period, the overall mean number of days of exposure to study medication including taper was 113.0 days for all patients who received paroxetine and 109.5 days for all patients who received placebo. The duration was similar for children across the two treatment groups. However, among adolescents, the paroxetine group had a higher overall mean duration including taper (paroxetine 115.7 days; placebo 109.8 days). The maximum number of days of exposure for any patient was 166 in the paroxetine group and 171 in the placebo group. Data for patient 676.021.24565, an adolescent in the paroxetine group, are not included in this table due to irreconcilable dosing data. This patient is included in Listing 13.17.1, Appendix B (see Section 15, Errata).

Table 60 Duration of Exposure to Study Medication by Time Intervals and Mean Treatment Duration (Excluding Taper)–Age Group: Total (ITT Population)

	Treatment Group			
Study Medication	**Paroxetine**		**Placebo**	
Exposure (Days)	**n**	**(%)**	**n**	**(%)**
≥1	162	(100.0)	155	(100.0)
>7	161	(99.4)	153	(98.7)
>14	159	(98.1)	149	(96.1)
>21	156	(96.3)	148	(95.5)
>28	153	(94.4)	144	(92.9)
>42	146	(90.1)	135	(87.1)
>56	141	(87.0)	124	(80.0)
>70	133	(82.1)	115	(74.2)
>84	130	(80.2)	111	(71.6)
>98	127	(78.4)	105	(67.7)
>112	79	(48.8)	56	(36.1)
Overall mean duration (days)	101.0		93.6	
Range (days)	1 to 147		2 to 138	

Note: Data for PID 676.021.24565, an adolescent in the paroxetine group, are not included in this table due to irreconcilable dosing data. This patient is included in Listing 13.17.1, Appendix B (see Section 15, Errata).
Source: Table 13.17.5.1, Section 11; Listing 13.17.1, Appendix B

Table 61 Duration of Exposure to Study Medication by Time Intervals and Mean Treatment Duration (Excluding Taper)–Age Group: Children/Adolescents (ITT Population)

	Treatment Group			
Study Medication	**Paroxetine**		**Placebo**	
Exposure (Days)	**n**	**(%)**	**n**	**(%)**
Age Group: Children				
≥1	46	(100.0)	45	(100.0)
>7	46	(100.0)	45	(100.0)
>14	46	(100.0)	45	(100.0)
>21	43	(93.5)	45	(100.0)
>28	42	(91.3)	44	(97.8)
>42	42	(91.3)	39	(86.7)
>56	40	(87.0)	35	(77.8)
>70	35	(76.1)	34	(75.6)
>84	35	(76.1)	31	(68.9)
>98	33	(71.7)	30	(66.7)
>112	17	(37.0)	19	(42.2)
Overall mean duration (days)	97.6		94.7	
Range	16 to 132		26 to 132	
Age Group: Adolescents				
≥1	116	(100.0)	110	(100.0)
>7	115	(99.1)	108	(98.2)
>14	113	(97.4)	104	(94.5)
>21	113	(97.4)	103	(93.6)
>28	111	(95.7)	100	(90.9)
>42	104	(89.7)	96	(87.3)
>56	101	(87.1)	89	(80.9)
>70	98	(84.5)	81	(73.6)
>84	95	(81.9)	80	(72.7)
>98	94	(81.0)	75	(68.2)
>112	62	(53.4)	37	(33.6)
Overall mean duration (days)	102.4		93.1	
Range	1 to 147		2 to 138	

Note: Data for PID 676.021.24565, an adolescent in the paroxetine group, are not included in this table due to irreconcilable dosing data. This patient is included in Listing 13.17.1, Appendix B (see Section 15, Errata).
Source: Table 13.17.5.1, Section 11; Listing 13.17.1, Appendix B

6.2 Adverse Events

The methodology for coding and tabulating AEs is described in Section 3.12.1, Adverse Events [Safety Assessments]. All AEs were summarized according to

the phase of the study in which they initially occurred, that is, Pre-Treatment Phase, Treatment Phase, Taper Phase, or Follow-up Phase.

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

All AEs that occurred after the last dose of 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 16 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.

Summaries of all AEs during the Treatment Phase, Taper Phase, and Follow-up Phase may be found in Tables 15.1.1.1 and 15.1.1.1.X for Treatment Phase-emergent AEs, 15.1.1.2 and 15.1.1.2.X for Taper Phase-emergent AEs, 15.1.1.3 and 15.1.1.3.X for combined Treatment Phase- and Taper Phase-emergent AEs, 15.1.1.4 and 15.1.1.4.X for Follow-up Phase-emergent AEs, 15.1.1.5 and 15.1.1.5.X for combined Taper- and Follow-up Phase-emergent AEs, and 15.1.1.6 and 15.1.1.6.X for combined Treatment, Taper Phase and Follow-up Phase-emergent AEs, all in Section 13. Individual patient information in regard to AEs may be found in Listings 15.1.1 (Treatment Phase) and 15.1.2 (Taper, Follow-up, and Post-follow-up Phases), Appendix D.

Table 15.1.1.0, Section 13, presents the incidence of patients with AEs prior to the start of study medication. These AEs are summarized in Section 4.6, Baseline Signs and Symptoms.

The incidence of AEs was determined for serious and non-serious combined, regardless of investigator-attributed relationship to study medication. See Section 3.15.7, Safety Evaluations [Statistical Evaluation] for a definition of emergent AEs in each Treatment Phase.

6.2.1 Treatment Phase-emergent Adverse Events

Table 62 presents a summary of the most frequently reported (≥ 5% in either treatment group) Treatment Phase-emergent AEs, regardless of treatment attribution, for both age groups combined and separately. Treatment Phase-emergent AEs are summarized in Table 15.1.1.1, Section 13 (by body system and

preferred term), and Table 15.1.1.1.X, Section 13 (by preferred term occurring in 1% or more of the population in descending order).

A total of 88.3% of patients (144/163) randomized to paroxetine reported gender-non-specific, emergent AEs during the Treatment Phase, compared to 80.1% of patients receiving placebo (125/156). Overall, the most common (>10%) gender-non-specific AEs for patients receiving paroxetine were headache, infection, respiratory disorder, abdominal pain, asthenia, insomnia, somnolence, rhinitis, and nausea while the most common AEs for patients receiving placebo were headache, infection, respiratory disorder, and rhinitis.

The overall AE frequency was similar among children and adolescents. A total of 83.5% of children (76/91) reported gender-non-specific emergent AEs during the Treatment Phase, 89.1% on paroxetine (41/46) and 77.8% (35/45) on placebo. A total of 84.6% of adolescents (193/228) reported gender-non-specific emergent AEs during the Treatment Phase, 88.0% (103/117) on paroxetine and 81.1% (90/111) on placebo.

During the Treatment Phase, there were no gender-specific AEs among children in either treatment group and few among adolescents. Among adolescents, 1 male patient on paroxetine (1.4%, 1/71) reported abnormal ejaculation. Five female patients on paroxetine (5.5%, 5/92) and 4 on placebo (6.0%, 4/67) reported AEs of dysmenorrhea; one female on paroxetine (1.1%, 1/92) reported an AE of amenorrhea (Table 15.1.1.1, Section 13).

Table 62 Most Frequent (≥5% in Either Treatment Group in Either Age Group) Treatment-Phase Emergent Adverse Events–Age Group: Total/Children/Adolescents (ITT Population)

	Age Group: Total		Age Group: Children		Age Group: Adolescents	
AE Preferred Term	**Paroxetine (N = 163**	**Placebo (N = 156)**	**Paroxetine (N = 46)**	**Placebo (N = 45)**	**Paroxetine (N = 117)**	**Placebo (N = 111)**
Patients with AEs	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Total Patients with at Least One AE	144 (88.3)	125 (80.1)	41 (89.1)	35 (77.8)	103 (88.0)	90 (81.1)
Headache	62 (38.0)	42 (26.9)	15 (32.6)	11 (24.4)	47 (40.2)	31 (27.9)
Infection	33 (20.2)	25 (16.0)	6 (13.0)	8 (17.8)	27 (23.1)	17 (15.3)
Respiratory Disorder	25 (15.3)	20 (12.8)	7 (15.2)	3 (6.7)	18 (15.4)	17 (15.3)
Abdominal Pain	24 (14.7)	15 (9.6)	10 (21.7)	5 (11.1)	14 (12.0)	10 (9.0)
Asthenia	24 (14.7)	12 (7.7)	3 (6.5)	1 (2.2)	21 (17.9)	11 (9.9)
Insomnia	23 (14.1)	9 (5.8)	6 (13.0)	3 (6.7)	17 (14.5)	6 (5.4)
Somnolence	21 (12.9)	13 (8.3)	4 (8.7)	5 (11.1)	17 (14.5)	8 (7.2)
Rhinitis	17 (10.4)	25 (16.0)	1 (2.2)	7 (15.6)	16 (13.7)	18 (16.2)
Nausea	17 (10.4)	12 (7.7)	2 (4.3)	4 (8.9)	15 (12.8)	8 (7.2)
Trauma	14 (8.6)	12 (7.7)	5 (10.9)	4 (8.9)	9 (7.7)	8 (7.2)
Nervousness	14 (8.6)	9 (5.8)	7 (15.2)	2 (4.4)	7 (6.0)	7 (6.3)
Pharyngitis	13 (8.0)	14 (9.0)	2 (4.3)	7 (15.6)	11 (9.4)	7 (6.3)
Decreased Appetite	13 (8.0)	5 (3.2)	3 (6.5)	2 (4.4)	10 (8.5)	3 (2.7)
Dyspepsia	12 (7.4)	6 (3.8)	2 (4.3)	2 (4.4)	10 (8.5)	4 (3.6)
Vomiting	11 (6.7)	3 (1.9)	3 (6.5)	2 (4.4)	8 (6.8)	1 (0.9)

Note: Sorted by decreasing frequency in the paroxetine group, age group = total
Source: Tables 15.1.1.1 and 15.1.1.1.X, Section 13; Listing 15.1.1, Appendix D

(Table continues)

Table 62 (Continued) Most Frequent (≥5% in Either Treatment Group in Either Age Group) Treatment-Phase Emergent Adverse Events–Age Group: Total/Children/Adolescents (ITT Population)

	Age Group: Total		Age Group: Children		Age Group: Adolescents	
AE Preferred Term	**Paroxetine (N = 163**	**Placebo (N = 156)**	**Paroxetine (N = 46)**	**Placebo (N = 45)**	**Paroxetine (N = 117)**	**Placebo (N = 111)**
Patients with AEs	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Cough Increased	9 (5.5)	11 (7.1)	3 (6.5)	5 (11.1)	6 (5.1)	6 (5.4)
Dizziness	8 (4.9)	10 (6.4)	1 (2.2)	1 (2.2)	7 (6.0)	9 (8.1)
Sinusitis	8 (4.9)	7 (4.5)	2 (4.3)	3 (6.7)	6 (5.1)	4 (3.6)
Rash	8 (4.9)	4 (2.6)	5 (10.9)	2 (4.4)	3 (2.6)	2 (1.8)
Diarrhea	6 (3.7)	7 (4.5)	2 (4.3)	4 (8.9)	4 (3.4)	3 (2.7)
Otitis Media	6 (3.7)	2 (1.3)	5 (10.9)	1 (2.2)	1 (0.9)	1 (0.9)
Conjunctivitis	6 (3.7)	1 (0.6)	3 (6.5)	0	3 (2.6)	1 (0.9)
Hyperkinesia	6 (3.7)	0	4 (8.7)	0	2 (1.7)	0
Hostility	5 (3.1)	2 (1.3)	3 (6.5)	0	2 (1.7)	2 (1.8)
Urinary Incontinence	5 (3.1)	0	5 (10.9)	0	0	0
Back Pain	3 (1.8)	7 (4.5)	1 (2.2)	1 (2.2)	2 (1.7)	6 (5.4)

Note: Sorted by decreasing frequency in the paroxetine group, age group = total
Source: Table 15.1.1.1 and 15.1.1.1.X, Section 13; Listing 15.1.1, Appendix D

As shown in Table 63, for both age groups combined, AEs that occurred with an incidence of 5% or greater in the paroxetine group and with an incidence at least twice that in the placebo group were insomnia (14.1% vs. 5.8%), decreased appetite (8.0% vs. 3.2%), and vomiting (6.7% vs. 1.9%). In addition to these AEs, children receiving paroxetine also experienced respiratory disorder, nervousness, rash, otitis media, urinary incontinence, hyperkinesia, asthenia, conjunctivitis, and hostility with an incidence of 5% or greater and with an incidence at least twice that of children receiving placebo (Table 62). Among adolescents, the pattern of AEs with an incidence of 5% or greater in the paroxetine group and with an incidence at least twice that in the placebo group was somewhat different, with somnolence, insomnia, dyspepsia, decreased appetite and vomiting meeting these criteria (Table 62). No gender-specific AEs met these criteria.

Table 63 Treatment-Phase Emergent Gender-non-specific Adverse Events with Incidence ≥5% in the Paroxetine Group and ≥Twice the Incidence in the Placebo Group–Age Group: Total (ITT Population)

	Treatment Group	
AE Preferred Term	**Paroxetine (N = 163)**	**Placebo (N = 156)**
Patients with AEs	**n (%)**	**n (%)**
Insomnia	23 (14.1)	9 (5.8)
Decreased Appetite	13 (8.0)	5 (3.2)
Vomiting	11 (6.7)	3 (1.9)

Note: Sorted by decreasing frequency in the paroxetine group.
Source: Table 15.1.1.1.X, Section 13; Listing 15.1.1, Appendix D

Table 64 presents Treatment-Phase emergent adverse events with an incidence of ≥5% in children or adolescents in the paroxetine group and at least twice the incidence of the paroxetine patients in the other age group. No gender-specific AEs met these criteria. The relative incidence of these AEs in paroxetine patients differed somewhat between the age groups.

Among adolescents in the paroxetine group, five of the more commonly reported (i. e., ≥5%) AEs occurred at an incidence at least twice that among children: asthenia (17.9% vs. 6.5%), nausea (12.8% vs. 4.3%), pharyngitis (9.4% vs. 4.3%), rhinitis (13.7% vs. 2.2%), and dizziness (6.0% vs. 2.2%). However, among these AEs, none occurred at a frequency at least twice that of placebo (Table 64).

Among children in the paroxetine group, seven of the more commonly reported (i. e., ≥5%) AEs occurred at an incidence at least twice that among adolescents: nervousness (15.2% vs. 6.0%), rash (10.9% vs. 2.6%), otitis media (10.9% vs. 0.9%), urinary incontinence (10.9% vs. none), hyperkinesia (8.7% vs. 1.7%), conjunctivitis (6.5% vs. 2.6%), and hostility (6.5% vs. 1.7%). All of these AEs also occurred at a rate at least twice that of placebo (Table 64).

Table 64 Treatment-Phase Emergent Adverse Events with Incidence ≥5% in Children or Adolescents in the Paroxetine Group and ≥Twice the Incidence in the Other Age Group–Age Group: Children/Adolescents (ITT Population)

	Age Group: Children		Age Group: Adolescents	
Preferred Term	**Paroxetine (N = 46)**	**Placebo (N = 45)**	**Paroxetine (N = 117)**	**Placebo N = 111)**
Patients with AEs	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Nervousness	7 (15.2)	2 (4.4)	7 (6.0)	7 (6.3)
Rash	5 (10.9)	2 (4.4)	3 (2.6)	2 (1.8)
Otitis Media	5 (10.9)	1 (2.2)	1 (0.9)	1 (0.9)
Urinary Incontinence	5 (10.9)	0	0	0
Hyperkinesia	4 (8.7)	0	2 (1.7)	0
Asthenia	3 (6.5)	1 (2.2)	21 (17.9)	11 (9.9)
Conjunctivitis	3 (6.5)	0	3 (2.6)	1 (0.9)
Hostility	3 (6.5)	0	2 (1.7)	2 (1.8)
Nausea	2 (4.3)	4 (8.9)	15 (12.8)	8 (7.2)
Pharyngitis	2 (4.3)	7 (15.6)	11 (9.4)	7 (6.3)
Rhinitis	1 (2.2)	7 (15.6)	16 (13.7)	18 (16.2)
Dizziness	1 (2.2)	1 (2.2)	7 (6.0)	9 (8.1)

Note: Sorted by decreasing frequency in the paroxetine group, age group = children
Source: Table 15.1.1.1.X, Section 13; Listing 15.1.1, Appendix D

6.2.1.1 Treatment Phase-emergent Adverse Events by Investigator-assessed Intensity

Overall, AEs tended to be mild to moderate in intensity. Table 65 presents a summary of all severe Treatment Phase-emergent AEs. Treatment Phase-emergent AEs for both age groups combined and separately are summarized by intensity as assessed by the investigator (by body system and preferred term) and occurring in 1% or more of the population by intensity (by descending order and preferred term) in Tables 15.1.3.1 and 15.1.3.1.X, respectively, in Section 13. Treatment Phase-emergent AEs are also summarized by maximum intensity (by body system and preferred term) in Table 15.1.7.1 in Section 13.

For both age groups combined, severe gender-non-specific AEs were reported in 11.7% of patients (19/163) in the paroxetine group and 5.8% of patients (9/156) in the placebo group. The only severe AEs occurring in more than one patient in either treatment group were infection (2.5%, 4/163 patients in the paroxetine-treated group vs. no patients in the placebo group); manic reaction (1.8%, 3/163 patients in the paroxetine-treated group vs. no patients in the placebo group); headache (1.2%, 2/163 patient in the paroxetine group vs. 1.3%, 2/156 patients in the placebo group); and back pain and nausea (no patients in the paroxetine group vs. 1.3%, 2/156 patients in the placebo group for both AEs). Severe abdominal pain, flu syndrome, and trauma occurred in one patient in each treatment group.

No severe male-specific AEs occurred in either treatment group. One female patient in the paroxetine group experienced severe dysmenorrhea (Table 15.1.3.1, Section 13; Listing 15.1.1, Appendix D).

Two patients, both randomized to paroxetine, had SAEs that were considered severe by the investigator. Patient 676.205.24985 experienced an SAE of severe anemia on therapy and was withdrawn from the study, and patient 676.202.24785 had an SAE of severe trauma prior to study start (see Section 6.4, Serious Adverse Events).

Table 65 Treatment Phase-emergent Severe Adverse Events–Age Group: Total (ITT Population)

	Treatment Group	
AE Preferred Term	**Paroxetine (N = 163) n (%)**	**Placebo (N = 156) n (%)**
Total Patients with at least one gender-non-specific severe AE	19 (11.7)	9 (5.8)
Infection	4 (2.5)	0
Manic reaction	3 (1.8)	0
Headache	2 (1.2)	2 (1.3)
Abdominal pain	1 (0.6)	1 (0.6)
Flu syndrome	1 (0.6)	1 (0.6)
Trauma	1 (0.6)	1 (0.6)
Abnormal dreams	1 (0.6)	0
Agitation	1 (0.6)	0
Anemia	1 (0.6)	0
Asthenia	1 (0.6)	0
Contact dermatitis	1 (0.6)	0
Dyspepsia	1 (0.6)	0
Gastritis	1 (0.6)	0
Hyperkinesia	1 (0.6)	0
Back pain	0	2 (1.3)
Nausea	0	2 (1.3)
Chills	0	1 (0.6)
Dizziness	0	1 (0.6)
Ear pain	0	1 (0.6)
Pharyngitis	0	1 (0.6)
Total patients with gender-specific adverse events *	1 (1.1)	0
Dysmenorrhea	1 (1.1)	0

Note: Sorted by decreasing frequency in the paroxetine group
* n = 92 females in the paroxetine treatment group
Source: Tables 15.1.3.1 and 15.1.3.1.X, Section 13; Listing 15.1.1, Appendix D

Table 66 presents details of the patients with severe on-therapy adverse events. Nine of the 21 severe AEs in the paroxetine group and 2 of the 13 in the placebo group were considered by the investigator to be related or possibly related to study medication (see Section 6.2.1.2, Treatment Phase-emergent Adverse Events by Relationship to Study Medication). During the Treatment Phase, 8.7% of the children on paroxetine (4/46) had severe AEs compared to 13.7% (16/117) of the adolescents.

Table 66 Randomized Patients with Severe Adverse Events During the Treatment Phase (ITT Population)

Patient Number	Age (yrs)	Gender (M/F)	AE (Preferred Term)	AE (Verbatim Term)	Relationship	Day of Onset*	Duration
Paroxetine							
676.001.24003	13	F	Gastritis	Gastritis	Unrelated	118 (-1)	2 Days
676.003.24073	18	F	Infection	Strep throat	Unrelated	34 (-30)	8 Days
676.006.24142	16	M	Infection	Flu	Unrelated	42 (-71)	4 Days
676.006.24143	15	F	Contact dermatitis	Poison Oak	Unrelated	35 (78-)	15 Days
676.006.24145	17	F	Dysmenorrhea	Menstrual cramps	Unrelated	20 (92-)	1 Day
			Dysmenorrhea	Menstrual cramps	Unrelated	55 (-57)	1 Day
676.011.24282	13	F	Manic reaction	Manic episode **	Related	41 (0)	Ongoing
676.014.24376	13	F	Abnormal dreams	Morbid thoughts **	Probably unrelated	30 (-4)	Ongoing
			Agitation	Panic attack worsening **	Possibly related	30 (-4)	1 Day
676.015.24409	9	M	Hyperkinesia	Hyperactivity ** †	Related	33 (-18)	11 Days
					Related	44 (-7)	8 Days
676.017.24453	10	F	Abdominal pain	Pains across lower abdomen	Possibly related	20 (-101)	2 Days
676.022.17841	15	M	Manic reaction	Behavioral activation / hypomania **	Possibly related	23 (-10)	11 Days

Note: If the same severe AE occurs in the same patient more than once, it is tabulated only once.
* Relative to the first day of study medication (relative to the last dose of study medication, excluding taper)
** Patient withdrew from the study due to this AE
† AE led to a dose reduction
†† AE was considered serious
Source: Table 15.1.3.1, Section 13; Listing 13.5.1, Appendix B; Listing 15.1.1, Appendix D

(Table continues)

Table 66 (continued) Randomized Patients with Severe Adverse Events During the Treatment Phase (ITT Population)

Patient Number	Age (yrs)	Gender (M/F)	AE (Preferred Term)	AE (Verbatim Term)	Relationship	Day of Onset*	Duration
Paroxetine (continued)							
676.023.17877	7	M	Manic reaction	Hypomania †	Related	14 (-42)	Ongoing
676.024.25151	17	M	Headache	Headache	Possibly related	11 (-88)	11 Days
676.101.24629	13	F	Infection	Flu	Probably unrelated	4 (-115)	8 Days
676.103.24649	14	F	Flu syndrome	Flu-like symptoms	Probably unrelated	39 (-78)	2 Days
676.202.24785	10	M	Infection	Left leg laceration from previous bicycle accident has become septic	Unrelated	20 (-92)	13 Days
676.205.24985	16	F	Anemia	Anemia ** ††	Unrelated	25 (-1)	3 Days
676.207.24911	14	M	Headache	Headache	Possibly related	19 (-94)	1 Day
676.209.24959	12	F	Asthenia	Tiredness (fatigue)	Probably unrelated	21 (-91)	32 Days
					Probably unrelated	73 (-39)	Ongoing
676.209.24961	14	M	Dyspepsia	Heartburn	Related	49 (-34)	33 Days
676.209.24966	16	M	Trauma	Soft tissue injury neck	Unrelated	32 (-88)	38 Days

Note: If the same severe AE occurs in the same patient more than once, it is tabulated only once.
* Relative to the first day of study medication (relative to the last dose of study medication, excluding taper)
** Patient withdrew from the study due to this AE
† AE led to a dose reduction
†† AE was considered serious
Source: Table 15.1.3.1, Section 13; Listing 13.5.1, Appendix B; Listing 15.1.1, Appendix D

(Table continues)

Table 66 (continued) Randomized Patients with Severe Adverse Events During the Treatment Phase (ITT Population)

Patient Number	Age (yrs)	Gender (M/F)	AE (Preferred Term)	AE (Verbatim Term)	Relationship	Day of Onset*	Duration
Placebo							
676.002.24040	17	F	Flu syndrome	Flu-like syndrome	Unrelated	1 (-117)	15 Days
676.006.24141	15	M	Chills	Chills, nausea (while swimming)	Unrelated	42 (-72)	1 Day
			Nausea	Chills, nausea (while swimming)	Unrelated	42 (-72)	1 Day
			Headache	Headache	Possibly related	21 (-93)	1 Day
			Dizziness	Dizzy (upon standing)	Possibly related	60 (-54)	4 Days
676.006.24144	13	M	Abdominal pain	Stomach ache	Probably unrelated	17 (-96)	3 Days
			Back pain	Backache	Unrelated	1 (-112)	17 Days
676.009.24225	17	F	Nausea	Nausea	Probably unrelated	9 (-105)	2 Days
676.014.24370	14	M	Headache	Headache	Probably unrelated	65 (-33)	3 Days
676.017.24451	13	F	Trauma	Stubbed toe	Unrelated	114 (-5)	2 Days
676.017.24456	11	M	Ear pain	Earache (left)	Unrelated	82 (-30)	23 Days
676.206.24879	9	M	Pharyngitis	Tonsillitis	Unrelated	11 (-97)	9 Days
676.207.24904	16	F	Back pain	Backache	Probably unrelated	95 (-117)	2 Days

Note: If the same severe AE occurs in the same patient more than once, it is tabulated only once.
* Relative to the first day of study medication (relative to the last dose of study medication, excluding taper)
** Patient withdrew from the study due to this AE
† AE led to a dose reduction
†† AE was considered serious
Source: Table 15.1.3.1, Section 13; Listing 13.5.1, Appendix B; Listing 15.1.1, Appendix D

6.2.1.2 Treatment Phase-emergent Adverse Events by Relationship to Study Medication

Table 67, Table 68, and Table 69 present the most common Treatment Phase-emergent AEs (incidence ≥5% in either treatment group) that were judged to be related or possibly related to study medication, for the overall population, children, and adolescents, respectively.

Treatment Phase-emergent AEs considered by the investigators to be related or possibly related to study medication are detailed in Listing 15.1.1, Appendix D (by preferred term). These AEs are summarized in Table 15.1.4.1 (by body system and preferred term) and Table 15.1.4.1.X (by preferred term occurring in 1% or more of the population in descending order) in Section 13.

For both age groups combined, 63.2% (103/163) of patients in the paroxetine group were reported to have at least one gender-non-specific AE related or possibly related to the use of study medication, compared to 40.4% (63/156) of patients in the placebo group (Table 67). The most frequent (≥10%) AEs reported to be related or possibly related to study medication in the paroxetine group were headache, asthenia, insomnia, and somnolence. Of these, insomnia and somnolence had an incidence in the paroxetine group that was at least twice that in the placebo group.

For children, 67.4% (31/46) of patients in the paroxetine group were reported to have at least one gender-non-specific AE related or possibly related to the use of study medication, compared to 48.9% (22/45) of patients in the placebo group (Table 68). The most frequent (≥10%) AEs reported to be related or possibly related to study medication in the paroxetine group of children were headache, nervousness, abdominal pain, and insomnia. Of these, nervousness had an incidence in the paroxetine group that was at least twice that in the placebo group.

For adolescents, 61.5% (72/117) of patients in the paroxetine group were reported to have at least one gender-non-specific AE related or possibly related to the use of study medication, compared to 36.9% (41/111) of patients in the placebo group (Table 69). The most frequent (≥10%) AEs reported to be related or possibly related to study medication in the paroxetine group of adolescents were headache, asthenia, somnolence, and insomnia. Of these, somnolence and insomnia had an incidence in the paroxetine group that was at least twice that in the placebo group.

Table 67 Treatment Phase-emergent Adverse Events Considered Related or Possibly Related to Study Medication Occurring in ≥3% Patients in Either Treatment Group–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group	
	Paroxetine (N = 163)	Placebo (N = 156)
Adverse event	**n (%)**	**n (%)**
Age Group: Total		
Total Patients with at Least One Related or Possibly Related AE	103 (63.2)	63 (40.4)
Headache	35 (21.5)	20 (12.8)
Asthenia	21 (12.9)	11 (7.1)
Insomnia	20 (12.3)	7 (4.5)
Somnolence	19 (11.7)	10 (6.4)
Nervousness	14 (8.6)	5 (3.2)
Abdominal pain	12 (7.4)	7 (4.5)
Nausea	12 (7.4)	7 (4.5)
Decreased appetite	12 (7.4)	4 (2.6)
Dizziness	6 (3.7)	7 (4.5)
Hyperkinesia	6 (3.7)	0
Diarrhea	5 (3.1)	3 (1.9)
Dyspepsia	5 (3.1)	2 (1.3)
Vomiting	5 (3.1)	1 (0.6)
Dry mouth	4 (2.5)	5 (3.2)

Source: Table 15.1.4.1 and 15.1.4.1.X, Section 13; Listing 15.1.1, Appendix D

Table 68 Treatment Phase-emergent Adverse Events Considered Related or Possibly Related to Study Medication Occurring in ≥3% Patients in Either Treatment Group–Age Group: Children (ITT Population)

	Treatment Group	
	Paroxetine (N = 46)	Placebo (N = 45)
Adverse event	**n (%)**	**n (%)**
Total Children with at Least One Related or Possibly Related AE	31 (67.4)	22 (48.9)
Headache	10 (21.7)	7 (15.6)
Nervousness	7 (15.2)	2 (4.4)
Abdominal pain	6 (13.0)	3 (6.7)
Insomnia	5 (10.9)	3 (6.7)
Somnolence	4 (8.7)	3 (6.7)
Hyperkinesia	4 (8.7)	0
Asthenia	3 (6.5)	1 (2.2)
Diarrhea	2 (4.3)	3 (6.7)
Nausea	2 (4.3)	2 (4.4)
Decreased appetite	2 (4.3)	1 (2.2)
Vomiting	2 (4.3)	1 (2.2)
Flatulence	2 (4.3)	0
Hostility	2 (4.3)	0
Urinary incontinence	2 (4.3)	0
Concentration impaired	1 (2.2)	2 (4.4)

Source: Table 15.1.4.1 and 15.1.4.1.X, Section 13; Listing 15.1.1, Appendix D

Table 69 Treatment Phase-emergent Adverse Events Considered Related or Possibly Related to Study Medication Occurring in ≥3% Patients in Either Treatment Group–Age Group: Adolescents (ITT Population)

	Treatment Group	
	Paroxetine (N = 117)	Placebo (N = 111)
Adverse event	**n (%)**	**n (%)**
Total Adolescents with at Least One Related or Possibly Related AE	72 (61.5)	41 (36.9)
Headache	25 (21.4)	13 (11.7)
Asthenia	18 (15.4)	10 (9.0)
Somnolence	15 (12.8)	7 (6.3)
Insomnia	15 (12.8)	4 (3.6)
Nausea	10 (8.5)	5 (4.5)
Decreased appetite	10 (8.5)	3 (2.7)
Nervousness	7 (6.0)	3 (2.7)
Abdominal pain	6 (5.1)	4 (3.6)
Dizziness	5 (4.3)	6 (5.4)
Dry mouth	4 (3.4)	5 (4.5)
Dyspepsia	4 (3.4)	1 (0.9)

Source: Table 15.1.4.1 and 15.1.4.1.X, Section 13; Listing 15.1.1, Appendix D

The only gender-related AE that was considered by the investigator to be related or possibly related to study medication was abnormal ejaculation in one male in the paroxetine group.

Patient 676.209.24958, in the placebo group, experienced an SAE of abnormal laboratory value (unintentional overdose of study medication) that was considered by the investigator to be related to study medication. Table 66, which contains a per-patient listing of all patients with severe AEs during the Treatment Phase, includes investigator-determined relationship to study medication.

6.2.1.3 Treatment Phase-emergent Adverse Events by Time of First Occurrence

Table 70 and Table 71 summarize the most frequently occurring Treatment Phase-emergent AEs (i. e., those occurring in at least 5% of patients in either treatment group) by the time of first occurrence, for paroxetine and placebo patients, respectively. Table 15.1.6.1.X, Section 13, presents the time of first occurrence for the paroxetine and placebo groups, respectively, and for both age groups

combined and separately, for all Treatment Phase-emergent AEs, by preferred term in descending order.

The time to first occurrence for many of the common AEs in both treatment groups was within the initial 1 to 2 weeks of study medication. Infection, trauma, pharyngitis, and dyspepsia (paroxetine patients) and trauma, insomnia, and nervousness (placebo patients) were notable exceptions, occurring with greater frequency at or after Week 4 than before.

The patterns of first occurrence of AEs differed somewhat between children and adolescents. Among children on paroxetine, the AEs that occurred with greater frequency at or after Week 4 than before were nervousness, infection, insomnia, and otitis media. Among adolescents on paroxetine, the AEs that occurred with greater frequency at or after Week 4 than before were infection, respiratory disorder, rhinitis, abdominal pain, and pharyngitis.

Table 70 Number (%) of Patients with the Most Frequent (≥5%) Treatment Phase-emergent Adverse Events by Time of First Occurrence (Paroxetine Patients)–Age Group: Total (ITT Population)

AE, n (%)	Time of First Occurrence (Week)									
	Week 1 n (%)	Week 2 n (%)	Week 3 n (%)	Week 4 n (%)	Week 6 n (%)	Week 8 n (%)	Week 10 n (%)	Week 12 n (%)	Week 16 n (%)	Total n (%)
Paroxetine (N = 163)										
Headache	30 (18.4)	5 (3.1)	4 (2.5)	8 (4.9)	3 (1.8)	4 (2.5)	0	4 (2.5)	4 (2.5)	62 (38.0)
Infection	3 (1.8)	5 (3.1)	5 (3.1)	5 (3.1)	6 (3.7)	0	3 (1.8)	3 (1.8)	3 (1.8)	33 (20.2)
Respiratory Disorder	5 (3.1)	1 (0.6)	4 (2.5)	0	4 (2.5)	3 (1.8)	1 (0.6)	2 (1.2)	5 (3.1)	25 (15.3)
Abdominal Pain	7 (4.3)	3 (1.8)	2 (1.2)	5 (3.1)	0	0	2 (1.2)	0	5 (3.1)	24 (14.7)
Asthenia	13 (8.0)	5 (3.1)	2 (1.2)	1 (0.6)	1 (0.6)	0	0	0	2 (1.2)	24 (14.7)
Insomnia	12 (7.4)	2 (1.2)	1 (0.6)	6 (3.7)	1 (0.6)	0	1 (0.6)	0	0	23 (14.1)
Somnolence	11 (6.7)	2 (1.2)	2 (1.2)	3 (1.8)	1 (0.6)	0	1 (0.6)	1 (0.6)	0	21 (12.9)
Nausea	9 (5.5)	0	0	0	3 (1.8)	0	3 (1.8)	1 (0.6)	1 (0.6)	17 (10.4)
Rhinitis	4 (2.5)	2 (1.2)	2 (1.2)	2 (1.2)	3 (1.8)	1 (0.6)	0	0	3 (1.8)	17 (10.4)
Nervousness	3 (1.8)	2 (1.2)	1 (0.6)	4 (2.5)	1 (0.6)	1 (0.6)	2 (1.2)	0	0	14 (8.6)
Trauma	1 (0.6)	0	0	2 (1.2)	3 (1.8)	4 (2.5)	2 (1.2)	2 (1.2)	0	14 (8.6)
Decreased Appetite	5 (3.1)	0	3 (1.8)	2 (1.2)	2 (1.2)	0	1 (0.6)	0	0	13 (8.0)
Pharyngitis	3 (1.8)	0	1 (0.6)	0	2 (1.2)	1 (0.6)	2 (1.2)	1 (0.6)	3 (1.8)	13 (8.0)
Dyspepsia	1 (0.6)	0	4 (2.5)	2 (1.2)	2 (1.2)	2 (1.2)	1 (0.6)	0	0	12 (7.4)
Vomiting	3 (1.8)	1 (0.6)	1 (0.6)	1 (0.6)	0	1 (0.6)	0	0	4 (2.5)	11 (6.7)
Cough Increased	2 (1.2)	0	1 (0.6)	1 (0.6)	2 (1.2)	1 (0.6)	0	1 (0.6)	1 (0.6)	9 (5.5)
Dysmenorrhea *	1 (1.1)	0	2 (2.2)	1 (1.1)	0	0	1 (1.1)	0	0	5 (5.4)

Note: Sorted by total number of AEs

* Percentages are based on 92 female patients in the paroxetine group

Source: Table 15.1.6.1.X, Section 13; Listing 15.1.1, Appendix D

Table 71 Number (%) of Patients with the Most Frequent (≥5%) Treatment Phase-emergent Adverse Events by Time of First Occurrence (Placebo Patients)–Age Group: Total (ITT Population)

AE, n (%)	Time of First Occurrence (Week)									
	Week 1 n (%)	Week 2 n (%)	Week 3 n (%)	Week 4 n (%)	Week 6 n (%)	Week 8 n (%)	Week 10 n (%)	Week 12 n (%)	Week 16 n (%)	Total n (%)
Placebo (N = 156)										
Headache	16 (10.3)	3 (1.9)	4 (2.6)	4 (2.6)	6 (3.8)	3 (1.9)	4 (2.6)	1 (0.6)	1 (0.6)	42 (26.9)
Infection	11 (7.1)	2 (1.3)	2 (1.3)	3 (1.9)	2 (1.3)	2 (1.3)	2 (1.3)	1 (0.6)	0	25 (16.0)
Rhinitis	4 (2.6)	6 (3.8)	3 (1.9)	1 (0.6)	3 (1.9)	3 (1.9)	1 (0.6)	3 (1.9)	1 (0.6)	25 (16.0)
Respiratory Disorder	6 (3.8)	3 (1.9)	2 (1.3)	1 (0.6)	2 (1.3)	3 (1.9)	0	2 (1.3)	1 (0.6)	20 (12.8)
Abdominal Pain	6 (3.8)	3 (1.9)	1 (0.6)	3 (1.9)	1 (0.6)	0	1 (0.6)	0	0	15 (9.6)
Pharyngitis	2 (1.3)	6 (3.8)	0	2 (1.3)	1 (0.6)	0	1 (0.6)	1 (0.6)	1 (0.6)	14 (9.0)
Somnolence	6 (3.8)	1 (0.6)	2 (1.3)	1 (0.6)	3 (1.9)	0	0	0	0	13 (8.3)
Asthenia	7 (4.5)	2 (1.3)	1 (0.6)	2 (1.3)	0	0	0	0	0	12 (7.7)
Nausea	6 (3.8)	1 (0.6)	2 (1.3)	1 (0.6)	2 (1.3)	0	0	0	0	12 (7.7)
Trauma	0	2 (1.3)	1 (0.6)	5 (3.2)	1 (0.6)	0	0	0	3 (1.9)	12 (7.7)
Cough Increased	2 (1.3)	3 (1.9)	3 (1.9)	2 (1.3)	0	1 (0.6)	0	0	0	11 (7.1)
Dizziness	5 (3.2)	1 (0.6)	1 (0.6)	1 (0.6)	1 (0.6)	1 (0.6)	0	0	0	10 (6.4)
Dysmenorrhea *	1 (1.5)	0	0	1 (1.5)	1 (1.5)	0	0	1 (1.5)	0	4 (6.0)
Insomnia	0	2 (1.3)	1 (0.6)	3 (1.9)	1 (0.6)	1 (0.6)	0	0	1 (0.6)	9 (5.8)
Nervousness	2 (1.3)	0	1 (0.6)	1 (0.6)	3 (1.9)	0	2 (1.3)	0	0	9 (5.8)

Note: Sorted by total number of AEs

* Percentages are based on 67 female patients in the placebo group

Source: Table 15.1.6.1.X, Section 13; Listing 15.1.1, Appendix D

6.2.1.4 Dose Reductions for Treatment Phase-emergent Adverse Events

A dose reduction to the next lower dose level consequent to an AE was permitted once a patient had reached at least DL 2 (20 mg/day paroxetine or matching placebo) and was brought in for a visit. Table 72 presents the number (%) of patients by treatment group in both age groups combined whose dose of study medication was decreased during the Treatment Phase due to an AE. In the paroxetine group, 17.2% (28/163) of patients had dose reductions due to an AE compared to 3.8% (6/156) of patients in the placebo group.

AEs leading to dose reduction occurred with greatest frequency in both treatment groups in the body system Nervous System. The AE that most frequently led to a dose reduction in both treatment groups was nervousness, occurring in 3.7% (6/163) of patients in the paroxetine group and 2.6% (4/156) of patients in the placebo group. In the paroxetine group, nervousness, hyperkinesia, hostility, insomnia, asthenia, and headache all led to dose reductions in more than one patient. In the placebo group, nervousness was the only AE that led to a dose reduction in more than one patient. No gender-specific AEs led to dose reductions.

According to the investigators' AE reporting of "drug dose decreased" as action taken for an AE or SAE, two patients (both adolescents on paroxetine) had more than one dose reduction during the Treatment Phase (Listing 15.1.1, Appendix D). Patient 676.005.24124, in the paroxetine group, had two dose reductions reported, one at Day 40 and one at Day 46, both due to nervousness. The patient was terminated from the study at Week 8 due to non-compliance. Patient 676.205.24982 had one dose reduction reported for headache at Day 56 and another for nausea at Day 71. The patient completed the study. However, neither patient was considered a protocol violator because the study medication record (Listing 13.17.1, Appendix B), from which the data in regard to protocol violations were derived algorithmically, reflected only one dose reduction for each of these patients during the Treatment Phase.

Additionally, the two patients identified as protocol violators in Listing 13.2.1, Appendix B, did not have two dose reductions recorded by the investigator on the AE page, and so do not appear in Table 15.1.8 as having two dose reductions: patient 676.204.24843 is recorded as having only one dose reduction, and patient 676.003.24071 is not recoded as having any.

Table 72 Treatment Phase-emergent Adverse Events That Led to Dose Reductions by Body System–Age Group: Total (ITT Population)

		Treatment Group	
		Paroxetine (N = 163)	Placebo (N = 156)
Body system	**AE Preferred Term**	**n (%)**	**n (%)**
Total Patients with Dose Reductions *		28 (17.2)	6 (3.8)
Nervous System	**Total**	22 (13.5)	5 (3.2)
	Nervousness	6 (3.7)	4 (2.6)
	Hyperkinesia	5 (3.1)	0
	Hostility	4 (2.5)	0
	Insomnia	4 (2.5)	0
	Agitation	1 (0.6)	0
	Amnesia	1 (0.6)	0
	Concentration impaired	1 (0.6)	0
	Depersonalization	1 (0.6)	0
	Dizziness	1 (0.6)	0
	Manic reaction	1 (0.6)	0
	Neurosis	1 (0.6)	0
	Speech disorder	1 (0.6)	0
	Tremor	1 (0.6)	0
	Extrapyramidal syndrome	0	1 (0.6)
Body as a Whole	**Total**	5 (3.1)	0
	Asthenia	3 (1.8)	0
	Headache	2 (1.2)	0
Digestive System	**Total**	3 (1.8)	1 (0.6)
	Nausea	1 (0.6)	1 (0.6)
	Decreased appetite	1 (0.6)	0
	Diarrhea	1 (0.6)	0
	Vomiting	1 (0.6)	0
Cardiovascular System	**Total**	1 (0.6)	0
	QT interval prolonged	1 (0.6)	0
Metabolic and Nutritional Disorders	**Total**	1 (0.6)	0
	Weight gain	1 (0.6)	0

* A patient may have more than 1 AE that led to dose reduction
Source: Table 15.1.8, Section 13; Listing 15.1.1, Appendix D

(Table continues)

Table 72 (Continued) Treatment Phase-emergent Adverse Events That Led to Dose Reductions by Body System–Age Group: Total (ITT Population)

		Treatment Group	
Body system	**Preferred Term**	**Paroxetine (N = 163)**	**Placebo (N = 156)**
Musculoskeletal System	**Total**	1 (0.6)	0
	Myalgia	1 (0.6)	0
Urogenital System	**Total**	1 (0.6)	0
	Urinary frequency	1 (0.6)	0
Respiratory System	**Total**	0	1 (0.6)
	Yawn	0	1 (0.6)
Special Senses	**Total**	0	1 (0.6)
	Abnormal vision	0	1 (0.6)

Source: Table 15.1.8, Section 13; Listing 15.1.1, Appendix D

Table 73 presents a listing of specific patients who had one or more AEs identified as leading to a dose reduction during the course of the study. Thirty-one of the 34 patients had dose reductions for AEs considered related or possibly related to study medication. The majority of AEs leading to dose reductions were considered mild to moderate in nature.

Twelve of the 28 paroxetine patients and 2 of the 6 placebo patients with dose reductions were children.

Table 73 Treatment-Phase Emergent Adverse Events That Led to Dose Reductions by Patient (ITT Population)

Patient No	Sex	Age (yrs)	Dose Reduction From	Dose Reduction To	Adverse Event (Preferred Term)	Intensity	Investigator Attribution to Study Medication
Paroxetine							
676.002.24034	F	10	30	20	Hostility	Moderate	Probably unrelated
676.003.24058	F	11	30	20	Nervousness	Moderate	Related
676.003.24066	F	16	20	10	Insomnia	Mild	Possibly related
676.005.24122	M	14	50	40	Asthenia	Moderate	Possibly related
676.005.24124 *	M	12	50	40	Nervousness	Moderate	Possibly related
			40	30	Nervousness	Mild	Possibly related
676.005.24126	F	15	40	30	Agitation	Moderate	Possibly related
676.005.24127	M	11	40	30	Asthenia	Moderate	Possibly related
					Nervousness	Moderate	Possibly related
676.006.24143	F	15	50	40	QT interval prolonged	Mild	Possibly related
676.006.24145	F	17	50	40	Hostility	Mild	Probably unrelated
676.007.24177	F	9	40	30	Hostility	Mild	Related
676.007.24179	F	8	20	10	Hyperkinesia	Moderate	Possibly related
676.014.24377	M	9	40	30	Nervousness	Mild	Possibly related
676.015.24397	F	7	30	20	Hyperkinesia	Mild	Possibly related
					Speech disorder	Mild	Possibly related
676.015.24407	M	16	50	40	Hyperkinesia	Mild	Related

* Patient had two dose reductions

Source: Table 15.1.8, Section 13; Listing 13.5.1, Appendix B, Listing 15.1.1, Appendix D

(Table continues)

Table 73 (Continued) Treatment-Phase Emergent Adverse Events That Led to Dose Reductions by Patient (ITT Population)

Patient No	Sex	Age	Dose Reduction From	Dose Reduction To	Adverse Event (Preferred Term)	Severity	Investigator Attribution to Study Medication
Paroxetine (continued)							
676.015.24409	M	9	40	30	Hyperkinesia	Severe	Related
676.015.24411	F	8	30	20	Hyperkinesia	Mild	Possibly related
676.019.24511	M	12	40	30	Myalgia	Mild	Possibly related
676.019.24520	M	10	20	10	Headache	Moderate	Possibly related
					Diarrhea	Moderate	Possibly related
					Vomiting	Moderate	Possibly related
					Dizziness	Moderate	Possibly related
676.022.17841	M	15	30	20	Insomnia	Moderate	Possibly related
					Tremor	Moderate	Possibly related
676.022.17845	F	13	20	10	Amnesia	Mild	Possibly related
					Concentration impaired	Mild	Possibly related
676.023.17877	M	7	20	10	Hostility	Moderate	Related
					Manic reaction	Severe	Related
					Neurosis	Moderate	Related
676.023.17879	F	13	30	20	Insomnia	Moderate	Probably unrelated
676.103.24654	M	12	30	20	Weight gain	Mild	Possibly related

* Patient had two dose reductions

Source: Table 15.1.8, Section 13; Listing 13.5.1, Appendix B, Listing 15.1.1, Appendix D

(Table continues)

Table 73 (Continued) Treatment-Phase Emergent Adverse Events That Led to Dose Reductions by Patient (ITT Population)

Patient No	Sex	Age	Dose Reduction From	Dose Reduction To	Adverse Event (Preferred Term)	Severity	Investigator Attribution to Study Medication
Paroxetine (continued)							
676.202.24798	F	14	30	20	Decreased appetite	Moderate	Possibly related
676.203.24813	F	15	20	10	Insomnia	Moderate	Related
					Urinary frequency	Moderate	Related
676.205.24982 *	M	12	30	20	Headache	Moderate	Possibly related
			40	30	Nausea	Moderate	Possibly related
676.207.24898	M	9	40	30	Nervousness	Moderate	Possibly related
676.207.24900	F	17	30	20	Asthenia	Moderate	Possibly related
					Depersonalization	Moderate	Possibly related
					Nervousness	Moderate	Possibly related
Placebo							
676.204.24847	F	15	0	0	Yawn	Mild	Related
					Nausea	Mild	Related
					Extrapyramidal syndrome	Moderate	Related
676.015.24413	F	13	0	0	Nervousness	Mild	Related
676.204.24843	M	13	0	0	Nervousness	Mild	Possibly related
676.003.24074	F	15	0	0	Abnormal vision	Mild	Possibly related
676.005.24123	M	8	0	0	Nervousness	Moderate	Possibly related
676.012.24316	F	10	0	0	Nervousness	Mild	Possibly related

* Patient had two dose reductions

Source: Table 15.1.8, Section 13; Listing 13.5.1, Appendix B, Listing 15.1.1, Appendix D

6.2.2 Taper/Follow-up-Emergent Adverse Events

Patients in both treatment groups were to be down-titrated in a blinded fashion at the conclusion of the Treatment Phase unless they were at DL 1. The blind was not broken for patients entering the Taper Phase. The duration of treatment in the Taper Phase varied from 1 to 4 weeks depending on the dose level from which the patient was down-titrated. No taper was required for patients at DL 1. See Section 3.5.3, Dosage and Administration, for details about down-titration. All patients, whether or not they completed the study and whether or not they required down-titration, were to return for a Follow-up visit 14 days after the last dose of study medication (including taper).

Of the 163 paroxetine patients in the Treatment Phase, 144 (88.3%) entered the Taper Phase and/or the Follow-up Phase. Of the 156 placebo patients in the Treatment Phase, 129 (82.7%) entered the Taper Phase and/or the Follow-up Phase.

Table 74 presents the number and percent of patients with the most frequent (≥2%) Taper Phase or Follow-up Phase-emergent AEs. The proportion of patients in the paroxetine group (47.2%, 68/144) having gender-non-specific AEs during the Taper or Follow-up Phase was somewhat higher than that in the placebo group (32.6%, 42/129). The most common AE in both treatment groups during the Taper or Follow-up Phase was headache (15.3%, 22/144 paroxetine patients, and 10.9%, 14/129 placebo patients). Nausea and/or dizziness also occurred in more than 10% of paroxetine patients during the Taper or Follow-up Phase (11.1%, 16/144 patients each). Only headache occurred in more than 10% of placebo patients during the Taper or Follow-up Phase. Dizziness, nausea, and abdominal pain occurred in over 5% of paroxetine patients and at twice the frequency at which they occurred in placebo patients.

Dysmenorrhea was the only gender-specific AE that occurred during the Taper or Follow-up Phase, occurring in one female patient in the placebo group.

Taper or Follow-up Phase-emergent AEs may be found in Table 15.1.1.5, Section 13 (by body system and preferred term), and Table 15.1.1.5.X, Section 13 (by preferred term occurring in 1% or more of the population in descending order), and Listing 15.1.2, Appendix D. Treatment, Taper or Follow-up Phase-emergent AEs may be found in Table 15.1.1.6, Section 13 (by body system and preferred term), and Table 15.1.1.6.X, Section 13 (by preferred term occurring in 1% or more of the population in descending order), and Listings 15.1.1 and 15.1.2, Appendix D.

Table 74 Number (%) of Patients with the Most Frequent (≥2%) Taper or Follow-up Phase-emergent Adverse Events–Age Group: Total (ITT Population Entering the Taper or Follow-up Phase)

	Treatment Group	
AE Preferred Term	**Paroxetine (N = 144) n (%)**	**Placebo (N = 129) n (%)**
Total Patients with at Least One AE	68 (47.2)	42 (32.6)
Headache	22 (15.3)	14 (10.9)
Nausea	16 (11.1)	3 (2.3)
Dizziness	16 (11.1)	2 (1.6)
Abdominal pain	10 (6.9)	2 (1.6)
Nervousness	7 (4.9)	1 (0.8)
Asthenia	5 (3.5)	2 (1.6)
Respiratory disorder	4 (2.8)	7 (5.4)
Anxiety	4 (2.8)	3 (2.3)
Emotional lability	4 (2.8)	0
Infection	3 (2.1)	4 (3.1)
Trauma	3 (2.1)	2 (1.6)
Insomnia	3 (2.1)	1 (0.8)
Somnolence	3 (2.1)	1 (0.8)
Vomiting	3 (2.1)	1 (0.8)
Sinusitis	3 (2.1)	0
Pharyngitis	2 (1.4)	3 (2.3)
Rhinitis	2 (1.4)	3 (2.3)

N = number of patients entering the Taper Phase or Follow-up Phase
Source: Tables 15.1.1.5 and 15.1.1.5.X, Section 13; Listing 15.1.2, Appendix D

6.2.2.1 Taper Phase-emergent Adverse Events

Of the 163 paroxetine patients in the Treatment Phase, 106 (65.0%) entered the Taper Phase. Of the 156 placebo patients in the Treatment Phase, 108 (69.2%) entered the Taper Phase.

Table 75 presents a summary of the most frequent (≥2%) AEs that emerged during the Taper Phase. In the paroxetine group, 31.1% (33/106) of patients had AEs during the Taper Phase, compared to 20.4% (22/108) of patients in the placebo group. Headache was the most common AE in both treatment groups, followed by dizziness, abdominal pain, nervousness, and nausea in the paroxetine

group, and respiratory disorder in the placebo group. No gender-specific AEs occurred during the Taper Phase in either treatment group.

Larynx disorder (verbatim: laryngitis) was the only AE that emerged during the Taper Phase that had not occurred in either treatment group during the Treatment Phase. There were two events; both events occurred in placebo patients, and both were considered mild (Tables 15.1.1.1.X and 15.1.1.2.X, Section 13; Listing 15.1.2, Appendix D).

Table 15.1.1.2, Section 13, summarizes all Taper Phase-emergent AEs by body system; Table 15.1.1.2.X, Section 13, presents all Taper Phase-emergent AEs by preferred term occurring in 1% or more of the population in descending order.

Table 75 Number (%) of Patients with the Most Frequent (≥2%) Taper Phase-emergent Adverse Events–Age Group: Total (ITT Population Entering the Taper Phase)

	Treatment Group	
	Paroxetine (N = 106)	**Placebo (N = 108)**
AE Preferred Term	**n (%)**	**n (%)**
Total Patients with at Least One AE	33 (31.1)	22 (20.4)
Headache	8 (7.5)	8 (7.4)
Dizziness	5 (4.7)	0
Abdominal pain	4 (3.8)	2 (1.9)
Nervousness	4 (3.8)	1 (0.9)
Nausea	4 (3.8)	0
Trauma	3 (2.8)	1 (0.9)
Respiratory disorder	1 (0.9)	4 (3.7)

N = number of patients entering the Taper Phase
Source: Table 15.1.1.2 and 15.1.1.2.X, Section 13; Listing 15.1.2, Appendix D

Among children entering the Taper Phase, 40.0% (10/25) of the patients on paroxetine had at least one Taper Phase AE, compared with 20.7% (6/29) of patients on placebo. Among adolescents entering the Taper Phase, 28.4% (23/81) of the patients on paroxetine had at least one Taper Phase AE, compared to 20.3% (16/79) of patients on placebo. Four of these children (3 on paroxetine) and 11 of these adolescents (9 on paroxetine) had Taper Phase AEs in the body system Nervous System.

Tables 15.1.1.3 and 15.1.1.3.X, Section 13, present Treatment or Taper Phase-emergent AEs by body system and by preferred term occurring in 1% or more of the population in descending order, respectively. Patient information for these AEs may be found in Listings 15.1.1 (Treatment Phase) and 15.1.2 (Taper, Follow-up, and Post-Follow-up Phases), Appendix D.

Tables 15.1.3.2 and 15.1.7.2, Section 13, present Taper Phase-emergent AEs by body system by intensity, and by maximum intensity, respectively. Table 15.1.3.2.X, Section 13, presents Taper Phase-emergent AEs by intensity by preferred term occurring in 1% or more of the population in descending order.

The majority of Taper Phase-emergent AEs among paroxetine patients were mild in intensity, 20 of 36 AEs (55.6%). In the placebo group, 16 of 33 AEs (48.5%) were mild in intensity.

Three patients in the paroxetine group and one patient in the placebo group had a Taper Phase-emergent AE that was considered severe by the investigator (Table 76). These patients are listed below :

- Patient 676.017.24453, a child in the paroxetine group, had severe sinusitis (sinus infection) 8 days after the last dose of Treatment-Phase medication, while on a Taper dose of 40 mg/day. The investigator considered the sinusitis probably unrelated to study medication.

- Patient 676.015.24407, an adolescent in the paroxetine group, experienced severe trauma (fractured arm) 20 days after the last dose of Treatment-Phase medication, while on a Taper dose of 30 mg/day. The investigator considered the event unrelated to study medication.

- Patient 676.006.24145, an adolescent in the paroxetine group, experienced severe dizziness 7 days after the last dose of Treatment-Phase medication, while on a Taper dose of 30 mg/day. The investigator considered the event related to study medication.

- Patient 676.209.24962, an adolescent in the placebo group, experienced severe headache 15 days after the last dose of Treatment-Phase medication. The investigator considered the event unrelated to study medication.

No specific severe AE occurred in more than one patient in either treatment group during the Taper Phase.

Table 76 Number (%) of Patients with Severe Taper Phase-Emergent Adverse Events–Age Group: Total (ITT Population Entering the Taper Phase)

	Treatment Group	
AE Preferred Term	**Paroxetine (N = 106) n (%)**	**Placebo (N = 108) n (%)**
Total Patients with at Least One Severe AE	3 (2.8)	1 (0.9)
Dizziness	1 (0.9)	0
Sinusitis	1 (0.9)	0
Trauma	1 (0.9)	0
Headache	0	1 (0.9)

Source: Tables 15.1.3.2 and 15.1.3.2.X, Section 13; Listing 15.1.2, Appendix D

Tables 15.1.3.3 and 15.1.7.3, Section 13, present patients with emergent adverse events during the Treatment Phase or Taper Phase by intensity by body system, and by maximum intensity, respectively. Patient information for these AEs may be found in Listings 15.1.1 (Treatment Phase) and 15.1.2 (Taper, Follow-up, and Post-Follow-up Phases), Appendix D.

Tables 15.1.4.2 and 15.1.4.2.X, Section 13, present Taper Phase-emergent AEs that are related or possibly related to study medication by body system and by preferred term occurring in 1% or more of the population in descending order, respectively. Fourteen patients in the paroxetine group and 7 patients in the placebo group had Taper Phase-emergent AEs judged by the investigator to be related or possibly related to the use of study medication (Table 77). The most frequent event among paroxetine patients was dizziness, followed by headache, abdominal pain, and nausea. The most frequent event among placebo patients was headache.

Table 77 Number (%) of Patients with the Most Frequent (≥2%) Related or Possibly Related Taper Phase-emergent Adverse Events–Age Group: Total (ITT Population Entering the Taper Phase)

	Treatment Group	
AE Preferred Term	**Paroxetine (N = 106) n (%)**	**Placebo (N = 108) n (%)**
Total Patients with at Least One Related or Possibly Related AE	14 (13.2)	7 (6.5)
Dizziness	5 (4.7)	0
Headache	4 (3.8)	3 (2.8)
Abdominal pain	3 (2.8)	1 (0.9)
Nausea	3 (2.8)	0

N = number of patients entering the Taper Phase
Source: Table 15.1.4.2, Section 13; Listing 15.1.2, Appendix D

Table 15.1.4.3, Section 13, presents patients with related or possibly related emergent adverse events during the Treatment Phase or Taper Phase by body system. Patient information for these AEs may be found in Listings 15.1.1 (Treatment Phase) and 15.1.2 (Taper, Follow-up, and Post-Follow-up Phases), Appendix D.

6.2.2.2 Follow-up Phase-emergent Adverse Events

Patients were to return for a Follow-up Visit 14 days after the last dose of study medication (including taper). Of the 163 paroxetine patients in the Treatment Phase, 118 (72.4%) returned for a Follow-up Visit. Of the 156 placebo patients in the Treatment Phase, 100 returned for a Follow-up Visit (Table 15.1.1.4, Section 13; Listing 15.1.2, Appendix D).

Of the 218 patients who entered the Follow-up Phase, 45.8% (54/118) of patients in the paroxetine group and 27.0% (27/100) of patients in the placebo group had an AE emergent during the Follow-up Phase (Table 78). The most frequent AEs among paroxetine patients during the Follow-up Phase were headache, dizziness, and nausea, each occurring in >10% of patients. The most frequent AE among placebo patients during the Follow-up Phase was headache, occurring in 7.0% of patients. Dysmenorrhea was the only gender-specific AE that occurred during the Follow-up Phase, occurring in one female patient in the placebo group.
Table 15.1.1.4, Section 13, presents all Follow-up Phase-emergent AEs by body

system; Table 15.1.1.4.X, Section 13, presents the AEs by preferred term occurring in 1% or more of the population in descending order.

No AEs emerged during the Follow-up Phase that had not occurred in either treatment group during the Treatment Phase (Tables 15.1.1.1.X, 15.1.1.2.X, and 15.1.1.4.X, Section 13).

Table 78 Number (%) of Patients with the Most Frequent (≥2%) Follow-up Phase-emergent Adverse Events–Age Group: Total (ITT Population Entering the Follow-up Phase)

	Treatment Group	
AE Preferred Term	**Paroxetine (N = 118) n (%)**	**Placebo (N = 100) n (%)**
Total Patients with at Least One AE	54 (45.8)	27 (27.0)
Headache	16 (13.6)	7 (7.0)
Dizziness	13 (11.0)	2 (2.0)
Nausea	12 (10.2)	3 (3.0)
Abdominal pain	6 (5.1)	1 (1.0)
Anxiety	4 (3.4)	1 (1.0)
Asthenia	4 (3.4)	1 (1.0)
Respiratory disorder	3 (2.5)	3 (3.0)
Vomiting	3 (2.5)	1 (1.0)
Emotional lability	3 (2.5)	0
Nervousness	3 (2.5)	0
Infection	2 (1.7)	3 (3.0)
Pharyngitis	1 (0.8)	2 (2.0)
Rhinitis	1 (0.8)	2 (2.0)
Total patients with at least one female-specific AE*	0	1 (2.3)
Dysmenorrhea	0	1 (2.3)

N = Patients entering the Follow-up Phase
* n = 65 female patients in the paroxetine group, 43 female patients in the placebo group
Source: Tables 15.1.1.4 and 15.1.1.4.X, Section 13; Listing 15.1.2, Appendix D

The majority of Follow-up Phase-emergent AEs were mild in intensity, 35 of 60 AEs (58.3%) in the paroxetine group and 17 of 29 (58.6%) in the placebo group.

Two patients in the paroxetine group and three patients in the placebo group had Follow-up Phase-emergent AEs that were judged by the investigator to be severe in intensity (Table 79):

- Patient 676.202.24789, an adolescent in the paroxetine group, had a severe headache 8 days after the last dose of Treatment-Phase medication. The investigator considered the headache possibly related to study medication.

- Patient 676.014.24376, an adolescent in the paroxetine group, experienced severe insomnia 8 days after the last dose of Treatment-Phase medication. The investigator considered the insomnia probably unrelated to study medication.

- Patient 676.003.24074, an adolescent in the placebo group, had a severe infection (verbatim: yeast infection) 13 days after the last dose of Treatment-Phase medication. The investigator considered the infection unrelated to study medication.

- Patient 676.209.24957, an adolescent in the placebo group, experienced severe trauma (verbatim: multiple abrasions hands, forehead, knee; laceration lip; patient fell off a bicycle) 9 days after the last dose of Treatment-Phase medication. The investigator considered the event unrelated to study medication.

- Patient 676.202.24797, an adolescent in the placebo group, experienced severe gingivitis (verbatim: dental abscess) 18 days after the last dose of Treatment-Phase medication. The investigator considered the gingivitis unrelated to study medication.

No specific severe AE was experienced in the Follow-up Phase by more than one patient. Severe AEs emergent in the Follow-up Phase may be found in Table 15.1.3.4, Section 13, by body system, and in Table 15.1.3.4.X, Section 13, by preferred term occurring in 1% or more of the population in descending order. Table 15.1.7.4 presents Follow-up Phase-emergent AEs by maximum intensity by body system.

Table 79 Number (%) of Patients with Severe Follow-up-Phase Emergent Adverse Events–Age Group: Total (ITT Population Entering Follow-up Phase)

	Treatment Group	
AE Preferred Term	**Paroxetine (n = 118) n (%)**	**Placebo (n = 100) n (%)**
Total Patients with at Least One AE During the Follow-up Phase	2 (1.7)	3 (3.0)
Headache	1 (0.8)	0
Insomnia	1 (0.8)	0
Gingivitis	0	1 (1.0)
Infection	0	1 (1.0)
Trauma	0	1 (1.0)

Source: Tables 15.1.3.4 and 15.1.3.4.X, Section 13; Listing 15.1.2, Appendix D

During the Follow-up Phase, 29.7% (35/118) of patients in the paroxetine group and 6.0% (6/100) of patients in the placebo group had AEs that were considered by the investigator to be related or possibly related to study medication (Table 80). The single gender-specific AE during the Follow-up Phase (dysmenorrhea), which occurred in the placebo group, was considered unrelated to study medication. Table 15.1.4.4, Section 13, presents Follow-up Phase-emergent AEs that are related or possibly related to study medication by body system.

Table 80 Number (%) of Patients with Most Frequent (≥2%) Follow-up Phase-Emergent Adverse Events Reported as Related or Possibly Related to Study Medication–Age Group: Total (ITT Population Entering the Follow-up Phase)

	Treatment Group	
AE Preferred Term	**Paroxetine (n = 118) n (%)**	**Placebo (n = 100) n (%)**
Total Patients with at Least One AE	35 (29.7)	6 (6.0)
Headache	13 (11.0)	2 (2.0)
Dizziness	11 (9.3)	0
Nausea	10 (8.5)	2 (2.0)
Abdominal pain	4 (3.4)	0
Asthenia	4 (3.4)	0
Anxiety	3 (2.5)	1 (1.0)
Nervousness	3 (2.5)	0

Note: Sorted by number of AEs among paroxetine patients
Source: Table 15.1.4.4, Section 13; Listing 15.1.2, Appendix D

6.3 Deaths

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

6.4 Serious Adverse Events

Three patients (1.8%) in the paroxetine group and one patient (0.6%) in the placebo group reported a serious adverse event after the first dose of randomized medication, including the 30-day period following the last dose of study medication. All of the SAEs were considered unrelated to study medication, except for accidental overdose (preferred term abnormal lab value) in the one placebo patient. Anemia, which also led to withdrawal from the Treatment Phase, was considered serious in one patient in the paroxetine group. The other two patients in the paroxetine group experienced the SAEs post-treatment: fear (coded to anxiety) and depression related to Social Anxiety Disorder (14 days post-treatment) and trauma (fractured arm) (20 days post-treatment).

Table 81 presents all SAEs occurring at any time post-randomization.

Table 81 Number (%) of Patients with Serious Nonfatal Emergent Adverse Events (On-therapy Plus 30 Days Post-Therapy)–Age Group: Total (All Randomized Patients)

	Treatment Group	
	Paroxetine (N = 165)	**Placebo (N = 157)**
SAE Preferred Term	**n (%)**	**n (%)**
Total Patients with at Least One SAE *	3 (1.8)	1 (0.6)
Depression **	1 (0.6)	0
Anxiety **	1 (0.6)	0
Trauma **	1 (0.6)	0
Anemia	1 (0.6)	0
Abnormal laboratory value	0	1 (0.6)

N = Number of patients randomized, including 3 patients who were randomized but did not receive any study medication
* Serious AEs up to 30 days after the last dose of randomized treatment are included in this summary.
** AEs occurred after the last dose of study medication (depression and anxiety, 14 days; trauma, 20 days)
Source: Table 15.1.2.1, Section 13; Listing 15.1.3.2, 15.1.3.3, Appendix D

In addition, 1 patient had an SAE prior to randomization (Listing 15.1.3.1, Appendix D). Patient 676.202.24785, a 10-year-old male, fell off his bicycle during the Screening Phase of the study and experienced a concussion and lacerations (ADECS code Trauma; MEDRA code Injury NOS) and was hospitalized. The investigator reported the events as not related to treatment with study medication. The patient was randomized to paroxetine five days later.

Table 82 presents a listing of all patients with an SAE occurring at any time post-randomization.

One paroxetine patient was withdrawn from the study due to an SAE (ADECS code anemia; MEDRA code Anemia NOS), although the SAE was considered unrelated to study medication. Patient 676.205.24985, a 16-year-old female, experienced two episodes of non-serious confusion and headache approximately one month after the first dose of study medication. She collapsed and was admitted to the hospital. There were no signs of expansion or bleeding. Electroencephalogram and electrocardiogram were normal. Magnetic resonance imaging of the brain revealed a small encephalomalatic cystic lesion involving the head of the caudate nucleus on the right side and the putamen on the right side.

The patient had previously experienced transient left hemiparesis, which was attributed to acephalic migraine. Laboratory results indicated that the patient had an iron deficiency-induced anemia, which was in the patient's medical history. The investigator suspected the patient had experienced temporal lobe epileptic fits, which may be associated with the anemia. Treatment with study medication was stopped due to this event. The investigator considered that the events were not related to treatment with study medication.

Two patients randomized to paroxetine had SAEs after the last dose of study medication. Patient 676.015.24407, a 16-year-old male, completed the study. Twenty days after the last dose, the patient was in an automobile accident and was admitted to the hospital for a broken arm that required surgery (ADECS code Trauma; MEDRA code Injury NOS). The patient admitted smoking marijuana prior to the accident. At the time of the event, the patient was in the last week of his taper study medication, Week 19 DL 1. The investigator reported the event as not related to treatment with study medication. Patient 676.005.24122, a 14-year-old male, withdrew consent from the study approximately 2 months after randomization. Fourteen days after the last dose of study medication, the patient was hospitalized for fears and depression (ADECS code Anxiety and Depression; MEDRA code Fear, focus NEC, Depression) related to Social Anxiety Disorder. The investigator reported the events as not related to treatment with study medication.

One placebo patient had an SAE on therapy. Patient 676.209.24958, a 10-year-old male, accidentally overdosed on study medication 42 days after the first dose (ADECS code Abnormal Laboratory Value; MEDRA code Overdose NOS). The patient had taken four capsules daily, instead of the recommended two capsules. The patient was asymptomatic. Treatment with study medication was not stopped due to this event. The investigator reported the overdose as related to treatment with study medication.

Complete narratives for these patients may be found in Table 15.1.2.2, Section 13. There may be minor discrepancies in the details of the SAEs included in the clinical narratives compared to 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 SAEs.

Table 82 Randomized Patients with Serious Nonfatal Adverse Events (On-therapy Plus 30 Days Post-Therapy) (All Randomized Patients)

Patient Number	Age (yrs)	Gender (M/F)	Preferred Term	Verbatim Term	Intensity	Relation-ship	Day of Onset*	Duration
Paroxetine								
676.005.24122	14	M	Anxiety ** Depression **	Hospitalization due to fears and depression disease under study	Moderate	Not related	84 (14)	5 days
676.015.24407	16	M	Trauma **	Fractured arm	Severe	Not related	139 (20)	Ongoing
676.202.24785	10	M	Trauma †	Concussion due to fall from bike; headache, nausea, vomiting. Hospitalized for two days.	Severe	Not related	–4 (–116)	3 days
				Lacerations upper left leg and chin	Moderate	Not related	–4 (–116)	37 days
676.205.24985	16	F	Anemia ††	Anemia	Severe	Not related	25 (–1)	3 days
Placebo								
676.209.24958	10	M	Abnormal laboratory value	Unintentional overdose of study medication	Mild	Related	42 (-70)	11 days

* Relative to the first day of study medication (relative to the last dose of study medication, excluding taper).
** SAE occurred post-therapy
† SAE occurred during the Screening Phase
†† Patient was withdrawn from the study because of this SAE.
Source: Tables 15.1.2.1 and 15.1.3.1, Section 13; Listing 13.5.1, Appendix B, Listing 15.1.3.2, 15.1.3.3, Appendix D

6.5 Withdrawals Due to Adverse Events

Table 83 presents a summary of the number of patients who were withdrawn for an AE during the Treatment Phase. Tables 15.1.5.1 and 15.1.5.1.X, Section 13, present AEs leading to withdrawal by body system and by preferred term occurring in 1% or more of the population in descending order, respectively. Listing 15.1.4, Appendix D, provides additional details regarding the events, including intensity and time of occurrence relative to the start of study medication.

Withdrawals due to AEs were tabulated for those patients who had AEs and withdrew during the Treatment Phase. According to data source table 15.1.5.1, Section 13, a total of 6.1% (10/163) of paroxetine patients and 1.3% (2/156) of placebo patients were reported as having withdrawn from the study because of one or more AEs. However, one patient was included in error because of incorrect coding (see Table 83), so that only 9 paroxetine patients (5.5%, 9/163) were withdrawn during the Treatment Phase due to an AE.

The only AE leading to withdrawal that occurred in more than one patient in the same treatment group was manic reaction, experienced by 2 patients in the paroxetine group. Agitation leading to withdrawal was experienced by 1 patient in each treatment group. All other AEs leading to withdrawal were each experienced by a single patient. No gender-specific AEs led to withdrawal.

Complete narratives for patients with AEs leading to withdrawal may be found in Table 15.1.5.2, Section 13.

Table 83 Number (%) of Patients Withdrawn During the Treatment Phase for at Least One AE Regardless of Treatment Attribution–Age Group: Total (ITT Population)

	Treatment Group	
	Paroxetine (N = 163)	Placebo (N = 156)
AE Preferred Term	**n (%)**	**n (%)**
Total Patients with at Least One AE Leading to Withdrawal	10 (6.1)	2 (1.3)
Manic reaction	2 (1.2)	0
Agitation	1 (0.6)	1 (0.6)
Abnormal dreams	1 (0.6)	0
Depression	1 (0.6)	0
Emotional lability	1 (0.6)	0
Hostility	1 (0.6)	0
Hyperkinesia	1 (0.6)	0
Asthenia	1 (0.6)	0
Headache *	1 (0.6)	0
Vomiting	1 (0.6)	0
Anemia	1 (0.6)	0
Pruritus	1 (0.6)	0
Urinary retention	0	1 (0.6)

Note: A patient may have more than one AE leading to withdrawal.
* Patient 676.101.24629 had a headache on Day 3 that was coded medication stopped. However, the patient took study medication for 119 days and completed the study. It appears that the AE coding was in error, and the actual number of paroxetine patients withdrawn due to an AE was 9 (5.5%) See Errata, Section 15.
Source: Table 15.1.5.1 and 15.1.5.1.X, Section 13; Listing 15.1.4, Appendix D. Listing 15.1.4 reflects all Treatment-Phase emergent AEs for these patients, not just the AEs that led to withdrawal.

Table 84 presents per-patient information about the 11 patients withdrawn from the study due to an AE, excluding the patient tabulated in error because of incorrect coding. The patients who withdrew during the Treatment Phase were somewhat proportionately divided between children (4 of 91) and adolescents (7 of 228). Fourteen of the 16 AEs leading to withdrawal were considered moderate or severe in intensity, and 12 of the AEs were considered by the investigator to be related or possibly related to study medication.

One patient in the paroxetine group experienced a serious AE that led to withdrawal. Patient 676.205.24985, a 16-year-old female, experienced severe anemia on Day 25, considered a serious adverse event, and was withdrawn from

the study. The investigator considered the anemia not related to study medication. Section 6.4, Serious Adverse Events, provides more detailed information about this event. A complete narrative for this patient may be found in Table 15.1.2.2, Section 13.

Two patients on paroxetine experienced manic reactions on therapy that led to withdrawal from the study:

- Patient 676.011.24282, a 13-year-old female, experienced a severe manic reaction (verbatim: manic episode) on Day 41, which was considered to be related to treatment with study medication. She had been experiencing mild nervousness (verbatim: restlessness) since Day 10, which was considered to be possibly related to treatment with study medication.

- Patient 676.022.17841, a 15-year-old male, experienced a severe manic reaction (verbatim: behavioral activation, hypomania) on Day 23, which was considered to be possibly related to treatment with study medication. He had experienced moderately severe tremor (verbatim: bilateral hand tremor) on Day 28, which was considered to be possibly related to treatment with study medication. The dose of study medication was decreased in response to the tremor but the condition continued to the end of the study. The patient was withdrawn due to the manic reaction.

Five other paroxetine patients experienced other psychiatric events on therapy that led to withdrawal from the study:

- Patient 676.100.24705, a 16-year-old female, experienced mild emotional lability (verbatim: self-inflicted scratch on right wrist) on Day 38. This condition abated in one day without corrective therapy, and was considered to be probably unrelated to treatment with study medication. On Day 43, the patient experienced moderately severe depression (verbatim: worsening depression), which continued to the end of the study. The investigator considered this event to be possibly related to treatment with study medication and the patient was withdrawn from the study for this event.

- Patient 676.014.24376, a 13-year-old female, experienced moderately severe agitation (verbatim: panic attack) on Day 16, which resolved in one day. On Day 30, the patient experienced severe agitation (verbatim: panic attack worsening), severe abnormal dreams (verbatim: morbid thoughts), and moderately severe emotional lability (verbatim: suicidal thoughts). The agitation was considered possibly related to study medication, and the abnormal dreams and emotional lability were considered to be probably

unrelated to study medication. All three conditions resulted in withdrawal from the study.

- Patient 676.015.24409, a 9-year-old male, experienced severe hyperkinesia (verbatim: hyperactivity) on Day 33. The dose of study medication was reduced in response to this event, which resolved in 11 days. The patient experienced severe hyperkinesia (verbatim: hyperactivity) again on Day 44, which resolved without treatment in eight days. The investigator considered this event to be related to treatment with study medication and the patient was withdrawn from the study.

- Patient 676.023.17877, a 7-year-old male, experienced onset of moderately severe hostility (verbatim: disinhibition) on Day 7. The hostility continued to the end of the study. This condition was considered to be related to treatment with study medication. On Day 14, the onset of severe manic reaction (verbatim: hypomania) was reported. The investigator considered this event to be related to treatment with study medication and the dose of study medication was decreased in response. The manic reaction continued to the end of the study. On Day 29, mild pruritus was reported. The investigator considered this event to be possibly related to treatment with study medication and the patient was withdrawn from the study for the hostility and the pruritus.

- Patient 676.024.25150, a 14-year-old female, experienced moderately severe asthenia (verbatim: fatigue) on Day 11, which continued for 51 days. The investigator considered this event to be possibly related to treatment with study medication and the patient was withdrawn from the study.

In addition to the patient with anemia, one paroxetine patient experienced a non-psychiatric event that led to withdrawal from the study:

- Patient 676.015.24406, a 17-year-old male, experienced mild vomiting (verbatim: nausea and vomiting) on Day 1, which resolved with treatment in one day. The patient was withdrawn from the study as a result of this event. The investigator considered this event to be possibly related to treatment with study medication.

One placebo patient experienced psychiatric events that led to withdrawal from the study:

- Patient 676.023.17878, a 9-year-old male, experienced moderately severe agitation (verbatim: agitation) on Day 28 that resolved without treatment in

15 days. The investigator considered this event to be related to treatment with study medication and the patient was withdrawn from the study.

One placebo patient experienced a non-psychiatric event that led to withdrawal from the study:

- Patient 676.205.24989, a 9-year-old male, experienced moderately severe urinary retention on Day 12, which resolved in 57 days. The investigator considered this event to be possibly related to treatment with study medication and the patient was withdrawn from the study for this event.

Table 84 Patients with Adverse Events Leading to Withdrawal (ITT Population)

PID	Sex, Age	Preferred Term (Verbatim Term)	Onset Dose (mg)	Rel. Days *	Duration	Inv. Int.	Inv. Rel.
Paroxetine							
676.015.24409	M 9	Hyperkinesia (Hyperactivity)	30	44 (-7)	8 days	Severe	Rel
676.023.17877	M 7	Hostility (Disinhibited)	10	7 (-49)	Ongoing	Mod	Rel
		Pruritus (Itchy back)	10	29 (-27)	Ongoing	Mild	Psr
676.011.24282	F 13	Manic reaction (Manic episode)	30	41 (0)	Ongoing	Severe	Rel
676.014.24376	F 13	Abnormal dreams (Morbid thoughts)	40	30 (-4)	Ongoing	Severe	Pbu
		Agitation (Panic attack worsening)	40	30 (-4)	1 day	Severe	Psr
		Emotional lability (Suicidal thoughts)	40	30 (-4)	Ongoing	Mod	Pbu
676.015.24406	M 17	Vomiting (Nausea/vomiting)	10	1 (0)	1 day	Mild	Psr
676.022.17841	M 15	Manic reaction (Behavioral activation/hypomania)	20	23 (-10)	11 days	Severe	Psr
676.024.25150	F 14	Asthenia (Fatigue)	20	11 (-30)	51 days	Mod	Psr
676.100.24705	F 16	Depression (Worsening depression)	20	43 (0)	Ongoing	Mod	Psr
676.205.24985	F 16	Anemia (Anemia) **	20	25 (-1)	3 days	Severe	Unr
Placebo							
676.023.17878	M 9	Agitation (Agitation)	0	28 (-12)	15 days	Mod	Rel
676.205.24989	M 9	Urinary Retention (Urine retention)	0	12 (-44)	57 days	Mod	Psr

Inv. Int. = Investigator-assigned intensity; Int. Rel. = Investigator-assigned relationship to study medication; Mod = moderate intensity; Rel = related; Psr = possibly related; Pbu = probably unrelated; Unr = unrelated to study medication

* Relative to the first day of study medication (relative to the last dose of study medication, excluding taper).

** Event was a serious AE

Source: Table 15.1.5.1, Section 13; Listings 13.5.1 and 13.17.1, Appendix B; Listing 15.1.4, Appendix D

Two additional patients, one from each treatment group, were withdrawn from taper medication due to an AE, which was incorrectly coded by the investigator as an AE withdrawal. Both patients appear in Listing 15.1.4, Appendix D, but not in Table 15.1.5.1, Section 13:

- Patient 676.200.24742, a 13-year-old male in the paroxetine group, experienced a moderately severe infection (verbatim: infected foot) on Day 110, one day after the last dose of study medication. The infection resolved, with treatment, in 6 days. The patient had completed 16 weeks of study medication. The patient was withdrawn from a taper dose of 30 mg bid paroxetine. The investigator considered this event to be unrelated to treatment with study medication.

- Patient 676.021.24562, a 16-year-old female in the placebo group, took study medication for 2 days. On Day 9, 7 days after the last dose of study medication, the patient experienced moderately severe agitation (verbatim: increased agitation) that resolved without treatment in 7 days. The patient was withdrawn from taper DL 1 of placebo. The investigator considered this event to be possibly related to treatment with study medication. This patient does not appear in Table 15.1.5.1 but does appear in Listing 15.1.4.

Complete narratives for these patients may be found in Table 15.1.5.2, Section 13

6.6 Medical Procedures

Elective therapeutic, diagnostic or surgical 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 AEs and were to be recorded on the medical procedures page of the eCRF. A listing of non-medication therapeutic, diagnostic or surgical procedures performed during this study may be found in Listing 15.4.1, Appendix D.

Of the 43 procedures among 26 paroxetine patients and the 28 procedures among 24 placebo patients, 12 procedures among paroxetine patients and 5 procedures among placebo patients were elective (mostly orthodontic work) and were not associated with an on-therapy AE.

Three patients in the paroxetine group had medical procedures consequent to SAEs. Patient 676.015.24407 had surgery for a fractured arm; patient 676.202.24785 had sutures for lacerations from a fall; and patient 676.205.24985 had diagnostic MRI and EEG following collapse that was subsequently attributed

to anemia. Detailed narratives for these patients may be found in Table 15.1.2.2, Section 13.

Patient 676.015.24403 is listed as having a medical procedure of nosebleeds, consequent to an AE of nosebleed. This event was not to have been considered a medical procedure. See Errata, Section 15.

All other patients with medical procedures in both treatment groups had either non-routine dental work, treatment for injury, or diagnostic procedures for concurrent non-serious AEs.

6.7 Pregnancy

None of the randomized patients in this study had a positive urine dipstick pregnancy test at screening. No patient became pregnant during the course of the study (Table 15.1.2.1, Section 13; Listing 15.3.2, Appendix B).

6.8 Vital Signs

6.8.1 Vital Signs of Potential Clinical Concern

The number of patients in each treatment group with values of blood pressure (BP), heart rate, and weight meeting clinical concern criteria predefined by the sponsor and with increases or decreases from Baseline meeting predefined criteria were tabulated. In addition, summary statistics for changes from Baseline for BP, heart rate, weight, height and body mass index (BMI) are presented by treatment group. Table 6 in Section 3.15.7, Safety Evaluations, shows the pre-determined levels of potential clinical concern.

All vital signs that were assessed after the last dose of 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 16 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. Summary statistics for vital signs change from baseline by post-randomization treatment phase may be found in Tables 15.2.1.1 and 15.2.1.2, Section 13; Listing 15.2.1, Appendix E. Table 85 presents a summary of the number and percentage of patients within each treatment group with vital sign measurements meeting the predefined clinical concern criteria (i. e., both an absolute value of concern and a significant increase

or decrease on therapy in the same direction). There were no important differences between the treatment groups in the number or the type of vital signs meeting this combination of clinical concern criteria.

Twenty-two patients in the paroxetine group and 17 patients in the placebo group were identified as having an on-therapy absolute value and change in value in the same direction in one or more of the vital signs that met the criteria for potential clinical concern.

One patient in each treatment group had more than one value of concern. In the paroxetine group, patient 676.102.24589 had a low and significant decrease in systolic blood pressure at Weeks 3 and 12 (baseline, 124/60; Week 3, 92/64; Week 12, 94/62) and a high and significant increase in weight at Week 16 (64.0 kg, from 58.4 kg at Baseline) that met the criteria for potential clinical concern. An AE was reported in association with the weight gain but not for the decrease in systolic blood pressure. A brief narrative for this patient appears below, and a detailed narrative for this patient may be found in Table 15.2.2.3, Section 13.

In the placebo group, patient 676.208.24926, an 11-year-old male, had a low and significant decrease in diastolic blood pressure: from 100/60 mmHg at Screening and 80/60 mmHg at Baseline to 80/40 mmHg at Weeks 10 and 12. The patient also had a low and significant decrease in heart rate at Week 16 (from 67 beats per minute [bpm] at Screening and 96 bpm at Baseline to 55 bpm at Week 16). The patient had no associated AEs and completed the study as planned.

No patient in either treatment group had blood pressure, heart rate, or decreased weight values of concern in association with a related AE.

Table 85 Number (%) of Patients with Vital Signs Values Meeting Predefined Clinical Concern Criteria (Treatment or Taper Phase)–Age Group: Total (ITT Population)

Vital Sign Sponsor-defined Clinical Concern Criteria	Treatment group: Paroxetine (N = 163)	Treatment group: Placebo (N = 156)
	n (%)	**n (%)**
Total Patients with a Vital Sign of Clinical Concern	22	17
Systolic BP (mmHg)	**(N = 162)**	**(N = 153)**
>145, and increase ≥40	1 (0.6)	0
<95, and decrease ≥30	5 (3.1)	1 (0.7)
Diastolic BP (mmHg)	**(N = 162)**	**(N = 153)**
>85, and increase ≥30	0	1 (0.7)
<50, and decrease ≥20	3 (1.9)	3 (2.0)
Pulse (bpm [beats per minute])	**(N = 162)**	**(N = 153)**
Ages 7 to 12 >115, ages 13 to 17 >110, and increase ≥30	1 (0.6) †	2 (1.3)
Ages 7 to 12 <65, ages 13 to 17, <55, and decrease ≥30	1 (0.6)	2 (1.3)
Weight (kg)	**(N = 135)**	**(N = 129)**
Above normal range,* and increase ≥7%	12 (8.9)	9 (7.0)
Below normal range,* and decrease ≥7%	0	0

N = Number of patients with Baseline and post-Baseline assessment
* Normal ranges for vital signs and weight may be found in Table 6.
† Patient 676.201.24762 had heart rate entered as 176 bpm at Week 12. Heart rate at all other visits was between 50 and 77 bpm, and no AE was reported at Week 12. It appears that the heart rate was entered in the eCRF incorrectly. See Section 15, Errata.
Source: Table 15.2.2.1, Section 13; Listing 15.2.1, Appendix E

Table 85 does not necessarily include all vital sign changes determined by the investigator to be clinically significant. 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 AEs in the eCRF. One patient in each treatment group had weight loss reported as an AE by the investigator; 1 paroxetine patient and 2 placebo patients had hypotension reported as an AE; and 1 placebo patient had tachycardia reported as an AE. None of these patients had vital signs meeting predefined concern criteria in association with these events. In addition, 7 paroxetine patients and 4 placebo

patients had weight gain reported as an AE; in 4 of these paroxetine patients and 3 placebo patients, the actual weight gain did not meet predefined concern criteria.

Detailed patient narratives were prepared for patients with any vital sign value that met the criteria both for absolute value of clinical concern and an increase or decrease from Baseline (in the same direction as the absolute value), and that was reported as an AE by the investigator. Three paroxetine patients and one placebo patient met this combination of criteria, all for weight above normal range, an increase in weight from Baseline ≥7%, and an AE of increased body weight. Narratives for these patients may be found in Table 15.2.2.3, Section 13. All were considered possibly related to treatment with study medication:

- Patient 676.013.24344, a 10-year-old female randomized to paroxetine, weighed 50.8 kg (111.8 lbs) at Screening (normal range 21.8 to 49.5 kg, 48 to 109 lbs). By Week 16, the patient's weight had increased by 3.7 kg (8.1 lbs) to 54.5 kg (119.9 lbs). The patient completed the study as planned.

- Patient 676.013.24352, a 15-year-old female randomized to paroxetine, weighed 87.6 kg (192.7 lbs) at Screening (normal range 38.6 to 80.0 kg, 85 to 176 lbs). By Week 16, the patient's weight had increased by 6.8 kg (15 lbs) to 94.4 kg (207.7 lbs). The patient completed the study as planned.

- Patient 676.102.24589, a 12-year-old female randomized to paroxetine, weighed 58.4 kg (128.5 lbs) at Screening (normal range 28.2 to 63.2 kg, 62 to 139 lbs). By Week 16, the patient's weight had increased by 5.6 kg (12.3 lbs) to 64.0 kg (140.8 lbs). The patient's mother withdrew consent for the study at Week 16.

- Patient 676.013.24346, a 14-year-old male randomized to placebo, weighed 79.5 kg (174.9 lbs) at Screening (normal range 35.9 to 74.5 kg, 79 to 164 lbs). The patient withdrew from the study at Week 8 due to lack of efficacy. At that time, the patient's weight had increased by 7.2 kg (15.8 lbs) to 86.7 kg (190.7 lbs).

During the Follow-up Phase, 3 patients had vital sign values meeting the predefined clinical concern criteria (i. e., both an absolute value of concern and a significant increase or decrease on therapy in the same direction) (Table 15.2.2.2, Section 13). In the paroxetine group, patient 676.003.24071 had a low and significant decrease in diastolic blood pressure, and patient 676. 003.24063 had a high and significant increase in weight. In the placebo group, patient 676.201.24756 had a low and significant decrease in heart rate. None of these patients had AEs reported in association with the vital sign changes.

6.8.2 Changes in Vital Signs

Table 86 presents a summary of BP, pulse and body weight values at Baseline and change from Baseline at Week 16. Data are included in the summary for those patients who had a value both at Baseline and at Week 16. Approximately 68% of patients in the paroxetine group and approximately 57% of patients in the placebo group contributed to this summary.

Baseline values were comparable in both treatment groups, and mean changes in all vital sign parameters were very small and generally comparable between groups.

Table 86 Mean Change from Baseline to Week 16 in Vital Signs, Weight, and BMI–Age Group: Total (ITT Population)

	Treatment Group			
	Paroxetine (N = 163)		Placebo (N = 155)	
Vital Sign	**N**	**Mean (SD)**	**N**	**Mean (SD)**
Systolic BP (mmHg)				
Baseline	163	107.4 (13.01)	155	108.8 (13.23)
Change at Week 16	112	1.3 (11.64)	89	3.3 (12.16)
BP Diastolic (mmHg)				
Baseline	163	67.7 (8.80)	155	68.1 (8.96)
Change at Week 16	112	0.1 (8.12)	89	1.3 (8.91)
Pulse (bpm)				
Baseline	163	76.1 (11.23)	155	75.4 (11.32)
Change at Week 16	111	3.8 (11.77)	88	2.0 (15.06)
Weight (kg)				
Baseline *	163	55.1 (20.14)	154	58.8 (20.30)
Change at Week 16	110	1.7 (3.05)	88	1.2 (2.95)
BMI (kg/m^2)				
Baseline	163	22.1 (6.57)	153	22.6 (6.52)
Change at Week 16	110	1.2 (9.29)	87	0.2 (1.58)

N = patients who had a value both at Baseline and at Week 16
* For weight, the last pre-treatment value was considered the Baseline value
Source: Table 15.2.1.1, Section 13; Listing 15.2.1, Appendix E

The mean change from Baseline to Taper End and/or Follow-up in vital signs may be found in Table 15.2.1.2, Section 13. Mean changes in vital signs for patients who withdrew early from the study were generally greater than those for the Week 16 OC dataset. However, the numbers are too small to draw any meaningful conclusions.

6.9 Laboratory Data

6.9.1 Laboratory Values of Potential Clinical Concern

Laboratory values meeting potential clinical concern criteria predefined by the sponsor were identified and tabulated. Table 7, Laboratory Values of Potential Clinical Concern, in Section 3.15.7.3, Vital Signs and Laboratory Values of Potential Clinical Concern, shows these values.

All laboratory parameters that were measured after the last dose of 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 16 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. The number and percentage of patients with laboratory values of potential clinical concern by post-randomization phase may be found in Tables 15.3.1.2 (Treatment Phase and Taper Phase), 15.3.1.3 (Follow-up Phase), and 15.3.1.4 (Treatment, Taper or Follow-up Phase), Section 13; Listings 15.3.1 (by patient) and 15.3.2 (by parameter), Appendix F. The number and percentage of patients with pre-treatment laboratory values of potential clinical concern may be found in Table 15.3.1.1, Section 13. All individual patient values of potential clinical concern are provided in Listing 15.3.3, Appendix F.

A total of 25 patients in the paroxetine group and 15 patients in the placebo group had at least one laboratory value during the Treatment, Taper, or Follow-up Phase that met the sponsor-defined value of potential clinical concern (Table 87). The most common value meeting the concern criteria was low hematocrit (13 patients in the paroxetine group and 6 patients in the placebo group); of these, 4 paroxetine patients and 1 placebo patient had had low hematocrit at Screening (Listing 15.3.1, Appendix F). Other laboratory parameters for which more than one patient in either treatment group had a value of concern was low neutrophils (4 paroxetine patients, 3 placebo patients, with 1 of the paroxetine patients having had low neutrophils at Baseline); high neutrophils (3 patients in each treatment group, with 1 of the placebo patients having had high neutrophils at Baseline); and high eosinophils (2 patients in the paroxetine group and 4 in the placebo group).

Table 87 Number (%) of Patients with Laboratory Values Meeting Sponsor-Defined Criteria for Potential Clinical Concern During the Treatment, Taper, or Follow-up Phase–Age Group: Total (ITT Population)

		Treatment Group			
Laboratory Parameter		**Paroxetine**		**Placebo**	
Total Patients with a Value of Clinical Concern		**N**	**n (%)** 25	**N**	**n (%)** 15
Hemoglobin	Low	130	2 (1.5)	117	0
Hematocrit	Low	130	13 (10.0)	117	6 (5.1)
WBC	Low	134	1 (0.7)	119	0
	High	134	0	119	1 (0.8)
Neutrophils, Absolute	Low	133	4 (3.0)	118	3 (2.5)
	High	133	3 (2.3)	118	3 (2.5)
Monocytes Absolute	High	133	0	118	1 (0.8)
Lymphocytes Absolute	High	133	1 (0.8)	118	0
Eosinophils, Absolute	High	133	2 (1.5)	118	4 (3.4)
Total Bilirubin	High	136	1 (0.7)	116	0
Potassium	High	137	1 (0.7)	116	0

N = Number of patients who had an assessment for this parameter at any time during the Treatment or Taper Phase
Source: Table 15.3.1.4, Section 13; Listing 15.3.3, Appendix F

Five patients had more than one laboratory value of potential clinical concern:

- Patient 676.015.24409, a 9-year-old male randomized to paroxetine, had low values of concern for both hemoglobin and hematocrit at Week 8 (at an Early Withdrawal visit for an adverse event of severe hyperkinesia). However, the hematocrit level had been low at Baseline. No adverse events were reported for these values.

- Patient 676.204.24851, a 14-year-old male randomized to paroxetine, had high values of concern for both eosinophils and neutrophils at Week 16. No adverse event was specifically reported for these values (e. g., eosinophilia), but the patient had a concurrent upper respiratory tract infection and herpes stomatitis.

- Patient 676.209.24953, an 11-year-old male randomized to placebo, had high values of concern for three laboratory parameters at Week 16: WBC, monocytes, and neutrophils. No adverse event was reported for these values.

- Patient 676.100.24704, a 12-year-old female randomized to placebo, had values of concern for both low neutrophils and low hematocrit at Week 16; hematocrit had been low at Baseline. No adverse event was reported for these values.

- Patient 676.204.24841, a 9-year-old male randomized to paroxetine, had low values of concern for both hemoglobin and hematocrit at Follow-up. However, both parameters had been low at Baseline. No adverse events were reported for these values.

Among patients identified in Table 87, only one patient had a laboratory value of concern reported as an AE. Patient 676.020.24536, a 16-year-old male randomized to paroxetine, had absolute neutrophil count of 3.23 x 10^9/L (normal range: 1.80 to 8.00 x 10^9/L) and absolute lymphocyte count of 1.93 x 10^9/L (normal range: 0.85 to 4.10 x 10^9/L) at Screening. The patient completed the study and at Week 16 had an increased absolute neutrophil count of 8.90 x 10^9/L, a value and increase of potential clinical concern; absolute lymphocyte count decreased to 1.65 x 10^9/L, still within normal range. Mild leukocytosis and leukopenia were reported as AEs, considered by the investigator to be probably unrelated to treatment with study medication. A repeat laboratory test 17 days later showed an absolute neutrophil count of 4.64 x 10^9/L and absolute lymphocyte count of 1.92 x 10^9/L, both within normal range. A detailed narrative for this patient may be found Table 15.3.1.5, Section 13.

Table 87 does not necessarily include all laboratory values determined by the investigator to be clinically significant. If a laboratory finding was judged to be clinically significant by the investigator, whether or not it met the sponsor-defined potential clinical concern criteria, the finding was to be recorded as an AE in the eCRF. Two additional patients who received paroxetine and 3 patients who received placebo had AEs related to laboratory findings, none of which met the concern criteria:

- Patient 676.205.24985 had severe anemia (final diagnosis: mild hypochromic anemia) on Day 25 of treatment with paroxetine. The investigator considered the AE of anemia to be serious (see Section 6.4, Serious Adverse Events, for detailed narrative) and both events to be unrelated to study medication. Blood hematology results were not available at Screening or upon early withdrawal. Laboratory measurements taken at hospitalization included hemoglobin 11.9 g/dL (normal range 12.5 to 16.5)

- Patient 676.005.24126, had mild hyperkalemia, considered unrelated to study medication by the investigator, reported on Day 119 (Week 16) of treatment with paroxetine. The patient's potassium increased from normal at Screening (4.6 mmol/L) to above the normal range at Week 16 (7.1 mmol/L, normal range = 3.5 to 5.3 mmol/L).

- Patient 676.013.24353, had mild hyponatremia, considered possibly related to study medication by the investigator, reported on Day 57 (Week 8) of treatment with placebo. The patient's sodium decreased from normal at Screening (141.0 mmol/L) to below the normal range at Week 8 (131.0 mmol/L, normal range = 135.0 to 146.0 mmol/L).

- Patient 676.200.24736 had mild liver function tests abnormal, eosinophilia, leukopenia and bilirubinemia (verbatim: eosinophils absolute 0.63 higher than range; neutrophils 1.72 lower than range; eosinophils 11.8 higher than range; urea nitrogen 2.3 lower than range; bilirubin 26 higher than range) considered unrelated to study medication by the investigator, reported on Day 108 (Week 16) of treatment with placebo. Eosinophils absolute (0.72 x 10^9/L, normal range 0.05 to 0.55 x 10^9/L) and bilirubin (35.0 umol/L, normal range 0.0 to 22.0 umol /L) were actually higher at Screening, whereas neutrophils (3.48 x 10^9/L, normal range 1.8 to 8.0 x 10^9/L) and blood urea nitrogen (2.6 mmol/L, normal range 2.5 to 9.0 mmol/L) were within normal limits.

- Patient 676.020.24537 had mild polycythemia, considered probably unrelated to study medication by the investigator, reported on Day 126 (Week 16) of treatment with placebo. The patient's red blood cell count was only slightly higher (6.30 x 10^{12}/L, normal range 4.1 to 5.3 x 10^{12}/L) at Week 16 compared to Screening (6.1 x 10^{12}/L).

6.9.2 Changes in Laboratory Values

Table 88 presents descriptive statistics (means, standard deviations, and ranges) for Baseline, Week 16, endpoint (last on-therapy assessment including Taper Phase), and change at endpoint for each of the laboratory parameters monitored during the study. The treatment groups were comparable at Baseline and there were no substantial differences between the paroxetine and the placebo groups at Week 16, at endpoint, or in the change from Baseline at endpoint.

Twelve paroxetine patients and 3 placebo patients had thyroid tests (free T3, thyroid stimulating hormone, and total free thyroxine) conducted at endpoint,

which was not required by the protocol. Means for these small numbers of patients are not reported in Table 88.

Table 88 Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 163) N	Mean	(SD)	Range	Placebo (N = 156) N	Mean	(SD)	Range
Hemoglobin (g/L)								
Baseline	151	134.9	(9.46)	108.8 to 159.0	150	137.9	(11.01)	114.0 to 170.8
Week 16 OC	102	133.2	(11.16)	106.0 to 163.0	89	137.6	(11.79)	118.0 to 178.9
Endpoint	117	132.7	(10.80)	106.0 to 163.0	110	137.4	(11.75)	113.0 to 178.9
Change at Endpoint	112	-3.5	(6.25)	-18.0 to 10.5	109	-1.1	(6.15)	-20.3 to 12.1
Hematocrit (%)								
Baseline	151	40.0	(2.76)	32.7 to 46.5	150	40.9	(3.29)	34.3 to 51.0
Week 16 OC	102	39.6	(3.28)	33.1 to 48.7	89	40.8	(3.35)	34.4 to 52.3
Endpoint	117	39.5	(3.17)	33.1 to 48.7	110	40.8	(3.37)	34.0 to 52.3
Change at Endpoint	112	-0.9	(1.93)	-5.3 to 3.6	109	-0.4	(2.12)	-4.6 to 4.6
RBC Count (10^{12}/L)								
Baseline	151	4.6	(0.34)	3.6 to 5.4	150	4.7	(0.40)	3.8 to 6.1
Week 16 OC	102	4.5	(0.38)	3.6 to 5.7	89	4.7	(0.45)	3.4 to 6.3
Endpoint	117	4.5	(0.37)	3.6 to 5.7	110	4.7	(0.44)	3.4 to 6.3
Change at Endpoint	112	-0.1	(0.22)	-0.6 to 0.4	109	-0.03	(0.24)	-0.6 to 0.5

Baseline = last pre-treatment assessment
Endpoint = last on-therapy assessment (including Taper Phase)
Source: Table 15.3.6, Section 13; Listing 15.3.1 and 15.3.2, Appendix F

(Table continues)

Table 88 (Continued) Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 163) N	Mean	(SD)	Range	Placebo (N = 156) N	Mean	(SD)	Range
WBC (10^9/L)								
Baseline	158	7.0	(1.79)	3.5 to 12.2	153	6.7	(1.94)	2.4 to 21.5
Week 16 OC	106	7.0	(1.94)	1.9 to 13.0	91	6.9	(2.60)	3.5 to 24.5
Endpoint	121	6.9	(1.85)	3.1 to 13.0	111	7.0	(2.51)	3.5 to 24.5
Change at Endpoint	118	0.0	(1.75)	-5.1 to 6.5	109	2.0	(1.99)	-4.9 to 7.5
Platelets (10^9/L)								
Baseline	151	284.2	(60.17)	121.0 to 479.0	150	272.8	(61.12)	93.0 to 469.0
Week 16 OC	102	283.3	(57.34)	149.0 to 453.0	89	273.6	(50.99)	178.0 to 404.0
Endpoint	117	283.4	(57.99)	149.0 to 453.0	110	273.0	(54.60)	170.0 to 472
Change at Endpoint	112	-5.3	(41.12)	-156.0 to 69.0	109	1.1	(50.02)	-108.0 to 203.0
Basophils (10^9/L)								
Baseline	156	0.024	(0.0204)	0.00 to 0.18	151	0.022	(0.0153)	0.00 to 0.09
Week 16 OC	105	0.022	(0.0150)	0.00 to 0.10	90	0.018	(0.0122)	0.00 to 0.06
Endpoint	120	0.023	(0.0172)	0.00 to 0.11	110	0.019	(0.0140)	0.00 to 0.09
Change at Endpoint	117	-0.002	(0.0247)	-0.14 to 0.09	108	-0.003	(0.0187)	-0.08 to 0.09

Baseline = last pre-treatment assessment
Endpoint = last on-therapy assessment (including Taper Phase)
Source: Table 15.3.6, Section 13; Listing 15.3.1 and 15.3.2, Appendix F

(Table continues)

Table 88 (Continued) Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 163) N	Mean	(SD)	Range	Placebo (N = 156) N	Mean	(SD)	Range
Eosinophils (10^9/L)								
Baseline	158	0.21	(0.163)	0.0 to 0.9	152	0.25	(0.189)	0.0 to 1.1
Week 16 OC	105	0.22	(0.174)	0.0 to 0.9	90	0.26	(0.287)	0.0 to 2.2
Endpoint	120	0.22	(0.168)	0.0 to 0.9	110	0.25	(0.271)	0.0 to 2.2
Change at Endpoint	117	0.01	(0.152)	-0.7 to 0.8	108	-0.01	(0.230)	-0.6 to 1.5
Lymphocytes (10^9/L)								
Baseline	158	2.44	(0.647)	1.2 to 4.5	152	2.37	(0.671)	0.9 to 5.1
Week 16 OC	105	2.35	(0.686)	1.1 to 4.8	90	2.31	(0.614)	1.1 to 4.3
Endpoint	120	2.34	(0.685)	1.1 to 4.8	110	2.36	(0.650)	1.1 to 4.3
Change at Endpoint	117	-0.07	(0.526)	-1.7 to 1.7	108	-0.05	(0.516)	-1.7 to 1.2
Monocytes (10^9/L)								
Baseline	158	0.41	(0.233)	0.01 to 2.34	152	0.38	(0.180)	0.00 to 1.27
Week 16 OC	105	0.39	(0.185)	0.00 to 1.12	90	0.39	(0.205)	0.02 to 1.60
Endpoint	120	0.38	(0.176)	0.00 to 1.12	110	0.38	(0.194)	0.02 to 1.60
Change at Endpoint	117	-0.02	(0.256)	-1.92 to 0.36	108	0.01	(0.200)	-1.05 to 0.49

Baseline = last pre-treatment assessment
Endpoint = last on-therapy assessment (including Taper Phase)
Source: Table 15.3.6, Section 13; Listing 15.3.1 and 15.3.2, Appendix F

(Table continues)

Table 88 (Continued) Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 163) N	Mean	(SD)	Range	Placebo (N = 156) N	Mean	(SD)	Range
Neutrophils (10^9/L)								
Baseline	158	4.0	(1.43)	1.3 to 8.3	152	3.7	(1.53)	1.0 to 14.8
Week 16 OC	105	4.0	(1.56)	0.7 to 10.2	90	4.0	(2.21)	1.3 to 18.8
Endpoint	120	3.9	(1.49)	0.7 to 10.2	110	4.0	(2.14)	1.3 to 18.8
Change at Endpoint	117	0.1	(1.51)	-5.0 to 6.6	108	0.2	(1.78)	-4.8 to 7.3
Sodium (mmol/L)								
Baseline	162	140.7	(2.28)	134.0 to 149.0	156	140.8	(2.35)	136.0 to 147.0
Week 16 OC	106	141.1	(2.53)	134.0 to 150.0	88	141.4	(1.75)	137.0 to 145.0
Endpoint	121	141.0	(2.45)	134.0 to 150.0	107	141.3	(2.01)	131.0 to 145.0
Change at Endpoint	120	0.4	(3.16)	-6.0 to 12.0	107	0.5	(2.93)	-10.0 to 9.0
Potassium (mmol/L)								
Baseline	162	4.3	(0.31)	3.5 to 5.2	156	4.3	(0.59)	3.6 to 10.0
Week 16 OC	106	4.3	(0.46)	3.5 to 7.1	88	4.3	(0.37)	3.7 to 5.8
Endpoint	121	4.3	(0.45)	3.5 to 7.1	107	4.3	(0.34)	3.7 to 5.8
Change at Endpoint	120	0.0	(0.47)	-1.3 to 2.5	107	-0.1	(0.75)	-5.8 to 1.9

Baseline = last pre-treatment assessment
Endpoint = last on-therapy assessment (including Taper Phase)
Source: Table 15.3.6, Section 13; Listing 15.3.1 and 15.3.2, Appendix F

(Table continues)

Table 88 (Continued) Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 163) N	Mean	(SD)	Range	Placebo (N = 156) N	Mean	(SD)	Range
BUN (mmol/L)								
Baseline	162	4.2	(1.15)	1.8 to 8.6	155	4.2	(1.20)	1.8 to 8.2
Week 16 OC	103	4.3	(1.08)	2.1 to 6.8	88	4.4	(1.22)	2.1 to 9.3
Endpoint	118	4.3	(1.11)	2.1 to 6.8	107	4.4	(1.27)	2.1 to 9.3
Change at Endpoint	117	0.2	(1.25)	-3.2 to 3.2	106	0.2	(1.10)	-2.5 to 3.6
Creatinine (umol/L)								
Baseline	162	55.2	(16.39)	26.5 to 176.8	155	57.2	(15.67)	28.0 to 123.8
Week 16 OC	104	55.8	(11.83)	35.4 to 97.2	88	58.0	(14.90)	25.5 to 106.1
Endpoint	119	56.2	(11.84)	35.4 to 97.2	107	57.4	(14.69)	26.5 to 106.1
Change at Endpoint	118	1.7	(9.21)	-26.5 to 44.2	106	0.7	(12.04)	-79.6 to 26.5
Alkaline Phosphatase (IU/L)								
Baseline	162	183.0	(99.55)	46.0 to 526.0	155	205.2	(102.63)	50.0 to 638.0
Week 16 OC	105	166.3	(85.87)	49.0 to 365.0	88	187.1	(96.21)	51.0 to 445.0
Endpoint	120	168.0	(84.80)	49.0 to 365.0	107	192.7	(96.12)	51.0 to 445.0
Change at Endpoint	119	-13.0	(33.40)	-161.0 to 83.0	106	-8.5	(54.83)	-464.0 to 135.0

Baseline = last pre-treatment assessment
Endpoint = last on-therapy assessment (including Taper Phase)
Source: Table 15.3.6, Section 13; Listing 15.3.1 and 15.3.2, Appendix F

(Table continues)

Table 88 (Continued) Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 163) N	Mean	(SD)	Range	Placebo (N = 156) N	Mean	(SD)	Range
SGOT (AST) (IU/L)								
Baseline	162	21.5	(6.56)	12.0 to 68.0	156	21.1	(5.54)	11.0 to 42.0
Week 16 OC	105	21.9	(5.84)	9.0 to 51.0	88	20.7	(5.69)	11.0 to 42.0
Endpoint	120	22.5	(8.22)	9.0 to 84.0	107	20.8	(5.70)	11.0 to 42.0
Change at Endpoint	119	1.6	(5.80)	-12.0 to 44.0	107	0.1	(4.55)	-11.0 to 23.0
SGPT (ALT) (IU/L)								
Baseline	162	15.3	(7.98)	5.0 to 63.0	156	15.2	(8.38)	5.0 to 52.0
Week 16 OC	88	15.4	(8.67)	7.0 to 52.0	105	16.3	(8.22)	6.0 to 68.0
Endpoint	107	15. 4	(8.36)	4.0 to 104.0	120	16.8	(11.35)	6.0 to 68.0
Change at Endpoint	107	0.1	(6.27)	-19.0 to 41.0	119	1.7	(7.55)	-30.0 to 20.0
Total Bilirubin (umol/L)								
Baseline	162	9.1	(6.20)	0.0 to 44.0	155	9.7	(5.32)	3.0 to 40.0
Week 16 OC	105	8.5	(4.87)	1.7 to 30.8	88	10.5	(5.66)	3.4 to 33.0
Endpoint	120	8.5	(4.70)	1.7 to 30.8	107	10.1	(5.45)	3.4 to 33.0
Change at Endpoint	119	-0.9	(4.37)	-23.0 to 9.0	106	0.1	(4.05)	-9.0 to 18.8

Baseline = last pre-treatment assessment
Endpoint = last on-therapy assessment (including Taper Phase)
Source: Table 15.3.6, Section 13; Listing 15.3.1 and 15.3.2, Appendix F

Baseline values, endpoint values (including Taper Phase), and Follow-up values were categorized as high and of clinical concern, above normal range, within range, below normal range, and low and of clinical concern. Table 15.3.4, Section 13, presents the number of patients with transitions in laboratory values from one categorization to another per parameter from Baseline to endpoint and from Baseline to Follow-up. Among paroxetine patients, slightly more values transitioned from an in-range value at Baseline to a low or high value at endpoint than transitioned from abnormal to normal. However, transitions occurred infrequently and few values were of potential clinical concern.

6.9.3 Urinalysis Results

The number and percentage of patients with abnormal urine test results during the Treatment or Taper Phase may be found in Table 15.3.5.2, Section 13. Results were comparable between the treatment groups and generally unremarkable. 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 13. Abnormal results at Screening may be found in Table 15.3.5.1, Section 13. Urinalysis results for each patient are provided by patient and by parameter in Listings 15.3.1 and 15.3.2, Appendix F, respectively.

Two patients in the paroxetine group had urine abnormalities associated with an AE during treatment (Listings 15.1.1 and 15.1.2, Appendix D).

- Patient 676.207.24901, a 15-year-old female, had AEs of mild albuminuria (verbatim: protein in urine positive) and mild ketosis (verbatim: ketones positive in urine) on Day 15 of treatment and a mild urinary abnormality (verbatim: trace urobilinogen urine) on Day 28 of treatment. All three events were judged unrelated to treatment with study medication by the investigator. Urine abnormalities included a positive urine dipstick for protein and blood and many urine RBCs. At Screening, urinalysis results included a positive urine dipstick, many WBCs, and few amorphous sediment.

- Patient 676.023.17877, a 7-year-old male, had an AE of mild albuminuria (verbatim: protein in urine), considered unrelated to treatment with study medication by the investigator, on Day 56 of treatment. Urine dipstick was positive and many mucous threads and moderate urine squamous epithelial cells were noted upon urinalysis. Urine dipstick results were negative at Screening. There were no urine abnormalities associated with an AE during the Taper or Follow-up phases for paroxetine-treated patients.

Urine abnormalities associated with an AE were reported for one patient in the placebo group during the Treatment Phase and in 1 placebo patient during the Taper and Follow-up Phases (Listings 15.1.1 and 15.1.2, Appendix D):

- Patient 676.020.24535, a 14-year-old male, had mild albuminuria (verbatim: protein in urine), judged unrelated to treatment with study medication by the investigator, on Day 45 of the Treatment Phase. Protein dipstick results were positive.

- Patient 676.207.24899, a 11-year-old female, had mild pyuria (verbatim: leukocytes in urine, positive) and a mild urinary tract infection (verbatim: urinary tract infection), reported approximately 30 days after the last dose of placebo. Both AEs were judged unrelated to treatment with study medication by the investigator. Urine dipstick was positive for protein and trace amounts of blood and many WBCs and few bacteria were found upon urinalysis.

Three placebo patients reported an AE associated with a urine abnormality during the Treatment Phase, but no abnormal urinalysis findings were noted. Patient 676.100.24707 had mild albuminuria (verbatim: proteinuria) and moderate cystitis; patient 676.002.24037 had a moderate urinary tract infection; and patient 676.009.24225 had a mild urinary tract infection.

7 Pharmacokinetic Evaluation

The collection of pharmacokinetic (PK) samples was optional (i. e., it was not required by the protocol) and only patients consenting to this additional assessment had samples obtained. Blood samples for PK evaluation at Weeks 4 and/or 16 were obtained from 112 patients: 10 only at Week 4; 12 at Week 4 and Early Withdrawal; 22 only at Week 16; 4 only at Early Withdrawal; and 64 at both Week 4 and Week 16.

Paroxetine plasma concentration data from this study were determined by HPLC/MS/MS [24], and will be combined and reported with similar data from studies 704 and 701 [13] [14]. The complete dataset will be explored, using graphical techniques supported by descriptive statistics, to describe the effects of dose and selected demographic characteristics on paroxetine steady state plasma concentrations in the pediatric population [25].

8 Discussion

This 16-week, double-blind, placebo-controlled, randomized study evaluated the efficacy and tolerability of paroxetine in the treatment of 91 children and 228 adolescents who met the DSM-IV criteria for Social Anxiety Disorder/Social Phobia. The study objectives were prospectively defined and the trial used six different rating instruments to assess Social Anxiety treatment response: the Clinical Global Impression Global Improvement (CGI-I), the CGI Severity of Illness (CGI-S), the Liebowitz Social Anxiety Scale for Children and Adolescents (LSAS–CA), the Dalhousie Generalized Social Anxiety Disorder Scale for Adolescents (D–GSADS–A, ages 11 to 17 only); the Social Phobia Anxiety Inventory (SPAI–C, ages 8 years to 13 years 11 months; SPAI, ages 14 years to 17 years 11 months); and the Global Assessment of Functioning Scale (GAF). An additional variable of interest was the Children's Depression Rating Scale–Revised (CDRS–R).

The statistical methodology used to analyze the data employed standard practices. Although only 29.8%(96/322) of patients withdrew from the study, conservative analytical techniques, such as last observation carried forward (LOCF), were used to estimate missing data.

More patients in the paroxetine group (74.5%, 123/165) completed the study than in the placebo group (65.6%, 103/157), with the difference more pronounced among adolescents. The primary reason for withdrawal among paroxetine patients was protocol deviation (6.7%, 11/163), while the primary reason for withdrawal in the placebo group was lack of efficacy (14.1%, 22/156). The two treatment groups were similar in regard to race, age and weight; however, there were more females than males among paroxetine patients, and more males than females among placebo patients, with the difference accounted for entirely among adolescents.

Mean baseline scores for the efficacy instruments were similar in both treatment groups. Although there are more assessment categories in the CGI Severity of Illness item than in the ADIS for DSM-IV:C, the severity of Social Anxiety Disorder as determined by the ADIS for DSM-IV:C correlates well with the overall severity of illness as determined by the CGI-S in both treatment groups at Baseline in that over 95% of patients had a severity rating of moderately ill or worse according to both scales. Mean CDRS–R baseline scores indicated a very low level of depressive symptoms, with only approximately 3% of patients in each treatment group having a history of Major Depressive Disorder. Over 80%

of patients in both treatment groups had taken no previous psychoactive medication.

Efficacy

As of the commencement of this study, there was no validated clinician-rated instrument for assessing social anxiety symptoms in children or adolescents. Therefore, the proportion of responders according to the CGI Global Improvement scale was selected as the primary efficacy endpoint. Analysis of this endpoint at Week 16 LOCF, for the ITT population, provided statistically significant and clinically relevant evidence that paroxetine was more efficacious than placebo in the treatment of children and adolescents with Social Anxiety Disorder. The treatment difference at Week 16 LOCF was substantial (77.6% response rate for paroxetine vs. 38.3% response rate for placebo, corresponding to an odds ratio of 7.02 [95% CI 4.07, 12.11], $p<0.001$), and compared favorably with reductions reported in an open-label pediatric trial with sertraline [7], with CGI-I results reported in a double-blind study of patients with mixed anxiety with fluvoxamine [10], and with the results reported in an open-label study of patients with Social Anxiety Disorder with fluoxetine [9]. In particular, the difference between paroxetine and placebo with regard to the percentage of patients who were “very much improved” at Week 16 LOCF was particularly pronounced, 47.5% (77/162) of paroxetine patients compared to 14.9% (23/154) of placebo patients. There was no evidence of any statistically significant treatment by covariate interactions for the primary endpoint (ITT, Week 16 LOCF), indicating that the treatment effect was consistent across age group, gender, CGI-S baseline score, and country grouping.

Statistically significant differences in the proportion of CGI-I responders between paroxetine and placebo were also observed for the Week 16 OC and 70% LOCF datasets. The per-protocol analysis also supported these findings.

Analysis of all secondary efficacy parameters, the CGI-S, the LSAS–CA, the D–GSADS–A, the SPAI and SPAI–C, and the GAF, showed a statistically significant benefit of paroxetine over placebo for the Week 16 LOCF, Week 16 OC and 70% LOCF datasets. The findings in regard to the additional variable of interest, the CDRS–R, are not clinically significant because the level of depressive symptomatology in both treatment groups and both age groups was very low at Baseline.

Children received a lower overall mean daily dose of paroxetine, 21.7 mg/day compared with 26.1 mg/day for adolescents, as well as a lower mean dose at the

Week 16 LOCF endpoint, 26.5 mg/day compared with 35.0 mg/day for adolescents. Slightly more than half the children (56.5%, 26/46) took a dose higher than 20 mg/day, compared to 78.4% (91/116) of the adolescents, and the mean duration of exposure for children (97.6 days) was slightly lower than that for adolescents (102.4 days). However, across the efficacy scales, the treatment benefit was not consistently greater in one age group than in the other age group.

Safety

This study indicates that paroxetine is safe when used in children and adolescents with Social Anxiety Disorder for a period of up to 16 weeks over the dosage range of 10–50 mg/day. There were no deaths or any other unexpected safety findings, and paroxetine was generally well tolerated compared with placebo. Fairly comparable percentages of patients in the two treatment groups reported at least one emergent AE during the Treatment Phase (88.3%, 144/163 in the paroxetine group vs. 80.1%, 125/156 in the placebo group). More paroxetine patients than placebo patients experienced AEs judged to be severe (19/163 patients vs. 9/156 patients, respectively), AEs leading to dose reduction (28/163 patients vs. 6/156 patients, respectively), and AEs that led to withdrawal from the study (9/163 patients vs. 2/156 patients, respectively). The withdrawal rate due to AEs was relatively low compared to other pediatric studies, 5.5% (9/163) in the paroxetine group and 1.3% (2/156) in the placebo group; among other pediatric studies, the rates of withdrawal in the paroxetine group due to AEs were 9.7% (9/93) in study 329, 8.9% (9/101) in study 701, and 10.2% in study 704 (10/98) [12],[13],[14]. The difference cannot be accounted for by duration of study, since the duration of the other studies (8, 8, and 10 weeks, respectively) was considerably less than the duration of the present study (16 weeks).

The overall rate of SAEs in this study is also quite low compared to previous pediatric experience with paroxetine [12] [13] [14]. The single on-treatment SAE in a paroxetine patient (anemia) was considered unrelated to treatment by the investigator. One paroxetine patient experienced an SAE of “fear and depression related to Social Anxiety Disorder” 14 days after the last dose of study medication. The event appears to be a return of symptoms upon discontinuation of the study medication.

The AE profile reported in this study is consistent with that reported in previous paroxetine studies in pediatric patients. Not unexpectedly for antidepressants with a predominant action on serotonin uptake, common (>5%) AEs that occurred during the Treatment Phase in the paroxetine group at an incidence at least twice that in the placebo group were primarily associated with the nervous (insomnia)

and digestive (decreased appetite and vomiting) body systems. Overall, the most common (>10%) gender-non-specific AEs for patients receiving paroxetine were headache, infection, respiratory disorder, abdominal pain, asthenia, insomnia, somnolence, rhinitis, and nausea. For the overall population (both age subgroups combined), the following AEs occurred with an incidence of 5% or greater in the paroxetine group and with an incidence at least twice that in the placebo group: insomnia (14.1% vs. 5.8%), decreased appetite (8.0% vs. 3.2%), and vomiting (6.7% vs. 1.9%). As noted above, this is not inconsistent with previous findings.

Data from this study show that the overall incidence of AEs in patients who received paroxetine is similar in both age subgroups, and that younger children (i.e., less than age 12) generally tolerate paroxetine treatment as well as older children (adolescents), but that the specific safety profile of paroxetine may differ somewhat in children and adolescents. The numbers of patients in each group are relatively small when broken down by age subgroup, therefore caution is required when interpreting this data. In children receiving paroxetine, nervousness, rash, otitis media, conjunctivitis, hyperkinesia, hostility, and urinary incontinence occurred in ≥5% of patients at an incidence at least twice that among adolescents receiving paroxetine. In adolescents receiving paroxetine, asthenia, rhinitis, nausea, pharyngitis, and dizziness occurred in ≥5% of patients at an incidence at least twice that among children receiving paroxetine. Again, these findings are generally consistent with results from previous pediatric studies. The incidence of AEs leading to withdrawal was not substantially different between children who received paroxetine (4.3%, 2/46) and adolescents who received paroxetine (6.0%, 7/117). In the placebo group, 4.4% of children (2/45) and no adolescents were withdrawn due to AEs.

The safety profile of paroxetine observed in pediatric patients with Social Anxiety Disorder in this 16-week trial appears to differ somewhat from that observed in 522 adult patients with Social Anxiety Disorder randomized to paroxetine who participated in three acute trials [26][27][28]. As expected, there were few gender-specific adverse events reported in adolescents and none in children. However, of the nine AEs among children in this pediatric study that occurred in patients receiving paroxetine at an incidence ≥5% and at an incidence at least twice that for patients receiving placebo (respiratory disorder, nervousness, rash, otitis media, urinary incontinence, hyperkinesia, asthenia, conjunctivitis, and hostility), none met these criteria in the adult studies. Similarly, 3 of the 5 AEs meeting these criteria in adolescents (insomnia, dyspepsia, and vomiting) did not meet these criteria in adults. These findings are not inconsistent with the reported occurrence of AEs with the use of other SSRIs for the treatment of pediatric patients with Social Anxiety Disorder or mixed anxiety disorders [7] [9] [10].

Taper and Follow-up Phase emergent AEs in this study were more frequent than has been seen in other pediatric studies with paroxetine. The reason for this is unclear, although the longer duration of the study (and longer duration of exposure to paroxetine) may be a factor. More patients in the paroxetine group had Taper or Follow-up Phase emergent AEs (47.2%, 68/144) than in the placebo group (32.6%, 42/129). As in the Treatment Phase, common AEs that occurred during the Taper or Follow-up Phases in the paroxetine group at an incidence at least twice that in the placebo group were primarily associated with the nervous (dizziness) and digestive (nausea and abdominal pain) body systems.

The only AE that occurred during the Taper Phase in more than 5% of patients was headache, occurring with similar frequency in both treatment groups. Taper Phase-emergent AEs in the paroxetine group that were considered severe were sinusitis, a fractured arm, and dizziness (one patient each); the dizziness was considered related to study medication. During the Follow-up Phase, AEs that occurred in more than 5% of patients receiving paroxetine were headache, dizziness, nausea, and abdominal pain. Follow-up Phase-emergent AEs in the paroxetine group that were considered severe were headache (possibly related) and insomnia (probably unrelated) (one patient each).

Consistent with previous paroxetine pediatric study results, vital sign and laboratory results were generally unremarkable. Few vital sign measurements met predefined potential clinical concern criteria, although three paroxetine patients and one placebo patient had weight gain meeting the concern criteria that was reported as an AE by the Investigator. Similarly, clinical laboratory abnormalities meeting concern criteria were few in number and similar in both treatment groups. The most common lab value of concern was low hematocrit (13 paroxetine patients and 6 placebo patients). One patient had a laboratory value of concern that was reported as an AE by the investigator, a patient in the paroxetine group with high neutrophils and AEs of leukocytosis and leukopenia, considered probably unrelated to study medication. There were no substantial differences between the paroxetine and the placebo groups in mean changes in any laboratory values.

9 Conclusions

Assessment of the primary efficacy variable, the proportion of responders based on the Clinical Global Impression–Global Improvement item at the Week 16 last observation carried forward (LOCF) endpoint, provided statistically significant and clinically relevant evidence that paroxetine was more efficacious than placebo in treating children and adolescents with Social Anxiety Disorder. This conclusion was supported by statistically significant results favoring paroxetine over placebo for all secondary efficacy variables. This conclusion was further supported by statistically significant results from analysis of all efficacy variables using the Week 16 Observed Cases (OC) dataset and the 70% LOCF dataset.

Data from this study demonstrated that paroxetine was safe and generally well tolerated compared to placebo when used in children and adolescents with Social Anxiety Disorder over a period of up to 16 weeks over the dosage range of 10-50 mg/day. There were no serious unexpected adverse events or findings in laboratory tests or vital signs. There was some indication that the AE profile in children may differ slightly from that in adolescents.

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11 Source Tables: Study Population

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Table 13.1.1

Number (%) of Patients by Population
All Patients

Age Group : Children

Study Stage/Population	Paroxetine (N=47)		Placebo (N=45)		Total (N=129)	
	Treatment Group					
Screened Only	0		0		37	
Randomised	47	(100.0%)	45	(100.0%)	92	(100.0%)
Completed*	31	(66.0%)	29	(64.4%)	60	(65.2%)
Early Withdrawal	16	(34.0%)	16	(35.6%)	32	(34.8%)
Intention-to-Treat Population	46	(97.9%)	45	(100.0%)	91	(98.9%)
Per-Protocol Population	32	(68.1%)	32	(71.1%)	64	(69.6%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: PID 004.24086/004.24089 was screened and failed, then was screened and randomised at a later date, therefore is counted twice
* Completed=Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

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Table 13.1.1

Number (%) of Patients by Population
All Patients

Age Group : Adolescents

Study Stage/Population	Paroxetine (N=118)		Placebo (N=112)		Total (N=296)	
	Treatment Group					
Screened Only	0		0		66	
Randomised	118	(100.0%)	112	(100.0%)	230	(100.0%)
Completed*	92	(78.0%)	74	(66.1%)	166	(72.2%)
Early Withdrawal	26	(22.0%)	38	(33.9%)	64	(27.8%)
Intention-to-Treat Population	117	(99.2%)	111	(99.1%)	228	(99.1%)
Per-Protocol Population	92	(78.0%)	78	(69.6%)	170	(73.9%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: PID 004.24086/004.24089 was screened and failed, then was screened and randomised at a later date, therefore is counted twice
* Completed=Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

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Table 13.1.1

Number (%) of Patients by Population
All Patients

Age Group : Total

Study Stage/Population	Paroxetine (N=165)		Placebo (N=157)		Total (N=425)	
	Treatment Group					
Screened Only	0		0		103	
Randomised	165	(100.0%)	157	(100.0%)	322	(100.0%)
Completed*	123	(74.5%)	103	(65.6%)	226	(70.2%)
Early Withdrawal	42	(25.5%)	54	(34.4%)	96	(29.8%)
Intention-to-Treat Population	163	(98.8%)	156	(99.4%)	319	(99.1%)
Per-Protocol Population	124	(75.2%)	110	(70.1%)	234	(72.7%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: PID 004.24086/004.24089 was screened and failed, then was screened and randomised at a later date, therefore is counted twice
* Completed=Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : Canada (4 Centres)
Age Group : Children

Study Stage/Population	Treatment Group: Paroxetine (N=1)	Placebo (N=4)	Total (N=6)
Screened Only	0	0	1
Randomised	1 (100.0%)	4 (100.0%)	5 (100.0%)
Completed*	0	3 (75.0%)	3 (60.0%)
Early Withdrawal	1 (100.0%)	1 (25.0%)	2 (40.0%)
Intention-to-Treat Population	1 (100.0%)	4 (100.0%)	5 (100.0%)
Per-Protocol Population	1 (100.0%)	3 (75.0%)	4 (80.0%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: PID 004.24086/004.24089 was screened and failed, then was screened and randomised at a later date, therefore is counted twice
* Completed=Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : Canada (4 Centres)
Age Group : Adolescents

Study Stage / Population	Treatment Group: Paroxetine (N=14)		Placebo (N=10)		Total (N=36)	
Screened Only	0		0		12	
Randomised	14	(100.0%)	10	(100.0%)	24	(100.0%)
Completed*	11	(78.6%)	9	(90.0%)	20	(83.3%)
Early Withdrawal	3	(21.4%)	1	(10.0%)	4	(16.7%)
Intention-to-Treat Population	14	(100.0%)	10	(100.0%)	24	(100.0%)
Per-Protocol Population	10	(71.4%)	8	(80.0%)	18	(75.0%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: PID 004.24086/004.24089 was screened and failed, then was screened and randomised at a later date, therefore is counted twice
* Completed=Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : Canada (4 Centres)
Age Group : Total

Study Stage / Population	Paroxetine (N=15)		Placebo (N=14)		Total (N=42)	
	Treatment Group					
Screened Only	0		0		13	
Randomised	15	(100.0%)	14	(100.0%)	29	(100.0%)
Completed*	11	(73.3%)	12	(85.7%)	23	(79.3%)
Early Withdrawal	4	(26.7%)	2	(14.3%)	6	(20.7%)
Intention-to-Treat Population	15	(100.0%)	14	(100.0%)	29	(100.0%)
Per-Protocol Population	11	(73.3%)	11	(78.6%)	22	(75.9%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: PID 004.24086/004.24089 was screened and failed, then was screened and randomised at a later date, therefore is counted twice
* Completed=Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : United States of America (22 Centres)
Age Group : Children

Study Stage/Population	Paroxetine (N=36)		Placebo (N=28)		Total (N=90)	
	Treatment Group					
Screened Only	0		0		26	
Randomised	36	(100.0%)	28	(100.0%)	64	(100.0%)
Completed*	25	(69.4%)	17	(60.7%)	42	(65.6%)
Early Withdrawal	11	(30.6%)	11	(39.3%)	22	(34.4%)
Intention-to-Treat Population	35	(97.2%)	28	(100.0%)	63	(98.4%)
Per-Protocol Population	23	(63.9%)	20	(71.4%)	43	(67.2%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: PID 004.24086/004.24089 was screened and failed, then was screened and randomised at a later date, therefore is counted twice
* Completed=Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : United States of America (22 Centres)
Age Group : Adolescents

Study Stage / Population	Paroxetine (N=58)		Placebo (N=60)		Total (N=157)	
	Treatment Group					
Screened Only	0		0		39	
Randomised	58	(100.0%)	60	(100.0%)	118	(100.0%)
Completed*	42	(72.4%)	35	(58.3%)	77	(65.3%)
Early Withdrawal	16	(27.6%)	25	(41.7%)	41	(34.7%)
Intention-to-Treat Population	58	(100.0%)	59	(98.3%)	117	(99.2%)
Per-Protocol Population	45	(77.6%)	40	(66.7%)	85	(72.0%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: PID 004.24086/004.24089 was screened and failed, then was screened and randomised at a later date, therefore is counted twice
* Completed=Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : United States of America (22 Centres)
Age Group : Total

Study Stage / Population	Paroxetine (N=94)		Placebo (N=88)		Total (N=247)	
	Treatment Group					
Screened Only	0		0		65	
Randomised	94	(100.0%)	88	(100.0%)	182	(100.0%)
Completed*	67	(71.3%)	52	(59.1%)	119	(65.4%)
Early Withdrawal	27	(28.7%)	36	(40.9%)	63	(34.6%)
Intention-to-Treat Population	93	(98.9%)	87	(98.9%)	180	(98.9%)
Per-Protocol Population	68	(72.3%)	60	(68.2%)	128	(70.3%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: PID 004.24086/004.24089 was screened and failed, then was screened and randomised at a later date, therefore is counted twice
* Completed=Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : Belgium (2 Centres)
Age Group : Children

Study Stage/Population	Treatment Group: Paroxetine (N=1)	Placebo (N=0)	Total (N=1)
Screened Only	0	0	0
Randomised	1 (100.0%)	0	1 (100.0%)
Completed*	1 (100.0%)	0	1 (100.0%)
Early Withdrawal	0	0	0
Intention-to-Treat Population	1 (100.0%)	0	1 (100.0%)
Per-Protocol Population	1 (100.0%)	0	1 (100.0%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: PID 004.24086/004.24089 was screened and failed, then was screened and randomised at a later date, therefore is counted twice
* Completed=Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : Belgium (2 Centres)
Age Group : Adolescents

Study Stage / Population	Treatment Group: Paroxetine (N=5)		Placebo (N=5)		Total (N=10)	
Screened Only	0		0		0	
Randomised	5	(100.0%)	5	(100.0%)	10	(100.0%)
Completed*	4	(80.0%)	2	(40.0%)	6	(60.0%)
Early Withdrawal	1	(20.0%)	3	(60.0%)	4	(40.0%)
Intention-to-Treat Population	4	(80.0%)	5	(100.0%)	9	(90.0%)
Per-Protocol Population	3	(60.0%)	2	(40.0%)	5	(50.0%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: PID 004.24086/004.24089 was screened and failed, then was screened and randomised at a later date, therefore is counted twice
* Completed=Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : Belgium (2 Centres)
Age Group : Total

Study Stage / Population	Paroxetine (N=6)		Placebo (N=5)		Total (N=11)	
	Treatment Group					
Screened Only	0		0		0	
Randomised	6	(100.0%)	5	(100.0%)	11	(100.0%)
Completed*	5	(83.3%)	2	(40.0%)	7	(63.6%)
Early Withdrawal	1	(16.7%)	3	(60.0%)	4	(36.4%)
Intention-to-Treat Population	5	(83.3%)	5	(100.0%)	10	(90.9%)
Per-Protocol Population	4	(66.7%)	2	(40.0%)	6	(54.5%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: PID 004.24086/004.24089 was screened and failed, then was screened and randomised at a later date, therefore is counted twice
* Completed=Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : South Africa (10 Centres)
Age Group : Children

Study Stage/Population	Paroxetine (N=9)		Placebo (N=13)		Total (N=32)	
	Treatment Group					
Screened Only	0		0		10	
Randomised	9	(100.0%)	13	(100.0%)	22	(100.0%)
Completed*	5	(55.6%)	9	(69.2%)	14	(63.6%)
Early Withdrawal	4	(44.4%)	4	(30.8%)	8	(36.4%)
Intention-to-Treat Population	9	(100.0%)	13	(100.0%)	22	(100.0%)
Per-Protocol Population	7	(77.8%)	9	(69.2%)	16	(72.7%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: PID 004.24086/004.24089 was screened and failed, then was screened and randomised at a later date, therefore is counted twice
* Completed=Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : South Africa (10 Centres)
Age Group : Adolescents

Study Stage / Population	Treatment Group: Paroxetine (N=41)		Placebo (N=37)		Total (N=93)	
Screened Only	0		0		15	
Randomised	41	(100.0%)	37	(100.0%)	78	(100.0%)
Completed*	35	(85.4%)	28	(75.7%)	63	(80.8%)
Early Withdrawal	6	(14.6%)	9	(24.3%)	15	(19.2%)
Intention-to-Treat Population	41	(100.0%)	37	(100.0%)	78	(100.0%)
Per-Protocol Population	34	(82.9%)	28	(75.7%)	62	(79.5%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: PID 004.24086/004.24089 was screened and failed, then was screened and randomised at a later date, therefore is counted twice
* Completed=Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : South Africa (10 Centres)
Age Group : Total

Study Stage / Population	Paroxetine (N=50)		Placebo (N=50)		Total (N=125)	
	Treatment Group					
Screened Only	0		0		25	
Randomised	50	(100.0%)	50	(100.0%)	100	(100.0%)
Completed*	40	(80.0%)	37	(74.0%)	77	(77.0%)
Early Withdrawal	10	(20.0%)	13	(26.0%)	23	(23.0%)
Intention-to-Treat Population	50	(100.0%)	50	(100.0%)	100	(100.0%)
Per-Protocol Population	41	(82.0%)	37	(74.0%)	78	(78.0%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Note: PID 004.24086/004.24089 was screened and failed, then was screened and randomised at a later date, therefore is counted twice
* Completed=Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

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Table 13.2.1

Number (%) of Patients with Protocol Violations Leading to Exclusion from the Per-Protocol Analysis

Intention-To-Treat Population

Age Group:Children

	Treatment Group Paroxetine (N=46)	Placebo (N=45)	Total (N=91)
Total number of patients excluded*	13(28.3%)	13(28.9%)	26(28.6%)
Patient is taking or has taken psychoactive medications	3(6.5%)	3(6.7%)	6(6.6%)
Patient Requiring More Than One Dosage Reduction	1(2.2%)	0	1(1.1%)
Patient Missed more than 3 Consecutive days Medication	5(10.9%)	7(15.6%)	12(13.2%)
Patient had exposure to less than 4 weeks Duration of Randomised Study Medication	4(8.7%)	1(2.2%)	5(5.5%)
Study medication non-compliance	1(2.2%)	2(4.4%)	3(3.3%)
Total number of patients with no protocol violations	33(71.7%)	32(71.1%)	65(71.4%)

* a patient could have more than one protocol violation leading to exclusion

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Table 13.2.1

Number (%) of Patients with Protocol Violations Leading to Exclusion from the Per-Protocol Analysis

Intention-To-Treat Population

Age Group:Adolescents

	Treatment Group Paroxetine (N=117)	Placebo (N=111)	Total (N=228)
Total number of patients excluded*	24(20.5%)	32(28.8%)	56(24.6%)
Patients had concurrent major depressive episode	4(3.4%)	1(0.9%)	5(2.2%)
Patient is taking or has taken psychoactive medications	6(5.1%)	3(2.7%)	9(3.9%)
Patient Requiring More Than One Dosage Reduction	0	1(0.9%)	1(0.4%)
Patient Missed more than 3 Consecutive days Medication	11(9.4%)	18(16.2%)	29(12.7%)
Patient had exposure to less than 4 weeks Duration of Randomised Study Medication	5(4.3%)	11(9.9%)	16(7.0%)
Study medication non-compliance	1(0.9%)	1(0.9%)	2(0.9%)
Total number of patients with no protocol violations	93(79.5%)	79(71.2%)	172(75.4%)

* a patient could have more than one protocol violation leading to exclusion

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Table 13.2.1

Number (%) of Patients with Protocol Violations Leading to Exclusion from the Per-Protocol Analysis

Intention-To-Treat Population

Age Group:Total

	Treatment Group Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Total number of patients excluded*	37(22.7%)	45(28.8%)	82(25.7%)
Patients had concurrent major depressive episode	4(2.5%)	1(0.6%)	5(1.6%)
Patient is taking or has taken psychoactive medications	9(5.5%)	6(3.8%)	15(4.7%)
Patient Requiring More Than One Dosage Reduction	1(0.6%)	1(0.6%)	2(0.6%)
Patient Missed more than 3 Consecutive days Medication	16(9.8%)	25(16.0%)	41(12.9%)
Patient had exposure to less than 4 weeks Duration of Randomised Study Medication	9(5.5%)	12(7.7%)	21(6.6%)
Study medication non-compliance	2(1.2%)	3(1.9%)	5(1.6%)
Total number of patients with no protocol violations	126(77.3%)	111(71.2%)	237(74.3%)

* a patient could have more than one protocol violation leading to exclusion

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Table 13.2.2

Number (%) of Patients with Protocol Deviations Included in the Per-Protocol Analysis

Intention-To-Treat Population

Age Group:Children

	Treatment Group Paroxetine (N=46)	Placebo (N=45)	Total (N=91)
Total number of patients included with a deviation**	1(2.2%)	1(2.2%)	2(2.2%)
Patient has serious illness that contraindicates use of Paroxetine	1(2.2%)	0	1(1.1%)
Clinically significant abnormal ECGs(PD)	0	1(2.2%)	1(1.1%)
Total number of patients with no protocol deviations	45(97.8%)	44(97.8%)	89(97.8%)

** a patient could have more than one protocol deviation

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Table 13.2.2

Number (%) of Patients with Protocol Deviations Included in the Per-Protocol Analysis

Intention-To-Treat Population

Age Group:Adolescents

	Treatment Group Paroxetine (N=117)	Placebo (N=111)	Total (N=228)
Total number of patients included with a deviation**	0	0	0
Total number of patients with no protocol deviations	117(100.0%)	110(99.1%)	227(99.6%)

** a patient could have more than one protocol deviation

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Table 13.2.2

Number (%) of Patients with Protocol Deviations Included in the Per-Protocol Analysis

Intention-To-Treat Population

Age Group:Total

	Treatment Group Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Total number of patients included with a deviation**	1(0.6%)	1(0.6%)	2(0.6%)
Patient has serious illness that contraindicates use of Paroxetine	1(0.6%)	0	1(0.3%)
Clinically significant abnormal ECGs(PD)	0	1(0.6%)	1(0.3%)
Total number of patients with no protocol deviations	162(99.4%)	154(98.7%)	316(99.1%)

** a patient could have more than one protocol deviation

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Table 13.3.1a

Number (%) of Patients Who Were Withdrawn Pre-Randomisation by the Reason for Withdrawal

Screening Only Population

Reason For Early Withdrawal	--Treatment Group--- No Therapy Dispensed (N=103)	
Baseline Adverse Experience	0	
Does not meet inclusion/exclusion criteria	64	(62.1%)
Protocol deviation (including non-compliance)	4	(3.9%)
Lost to Follow-up	7	(6.8%)
Other+	28	(27.2%)
Total withdrawn	103	(100.0%)

+ Includes unknown and non-study-related personal reasons

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Table 13.3.1b

Number (%) of Randomised Patients Who Completed the Study or Were Withdrawn (by Reason)

Intention-To-Treat Population

Age Group:Children

Reason For Study Conclusion	Treatment Group: Paroxetine (N=46)		Placebo (N=45)		Total (N=91)	
Completed Study*	31	(67.4%)	29	(64.4%)	60	(65.9%)
Adverse Experience	2	(4.3%)	2	(4.4%)	4	(4.4%)
Lack of Efficacy	1	(2.2%)	7	(15.6%)	8	(8.8%)
Protocol deviation (including non-compliance)	6	(13.0%)	4	(8.9%)	10	(11.0%)
Lost to Follow-up	1	(2.2%)	3	(6.7%)	4	(4.4%)
Other+	5	(10.9%)	0		5	(5.5%)
Total withdrawn	15	(32.6%)	16	(35.6%)	31	(34.1%)

* Completed= Subjects who completed a week 16 visit CRF,note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

+ Includes unknown and non-study-related personal reasons

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Table 13.3.1b

Number (%) of Randomised Patients Who Completed the Study or Were Withdrawn (by Reason)

Intention-To-Treat Population

Age Group:Adolescents

Reason For Study Conclusion	Treatment Group: Paroxetine (N=117)		Placebo (N=111)		Total (N=228)	
Completed Study*	92	(78.6%)	74	(66.7%)	166	(72.8%)
Adverse Experience	8	(6.8%)	1	(0.9%)	9	(3.9%)
Lack of Efficacy	5	(4.3%)	15	(13.5%)	20	(8.8%)
Protocol deviation (including non-compliance)	5	(4.3%)	7	(6.3%)	12	(5.3%)
Lost to Follow-up	3	(2.6%)	7	(6.3%)	10	(4.4%)
Other+	4	(3.4%)	7	(6.3%)	11	(4.8%)
Total withdrawn	25	(21.4%)	37	(33.3%)	62	(27.2%)

* Completed= Subjects who completed a week 16 visit CRF,note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

+ Includes unknown and non-study-related personal reasons

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Table 13.3.1b

Number (%) of Randomised Patients Who Completed the Study or Were Withdrawn (by Reason)

Intention-To-Treat Population

Age Group:Total

Reason For Study Conclusion	Treatment Group: Paroxetine (N=163)		Placebo (N=156)		Total (N=319)	
Completed Study*	123	(75.5%)	103	(66.0%)	226	(70.8%)
Adverse Experience	10	(6.1%)	3	(1.9%)	13	(4.1%)
Lack of Efficacy	6	(3.7%)	22	(14.1%)	28	(8.8%)
Protocol deviation (including non-compliance)	11	(6.7%)	11	(7.1%)	22	(6.9%)
Lost to Follow-up	4	(2.5%)	10	(6.4%)	14	(4.4%)
Other+	9	(5.5%)	7	(4.5%)	16	(5.0%)
Total withdrawn	40	(24.5%)	53	(34.0%)	93	(29.2%)

* Completed= Subjects who completed a week 16 visit CRF,note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

+ Includes unknown and non-study-related personal reasons

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Table 13.3.1c

Number (%) of Randomised Patients Who Completed the Study or Were Withdrawn (by Reason)

Per-Protocol Population

Age Group:Children

Reason For Study Conclusion	Treatment Group: Paroxetine (N=32)		Placebo (N=32)		Total (N=64)	
Completed Study*	26	(81.3%)	24	(75.0%)	50	(78.1%)
Adverse Experience	2	(6.3%)	1	(3.1%)	3	(4.7%)
Lack of Efficacy	1	(3.1%)	6	(18.8%)	7	(10.9%)
Protocol deviation (including non-compliance)	2	(6.3%)	0		2	(3.1%)
Lost to Follow-up	1	(3.1%)	1	(3.1%)	2	(3.1%)
Other+	0		0		0	
Total withdrawn	6	(18.8%)	8	(25.0%)	14	(21.9%)

*Completed= Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

+ Includes unknown and non-study-related personal reasons

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Table 13.3.1c

Number (%) of Randomised Patients Who Completed the Study or Were Withdrawn (by Reason)

Per-Protocol Population

Age Group:Adolescents

Reason For Study Conclusion	Treatment Group: Paroxetine (N=92)		Placebo (N=78)		Total (N=170)	
Completed Study*	78	(84.8%)	63	(80.8%)	141	(82.9%)
Adverse Experience	4	(4.3%)	0		4	(2.4%)
Lack of Efficacy	4	(4.3%)	8	(10.3%)	12	(7.1%)
Protocol deviation (including non-compliance)	1	(1.1%)	0		1	(0.6%)
Lost to Follow-up	1	(1.1%)	3	(3.8%)	4	(2.4%)
Other+	4	(4.3%)	4	(5.1%)	8	(4.7%)
Total withdrawn	14	(15.2%)	15	(19.2%)	29	(17.1%)

*Completed= Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

+ Includes unknown and non-study-related personal reasons

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Table 13.3.1c

Number (%) of Randomised Patients Who Completed the Study or Were Withdrawn (by Reason)

Per-Protocol Population

Age Group:Total

Reason For Study Conclusion	Treatment Group: Paroxetine (N=124)		Placebo (N=110)		Total (N=234)	
Completed Study*	104	(83.9%)	87	(79.1%)	191	(81.6%)
Adverse Experience	6	(4.8%)	1	(0.9%)	7	(3.0%)
Lack of Efficacy	5	(4.0%)	14	(12.7%)	19	(8.1%)
Protocol deviation (including non-compliance)	3	(2.4%)	0		3	(1.3%)
Lost to Follow-up	2	(1.6%)	4	(3.6%)	6	(2.6%)
Other+	4	(3.2%)	4	(3.6%)	8	(3.4%)
Total withdrawn	20	(16.1%)	23	(20.9%)	43	(18.4%)

*Completed= Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication before relative day 99 and hence had their visit re-categorised as Week 12

+ Includes unknown and non-study-related personal reasons

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Table 13.3.2

Number (%) of Patients Remaining / Withdrawing from the Study at Each Visit

Intention-To-Treat Population

Visit	Status	Paroxetine (N=163)		Placebo (N=156)		Total (N=319)	
Baseline	Entered	163	(100.0%)	156	(100.0%)	319	(100.0%)
Week 1	Still in Study	160	(98.2%)	151	(96.8%)	311	(97.5%)
	Withdrawn	3	(1.8%)	5	(3.2%)	8	(2.5%)
Week 2	Still in Study	158	(96.9%)	149	(95.5%)	307	(96.2%)
	Withdrawn	2	(1.3%)	2	(1.3%)	4	(1.3%)
Week 3	Still in Study	157	(96.3%)	147	(94.2%)	304	(95.3%)
	Withdrawn	1	(0.6%)	2	(1.3%)	3	(1.0%)
Week 4	Still in Study	149	(91.4%)	141	(90.4%)	290	(90.9%)
	Withdrawn	8	(5.1%)	6	(4.1%)	14	(4.6%)
Week 6	Still in Study	145	(89.0%)	131	(84.0%)	276	(86.5%)
	Withdrawn	4	(2.7%)	10	(7.1%)	14	(4.8%)
Week 8	Still in Study	140	(85.9%)	118	(75.6%)	258	(80.9%)
	Withdrawn	5	(3.4%)	13	(9.9%)	18	(6.5%)
Week 10	Still in Study	134	(82.2%)	113	(72.4%)	247	(77.4%)
	Withdrawn	6	(4.3%)	5	(4.2%)	11	(4.3%)
Week 12	Still in Study	128	(78.5%)	105	(67.3%)	233	(73.0%)
	Withdrawn	6	(4.5%)	7	(6.2%)	13	(5.3%)
	Completed	0		1	(0.6%)	1	(0.3%)
Week 16	Still in Study	1	(0.6%)	0		1	(0.3%)
	Withdrawn	5	(3.9%)	3	(2.9%)	8	(3.4%)
	Completed	122	(74.8%)	102	(65.4%)	224	(70.2%)
Post Week 16	Completed	1	(0.6%)	0		1	(0.3%)

* Completed = Subjects who completed a week 16 visit CRF, note 1 subject(s) took their last dose of non-taper study medication befor relative day 99 and hence had their visit re-categorised as Week 12
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 number of patients at baseline, percentages for patients withdrawing at each visit are based on the total number of patients at each visit.

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Table 13.3.3

Cumulative Number (%) of All Randomised Patients Withdrawn During the Study by Reason for Withdrawal

Intention-To-Treat Population
Age Group : Children

	Treatment Group																							
	Paroxetine (N = 46)								Placebo (N = 45)								Total (N = 91)							
	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	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Week 2	0	0.0	0	0.0	2	4.3	2	4.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.2	2	2.2
Week 3	0	0.0	0	0.0	3	6.5	3	6.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3.3	3	3.3
Week 4	0	0.0	0	0.0	4	8.7	4	8.7	0	0.0	3	6.7	0	0.0	3	6.7	0	0.0	3	3.3	4	4.4	7	7.7
Week 6	0	0.0	0	0.0	4	8.7	4	8.7	1	2.2	4	8.9	2	4.4	7	15.6	1	1.1	4	4.4	6	6.6	11	12.1
Week 8	2	4.3	0	0.0	5	10.9	7	15.2	2	4.4	6	13.3	3	6.7	11	24.4	4	4.4	6	6.6	8	8.8	18	19.8
Week 10	2	4.3	1	2.2	8	17.4	11	23.9	2	4.4	6	13.3	4	8.9	12	26.7	4	4.4	7	7.7	12	13.2	23	25.3
Week 12	2	4.3	1	2.2	10	21.7	13	28.3	2	4.4	7	15.6	6	13.3	15	33.3	4	4.4	8	8.8	16	17.6	28	30.8
Week 16	2	4.3	1	2.2	12	26.1	15	32.6	2	4.4	7	15.6	7	15.6	16	35.6	4	4.4	8	8.8	19	20.9	31	34.1
Post Week 16	2	4.3	1	2.2	12	26.1	15	32.6	2	4.4	7	15.6	7	15.6	16	35.6	4	4.4	8	8.8	19	20.9	31	34.1

AE = adverse experience LE = lack of efficacy
Other = Protocol Deviation (including non-compliance), Lost to follow-up, Unknown and non-study related personal reasons

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Table 13.3.3

Cumulative Number (%) of All Randomised Patients Withdrawn During the Study by Reason for Withdrawal

Intention-To-Treat Population
Age Group : Adolescents

	Treatment Group																							
	Paroxetine (N = 117)								Placebo (N = 111)								Total (N = 228)							
	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	1	0.9	1	0.9	1	0.9	3	2.6	1	0.9	0	0.0	4	3.6	5	4.5	2	0.9	1	0.4	5	2.2	8	3.5
Week 2	1	0.9	1	0.9	1	0.9	3	2.6	1	0.9	2	1.8	4	3.6	7	6.3	2	0.9	3	1.3	5	2.2	10	4.4
Week 3	1	0.9	1	0.9	1	0.9	3	2.6	1	0.9	4	3.6	4	3.6	9	8.1	2	0.9	5	2.2	5	2.2	12	5.3
Week 4	4	3.4	1	0.9	5	4.3	10	8.5	1	0.9	5	4.5	6	5.4	12	10.8	5	2.2	6	2.6	11	4.8	22	9.6
Week 6	7	6.0	2	1.7	5	4.3	14	12.0	1	0.9	7	6.3	10	9.0	18	16.2	8	3.5	9	3.9	15	6.6	32	14.0
Week 8	7	6.0	2	1.7	7	6.0	16	13.7	1	0.9	10	9.0	16	14.4	27	24.3	8	3.5	12	5.3	23	10.1	43	18.9
Week 10	7	6.0	3	2.6	8	6.8	18	15.4	1	0.9	13	11.7	17	15.3	31	27.9	8	3.5	16	7.0	25	11.0	49	21.5
Week 12	7	6.0	5	4.3	10	8.5	22	18.8	1	0.9	14	12.6	20	18.0	35	31.5	8	3.5	19	8.3	30	13.2	57	25.0
Week 16	8	6.8	5	4.3	12	10.3	25	21.4	1	0.9	15	13.5	21	18.9	37	33.3	9	3.9	20	8.8	33	14.5	62	27.2
Post Week 16	8	6.8	5	4.3	12	10.3	25	21.4	1	0.9	15	13.5	21	18.9	37	33.3	9	3.9	20	8.8	33	14.5	62	27.2

AE = adverse experience LE = lack of efficacy
Other = Protocol Deviation (including non-compliance), Lost to follow-up, Unknown and non-study related personal reasons

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Table 13.3.3

Cumulative Number (%) of All Randomised Patients Withdrawn During the Study by Reason for Withdrawal

Intention-To-Treat Population
Age Group : Total

	Treatment Group																							
	Paroxetine (N = 163)								Placebo (N = 156)								Total (N = 319)							
	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	1	0.6	1	0.6	1	0.6	3	1.8	1	0.6	0	0.0	4	2.6	5	3.2	2	0.6	1	0.3	5	1.6	8	2.5
Week 2	1	0.6	1	0.6	3	1.8	5	3.1	1	0.6	2	1.3	4	2.6	7	4.5	2	0.6	3	0.9	7	2.2	12	3.8
Week 3	1	0.6	1	0.6	4	2.5	6	3.7	1	0.6	4	2.6	4	2.6	9	5.8	2	0.6	5	1.6	8	2.5	15	4.7
Week 4	4	2.5	1	0.6	9	5.5	14	8.6	1	0.6	8	5.1	6	3.8	15	9.6	5	1.6	9	2.8	15	4.7	29	9.1
Week 6	7	4.3	2	1.2	9	5.5	18	11.0	2	1.3	11	7.1	12	7.7	25	16.0	9	2.8	13	4.1	21	6.6	43	13.5
Week 8	9	5.5	2	1.2	12	7.4	23	14.1	3	1.9	16	10.3	19	12.2	38	24.4	12	3.8	18	5.6	31	9.7	61	19.1
Week 10	9	5.5	4	2.5	16	9.8	29	17.8	3	1.9	19	12.2	21	13.5	43	27.6	12	3.8	23	7.2	37	11.6	72	22.6
Week 12	9	5.5	6	3.7	20	12.3	35	21.5	3	1.9	21	13.5	26	16.7	50	32.1	12	3.8	27	8.5	46	14.4	85	26.6
Week 16	10	6.1	6	3.7	24	14.7	40	24.5	3	1.9	22	14.1	28	17.9	53	34.0	13	4.1	28	8.8	52	16.3	93	29.2
Post Week 16	10	6.1	6	3.7	24	14.7	40	24.5	3	1.9	22	14.1	28	17.9	53	34.0	13	4.1	28	8.8	52	16.3	93	29.2

AE = adverse experience LE = lack of efficacy
Other = Protocol Deviation (including non-compliance), Lost to follow-up, Unknown and non-study related personal reasons

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population
Age Group: Children
Country : Belgium

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=1)	Total (N=1)
301	xxxxxxx	Randomised	1 (100.0%)	1 (100.0%)
		Completed	1 (100.0%)	1 (100.0%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population
Age Group: Children
Country : Canada

Centre Number	Investigator	Status	Treatment Group: Paroxetine (N=1)	Placebo (N=4)	Total (N=5)
100	xxxxxxx	Randomised	0	1 (25.0%)	1 (20.0%)
		Completed	0	1 (25.0%)	1 (20.0%)
101	xxxxx	Randomised	1 (100.0%)	3 (75.0%)	4 (80.0%)
		Completed	0	2 (50.0%)	2 (40.0%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population
Age Group: Children
Country : South Africa

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=9)	Placebo (N=13)	Total (N=22)
201	xxxxx	Randomised	1 (11.1%)	0	1 (4.5%)
		Completed	1 (11.1%)	0	1 (4.5%)
202	xxxxx	Randomised	3 (33.3%)	3 (23.1%)	6 (27.3%)
		Completed	2 (22.2%)	1 (7.7%)	3 (13.6%)
203	xxxxxxxxx	Randomised	1 (11.1%)	0	1 (4.5%)
204	xxxxx	Randomised	1 (11.1%)	1 (7.7%)	2 (9.1%)
		Completed	0	1 (7.7%)	1 (4.5%)
205	xxxxxxxx	Randomised	0	1 (7.7%)	1 (4.5%)
206	xxxxxxxx	Randomised	1 (11.1%)	3 (23.1%)	4 (18.2%)
		Completed	1 (11.1%)	2 (15.4%)	3 (13.6%)
207	xxxxx	Randomised	2 (22.2%)	1 (7.7%)	3 (13.6%)
		Completed	1 (11.1%)	1 (7.7%)	2 (9.1%)
208	xxxxx	Randomised	0	1 (7.7%)	1 (4.5%)
		Completed	0	1 (7.7%)	1 (4.5%)
209	xxxxxxx	Randomised	0	3 (23.1%)	3 (13.6%)
		Completed	0	3 (23.1%)	3 (13.6%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population
Age Group: Children
Country : United States of America

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=35)	Placebo (N=28)	Total (N=63)
001	xxxxxx	Randomised	1 (2.9%)	1 (3.6%)	2 (3.2%)
		Completed	1 (2.9%)	1 (3.6%)	2 (3.2%)
002	xxxxxxx	Randomised	3 (8.6%)	0	3 (4.8%)
		Completed	1 (2.9%)	0	1 (1.6%)
003	xxxxxxx	Randomised	5 (14.3%)	2 (7.1%)	7 (11.1%)
		Completed	4 (11.4%)	2 (7.1%)	6 (9.5%)
005	xxxxxxxx	Randomised	3 (8.6%)	4 (14.3%)	7 (11.1%)
		Completed	2 (5.7%)	3 (10.7%)	5 (7.9%)
007	xxxxx	Randomised	4 (11.4%)	5 (17.9%)	9 (14.3%)
		Completed	4 (11.4%)	2 (7.1%)	6 (9.5%)
009	xxxxz	Randomised	1 (2.9%)	0	1 (1.6%)
010	xxxxxx	Randomised	1 (2.9%)	1 (3.6%)	2 (3.2%)
		Completed	1 (2.9%)	1 (3.6%)	2 (3.2%)
011	xxxxxxxxx	Randomised	0	1 (3.6%)	1 (1.6%)
012	xxxxx	Randomised	1 (2.9%)	2 (7.1%)	3 (4.8%)
		Completed	1 (2.9%)	2 (7.1%)	3 (4.8%)
013	xxxxx	Randomised	3 (8.6%)	1 (3.6%)	4 (6.3%)
		Completed	3 (8.6%)	0	3 (4.8%)
014	xxxxx	Randomised	2 (5.7%)	1 (3.6%)	3 (4.8%)
		Completed	2 (5.7%)	1 (3.6%)	3 (4.8%)
015	xxxxxxx	Randomised	4 (11.4%)	4 (14.3%)	8 (12.7%)
		Completed	2 (5.7%)	1 (3.6%)	3 (4.8%)
017	xxxxxxxx	Randomised	3 (8.6%)	1 (3.6%)	4 (6.3%)
		Completed	2 (5.7%)	1 (3.6%)	3 (4.8%)
019	xxxxxx	Randomised	2 (5.7%)	2 (7.1%)	4 (6.3%)
		Completed	1 (2.9%)	2 (7.1%)	3 (4.8%)
020	xxxxxxx	Randomised	1 (2.9%)	1 (3.6%)	2 (3.2%)
		Completed	1 (2.9%)	1 (3.6%)	2 (3.2%)
023	xxxxxxxxx	Randomised	1 (2.9%)	1 (3.6%)	2 (3.2%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population
Age Group: Children
Country : United States of America

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=35)	Placebo (N=28)	Total (N=63)
024	xxxxx	Randomised	0	1 (3.6%)	1 (1.6%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population
Age Group: Adolescents
Country : Belgium

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=4)	Placebo (N=5)	Total (N=9)
300	xxxxxxxx	Randomised	2 (50.0%)	3 (60.0%)	5 (55.6%)
		Completed	2 (50.0%)	1 (20.0%)	3 (33.3%)
301	xxxxxx	Randomised	2 (50.0%)	2 (40.0%)	4 (44.4%)
		Completed	2 (50.0%)	1 (20.0%)	3 (33.3%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population
Age Group: Adolescents
Country : Canada

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=14)	Placebo (N=10)	Total (N=24)
100	xxxxx	Randomised	5 (35.7%)	4 (40.0%)	9 (37.5%)
		Completed	3 (21.4%)	4 (40.0%)	7 (29.2%)
101	xxxxx	Randomised	4 (28.6%)	1 (10.0%)	5 (20.8%)
		Completed	4 (28.6%)	1 (10.0%)	5 (20.8%)
102	xxxxxxxxxxxx	Randomised	2 (14.3%)	2 (20.0%)	4 (16.7%)
		Completed	1 (7.1%)	1 (10.0%)	2 (8.3%)
103	xxxxxx	Randomised	3 (21.4%)	3 (30.0%)	6 (25.0%)
		Completed	3 (21.4%)	3 (30.0%)	6 (25.0%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population
Age Group: Adolescents
Country : South Africa

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=41)	Placebo (N=37)	Total (N=78)
200	xxxxxx	Randomised	8 (19.5%)	7 (18.9%)	15 (19.2%)
		Completed	6 (14.6%)	7 (18.9%)	13 (16.7%)
201	xxxxxx	Randomised	2 (4.9%)	2 (5.4%)	4 (5.1%)
		Completed	2 (4.9%)	1 (2.7%)	3 (3.8%)
202	xxxxx	Randomised	3 (7.3%)	3 (8.1%)	6 (7.7%)
		Completed	3 (7.3%)	2 (5.4%)	5 (6.4%)
203	xxxxxxxxx	Randomised	1 (2.4%)	3 (8.1%)	4 (5.1%)
		Completed	1 (2.4%)	1 (2.7%)	2 (2.6%)
204	xxxxxx	Randomised	4 (9.8%)	5 (13.5%)	9 (11.5%)
		Completed	4 (9.8%)	3 (8.1%)	7 (9.0%)
205	xxxxxxxx	Randomised	4 (9.8%)	4 (10.8%)	8 (10.3%)
		Completed	3 (7.3%)	4 (10.8%)	7 (9.0%)
206	xxxxxxx	Randomised	5 (12.2%)	3 (8.1%)	8 (10.3%)
		Completed	5 (12.2%)	3 (8.1%)	8 (10.3%)
207	xxxxx	Randomised	5 (12.2%)	5 (13.5%)	10 (12.8%)
		Completed	4 (9.8%)	4 (10.8%)	8 (10.3%)
209	xxxxxxx	Randomised	9 (22.0%)	5 (13.5%)	14 (17.9%)
		Completed	7 (17.1%)	3 (8.1%)	10 (12.8%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population
Age Group: Adolescents
Country : United States of America

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=58)	Placebo (N=59)	Total (N=117)
001	xxxxxx	Randomised	1 (1.7%)	1 (1.7%)	2 (1.7%)
		Completed	1 (1.7%)	1 (1.7%)	2 (1.7%)
002	xxxxxxxx	Randomised	4 (6.9%)	7 (11.9%)	11 (9.4%)
		Completed	3 (5.2%)	7 (11.9%)	10 (8.5%)
003	xxxxxxx	Randomised	3 (5.2%)	4 (6.8%)	7 (6.0%)
		Completed	3 (5.2%)	3 (5.1%)	6 (5.1%)
004	xxxxxx	Randomised	1 (1.7%)	1 (1.7%)	2 (1.7%)
		Completed	1 (1.7%)	0	1 (0.9%)
005	xxxxxx	Randomised	5 (8.6%)	4 (6.8%)	9 (7.7%)
		Completed	3 (5.2%)	2 (3.4%)	5 (4.3%)
006	xxxxxxx	Randomised	3 (5.2%)	2 (3.4%)	5 (4.3%)
		Completed	3 (5.2%)	2 (3.4%)	5 (4.3%)
007	xxxx	Randomised	7 (12.1%)	5 (8.5%)	12 (10.3%)
		Completed	5 (8.6%)	4 (6.8%)	9 (7.7%)
009	xxxxx	Randomised	2 (3.4%)	4 (6.8%)	6 (5.1%)
		Completed	2 (3.4%)	3 (5.1%)	5 (4.3%)
011	xxxxxxxxx	Randomised	2 (3.4%)	0	2 (1.7%)
		Completed	1 (1.7%)	0	1 (0.9%)
012	xxxxx	Randomised	2 (3.4%)	2 (3.4%)	4 (3.4%)
		Completed	1 (1.7%)	2 (3.4%)	3 (2.6%)
013	xxxxx	Randomised	2 (3.4%)	4 (6.8%)	6 (5.1%)
		Completed	2 (3.4%)	2 (3.4%)	4 (3.4%)
014	xxxxxxxx	Randomised	5 (8.6%)	5 (8.5%)	10 (8.5%)
		Completed	2 (3.4%)	2 (3.4%)	4 (3.4%)
015	xxxxxxx	Randomised	5 (8.6%)	5 (8.5%)	10 (8.5%)
		Completed	4 (6.9%)	2 (3.4%)	6 (5.1%)
017	xxxxxxx	Randomised	0	2 (3.4%)	2 (1.7%)
		Completed	0	1 (1.7%)	1 (0.9%)
019	xxxxxx	Randomised	4 (6.9%)	4 (6.8%)	8 (6.8%)
		Completed	4 (6.9%)	0	4 (3.4%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population
Age Group: Adolescents
Country : United States of America

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=58)	Placebo (N=59)	Total (N=117)
020	xxxxxx	Randomised	2 (3.4%)	2 (3.4%)	4 (3.4%)
		Completed	2 (3.4%)	1 (1.7%)	3 (2.6%)
021	xxxxxxx	Randomised	2 (3.4%)	2 (3.4%)	4 (3.4%)
		Completed	2 (3.4%)	1 (1.7%)	3 (2.6%)
022	xxxxxxxxxxxxxxxxxx	Randomised	3 (5.2%)	3 (5.1%)	6 (5.1%)
		Completed	2 (3.4%)	2 (3.4%)	4 (3.4%)
023	xxxxxxxxx	Randomised	1 (1.7%)	0	1 (0.9%)
		Completed	1 (1.7%)	0	1 (0.9%)
024	xxxxx	Randomised	4 (6.9%)	2 (3.4%)	6 (5.1%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population
Age Group: Total
Country : Belgium

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=5)	Placebo (N=5)	Total (N=10)
300	xxxxx	Randomised	2 (40.0%)	3 (60.0%)	5 (50.0%)
		Completed	2 (40.0%)	1 (20.0%)	3 (30.0%)
301	xxxxxxx	Randomised	3 (60.0%)	2 (40.0%)	5 (50.0%)
		Completed	3 (60.0%)	1 (20.0%)	4 (40.0%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population
Age Group: Total
Country : Canada

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=15)	Placebo (N=14)	Total (N=29)
100	xxxxxxxxxx	Randomised	5 (33.3%)	5 (35.7%)	10 (34.5%)
		Completed	3 (20.0%)	5 (35.7%)	8 (27.6%)
101	xxxxx	Randomised	5 (33.3%)	4 (28.6%)	9 (31.0%)
		Completed	4 (26.7%)	3 (21.4%)	7 (24.1%)
102	xxxxxxxxxxxx	Randomised	2 (13.3%)	2 (14.3%)	4 (13.8%)
		Completed	1 (6.7%)	1 (7.1%)	2 (6.9%)
103	xxxxxx	Randomised	3 (20.0%)	3 (21.4%)	6 (20.7%)
		Completed	3 (20.0%)	3 (21.4%)	6 (20.7%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population
Age Group: Total
Country : South Africa

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=50)	Placebo (N=50)	Total (N=100)
200	xxxxxx	Randomised	8 (16.0%)	7 (14.0%)	15 (15.0%)
		Completed	6 (12.0%)	7 (14.0%)	13 (13.0%)
201	xxxxxx	Randomised	3 (6.0%)	2 (4.0%)	5 (5.0%)
		Completed	3 (6.0%)	1 (2.0%)	4 (4.0%)
202	xxxxxx	Randomised	6 (12.0%)	6 (12.0%)	12 (12.0%)
		Completed	5 (10.0%)	3 (6.0%)	8 (8.0%)
203	xxxxxxxxx	Randomised	2 (4.0%)	3 (6.0%)	5 (5.0%)
		Completed	1 (2.0%)	1 (2.0%)	2 (2.0%)
204	xxxxx	Randomised	5 (10.0%)	6 (12.0%)	11 (11.0%)
		Completed	4 (8.0%)	4 (8.0%)	8 (8.0%)
205	xxxxxxxx	Randomised	4 (8.0%)	5 (10.0%)	9 (9.0%)
		Completed	3 (6.0%)	4 (8.0%)	7 (7.0%)
206	xxxxxxx	Randomised	6 (12.0%)	6 (12.0%)	12 (12.0%)
		Completed	6 (12.0%)	5 (10.0%)	11 (11.0%)
207	xxxxxx	Randomised	7 (14.0%)	6 (12.0%)	13 (13.0%)
		Completed	5 (10.0%)	5 (10.0%)	10 (10.0%)
208	xxxxx	Randomised	0	1 (2.0%)	1 (1.0%)
		Completed	0	1 (2.0%)	1 (1.0%)
209	xxxxxxx	Randomised	9 (18.0%)	8 (16.0%)	17 (17.0%)
		Completed	7 (14.0%)	6 (12.0%)	13 (13.0%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population
Age Group: Total
Country : United States of America

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=93)	Placebo (N=87)	Total (N=180)
001	xxxxxx	Randomised	2 (2.2%)	2 (2.3%)	4 (2.2%)
		Completed	2 (2.2%)	2 (2.3%)	4 (2.2%)
002	xxxxxxx	Randomised	7 (7.5%)	7 (8.0%)	14 (7.8%)
		Completed	4 (4.3%)	7 (8.0%)	11 (6.1%)
003	xxxxxx	Randomised	8 (8.6%)	6 (6.9%)	14 (7.8%)
		Completed	7 (7.5%)	5 (5.7%)	12 (6.7%)
004	xxxxxx	Randomised	1 (1.1%)	1 (1.1%)	2 (1.1%)
		Completed	1 (1.1%)	0	1 (0.6%)
005	xxxxxxx	Randomised	8 (8.6%)	8 (9.2%)	16 (8.9%)
		Completed	5 (5.4%)	5 (5.7%)	10 (5.6%)
006	xxxxxxx	Randomised	3 (3.2%)	2 (2.3%)	5 (2.8%)
		Completed	3 (3.2%)	2 (2.3%)	5 (2.8%)
007	xxxxx	Randomised	11 (11.8%)	10 (11.5%)	21 (11.7%)
		Completed	9 (9.7%)	6 (6.9%)	15 (8.3%)
009	xxxxx	Randomised	3 (3.2%)	4 (4.6%)	7 (3.9%)
		Completed	2 (2.2%)	3 (3.4%)	5 (2.8%)
010	xxxxxx	Randomised	1 (1.1%)	1 (1.1%)	2 (1.1%)
		Completed	1 (1.1%)	1 (1.1%)	2 (1.1%)
011	xxxxxxxxx	Randomised	2 (2.2%)	1 (1.1%)	3 (1.7%)
		Completed	1 (1.1%)	0	1 (0.6%)
012	xxxxx	Randomised	3 (3.2%)	4 (4.6%)	7 (3.9%)
		Completed	2 (2.2%)	4 (4.6%)	6 (3.3%)
013	xxxxx	Randomised	5 (5.4%)	5 (5.7%)	10 (5.6%)
		Completed	5 (5.4%)	2 (2.3%)	7 (3.9%)
014	xxxxxxxx	Randomised	7 (7.5%)	6 (6.9%)	13 (7.2%)
		Completed	4 (4.3%)	3 (3.4%)	7 (3.9%)
015	xxxxxxxx	Randomised	9 (9.7%)	9 (10.3%)	18 (10.0%)
		Completed	6 (6.5%)	3 (3.4%)	9 (5.0%)
017	xxxxxxx	Randomised	3 (3.2%)	3 (3.4%)	6 (3.3%)
		Completed	2 (2.2%)	2 (2.3%)	4 (2.2%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population
Age Group: Total
Country : United States of America

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=93)	Placebo (N=87)	Total (N=180)
019	xxxxxxx	Randomised	6 (6.5%)	6 (6.9%)	12 (6.7%)
		Completed	5 (5.4%)	2 (2.3%)	7 (3.9%)
020	xxxxxx	Randomised	3 (3.2%)	3 (3.4%)	6 (3.3%)
		Completed	3 (3.2%)	2 (2.3%)	5 (2.8%)
021	xxxxxxx	Randomised	2 (2.2%)	2 (2.3%)	4 (2.2%)
		Completed	2 (2.2%)	1 (1.1%)	3 (1.7%)
022	xxxxxxxxxxxxxxxxxx	Randomised	3 (3.2%)	3 (3.4%)	6 (3.3%)
		Completed	2 (2.2%)	2 (2.3%)	4 (2.2%)
023	xxxxxxxxx	Randomised	2 (2.2%)	1 (1.1%)	3 (1.7%)
		Completed	1 (1.1%)	0	1 (0.6%)
024	xxxxx	Randomised	4 (4.3%)	3 (3.4%)	7 (3.9%)

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Table 13.5.1b

Number (%) of Patients by Gender and Race

Intention-To-Treat Population

Age Group : Children

		Treatment Group Paroxetine (N=46)	Placebo (N=45)	Total (N=91)
Gender	Female	21 (45.7%)	22 (48.9%)	43 (47.3%)
	Male	25 (54.3%)	23 (51.1%)	48 (52.7%)
Race	White	38 (82.6%)	41 (91.1%)	79 (86.8%)
	Black	2 (4.3%)	0	2 (2.2%)
	Oriental	1 (2.2%)	1 (2.2%)	2 (2.2%)
	Other	5 (10.9%)	3 (6.7%)	8 (8.8%)

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Table 13.5.1b

Number (%) of Patients by Gender and Race

Intention-To-Treat Population

Age Group : Adolescents

		Treatment Group: Paroxetine (N=117)	Placebo (N=111)	Total (N=228)
Gender	Female	71 (60.7%)	45 (40.5%)	116 (50.9%)
	Male	46 (39.3%)	66 (59.5%)	112 (49.1%)
Race	White	101 (86.3%)	90 (81.1%)	191 (83.8%)
	Black	2 (1.7%)	6 (5.4%)	8 (3.5%)
	Oriental	1 (0.9%)	1 (0.9%)	2 (0.9%)
	Other	13 (11.1%)	14 (12.6%)	27 (11.8%)

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Table 13.5.1b

Number (%) of Patients by Gender and Race

Intention-To-Treat Population

Age Group : Total

		Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Gender	Female	92 (56.4%)	67 (42.9%)	159 (49.8%)
	Male	71 (43.6%)	89 (57.1%)	160 (50.2%)
Race	White	139 (85.3%)	131 (84.0%)	270 (84.6%)
	Black	4 (2.5%)	6 (3.8%)	10 (3.1%)
	Oriental	2 (1.2%)	2 (1.3%)	4 (1.3%)
	Other	18 (11.0%)	17 (10.9%)	35 (11.0%)

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Table 13.5.1c

Number (%) of Patients by Gender and Race

Per-Protocol Population

Age Group : Children

		Treatment Group: Paroxetine (N=32)	Placebo (N=32)	Total (N=64)
Gender	Female	14 (43.8%)	16 (50.0%)	30 (46.9%)
	Male	18 (56.3%)	16 (50.0%)	34 (53.1%)
Race	White	29 (90.6%)	30 (93.8%)	59 (92.2%)
	Black	0	0	0
	Oriental	0	0	0
	Other	3 (9.4%)	2 (6.3%)	5 (7.8%)

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Table 13.5.1c

Number (%) of Patients by Gender and Race

Per-Protocol Population

Age Group : Adolescents

		Treatment Group: Paroxetine (N=92)	Placebo (N=78)	Total (N=170)
Gender	Female	61 (66.3%)	33 (42.3%)	94 (55.3%)
	Male	31 (33.7%)	45 (57.7%)	76 (44.7%)
Race	White	79 (85.9%)	62 (79.5%)	141 (82.9%)
	Black	2 (2.2%)	5 (6.4%)	7 (4.1%)
	Oriental	1 (1.1%)	1 (1.3%)	2 (1.2%)
	Other	10 (10.9%)	10 (12.8%)	20 (11.8%)

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Table 13.5.1c

Number (%) of Patients by Gender and Race

Per-Protocol Population

Age Group : Total

		Treatment Group: Paroxetine (N=124)	Placebo (N=110)	Total (N=234)
Gender	Female	75 (60.5%)	49 (44.5%)	124 (53.0%)
	Male	49 (39.5%)	61 (55.5%)	110 (47.0%)
Race	White	108 (87.1%)	92 (83.6%)	200 (85.5%)
	Black	2 (1.6%)	5 (4.5%)	7 (3.0%)
	Oriental	1 (0.8%)	1 (0.9%)	2 (0.9%)
	Other	13 (10.5%)	12 (10.9%)	25 (10.7%)

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Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index

Intention-To-Treat Population

Age Group : Children

		Treatment Group		
	Statistic	Paroxetine (N=46)	Placebo (N=45)	Total (N=91)
Age (years)	N	46	45	91
	MEAN	9.3	9.8	9.5
	MEDIAN	9.0	10.0	10.0
	STDDEV	1.26	1.15	1.22
	MINIMUM	7	7	7
	MAXIMUM	11	11	11
	MISSING	0	0	0
Height (cm)	N	46	45	91
	MEAN	137.65	142.99	140.29
	MEDIAN	139.35	144.80	142.00
	STDDEV	15.174	10.991	13.469
	MINIMUM	70.0	114.3	70.0
	MAXIMUM	167.6	163.0	167.6
	MISSING	0	0	0
Weight (kg)	N	46	45	91
	MEAN	37.95	42.44	40.17
	MEDIAN	34.55	39.50	36.80
	STDDEV	11.549	14.509	13.218
	MINIMUM	20.5	24.1	20.5
	MAXIMUM	64.5	90.5	90.5
	MISSING	0	0	0
BMI (kg/m2)	N	46	45	91
	MEAN	20.40	20.38	20.39
	MEDIAN	17.55	20.30	18.20
	STDDEV	7.582	5.027	6.411
	MINIMUM	14.1	13.7	13.7
	MAXIMUM	57.1	34.5	57.1
	MISSING	0	0	0

Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index

Intention-To-Treat Population

Age Group : Adolescents

		Treatment Group		
	Statistic	Paroxetine (N=117)	Placebo (N=111)	Total (N=228)
Age (years)	N	117	111	228
	MEAN	14.5	14.7	14.6
	MEDIAN	14.0	15.0	14.0
	STDDEV	1.67	1.71	1.69
	MINIMUM	12	12	12
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	117	109	226
	MEAN	164.21	166.89	165.50
	MEDIAN	165.10	167.50	165.55
	STDDEV	10.220	9.773	10.074
	MINIMUM	134.0	127.0	127.0
	MAXIMUM	183.0	193.0	193.0
	MISSING	0	2	2
Weight (kg)	N	117	110	227
	MEAN	61.87	65.48	63.62
	MEDIAN	58.40	61.95	59.50
	STDDEV	18.760	18.395	18.631
	MINIMUM	27.2	30.6	27.2
	MAXIMUM	115.5	140.7	140.7
	MISSING	0	1	1
BMI (kg/m2)	N	117	109	226
	MEAN	22.76	23.55	23.14
	MEDIAN	21.30	22.40	21.75
	STDDEV	6.029	6.829	6.425
	MINIMUM	14.5	14.6	14.5
	MAXIMUM	43.7	59.6	59.6
	MISSING	0	2	2

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Table 13.5.2b

Summary Statistics for Age, Height, Weight and Body Mass Index

Intention-To-Treat Population

Age Group : Total

		Treatment Group		
	Statistic	Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Age (years)	N	163	156	319
	MEAN	13.0	13.3	13.1
	MEDIAN	13.0	14.0	14.0
	STDDEV	2.81	2.73	2.77
	MINIMUM	7	7	7
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	163	154	317
	MEAN	156.71	159.91	158.26
	MEDIAN	160.00	162.55	161.50
	STDDEV	16.808	14.868	15.950
	MINIMUM	70.0	114.3	70.0
	MAXIMUM	183.0	193.0	193.0
	MISSING	0	2	2
Weight (kg)	N	163	155	318
	MEAN	55.12	58.79	56.91
	MEDIAN	52.20	56.80	55.00
	STDDEV	20.142	20.241	20.242
	MINIMUM	20.5	24.1	20.5
	MAXIMUM	115.5	140.7	140.7
	MISSING	0	1	1
BMI (kg/m2)	N	163	154	317
	MEAN	22.10	22.62	22.35
	MEDIAN	20.40	21.35	20.80
	STDDEV	6.568	6.502	6.531
	MINIMUM	14.1	13.7	13.7
	MAXIMUM	57.1	59.6	59.6
	MISSING	0	2	2

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Table 13.5.2c

Summary Statistics for Age, Height, Weight and Body Mass Index

Per-Protocol Population

Age Group : Children

		Treatment Group		
	Statistic	Paroxetine (N=32)	Placebo (N=32)	Total (N=64)
Age (years)	N	32	32	64
	MEAN	9.3	9.9	9.6
	MEDIAN	9.0	10.0	10.0
	STDDEV	1.31	1.18	1.27
	MINIMUM	7	7	7
	MAXIMUM	11	11	11
	MISSING	0	0	0
Height (cm)	N	32	32	64
	MEAN	138.12	144.73	141.42
	MEDIAN	139.35	146.25	142.20
	STDDEV	11.883	10.594	11.653
	MINIMUM	119.0	114.3	114.3
	MAXIMUM	167.6	162.0	167.6
	MISSING	0	0	0
Weight (kg)	N	32	32	64
	MEAN	37.40	44.99	41.20
	MEDIAN	33.85	41.85	36.60
	STDDEV	11.748	15.601	14.224
	MINIMUM	20.5	24.1	20.5
	MAXIMUM	64.5	90.5	90.5
	MISSING	0	0	0
BMI (kg/m2)	N	32	32	64
	MEAN	19.52	21.12	20.32
	MEDIAN	17.45	20.65	18.25
	STDDEV	5.614	5.561	5.602
	MINIMUM	14.1	13.7	13.7
	MAXIMUM	37.1	34.5	37.1
	MISSING	0	0	0

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Table 13.5.2c

Summary Statistics for Age, Height, Weight and Body Mass Index

Per-Protocol Population

Age Group : Adolescents

		Treatment Group		
	Statistic	Paroxetine (N=92)	Placebo (N=78)	Total (N=170)
Age (years)	N	92	78	170
	MEAN	14.4	14.7	14.5
	MEDIAN	14.0	14.5	14.0
	STDDEV	1.60	1.63	1.62
	MINIMUM	12	12	12
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	92	77	169
	MEAN	163.17	167.74	165.25
	MEDIAN	163.90	167.60	165.10
	STDDEV	10.053	8.805	9.748
	MINIMUM	134.0	150.9	134.0
	MAXIMUM	183.0	193.0	193.0
	MISSING	0	1	1
Weight (kg)	N	92	77	169
	MEAN	61.20	64.25	62.59
	MEDIAN	56.90	62.20	58.80
	STDDEV	19.860	15.551	18.038
	MINIMUM	27.2	35.0	27.2
	MAXIMUM	115.5	109.3	115.5
	MISSING	0	1	1
BMI (kg/m2)	N	92	77	169
	MEAN	22.78	22.76	22.77
	MEDIAN	21.10	22.30	21.80
	STDDEV	6.430	5.067	5.832
	MINIMUM	14.5	14.6	14.5
	MAXIMUM	43.7	39.2	43.7
	MISSING	0	1	1

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Table 13.5.2c

Summary Statistics for Age, Height, Weight and Body Mass Index

Per-Protocol Population

Age Group : Total

		Treatment Group		
	Statistic	Paroxetine (N=124)	Placebo (N=110)	Total (N=234)
Age (years)	N	124	110	234
	MEAN	13.1	13.3	13.2
	MEDIAN	13.5	14.0	14.0
	STDDEV	2.69	2.67	2.68
	MINIMUM	7	7	7
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	124	109	233
	MEAN	156.70	160.98	158.71
	MEDIAN	160.00	162.00	161.00
	STDDEV	15.216	14.059	14.810
	MINIMUM	119.0	114.3	114.3
	MAXIMUM	183.0	193.0	193.0
	MISSING	0	1	1
Weight (kg)	N	124	109	233
	MEAN	55.05	58.59	56.71
	MEDIAN	51.75	58.00	55.00
	STDDEV	20.878	17.823	19.547
	MINIMUM	20.5	24.1	20.5
	MAXIMUM	115.5	109.3	115.5
	MISSING	0	1	1
BMI (kg/m2)	N	124	109	233
	MEAN	21.94	22.28	22.10
	MEDIAN	20.10	21.80	20.70
	STDDEV	6.371	5.244	5.861
	MINIMUM	14.1	13.7	13.7
	MAXIMUM	43.7	39.2	43.7
	MISSING	0	1	1

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Table 13.6.1.1

Significant Medical/Surgical History and Physical Examination (Excluding Psychiatric Disorders)
Prior Conditions by Body System and Preferred Term
Intention-To-Treat Population

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Patients with at least one Prior Condition		95 (58.3%)	85 (54.5%)	180 (56.4%)
CARDIOVASCULAR	Total	6 (3.7%)	4 (2.6%)	10 (3.1%)
	BRADYCARDIA	1 (0.6%)	0	1 (0.3%)
	CARDIAC MURMURS	1 (0.6%)	1 (0.6%)	2 (0.6%)
	CONDUCTION DISORD	1 (0.6%)	0	1 (0.3%)
	CONG ANOM, CIRC SYST	1 (0.6%)	0	1 (0.3%)
	CONG ANOM, HEART	2 (1.2%)	0	2 (0.6%)
	HYPOTENSION, OTHER	1 (0.6%)	0	1 (0.3%)
	MIGRAINE	0	3 (1.9%)	3 (0.9%)
	NEOPLASMS BENIGN	1 (0.6%)	0	1 (0.3%)
	OPERATION, HEART VALVE/SEPTA	1 (0.6%)	0	1 (0.3%)
CAUSES OF INJURY	Total	4 (2.5%)	5 (3.2%)	9 (2.8%)
	ACCIDENT/MOTOR VEHICLE	0	1 (0.6%)	1 (0.3%)
	ADVERSE EFF/ANALGESIC	0	1 (0.6%)	1 (0.3%)
	ADVERSE EFF/ANTIBIOTIC	3 (1.8%)	2 (1.3%)	5 (1.6%)
	ADVERSE EFF/SEDATIVE	1 (0.6%)	0	1 (0.3%)
	SUICIDE	0	1 (0.6%)	1 (0.3%)
DIAGNOSTIC/THERAPEUTIC PROCS	Total	3 (1.8%)	2 (1.3%)	5 (1.6%)
	EVALUATION, DX EXAM	0	1 (0.6%)	1 (0.3%)
	PROCEDURE, PSYCHE	2 (1.2%)	1 (0.6%)	3 (0.9%)
	PROCEDURES, OTHER NONOPERATIVE	1 (0.6%)	0	1 (0.3%)
DIGESTIVE	Total	15 (9.2%)	15 (9.6%)	30 (9.4%)
	CONG ANOM, GI	1 (0.6%)	0	1 (0.3%)
	CONSTIPATION	2 (1.2%)	1 (0.6%)	3 (0.9%)
	ESOPHAGITIS	0	4 (2.6%)	4 (1.3%)
	FLATULENCE	0	1 (0.6%)	1 (0.3%)
	GASTRITIS/DUODENITIS	0	1 (0.6%)	1 (0.3%)
	HEARTBURN	0	1 (0.6%)	1 (0.3%)
	HEPATITIS, VIRAL	1 (0.6%)	0	1 (0.3%)
	INCONTINENCE, FECAL	0	1 (0.6%)	1 (0.3%)
	INTEST INFECT DIS	1 (0.6%)	0	1 (0.3%)
	OPERATION, APPENDIX	3 (1.8%)	2 (1.3%)	5 (1.6%)
	OPERATION, INTEST	1 (0.6%)	0	1 (0.3%)
	OPERATION, NOSE/MOUTH	3 (1.8%)	4 (2.6%)	7 (2.2%)
	OPERATION, RECTUM/PERIRECT	0	1 (0.6%)	1 (0.3%)
	OPERATION, STOMACH	0	1 (0.6%)	1 (0.3%)
	STOMACH/DUODENUM DISORD	1 (0.6%)	1 (0.6%)	2 (0.6%)
	TEETH DISORD	2 (1.2%)	0	2 (0.6%)
	ULCER, GASTRIC	2 (1.2%)	0	2 (0.6%)
ENDOCRINE	Total	1 (0.6%)	1 (0.6%)	2 (0.6%)

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Table 13.6.1.1

Significant Medical/Surgical History and Physical Examination (Excluding Psychiatric Disorders)
Prior Conditions by Body System and Preferred Term
Intention-To-Treat Population

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
ENDOCRINE	CONG ANOM, ENDOCRINE	0	1 (0.6%)	1 (0.3%)
	DIABETES MELLITUS	1 (0.6%)	0	1 (0.3%)
	HYPOTHYROIDISM	0	1 (0.6%)	1 (0.3%)
FACTORS INFLUENCING HEALTH	Total	2 (1.2%)	1 (0.6%)	3 (0.9%)
	OBSERVATION, OTHER	1 (0.6%)	0	1 (0.3%)
	PROCEDURES, REHAB	0	1 (0.6%)	1 (0.3%)
	SURGERY, COSMETIC	1 (0.6%)	0	1 (0.3%)
GENERAL BODY OR SYS UNSPEC	Total	24 (14.7%)	28 (17.9%)	52 (16.3%)
	ALLERGIC REACTION, FOOD	1 (0.6%)	0	1 (0.3%)
	ALLERGY, NEC	2 (1.2%)	3 (1.9%)	5 (1.6%)
	BACK PAIN	2 (1.2%)	2 (1.3%)	4 (1.3%)
	BACT DIS, OTHER	1 (0.6%)	0	1 (0.3%)
	CELLULITIS/ABSCESS	0	1 (0.6%)	1 (0.3%)
	CONG ANOM, GI	1 (0.6%)	0	1 (0.3%)
	DEVELOPMENT, ABN	0	1 (0.6%)	1 (0.3%)
	HEADACHE	7 (4.3%)	11 (7.1%)	18 (5.6%)
	INJURY/POIS, OTHER	0	1 (0.6%)	1 (0.3%)
	LIMB, WEAKNESS	1 (0.6%)	0	1 (0.3%)
	OPEN WOUND	1 (0.6%)	0	1 (0.3%)
	OPERATION, HERNIA REPAIR	2 (1.2%)	2 (1.3%)	4 (1.3%)
	PAIN, ABDOMINO-PELVIC	3 (1.8%)	2 (1.3%)	5 (1.6%)
	PAIN, RESP	1 (0.6%)	0	1 (0.3%)
	PNEUMOTHORAX	1 (0.6%)	0	1 (0.3%)
	SALMONELLA INFECT	1 (0.6%)	0	1 (0.3%)
	TOXIC EFFECTS, NONMEDICINAL	0	1 (0.6%)	1 (0.3%)
	TOXIC EFFECTS, VENOM	1 (0.6%)	1 (0.6%)	2 (0.6%)
	TRAUMA/INJURIES, UNSPEC	0	1 (0.6%)	1 (0.3%)
	VIRAL DIS/EXANTHEM	3 (1.8%)	3 (1.9%)	6 (1.9%)
	VIRAL INFECTION	1 (0.6%)	0	1 (0.3%)
	VIRUS/CHLAMYD DIS, OTHER	0	3 (1.9%)	3 (0.9%)
GENITOURINARY	Total	8 (4.9%)	5 (3.2%)	13 (4.1%)
	CONDITIONS, PERINATAL	0	1 (0.6%)	1 (0.3%)
	CONG ANOM, GU	1 (0.6%)	0	1 (0.3%)
	CYSTITIS	1 (0.6%)	1 (0.6%)	2 (0.6%)
	GENITAL FEMALE DISORD, OTHER	1 (0.6%)	2 (1.3%)	3 (0.9%)
	KIDNEY DISORD	2 (1.2%)	0	2 (0.6%)
	OPERATION, FEM GENITAL	1 (0.6%)	2 (1.3%)	3 (0.9%)
	OPERATION, MALE GENITAL	2 (1.2%)	0	2 (0.6%)
	OPERATION, OTHER URINARY	1 (0.6%)	0	1 (0.3%)
	URINARY TRACT INFECTION	1 (0.6%)	1 (0.6%)	2 (0.6%)
HEMATIC/HEMATOPOIETIC/LYMPH	Total	0	2 (1.3%)	2 (0.6%)
	LEUCOCYTOSIS	0	1 (0.6%)	1 (0.3%)

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Table 13.6.1.1

Significant Medical/Surgical History and Physical Examination (Excluding Psychiatric Disorders)
Prior Conditions by Body System and Preferred Term
Intention-To-Treat Population

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
HEMATIC/HEMATOPOIETIC/LYMPH	NEOPLASM MALIG, LYMPH/HEMAT	0	1 (0.6%)	1 (0.3%)
INTEGUMENTARY	Total	8 (4.9%)	8 (5.1%)	16 (5.0%)
	INFLAM SKIN/SUBCUT	1 (0.6%)	1 (0.6%)	2 (0.6%)
	OPERATION, SKIN/SUBCUT	2 (1.2%)	2 (1.3%)	4 (1.3%)
	RASH/OTHER SKIN ERUPTION	0	1 (0.6%)	1 (0.3%)
	SCARRING	1 (0.6%)	0	1 (0.3%)
	SKIN/SUBCUT DISORD, OTHER	4 (2.5%)	4 (2.6%)	8 (2.5%)
	URTICARIA	0	1 (0.6%)	1 (0.3%)
	VIRUS/CHLAMYD DIS, OTHER	0	1 (0.6%)	1 (0.3%)
METABOLIC/NUTRITIONAL/IMMUNE	Total	5 (3.1%)	6 (3.8%)	11 (3.4%)
	CARBOHYDRATE DISORD	0	1 (0.6%)	1 (0.3%)
	HYPOGLYCEMIA	0	1 (0.6%)	1 (0.3%)
	OBESITY	3 (1.8%)	4 (2.6%)	7 (2.2%)
	WEIGHT LOSS	2 (1.2%)	0	2 (0.6%)
MUSCULOSKELETAL	Total	10 (6.1%)	9 (5.8%)	19 (6.0%)
	ARTHROPATHY	1 (0.6%)	0	1 (0.3%)
	CONG ANOM, MUSCULOSKEL	3 (1.8%)	1 (0.6%)	4 (1.3%)
	DEFORMITY, ACQUIRED	1 (0.6%)	0	1 (0.3%)
	DENTOFACIAL ANOM	0	2 (1.3%)	2 (0.6%)
	DISLOCATION	0	1 (0.6%)	1 (0.3%)
	FRACTURE, SKULL	0	1 (0.6%)	1 (0.3%)
	FRACTURE, UPPER LIMB	7 (4.3%)	3 (1.9%)	10 (3.1%)
	NEOPLASM MALIG, BONE	1 (0.6%)	0	1 (0.3%)
	NEOPLASMS BENIGN	0	1 (0.6%)	1 (0.3%)
	OPERATION, BONE/JOINT	1 (0.6%)	1 (0.6%)	2 (0.6%)
	PAIN, JOINT	1 (0.6%)	1 (0.6%)	2 (0.6%)
NERVOUS/SENSE ORGANS	Total	32 (19.6%)	20 (12.8%)	52 (16.3%)
	CONGEN ANOM, HEAD/NECK	1 (0.6%)	0	1 (0.3%)
	CONVULSIONS	2 (1.2%)	1 (0.6%)	3 (0.9%)
	DIZZINESS AND GIDDINESS	1 (0.6%)	1 (0.6%)	2 (0.6%)
	EAR/MASTOID DISORD	3 (1.8%)	0	3 (0.9%)
	EPILEPSY	1 (0.6%)	2 (1.3%)	3 (0.9%)
	EYE DISORD, OTHER	2 (1.2%)	0	2 (0.6%)
	GLAUCOMA	1 (0.6%)	0	1 (0.3%)
	HEMIPLEGIA	1 (0.6%)	0	1 (0.3%)
	HEMORRHAGE, INTRACRANIAL	0	1 (0.6%)	1 (0.3%)
	HYPOESTHESIA	1 (0.6%)	0	1 (0.3%)
	INJURY, INTRACRANIAL	0	1 (0.6%)	1 (0.3%)
	INSOMNIA	1 (0.6%)	1 (0.6%)	2 (0.6%)
	MENINGITIS	1 (0.6%)	1 (0.6%)	2 (0.6%)
	OPERATION, CNS	1 (0.6%)	0	1 (0.3%)
	OPERATION, EAR	10 (6.1%)	7 (4.5%)	17 (5.3%)

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Table 13.6.1.1

Significant Medical/Surgical History and Physical Examination (Excluding Psychiatric Disorders)
Prior Conditions by Body System and Preferred Term
Intention-To-Treat Population

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
NERVOUS/SENSE ORGANS	OPERATION, EYE	2 (1.2%)	2 (1.3%)	4 (1.3%)
	OTITIS MEDIA	8 (4.9%)	7 (4.5%)	15 (4.7%)
	PAPILLEDEMA	0	1 (0.6%)	1 (0.3%)
	POLIO AND CNS DIS, VIRAL	1 (0.6%)	0	1 (0.3%)
	TREMOR	1 (0.6%)	0	1 (0.3%)
	VISUAL DISTURB	3 (1.8%)	1 (0.6%)	4 (1.3%)
PSYCHOLOGICAL DISORDERS	Total	6 (3.7%)	3 (1.9%)	9 (2.8%)
	ANXIETY	3 (1.8%)	0	3 (0.9%)
	DEPRESSION	2 (1.2%)	1 (0.6%)	3 (0.9%)
	MENTAL DEVELOP DISORD	1 (0.6%)	0	1 (0.3%)
	NEUROSES	2 (1.2%)	0	2 (0.6%)
	SLEEP DISORD, NONORGANIC	0	2 (1.3%)	2 (0.6%)
RESPIRATORY	Total	44 (27.0%)	43 (27.6%)	87 (27.3%)
	ASTHMA	13 (8.0%)	16 (10.3%)	29 (9.1%)
	BRONCHITIS, ACUTE	1 (0.6%)	0	1 (0.3%)
	BRONCHITIS, OTHER	1 (0.6%)	1 (0.6%)	2 (0.6%)
	COUGH	0	1 (0.6%)	1 (0.3%)
	EPISTAXIS	1 (0.6%)	2 (1.3%)	3 (0.9%)
	HYPERVENTILATION	0	1 (0.6%)	1 (0.3%)
	INFECTION, BACTERIAL	1 (0.6%)	0	1 (0.3%)
	INFLUENZA	2 (1.2%)	0	2 (0.6%)
	LARYNGITIS/TRACH, ACUTE	0	1 (0.6%)	1 (0.3%)
	NASAL SEPTUM DEVIATED	1 (0.6%)	0	1 (0.3%)
	NASOPHARYNGITIS, ACUTE	2 (1.2%)	2 (1.3%)	4 (1.3%)
	OPERATION, HERNIA REPAIR	1 (0.6%)	0	1 (0.3%)
	OPERATION, NOSE/MOUTH	16 (9.8%)	17 (10.9%)	33 (10.3%)
	OPERATION, RESP	1 (0.6%)	0	1 (0.3%)
	PNEUMONIA, OTHER	1 (0.6%)	5 (3.2%)	6 (1.9%)
	RESP SYMPTOMS, OTHER	1 (0.6%)	0	1 (0.3%)
	RHINITIS, ALLERGIC	10 (6.1%)	10 (6.4%)	20 (6.3%)
	RHINITIS,NOS	1 (0.6%)	0	1 (0.3%)
	SINUSITIS,NOS	2 (1.2%)	1 (0.6%)	3 (0.9%)
	TONSILLITIS, ACUTE	1 (0.6%)	0	1 (0.3%)
	TUBERCULOSIS	1 (0.6%)	0	1 (0.3%)
	UPPER RESP DISORD, OTHER	0	1 (0.6%)	1 (0.3%)

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Table 13.6.1.2

Significant Medical/Surgical History and Physical Examination (Excluding Psychiatric Disorders)
Prior Conditions by Preferred Term Ordered by Decreasing Frequency
Intention-To-Treat Population

Preferred Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Patients with at least one Prior Condition	95 (58.3%)	85 (54.5%)	180 (56.4%)
OPERATION, NOSE/MOUTH	18 (11.0%)	19 (12.2%)	37 (11.6%)
ASTHMA	13 (8.0%)	16 (10.3%)	29 (9.1%)
RHINITIS, ALLERGIC	10 (6.1%)	10 (6.4%)	20 (6.3%)
OPERATION, EAR	10 (6.1%)	7 (4.5%)	17 (5.3%)
OTITIS MEDIA	8 (4.9%)	7 (4.5%)	15 (4.7%)
HEADACHE	7 (4.3%)	11 (7.1%)	18 (5.6%)
FRACTURE, UPPER LIMB	7 (4.3%)	3 (1.9%)	10 (3.1%)
SKIN/SUBCUT DISORD, OTHER	4 (2.5%)	4 (2.6%)	8 (2.5%)
OBESITY	3 (1.8%)	4 (2.6%)	7 (2.2%)
VIRAL DIS/EXANTHEM	3 (1.8%)	3 (1.9%)	6 (1.9%)
ADVERSE EFF/ANTIBIOTIC	3 (1.8%)	2 (1.3%)	5 (1.6%)
OPERATION, APPENDIX	3 (1.8%)	2 (1.3%)	5 (1.6%)
OPERATION, HERNIA REPAIR	3 (1.8%)	2 (1.3%)	5 (1.6%)
PAIN, ABDOMINO-PELVIC	3 (1.8%)	2 (1.3%)	5 (1.6%)
CONG ANOM, MUSCULOSKEL	3 (1.8%)	1 (0.6%)	4 (1.3%)
VISUAL DISTURB	3 (1.8%)	1 (0.6%)	4 (1.3%)
ANXIETY	3 (1.8%)	0	3 (0.9%)
EAR/MASTOID DISORD	3 (1.8%)	0	3 (0.9%)
ALLERGY, NEC	2 (1.2%)	3 (1.9%)	5 (1.6%)
BACK PAIN	2 (1.2%)	2 (1.3%)	4 (1.3%)
NASOPHARYNGITIS, ACUTE	2 (1.2%)	2 (1.3%)	4 (1.3%)
OPERATION, EYE	2 (1.2%)	2 (1.3%)	4 (1.3%)
OPERATION, SKIN/SUBCUT	2 (1.2%)	2 (1.3%)	4 (1.3%)
CONSTIPATION	2 (1.2%)	1 (0.6%)	3 (0.9%)
CONVULSIONS	2 (1.2%)	1 (0.6%)	3 (0.9%)
DEPRESSION	2 (1.2%)	1 (0.6%)	3 (0.9%)
PROCEDURE, PSYCHE	2 (1.2%)	1 (0.6%)	3 (0.9%)
SINUSITIS,NOS	2 (1.2%)	1 (0.6%)	3 (0.9%)
CONG ANOM, GI	2 (1.2%)	0	2 (0.6%)
CONG ANOM, HEART	2 (1.2%)	0	2 (0.6%)
EYE DISORD, OTHER	2 (1.2%)	0	2 (0.6%)
INFLUENZA	2 (1.2%)	0	2 (0.6%)
KIDNEY DISORD	2 (1.2%)	0	2 (0.6%)
NEUROSES	2 (1.2%)	0	2 (0.6%)
OPERATION, MALE GENITAL	2 (1.2%)	0	2 (0.6%)
TEETH DISORD	2 (1.2%)	0	2 (0.6%)
ULCER, GASTRIC	2 (1.2%)	0	2 (0.6%)
WEIGHT LOSS	2 (1.2%)	0	2 (0.6%)
PNEUMONIA, OTHER	1 (0.6%)	5 (3.2%)	6 (1.9%)
EPILEPSY	1 (0.6%)	2 (1.3%)	3 (0.9%)
EPISTAXIS	1 (0.6%)	2 (1.3%)	3 (0.9%)
GENITAL FEMALE DISORD, OTHER	1 (0.6%)	2 (1.3%)	3 (0.9%)
OPERATION, FEM GENITAL	1 (0.6%)	2 (1.3%)	3 (0.9%)
BRONCHITIS, OTHER	1 (0.6%)	1 (0.6%)	2 (0.6%)

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Table 13.6.1.2

Significant Medical/Surgical History and Physical Examination (Excluding Psychiatric Disorders)
Prior Conditions by Preferred Term Ordered by Decreasing Frequency
Intention-To-Treat Population

Preferred Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
CARDIAC MURMURS	1 (0.6%)	1 (0.6%)	2 (0.6%)
CYSTITIS	1 (0.6%)	1 (0.6%)	2 (0.6%)
DIZZINESS AND GIDDINESS	1 (0.6%)	1 (0.6%)	2 (0.6%)
INFLAM SKIN/SUBCUT	1 (0.6%)	1 (0.6%)	2 (0.6%)
INSOMNIA	1 (0.6%)	1 (0.6%)	2 (0.6%)
MENINGITIS	1 (0.6%)	1 (0.6%)	2 (0.6%)
NEOPLASMS BENIGN	1 (0.6%)	1 (0.6%)	2 (0.6%)
OPERATION, BONE/JOINT	1 (0.6%)	1 (0.6%)	2 (0.6%)
PAIN, JOINT	1 (0.6%)	1 (0.6%)	2 (0.6%)
STOMACH/DUODENUM DISORD	1 (0.6%)	1 (0.6%)	2 (0.6%)
TOXIC EFFECTS, VENOM	1 (0.6%)	1 (0.6%)	2 (0.6%)
URINARY TRACT INFECTION	1 (0.6%)	1 (0.6%)	2 (0.6%)
ADVERSE EFF/SEDATIVE	1 (0.6%)	0	1 (0.3%)
ALLERGIC REACTION, FOOD	1 (0.6%)	0	1 (0.3%)
ARTHROPATHY	1 (0.6%)	0	1 (0.3%)
BACT DIS, OTHER	1 (0.6%)	0	1 (0.3%)
BRADYCARDIA	1 (0.6%)	0	1 (0.3%)
BRONCHITIS, ACUTE	1 (0.6%)	0	1 (0.3%)
CONDUCTION DISORD	1 (0.6%)	0	1 (0.3%)
CONG ANOM, CIRC SYST	1 (0.6%)	0	1 (0.3%)
CONG ANOM, GU	1 (0.6%)	0	1 (0.3%)
CONGEN ANOM, HEAD/NECK	1 (0.6%)	0	1 (0.3%)
DEFORMITY, ACQUIRED	1 (0.6%)	0	1 (0.3%)
DIABETES MELLITUS	1 (0.6%)	0	1 (0.3%)
GLAUCOMA	1 (0.6%)	0	1 (0.3%)
HEMIPLEGIA	1 (0.6%)	0	1 (0.3%)
HEPATITIS, VIRAL	1 (0.6%)	0	1 (0.3%)
HYPOESTHESIA	1 (0.6%)	0	1 (0.3%)
HYPOTENSION, OTHER	1 (0.6%)	0	1 (0.3%)
INFECTION, BACTERIAL	1 (0.6%)	0	1 (0.3%)
INTEST INFECT DIS	1 (0.6%)	0	1 (0.3%)
LIMB, WEAKNESS	1 (0.6%)	0	1 (0.3%)
MENTAL DEVELOP DISORD	1 (0.6%)	0	1 (0.3%)
NASAL SEPTUM DEVIATED	1 (0.6%)	0	1 (0.3%)
NEOPLASM MALIG, BONE	1 (0.6%)	0	1 (0.3%)
OBSERVATION, OTHER	1 (0.6%)	0	1 (0.3%)
OPEN WOUND	1 (0.6%)	0	1 (0.3%)
OPERATION, CNS	1 (0.6%)	0	1 (0.3%)
OPERATION, HEART VALVE/SEPTA	1 (0.6%)	0	1 (0.3%)
OPERATION, INTEST	1 (0.6%)	0	1 (0.3%)
OPERATION, OTHER URINARY	1 (0.6%)	0	1 (0.3%)
OPERATION, RESP	1 (0.6%)	0	1 (0.3%)
PAIN, RESP	1 (0.6%)	0	1 (0.3%)
PNEUMOTHORAX	1 (0.6%)	0	1 (0.3%)
POLIO AND CNS DIS, VIRAL	1 (0.6%)	0	1 (0.3%)
PROCEDURES, OTHER NONOPERATIVE	1 (0.6%)	0	1 (0.3%)

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Table 13.6.1.2

Significant Medical/Surgical History and Physical Examination (Excluding Psychiatric Disorders)
Prior Conditions by Preferred Term Ordered by Decreasing Frequency
Intention-To-Treat Population

Preferred Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
RESP SYMPTOMS, OTHER	1 (0.6%)	0	1 (0.3%)
RHINITIS,NOS	1 (0.6%)	0	1 (0.3%)
SALMONELLA INFECT	1 (0.6%)	0	1 (0.3%)
SCARRING	1 (0.6%)	0	1 (0.3%)
SURGERY, COSMETIC	1 (0.6%)	0	1 (0.3%)
TONSILLITIS, ACUTE	1 (0.6%)	0	1 (0.3%)
TREMOR	1 (0.6%)	0	1 (0.3%)
TUBERCULOSIS	1 (0.6%)	0	1 (0.3%)
VIRAL INFECTION	1 (0.6%)	0	1 (0.3%)
ESOPHAGITIS	0	4 (2.6%)	4 (1.3%)
VIRUS/CHLAMYD DIS, OTHER	0	4 (2.6%)	4 (1.3%)
MIGRAINE	0	3 (1.9%)	3 (0.9%)
DENTOFACIAL ANOM	0	2 (1.3%)	2 (0.6%)
SLEEP DISORD, NONORGANIC	0	2 (1.3%)	2 (0.6%)
ACCIDENT/MOTOR VEHICLE	0	1 (0.6%)	1 (0.3%)
ADVERSE EFF/ANALGESIC	0	1 (0.6%)	1 (0.3%)
CARBOHYDRATE DISORD	0	1 (0.6%)	1 (0.3%)
CELLULITIS/ABSCESS	0	1 (0.6%)	1 (0.3%)
CONDITIONS, PERINATAL	0	1 (0.6%)	1 (0.3%)
CONG ANOM, ENDOCRINE	0	1 (0.6%)	1 (0.3%)
COUGH	0	1 (0.6%)	1 (0.3%)
DEVELOPMENT, ABN	0	1 (0.6%)	1 (0.3%)
DISLOCATION	0	1 (0.6%)	1 (0.3%)
EVALUATION, DX EXAM	0	1 (0.6%)	1 (0.3%)
FLATULENCE	0	1 (0.6%)	1 (0.3%)
FRACTURE, SKULL	0	1 (0.6%)	1 (0.3%)
GASTRITIS/DUODENITIS	0	1 (0.6%)	1 (0.3%)
HEARTBURN	0	1 (0.6%)	1 (0.3%)
HEMORRHAGE, INTRACRANIAL	0	1 (0.6%)	1 (0.3%)
HYPERVENTILATION	0	1 (0.6%)	1 (0.3%)
HYPOGLYCEMIA	0	1 (0.6%)	1 (0.3%)
HYPOTHYROIDISM	0	1 (0.6%)	1 (0.3%)
INCONTINENCE, FECAL	0	1 (0.6%)	1 (0.3%)
INJURY, INTRACRANIAL	0	1 (0.6%)	1 (0.3%)
INJURY/POIS, OTHER	0	1 (0.6%)	1 (0.3%)
LARYNGITIS/TRACH, ACUTE	0	1 (0.6%)	1 (0.3%)
LEUCOCYTOSIS	0	1 (0.6%)	1 (0.3%)
NEOPLASM MALIG, LYMPH/HEMAT	0	1 (0.6%)	1 (0.3%)
OPERATION, RECTUM/PERIRECT	0	1 (0.6%)	1 (0.3%)
OPERATION, STOMACH	0	1 (0.6%)	1 (0.3%)
PAPILLEDEMA	0	1 (0.6%)	1 (0.3%)
PROCEDURES, REHAB	0	1 (0.6%)	1 (0.3%)
RASH/OTHER SKIN ERUPTION	0	1 (0.6%)	1 (0.3%)
SUICIDE	0	1 (0.6%)	1 (0.3%)
TOXIC EFFECTS, NONMEDICINAL	0	1 (0.6%)	1 (0.3%)
TRAUMA/INJURIES, UNSPEC	0	1 (0.6%)	1 (0.3%)

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Table 13.6.1.2

Significant Medical/Surgical History and Physical Examination (Excluding Psychiatric Disorders)
Prior Conditions by Preferred Term Ordered by Decreasing Frequency
Intention-To-Treat Population

Preferred Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
UPPER RESP DISORD, OTHER	0	1 (0.6%)	1 (0.3%)
URTICARIA	0	1 (0.6%)	1 (0.3%)

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Table 13.6.2.1

Significant Medical/Surgical History and Physical Examination (Excluding Psychiatric Disorders)
Active Conditions by Body System and Preferred Term
Intention-To-Treat Population

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Patients with at least one Active Condition		93 (57.1%)	83 (53.2%)	176 (55.2%)
CARDIOVASCULAR	Total	7 (4.3%)	9 (5.8%)	16 (5.0%)
	ARRHYTHMIA	1 (0.6%)	1 (0.6%)	2 (0.6%)
	BLOOD PRESSURE, ELEVATED	0	1 (0.6%)	1 (0.3%)
	BRADYCARDIA	2 (1.2%)	0	2 (0.6%)
	CARDIAC MURMURS	2 (1.2%)	0	2 (0.6%)
	CARDIOMEGALY	0	1 (0.6%)	1 (0.3%)
	CARDIOVAS FUNCTIONS/ECG, ABN	1 (0.6%)	1 (0.6%)	2 (0.6%)
	CONDUCTION DISORD	1 (0.6%)	1 (0.6%)	2 (0.6%)
	CONG ANOM, CIRC SYST	1 (0.6%)	0	1 (0.3%)
	CONG ANOM, HEART	0	1 (0.6%)	1 (0.3%)
	EXTRASYSTOLES, VENTRICULAR	0	1 (0.6%)	1 (0.3%)
	HYPOTENSION, OTHER	1 (0.6%)	1 (0.6%)	2 (0.6%)
	MIGRAINE	0	4 (2.6%)	4 (1.3%)
CAUSES OF INJURY	Total	6 (3.7%)	9 (5.8%)	15 (4.7%)
	ADVERSE EFF/ANALGESIC	0	2 (1.3%)	2 (0.6%)
	ADVERSE EFF/ANTI-INFECT	0	1 (0.6%)	1 (0.3%)
	ADVERSE EFF/ANTIBIOTIC	4 (2.5%)	6 (3.8%)	10 (3.1%)
	ADVERSE EFF/RESP AGENT	0	1 (0.6%)	1 (0.3%)
	ADVERSE EFF/SEDATIVE	1 (0.6%)	0	1 (0.3%)
	ADVERSE EFF/SKIN,MUC MEMB DRUG	1 (0.6%)	0	1 (0.3%)
DIGESTIVE	Total	11 (6.7%)	9 (5.8%)	20 (6.3%)
	CONSTIPATION	4 (2.5%)	2 (1.3%)	6 (1.9%)
	DIGESTIVE DISORD, OTHER	0	1 (0.6%)	1 (0.3%)
	ESOPHAGITIS	1 (0.6%)	1 (0.6%)	2 (0.6%)
	FLATULENCE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	HEARTBURN	1 (0.6%)	1 (0.6%)	2 (0.6%)
	INCONTINENCE, FECAL	0	1 (0.6%)	1 (0.3%)
	NAUSEA	1 (0.6%)	2 (1.3%)	3 (0.9%)
	OPERATION, NOSE/MOUTH	1 (0.6%)	0	1 (0.3%)
	ORAL SOFT TISSUE DIS	1 (0.6%)	0	1 (0.3%)
	STOMACH/DUODENUM DISORD	0	1 (0.6%)	1 (0.3%)
	TEETH DISORD	1 (0.6%)	0	1 (0.3%)
	ULCER, GASTRIC	1 (0.6%)	0	1 (0.3%)
	VOMITING	1 (0.6%)	0	1 (0.3%)
ENDOCRINE	Total	2 (1.2%)	4 (2.6%)	6 (1.9%)
	CONG ANOM, ENDOCRINE	0	1 (0.6%)	1 (0.3%)
	DIABETES MELLITUS	1 (0.6%)	1 (0.6%)	2 (0.6%)
	HYPOTHYROIDISM	0	2 (1.3%)	2 (0.6%)
	SEX DEVELOP DISORD, OTHER	0	1 (0.6%)	1 (0.3%)
	THYROID FUNCTION, ABN	1 (0.6%)	0	1 (0.3%)

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Table 13.6.2.1

Significant Medical/Surgical History and Physical Examination (Excluding Psychiatric Disorders)
Active Conditions by Body System and Preferred Term
Intention-To-Treat Population

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
GENERAL BODY OR SYS UNSPEC	Total	28 (17.2%)	30 (19.2%)	58 (18.2%)
	ALLERGIC REACTION, FOOD	1 (0.6%)	0	1 (0.3%)
	ALLERGY, NEC	6 (3.7%)	8 (5.1%)	14 (4.4%)
	BACK PAIN	1 (0.6%)	1 (0.6%)	2 (0.6%)
	CONTUSION	0	1 (0.6%)	1 (0.3%)
	HEAD AND NECK SYMPTOMS, OTHER	0	1 (0.6%)	1 (0.3%)
	HEADACHE	18 (11.0%)	20 (12.8%)	38 (11.9%)
	INJURY, SUPERFICIAL	1 (0.6%)	0	1 (0.3%)
	MOTION SICKNESS	1 (0.6%)	0	1 (0.3%)
	OPEN WOUND	0	1 (0.6%)	1 (0.3%)
	PAIN, ABDOMINO-PELVIC	5 (3.1%)	3 (1.9%)	8 (2.5%)
	PAIN, RESP	1 (0.6%)	0	1 (0.3%)
	TOXIC EFFECTS, VENOM	1 (0.6%)	1 (0.6%)	2 (0.6%)
GENITOURINARY	Total	14 (8.6%)	7 (4.5%)	21 (6.6%)
	AMENORRHEA	1 (0.6%)	0	1 (0.3%)
	BREAST HYPERTROPHY, UNSP	0	1 (0.6%)	1 (0.3%)
	CONDITIONS, PERINATAL	1 (0.6%)	0	1 (0.3%)
	GENITAL FEMALE DISORD, OTHER	7 (4.3%)	5 (3.2%)	12 (3.8%)
	INCONTINENCE, URINARY	4 (2.5%)	0	4 (1.3%)
	URINARY CASTS/WBC'S	1 (0.6%)	0	1 (0.3%)
	URINARY TRACT INFECTION	1 (0.6%)	1 (0.6%)	2 (0.6%)
HEMATIC/HEMATOPOIETIC/LYMPH	Total	2 (1.2%)	3 (1.9%)	5 (1.6%)
	ANEMIA, IRON DEFIC	1 (0.6%)	0	1 (0.3%)
	EOSINOPHILIA	0	2 (1.3%)	2 (0.6%)
	LEUCOCYTOSIS	0	1 (0.6%)	1 (0.3%)
	LYMPHADENOPATHY	1 (0.6%)	0	1 (0.3%)
INTEGUMENTARY	Total	19 (11.7%)	20 (12.8%)	39 (12.2%)
	CONG ANOM, INTEGUMENT	0	1 (0.6%)	1 (0.3%)
	INFLAM SKIN/SUBCUT	2 (1.2%)	4 (2.6%)	6 (1.9%)
	MYCOSES	1 (0.6%)	0	1 (0.3%)
	RASH/OTHER SKIN ERUPTION	0	2 (1.3%)	2 (0.6%)
	SCARRING	1 (0.6%)	0	1 (0.3%)
	SKIN/SUBCUT DISORD, OTHER	15 (9.2%)	13 (8.3%)	28 (8.8%)
	VIRUS/CHLAMYD DIS, OTHER	0	1 (0.6%)	1 (0.3%)
METABOLIC/NUTRITIONAL/IMMUNE	Total	12 (7.4%)	11 (7.1%)	23 (7.2%)
	CARBOHYDRATE DISORD	0	1 (0.6%)	1 (0.3%)
	CHOLEST/TRIGLYCERIDE, ELEVATED	0	1 (0.6%)	1 (0.3%)
	HYPOGLYCEMIA	0	1 (0.6%)	1 (0.3%)
	OBESITY	9 (5.5%)	8 (5.1%)	17 (5.3%)
	SERUM BILIRUBIN, INCREASED	2 (1.2%)	0	2 (0.6%)
	WEIGHT LOSS	1 (0.6%)	0	1 (0.3%)

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Table 13.6.2.1

Significant Medical/Surgical History and Physical Examination (Excluding Psychiatric Disorders)
Active Conditions by Body System and Preferred Term
Intention-To-Treat Population

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
MUSCULOSKELETAL	Total	6 (3.7%)	3 (1.9%)	9 (2.8%)
	ARTHRITIS, RHEUMATOID	1 (0.6%)	0	1 (0.3%)
	ARTHROPATHY	1 (0.6%)	0	1 (0.3%)
	DEFORMITY, ACQUIRED	2 (1.2%)	0	2 (0.6%)
	DENTOFACIAL ANOM	0	1 (0.6%)	1 (0.3%)
	MYALGIA	1 (0.6%)	1 (0.6%)	2 (0.6%)
	PAIN, JOINT	2 (1.2%)	1 (0.6%)	3 (0.9%)
	SPASM, MUSCLE	1 (0.6%)	0	1 (0.3%)
NERVOUS/SENSE ORGANS	Total	17 (10.4%)	7 (4.5%)	24 (7.5%)
	CONGEN ANOM, HEAD/NECK	1 (0.6%)	0	1 (0.3%)
	EAR/MASTOID DISORD	3 (1.8%)	0	3 (0.9%)
	EYE DISORD, OTHER	2 (1.2%)	0	2 (0.6%)
	GLAUCOMA	1 (0.6%)	0	1 (0.3%)
	HEARING LOSS	2 (1.2%)	0	2 (0.6%)
	HEMIPARESIS	0	1 (0.6%)	1 (0.3%)
	INSOMNIA	2 (1.2%)	3 (1.9%)	5 (1.6%)
	LACK OF COORDINATION	0	1 (0.6%)	1 (0.3%)
	OPERATION, EAR	1 (0.6%)	0	1 (0.3%)
	OTITIS MEDIA	3 (1.8%)	2 (1.3%)	5 (1.6%)
	TREMOR	1 (0.6%)	0	1 (0.3%)
	VISUAL DISTURB	3 (1.8%)	1 (0.6%)	4 (1.3%)
PSYCHOLOGICAL DISORDERS	Total	2 (1.2%)	3 (1.9%)	5 (1.6%)
	ANXIETY	1 (0.6%)	0	1 (0.3%)
	MENTAL DEVELOP DISORD	0	1 (0.6%)	1 (0.3%)
	MENTAL STATUS, IMPAIRED	1 (0.6%)	0	1 (0.3%)
	NEUROSES	1 (0.6%)	0	1 (0.3%)
	SLEEP DISORD, NONORGANIC	0	2 (1.3%)	2 (0.6%)
RESPIRATORY	Total	37 (22.7%)	38 (24.4%)	75 (23.5%)
	ASTHMA	10 (6.1%)	12 (7.7%)	22 (6.9%)
	BRONCHITIS, CHRONIC	0	1 (0.6%)	1 (0.3%)
	BRONCHITIS, OTHER	0	1 (0.6%)	1 (0.3%)
	EPISTAXIS	0	2 (1.3%)	2 (0.6%)
	INFECTION, BACTERIAL	1 (0.6%)	0	1 (0.3%)
	INFLUENZA	1 (0.6%)	1 (0.6%)	2 (0.6%)
	NASAL SEPTUM DEVIATED	1 (0.6%)	0	1 (0.3%)
	OPERATION, NOSE/MOUTH	1 (0.6%)	0	1 (0.3%)
	PHARYNGITIS, ACUTE	1 (0.6%)	0	1 (0.3%)
	RHINITIS, ALLERGIC	22 (13.5%)	24 (15.4%)	46 (14.4%)
	SINUSITIS,NOS	4 (2.5%)	2 (1.3%)	6 (1.9%)
	UPPER RESP DISORD, OTHER	1 (0.6%)	2 (1.3%)	3 (0.9%)
	UPPER RESP INFECT, ACUTE	2 (1.2%)	1 (0.6%)	3 (0.9%)

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Table 13.6.2.2

Significant Medical/Surgical History and Physical Examination (Excluding Psychiatric Disorders)
Active Conditions by Preferred Term Ordered by Decreasing Frequency
Intention-To-Treat Population

Preferred Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Patients with at least one Active Condition	93 (57.1%)	83 (53.2%)	176 (55.2%)
RHINITIS, ALLERGIC	22 (13.5%)	24 (15.4%)	46 (14.4%)
HEADACHE	18 (11.0%)	20 (12.8%)	38 (11.9%)
SKIN/SUBCUT DISORD, OTHER	15 (9.2%)	13 (8.3%)	28 (8.8%)
ASTHMA	10 (6.1%)	12 (7.7%)	22 (6.9%)
OBESITY	9 (5.5%)	8 (5.1%)	17 (5.3%)
GENITAL FEMALE DISORD, OTHER	7 (4.3%)	5 (3.2%)	12 (3.8%)
ALLERGY, NEC	6 (3.7%)	8 (5.1%)	14 (4.4%)
PAIN, ABDOMINO-PELVIC	5 (3.1%)	3 (1.9%)	8 (2.5%)
ADVERSE EFF/ANTIBIOTIC	4 (2.5%)	6 (3.8%)	10 (3.1%)
CONSTIPATION	4 (2.5%)	2 (1.3%)	6 (1.9%)
SINUSITIS,NOS	4 (2.5%)	2 (1.3%)	6 (1.9%)
INCONTINENCE, URINARY	4 (2.5%)	0	4 (1.3%)
OTITIS MEDIA	3 (1.8%)	2 (1.3%)	5 (1.6%)
VISUAL DISTURB	3 (1.8%)	1 (0.6%)	4 (1.3%)
EAR/MASTOID DISORD	3 (1.8%)	0	3 (0.9%)
INFLAM SKIN/SUBCUT	2 (1.2%)	4 (2.6%)	6 (1.9%)
INSOMNIA	2 (1.2%)	3 (1.9%)	5 (1.6%)
PAIN, JOINT	2 (1.2%)	1 (0.6%)	3 (0.9%)
UPPER RESP INFECT, ACUTE	2 (1.2%)	1 (0.6%)	3 (0.9%)
BRADYCARDIA	2 (1.2%)	0	2 (0.6%)
CARDIAC MURMURS	2 (1.2%)	0	2 (0.6%)
DEFORMITY, ACQUIRED	2 (1.2%)	0	2 (0.6%)
EYE DISORD, OTHER	2 (1.2%)	0	2 (0.6%)
HEARING LOSS	2 (1.2%)	0	2 (0.6%)
OPERATION, NOSE/MOUTH	2 (1.2%)	0	2 (0.6%)
SERUM BILIRUBIN, INCREASED	2 (1.2%)	0	2 (0.6%)
NAUSEA	1 (0.6%)	2 (1.3%)	3 (0.9%)
UPPER RESP DISORD, OTHER	1 (0.6%)	2 (1.3%)	3 (0.9%)
ARRHYTHMIA	1 (0.6%)	1 (0.6%)	2 (0.6%)
BACK PAIN	1 (0.6%)	1 (0.6%)	2 (0.6%)
CARDIOVAS FUNCTIONS/ECG, ABN	1 (0.6%)	1 (0.6%)	2 (0.6%)
CONDUCTION DISORD	1 (0.6%)	1 (0.6%)	2 (0.6%)
DIABETES MELLITUS	1 (0.6%)	1 (0.6%)	2 (0.6%)
ESOPHAGITIS	1 (0.6%)	1 (0.6%)	2 (0.6%)
FLATULENCE	1 (0.6%)	1 (0.6%)	2 (0.6%)
HEARTBURN	1 (0.6%)	1 (0.6%)	2 (0.6%)
HYPOTENSION, OTHER	1 (0.6%)	1 (0.6%)	2 (0.6%)
INFLUENZA	1 (0.6%)	1 (0.6%)	2 (0.6%)
MYALGIA	1 (0.6%)	1 (0.6%)	2 (0.6%)
TOXIC EFFECTS, VENOM	1 (0.6%)	1 (0.6%)	2 (0.6%)
URINARY TRACT INFECTION	1 (0.6%)	1 (0.6%)	2 (0.6%)
ADVERSE EFF/SEDATIVE	1 (0.6%)	0	1 (0.3%)
ADVERSE EFF/SKIN,MUC MEMB DRUG	1 (0.6%)	0	1 (0.3%)
ALLERGIC REACTION, FOOD	1 (0.6%)	0	1 (0.3%)

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Table 13.6.2.2

Significant Medical/Surgical History and Physical Examination (Excluding Psychiatric Disorders)
Active Conditions by Preferred Term Ordered by Decreasing Frequency
Intention-To-Treat Population

Preferred Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
AMENORRHEA	1 (0.6%)	0	1 (0.3%)
ANEMIA, IRON DEFIC	1 (0.6%)	0	1 (0.3%)
ANXIETY	1 (0.6%)	0	1 (0.3%)
ARTHRITIS, RHEUMATOID	1 (0.6%)	0	1 (0.3%)
ARTHROPATHY	1 (0.6%)	0	1 (0.3%)
CONDITIONS, PERINATAL	1 (0.6%)	0	1 (0.3%)
CONG ANOM, CIRC SYST	1 (0.6%)	0	1 (0.3%)
CONGEN ANOM, HEAD/NECK	1 (0.6%)	0	1 (0.3%)
GLAUCOMA	1 (0.6%)	0	1 (0.3%)
INFECTION, BACTERIAL	1 (0.6%)	0	1 (0.3%)
INJURY, SUPERFICIAL	1 (0.6%)	0	1 (0.3%)
LYMPHADENOPATHY	1 (0.6%)	0	1 (0.3%)
MENTAL STATUS, IMPAIRED	1 (0.6%)	0	1 (0.3%)
MOTION SICKNESS	1 (0.6%)	0	1 (0.3%)
MYCOSES	1 (0.6%)	0	1 (0.3%)
NASAL SEPTUM DEVIATED	1 (0.6%)	0	1 (0.3%)
NEUROSES	1 (0.6%)	0	1 (0.3%)
OPERATION, EAR	1 (0.6%)	0	1 (0.3%)
ORAL SOFT TISSUE DIS	1 (0.6%)	0	1 (0.3%)
PAIN, RESP	1 (0.6%)	0	1 (0.3%)
PHARYNGITIS, ACUTE	1 (0.6%)	0	1 (0.3%)
SCARRING	1 (0.6%)	0	1 (0.3%)
SPASM, MUSCLE	1 (0.6%)	0	1 (0.3%)
TEETH DISORD	1 (0.6%)	0	1 (0.3%)
THYROID FUNCTION, ABN	1 (0.6%)	0	1 (0.3%)
TREMOR	1 (0.6%)	0	1 (0.3%)
ULCER, GASTRIC	1 (0.6%)	0	1 (0.3%)
URINARY CASTS/WBC'S	1 (0.6%)	0	1 (0.3%)
VOMITING	1 (0.6%)	0	1 (0.3%)
WEIGHT LOSS	1 (0.6%)	0	1 (0.3%)
MIGRAINE	0	4 (2.6%)	4 (1.3%)
ADVERSE EFF/ANALGESIC	0	2 (1.3%)	2 (0.6%)
EOSINOPHILIA	0	2 (1.3%)	2 (0.6%)
EPISTAXIS	0	2 (1.3%)	2 (0.6%)
HYPOTHYROIDISM	0	2 (1.3%)	2 (0.6%)
RASH/OTHER SKIN ERUPTION	0	2 (1.3%)	2 (0.6%)
SLEEP DISORD, NONORGANIC	0	2 (1.3%)	2 (0.6%)
ADVERSE EFF/ANTI-INFECT	0	1 (0.6%)	1 (0.3%)
ADVERSE EFF/RESP AGENT	0	1 (0.6%)	1 (0.3%)
BLOOD PRESSURE, ELEVATED	0	1 (0.6%)	1 (0.3%)
BREAST HYPERTROPHY, UNSP	0	1 (0.6%)	1 (0.3%)
BRONCHITIS, CHRONIC	0	1 (0.6%)	1 (0.3%)
BRONCHITIS, OTHER	0	1 (0.6%)	1 (0.3%)
CARBOHYDRATE DISORD	0	1 (0.6%)	1 (0.3%)
CARDIOMEGALY	0	1 (0.6%)	1 (0.3%)
CHOLEST/TRIGLYCERIDE, ELEVATED	0	1 (0.6%)	1 (0.3%)

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Table 13.6.2.2

Significant Medical/Surgical History and Physical Examination (Excluding Psychiatric Disorders)
Active Conditions by Preferred Term Ordered by Decreasing Frequency
Intention-To-Treat Population

Preferred Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
CONG ANOM, ENDOCRINE	0	1 (0.6%)	1 (0.3%)
CONG ANOM, HEART	0	1 (0.6%)	1 (0.3%)
CONG ANOM, INTEGUMENT	0	1 (0.6%)	1 (0.3%)
CONTUSION	0	1 (0.6%)	1 (0.3%)
DENTOFACIAL ANOM	0	1 (0.6%)	1 (0.3%)
DIGESTIVE DISORD, OTHER	0	1 (0.6%)	1 (0.3%)
EXTRASYSTOLES, VENTRICULAR	0	1 (0.6%)	1 (0.3%)
HEAD AND NECK SYMPTOMS, OTHER	0	1 (0.6%)	1 (0.3%)
HEMIPARESIS	0	1 (0.6%)	1 (0.3%)
HYPOGLYCEMIA	0	1 (0.6%)	1 (0.3%)
INCONTINENCE, FECAL	0	1 (0.6%)	1 (0.3%)
LACK OF COORDINATION	0	1 (0.6%)	1 (0.3%)
LEUCOCYTOSIS	0	1 (0.6%)	1 (0.3%)
MENTAL DEVELOP DISORD	0	1 (0.6%)	1 (0.3%)
OPEN WOUND	0	1 (0.6%)	1 (0.3%)
SEX DEVELOP DISORD, OTHER	0	1 (0.6%)	1 (0.3%)
STOMACH/DUODENUM DISORD	0	1 (0.6%)	1 (0.3%)
VIRUS/CHLAMYD DIS, OTHER	0	1 (0.6%)	1 (0.3%)

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Table 13.7.1

Psychiatric History - Number (%) of Patients In Each Category Of The ADIS C/P Based On Overall Diagnosis

Intention-To-Treat Population

Age Group : Children

	Treatment Group											
	Paroxetine (N=46)				Placebo (N=45)				Total (N=91)			
	Yes		No		Yes		No		Yes		No	
	n	%	n	%	n	%	n	%	n	%	n	%
Separation Anxiety Disorder	15	32.6	31	67.4	13	28.9	32	71.1	28	30.8	63	69.2
Social Phobia (Social Anxiety Disorder)	46	100.0	0	0	45	100.0	0	0	91	100.0	0	0
Specific Phobia	12	26.1	34	73.9	13	28.9	32	71.1	25	27.5	66	72.5
Panic Disorder	0	0	46	100.0	0	0	45	100.0	0	0	91	100.0
Agoraphobia (With or Without Panic Disorder)	2	4.3	44	95.7	0	0	45	100.0	2	2.2	89	97.8
Generalized Anxiety Disorder	7	15.2	39	84.8	13	28.9	32	71.1	20	22.0	71	78.0
Obsessive-Compulsive Disorder	0	0	46	100.0	1	2.2	44	97.8	1	1.1	90	98.9
Post traumatic Stress Disorder (PTSD) / Acute Stress Disorder	0	0	46	100.0	0	0	45	100.0	0	0	91	100.0
Dysthymia	2	4.3	44	95.7	4	8.9	41	91.1	6	6.6	85	93.4
Major Depressive Disorder	1	2.2	45	97.8	1	2.2	44	97.8	2	2.2	89	97.8
Externalizing Disorders	6	13.0	40	87.0	1	2.2	44	97.8	7	7.7	84	92.3
Additional Psychiatric Conditions	8	17.4	2	4.3	3	6.7	2	4.4	11	12.1	4	4.4

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Table 13.7.1

Psychiatric History - Number (%) of Patients In Each Category Of The ADIS C/P Based On Overall Diagnosis

Intention-To-Treat Population

Age Group : Adolescents

	Treatment Group											
	Paroxetine (N=117)				Placebo (N=111)				Total (N=228)			
	Yes		No		Yes		No		Yes		No	
	n	%	n	%	n	%	n	%	n	%	n	%
Separation Anxiety Disorder	13	11.1	104	88.9	11	9.9	100	90.1	24	10.5	204	89.5
Social Phobia (Social Anxiety Disorder)	117	100.0	0	0	111	100.0	0	0	228	100.0	0	0
Specific Phobia	27	23.1	90	76.9	27	24.3	84	75.7	54	23.7	174	76.3
Panic Disorder	2	1.7	115	98.3	1	0.9	110	99.1	3	1.3	225	98.7
Agoraphobia (With or Without Panic Disorder)	2	1.7	115	98.3	5	4.5	106	95.5	7	3.1	221	96.9
Generalized Anxiety Disorder	30	25.6	87	74.4	25	22.5	86	77.5	55	24.1	173	75.9
Obsessive-Compulsive Disorder	1	0.9	116	99.1	1	0.9	110	99.1	2	0.9	226	99.1
Post traumatic Stress Disorder (PTSD) / Acute Stress Disorder	2	1.7	115	98.3	4	3.6	107	96.4	6	2.6	222	97.4
Dysthymia	11	9.4	106	90.6	9	8.1	102	91.9	20	8.8	208	91.2
Major Depressive Disorder	3	2.6	114	97.4	4	3.6	107	96.4	7	3.1	221	96.9
Externalizing Disorders	7	6.0	110	94.0	7	6.3	104	93.7	14	6.1	214	93.9
Additional Psychiatric Conditions	16	13.7	4	3.4	6	5.4	3	2.7	22	9.6	7	3.1

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Table 13.7.1

Psychiatric History - Number (%) of Patients In Each Category Of The ADIS C/P Based On Overall Diagnosis

Intention-To-Treat Population

Age Group : Total

	Treatment Group											
	Paroxetine (N=163)				Placebo (N=156)				Total (N=319)			
	Yes		No		Yes		No		Yes		No	
	n	%	n	%	n	%	n	%	n	%	n	%
Separation Anxiety Disorder	28	17.2	135	82.8	24	15.4	132	84.6	52	16.3	267	83.7
Social Phobia (Social Anxiety Disorder)	163	100.0	0	0	156	100.0	0	0	319	100.0	0	0
Specific Phobia	39	23.9	124	76.1	40	25.6	116	74.4	79	24.8	240	75.2
Panic Disorder	2	1.2	161	98.8	1	0.6	155	99.4	3	0.9	316	99.1
Agoraphobia (With or Without Panic Disorder)	4	2.5	159	97.5	5	3.2	151	96.8	9	2.8	310	97.2
Generalized Anxiety Disorder	37	22.7	126	77.3	38	24.4	118	75.6	75	23.5	244	76.5
Obsessive-Compulsive Disorder	1	0.6	162	99.4	2	1.3	154	98.7	3	0.9	316	99.1
Post traumatic Stress Disorder (PTSD) / Acute Stress Disorder	2	1.2	161	98.8	4	2.6	152	97.4	6	1.9	313	98.1
Dysthymia	13	8.0	150	92.0	13	8.3	143	91.7	26	8.2	293	91.8
Major Depressive Disorder	4	2.5	159	97.5	5	3.2	151	96.8	9	2.8	310	97.2
Externalizing Disorders	13	8.0	150	92.0	8	5.1	148	94.9	21	6.6	298	93.4
Additional Psychiatric Conditions	24	14.7	6	3.7	9	5.8	5	3.2	33	10.3	11	3.4

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Table 13.7.2

Psychiatric History - Number (%) of Patients In Each Diagnostic Category Of The ADIS C/P by Overall Clinician Severity Rating

Intention-To-Treat Population

Diagnosis : Separation Anxiety Disorder

	Treatment Group											
	Paroxetine (N = 163)						Placebo (N = 156)					
	Children		Adolescents		Total		Children		Adolescents		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Severity Rating												
Not diagnosed	31	67.4	104	88.9	135	82.8	32	71.1	100	90.1	132	84.6
Mild (1-3)	4	8.7	3	2.6	7	4.3	1	2.2	3	2.7	4	2.6
Moderate (4-5)	10	21.7	7	6.0	17	10.4	9	20.0	6	5.4	15	9.6
Severe (6-7)	1	2.2	2	1.7	3	1.8	3	6.7	1	0.9	4	2.6
Very Severe (8)	0	0	1	0.9	1	0.6	0	0	1	0.9	1	0.6
Total diagnosed	15	32.6	13	11.1	28	17.2	13	28.9	11	9.9	24	15.4

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Table 13.7.2

Psychiatric History - Number (%) of Patients In Each Diagnostic Category Of The ADIS C/P by Overall Clinician Severity Rating

Intention-To-Treat Population

Diagnosis : Social Phobia

	Treatment Group											
	Paroxetine (N = 163)						Placebo (N = 156)					
	Children		Adolescents		Total		Children		Adolescents		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Severity Rating												
Not diagnosed	0	0	2	1.7	2	1.2	0	0	1	0.9	1	0.6
Mild (1-3)	0	0	0	0	0	0	1	2.2	1	0.9	2	1.3
Moderate (4-5)	14	30.4	31	26.5	45	27.6	14	31.1	35	31.5	49	31.4
Severe (6-7)	26	56.5	69	59.0	95	58.3	22	48.9	65	58.6	87	55.8
Very Severe (8)	6	13.0	15	12.8	21	12.9	8	17.8	9	8.1	17	10.9
Total diagnosed	46	100.0	115	98.3	161	98.8	45	100.0	110	99.1	155	99.4

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Table 13.7.2

Psychiatric History - Number (%) of Patients In Each Diagnostic Category Of The ADIS C/P by Overall Clinician Severity Rating

Intention-To-Treat Population

Diagnosis : Specific Phobia

	Treatment Group											
	Paroxetine (N = 163)						Placebo (N = 156)					
	Children		Adolescents		Total		Children		Adolescents		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Severity Rating												
Not diagnosed	34	73.9	91	77.8	125	76.7	32	71.1	84	75.7	116	74.4
Mild (1-3)	4	8.7	9	7.7	13	8.0	6	13.3	10	9.0	16	10.3
Moderate (4-5)	7	15.2	14	12.0	21	12.9	6	13.3	15	13.5	21	13.5
Severe (6-7)	1	2.2	2	1.7	3	1.8	0	0	2	1.8	2	1.3
Very Severe (8)	0	0	1	0.9	1	0.6	1	2.2	0	0	1	0.6
Total diagnosed	12	26.1	26	22.2	38	23.3	13	28.9	27	24.3	40	25.6

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Table 13.7.2

Psychiatric History - Number (%) of Patients In Each Diagnostic Category Of The ADIS C/P by Overall Clinician Severity Rating

Intention-To-Treat Population

Diagnosis : Panic Disorder

	Treatment Group											
	Paroxetine (N = 163)						Placebo (N = 156)					
	Children		Adolescents		Total		Children		Adolescents		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Severity Rating												
Not diagnosed	46	100.0	115	98.3	161	98.8	45	100.0	110	99.1	155	99.4
Mild (1-3)	0	0	1	0.9	1	0.6	0	0	1	0.9	1	0.6
Moderate (4-5)	0	0	1	0.9	1	0.6	0	0	0	0	0	0
Severe (6-7)	0	0	0	0	0	0	0	0	0	0	0	0
Very Severe (8)	0	0	0	0	0	0	0	0	0	0	0	0
Total diagnosed	0	0	2	1.7	2	1.2	0	0	1	0.9	1	0.6

Table 13.7.2

Psychiatric History - Number (%) of Patients In Each Diagnostic Category Of The ADIS C/P by Overall Clinician Severity Rating

Intention-To-Treat Population

Diagnosis : Agoraphobia

	Treatment Group											
	Paroxetine (N = 163)						Placebo (N = 156)					
	Children		Adolescents		Total		Children		Adolescents		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Severity Rating												
Not diagnosed	44	95.7	115	98.3	159	97.5	45	100.0	106	95.5	151	96.8
Mild (1-3)	1	2.2	1	0.9	2	1.2	0	0	2	1.8	2	1.3
Moderate (4-5)	1	2.2	1	0.9	2	1.2	0	0	1	0.9	1	0.6
Severe (6-7)	0	0	0	0	0	0	0	0	2	1.8	2	1.3
Very Severe (8)	0	0	0	0	0	0	0	0	0	0	0	0
Total diagnosed	2	4.3	2	1.7	4	2.5	0	0	5	4.5	5	3.2

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Table 13.7.2

Psychiatric History - Number (%) of Patients In Each Diagnostic Category Of The ADIS C/P by Overall Clinician Severity Rating

Intention-To-Treat Population

Diagnosis : Generalized anxiety disorder

	Treatment Group											
	Paroxetine (N = 163)						Placebo (N = 156)					
	Children		Adolescents		Total		Children		Adolescents		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Severity Rating												
Not diagnosed	39	84.8	87	74.4	126	77.3	32	71.1	86	77.5	118	75.6
Mild (1-3)	1	2.2	3	2.6	4	2.5	0	0	4	3.6	4	2.6
Moderate (4-5)	4	8.7	17	14.5	21	12.9	10	22.2	19	17.1	29	18.6
Severe (6-7)	2	4.3	10	8.5	12	7.4	3	6.7	2	1.8	5	3.2
Very Severe (8)	0	0	0	0	0	0	0	0	0	0	0	0
Total diagnosed	7	15.2	30	25.6	37	22.7	13	28.9	25	22.5	38	24.4

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Table 13.7.2

Psychiatric History - Number (%) of Patients In Each Diagnostic Category Of The ADIS C/P by Overall Clinician Severity Rating

Intention-To-Treat Population

Diagnosis : Obsessive Compulsive Disorder

	Treatment Group											
	Paroxetine (N = 163)						Placebo (N = 156)					
	Children		Adolescents		Total		Children		Adolescents		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Severity Rating												
Not diagnosed	46	100.0	116	99.1	162	99.4	44	97.8	110	99.1	154	98.7
Mild (1-3)	0	0	0	0	0	0	1	2.2	0	0	1	0.6
Moderate (4-5)	0	0	0	0	0	0	0	0	1	0.9	1	0.6
Severe (6-7)	0	0	1	0.9	1	0.6	0	0	0	0	0	0
Very Severe (8)	0	0	0	0	0	0	0	0	0	0	0	0
Total diagnosed	0	0	1	0.9	1	0.6	1	2.2	1	0.9	2	1.3

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Table 13.7.2

Psychiatric History - Number (%) of Patients In Each Diagnostic Category Of The ADIS C/P by Overall Clinician Severity Rating

Intention-To-Treat Population

Diagnosis : Post traumatic stress disorder

	Treatment Group											
	Paroxetine (N = 163)						Placebo (N = 156)					
	Children		Adolescents		Total		Children		Adolescents		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Severity Rating												
Not diagnosed	46	100.0	115	98.3	161	98.8	45	100.0	107	96.4	152	97.4
Mild (1-3)	0	0	1	0.9	1	0.6	0	0	0	0	0	0
Moderate (4-5)	0	0	1	0.9	1	0.6	0	0	4	3.6	4	2.6
Severe (6-7)	0	0	0	0	0	0	0	0	0	0	0	0
Very Severe (8)	0	0	0	0	0	0	0	0	0	0	0	0
Total diagnosed	0	0	2	1.7	2	1.2	0	0	4	3.6	4	2.6

Table 13.7.2

Psychiatric History - Number (%) of Patients In Each Diagnostic Category Of The ADIS C/P by Overall Clinician Severity Rating

Intention-To-Treat Population

Diagnosis : Dysthymia

	Treatment Group											
	Paroxetine (N = 163)						Placebo (N = 156)					
	Children		Adolescents		Total		Children		Adolescents		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Severity Rating												
Not diagnosed	44	95.7	106	90.6	150	92.0	41	91.1	102	91.9	143	91.7
Mild (1-3)	1	2.2	1	0.9	2	1.2	2	4.4	2	1.8	4	2.6
Moderate (4-5)	1	2.2	7	6.0	8	4.9	1	2.2	7	6.3	8	5.1
Severe (6-7)	0	0	3	2.6	3	1.8	1	2.2	0	0	1	0.6
Very Severe (8)	0	0	0	0	0	0	0	0	0	0	0	0
Total diagnosed	2	4.3	11	9.4	13	8.0	4	8.9	9	8.1	13	8.3

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Table 13.7.2

Psychiatric History - Number (%) of Patients In Each Diagnostic Category Of The ADIS C/P by Overall Clinician Severity Rating

Intention-To-Treat Population

Diagnosis : Major Depressive Disorder

	Treatment Group											
	Paroxetine (N = 163)						Placebo (N = 156)					
	Children		Adolescents		Total		Children		Adolescents		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Severity Rating												
Not diagnosed	45	97.8	114	97.4	159	97.5	44	97.8	107	96.4	151	96.8
Mild (1-3)	0	0	1	0.9	1	0.6	1	2.2	1	0.9	2	1.3
Moderate (4-5)	1	2.2	0	0	1	0.6	0	0	2	1.8	2	1.3
Severe (6-7)	0	0	2	1.7	2	1.2	0	0	1	0.9	1	0.6
Very Severe (8)	0	0	0	0	0	0	0	0	0	0	0	0
Total diagnosed	1	2.2	3	2.6	4	2.5	1	2.2	4	3.6	5	3.2

Table 13.7.2

Psychiatric History - Number (%) of Patients In Each Diagnostic Category Of The ADIS C/P by Overall Clinician Severity Rating

Intention-To-Treat Population

Diagnosis : Externalizing Disorders

	Treatment Group											
	Paroxetine (N = 163)						Placebo (N = 156)					
	Children		Adolescents		Total		Children		Adolescents		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Severity Rating												
Not diagnosed	40	87.0	110	94.0	150	92.0	44	97.8	104	93.7	148	94.9
Mild (1-3)	1	2.2	0	0	1	0.6	0	0	2	1.8	2	1.3
Moderate (4-5)	4	8.7	6	5.1	10	6.1	0	0	5	4.5	5	3.2
Severe (6-7)	1	2.2	1	0.9	2	1.2	1	2.2	0	0	1	0.6
Very Severe (8)	0	0	0	0	0	0	0	0	0	0	0	0
Total diagnosed	6	13.0	7	6.0	13	8.0	1	2.2	7	6.3	8	5.1

Table 13.7.2

Psychiatric History - Number (%) of Patients In Each Diagnostic Category Of The ADIS C/P by Overall Clinician Severity Rating

Intention-To-Treat Population

Diagnosis : Additional Psychiatric Conditions

	Treatment Group											
	Paroxetine (N = 163)						Placebo (N = 156)					
	Children		Adolescents		Total		Children		Adolescents		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Severity Rating												
Not diagnosed	2	18.2	6	27.3	8	24.2	2	40.0	3	33.3	5	35.7
Mild (1-3)	2	18.2	5	22.7	7	21.2	2	40.0	3	33.3	5	35.7
Moderate (4-5)	4	36.4	8	36.4	12	36.4	0	0	2	22.2	2	14.3
Severe (6-7)	3	27.3	3	13.6	6	18.2	0	0	1	11.1	1	7.1
Very Severe (8)	0	0	0	0	0	0	1	20.0	0	0	1	7.1
Total diagnosed	9	81.8	16	72.7	25	75.8	3	60.0	6	66.7	9	64.3

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Table 13.8.1

Number (%) of Patients by ECG Assessment

All Patients

Visit		Treatment Group: No Therapy Dispensed (N=103)	Paroxetine (N=165)	Placebo (N=157)	Total (N=425)
Screening	Abnormal	1 (1.9%)	2 (1.2%)	2 (1.3%)	5 (1.3%)
	Normal	50 (96.2%)	163 (98.8%)	155 (98.7%)	368 (98.4%)
	Missing	1 (1.9%)	0	0	1 (0.3%)
	Total	52 (100.0%)	165 (100.0%)	157 (100.0%)	374 (100.0%)
Baseline	Abnormal	0	0	1 (0.6%)	1 (0.3%)
	Normal	0	3 (1.9%)	5 (3.2%)	8 (2.5%)
	Unknown*	0	0	0	0
	Not Applicable**	6 (100.0%)	158 (98.1%)	151 (96.2%)	315 (97.2%)
	Total	6 (100.0%)	161 (100.0%)	157 (100.0%)	324 (100.0%)

* Abnormal at previous visit, but re-test not done or result of re-test unknown
** Not applicable, Normal at previous visit
Note: Percentages are based on number of patients with an assessment at that visit

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Table 13.9.1

Number (%) of Patients With Each CGI Severity of Illness Score at Baseline

Intention-To-Treat Population

Age Group : Children

	Treatment Group					
	Paroxetine (N = 46)		Placebo (N = 45)		Total (N = 91)	
	n	%	n	%	n	%
CGI Severity of Illness						
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)	1	2.2	3	6.7	4	4.4
Moderately ill (4)	25	54.3	20	44.4	45	49.5
Markedly ill (5)	16	34.8	20	44.4	36	39.6
Severely ill (6)	3	6.5	2	4.4	5	5.5
Among the most extremely ill patients (7)	0	0.0	0	0.0	0	0.0

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Table 13.9.1

Number (%) of Patients With Each CGI Severity of Illness Score at Baseline

Intention-To-Treat Population

Age Group : Adolescents

	Treatment Group					
	Paroxetine (N = 117)		Placebo (N = 111)		Total (N = 228)	
	n	%	n	%	n	%
CGI Severity of Illness						
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)	3	2.6	3	2.7	6	2.6
Moderately ill (4)	49	41.9	49	44.1	98	43.0
Markedly ill (5)	45	38.5	41	36.9	86	37.7
Severely ill (6)	18	15.4	15	13.5	33	14.5
Among the most extremely ill patients (7)	2	1.7	2	1.8	4	1.8

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Table 13.9.1

Number (%) of Patients With Each CGI Severity of Illness Score at Baseline

Intention-To-Treat Population

Age Group : Total

	Treatment Group					
	Paroxetine (N = 163)		Placebo (N = 156)		Total (N = 319)	
	n	%	n	%	n	%
CGI Severity of Illness						
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)	4	2.5	6	3.8	10	3.1
Moderately ill (4)	74	45.4	69	44.2	143	44.8
Markedly ill (5)	61	37.4	61	39.1	122	38.2
Severely ill (6)	21	12.9	17	10.9	38	11.9
Among the most extremely ill patients (7)	2	1.2	2	1.3	4	1.3

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Table 13.10.1

Summary Statistics for LSAS-CA Total Score at Baseline

Intention-To-Treat Population

Age Group : Children

Visit	Statistic	Treatment Group Paroxetine (N=46)	Placebo (N=45)	Total (N=91)
Baseline	N	44	45	89
	MEAN	70.7	71.2	70.9
	MEDIAN	71.5	69.0	70.0
	STDDEV	31.00	28.65	29.66
	MINIMUM	1	9	1
	MAXIMUM	127	132	132
	MISSING	2	0	2

Note: MISSING row indicates number of patients with either missing data at baseline or insufficient data to calculate total

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Table 13.10.1

Summary Statistics for LSAS-CA Total Score at Baseline

Intention-To-Treat Population

Age Group : Adolescents

Visit	Statistic	Treatment Group Paroxetine (N=117)	Placebo (N=111)	Total (N=228)
Baseline	N	117	110	227
	MEAN	80.3	80.3	80.3
	MEDIAN	79.0	84.0	82.0
	STDDEV	27.49	26.04	26.74
	MINIMUM	22	26	22
	MAXIMUM	133	130	133
	MISSING	0	0	0

Note: MISSING row indicates number of patients with either missing data at baseline or insufficient data to calculate total

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Table 13.10.1

Summary Statistics for LSAS-CA Total Score at Baseline

Intention-To-Treat Population

Age Group : Total

Visit	Statistic	Treatment Group Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Baseline	N	161	155	316
	MEAN	77.6	77.7	77.6
	MEDIAN	79.0	80.0	79.0
	STDDEV	28.72	27.05	27.87
	MINIMUM	1	9	1
	MAXIMUM	133	132	133
	MISSING	2	0	2

Note: MISSING row indicates number of patients with either missing data at baseline or insufficient data to calculate total

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Table 13.11.1

Summary Statistics for D-GSADS-A Total Score at Baseline

Intention-To-Treat Population
(>= 11 years)

Visit	Statistic	Treatment Group Paroxetine	Placebo	Total
Baseline	N	126	125	251
	MEAN	84.4	81.9	83.2
	MEDIAN	85.0	85.0	85.0
	STDDEV	25.42	26.25	25.82
	MINIMUM	18	15	15
	MAXIMUM	129	131	131

The table includes patients aged 11 years or older

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Table 13.12.1

Summary Statistics for SPAI-C Total Score at Baseline

Intention-To-Treat Population

Visit	Statistic	Treatment Group Paroxetine	Placebo	Total
Baseline	N	71	66	137
	MEAN	28.1	29.5	28.8
	MEDIAN	28.0	30.0	29.0
	STDDEV	11.71	11.06	11.39
	MINIMUM	2	3	2
	MAXIMUM	51	51	51

SPAI-C: The table includes patients 13 years or younger, however it may also include some patients aged 14 and 15 years old (see clinical report for details)

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Table 13.13.1

Summary Statistics for SPAI Difference Score at Baseline

Intention-To-Treat Population

Visit	Statistic	Treatment Group Paroxetine	Placebo	Total
Baseline	N	81	84	165
	MEAN	98.7	90.9	94.8
	MEDIAN	102.0	92.5	99.0
	STDDEV	31.56	32.23	32.04
	MINIMUM	19	11	11
	MAXIMUM	157	144	157

SPAI: The table includes patients 14 years or older, however it may also include some patients 13 years old (see clinical report for details)

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Table 13.14.1

Summary Statistics for GAF Score at Baseline

Intention-To-Treat Population

Age Group : Children

Visit	Statistic	Treatment Group Paroxetine (N=46)	Placebo (N=45)	Total (N=91)
Baseline	N	45	45	90
	MEAN	53.0	55.0	54.0
	MEDIAN	55.0	55.0	55.0
	STDDEV	6.30	7.70	7.07
	MINIMUM	31	31	31
	MAXIMUM	65	70	70
	MISSING	1	0	1

Note: 'MISSING' row indicates number of patients with missing data or inadequate information at baseline

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Table 13.14.1

Summary Statistics for GAF Score at Baseline

Intention-To-Treat Population

Age Group : Adolescents

Visit	Statistic	Treatment Group Paroxetine (N=117)	Placebo (N=111)	Total (N=228)
Baseline	N	117	110	227
	MEAN	52.9	52.8	52.9
	MEDIAN	51.0	52.0	52.0
	STDDEV	7.07	7.38	7.20
	MINIMUM	31	31	31
	MAXIMUM	72	78	78
	MISSING	0	0	0

Note: 'MISSING' row indicates number of patients with missing data or inadequate information at baseline

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Table 13.14.1

Summary Statistics for GAF Score at Baseline

Intention-To-Treat Population

Age Group : Total

Visit	Statistic	Treatment Group Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Baseline	N	162	155	317
	MEAN	53.0	53.5	53.2
	MEDIAN	53.0	55.0	55.0
	STDDEV	6.85	7.51	7.17
	MINIMUM	31	31	31
	MAXIMUM	72	78	78
	MISSING	1	0	1

Note: 'MISSING' row indicates number of patients with missing data or inadequate information at baseline

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Table 13.15.1

Summary Statistics for CDRS-R Total Score at Baseline

Intention-To-Treat Population

Age Group : Children

Visit	Statistic	Treatment Group Paroxetine (N=46)	Placebo (N=45)	Total (N=91)
Baseline	N	45	45	90
	MEAN	29.4	29.5	29.4
	MEDIAN	26.0	26.0	26.0
	STDDEV	10.05	10.58	10.26
	MINIMUM	17	17	17
	MAXIMUM	56	50	56
	MISSING	1	0	1

Note: MISSING row indicates number of patients with either missing data at baseline or insufficient data to calculate total

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Table 13.15.1

Summary Statistics for CDRS-R Total Score at Baseline

Intention-To-Treat Population

Age Group : Adolescents

Visit	Statistic	Treatment Group Paroxetine (N=117)	Placebo (N=111)	Total (N=228)
Baseline	N	117	110	227
	MEAN	29.6	31.3	30.4
	MEDIAN	28.0	27.5	28.0
	STDDEV	10.62	12.41	11.53
	MINIMUM	17	17	17
	MAXIMUM	65	75	75
	MISSING	0	0	0

Note: MISSING row indicates number of patients with either missing data at baseline or insufficient data to calculate total

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Table 13.15.1

Summary Statistics for CDRS-R Total Score at Baseline

Intention-To-Treat Population

Age Group : Total

Visit	Statistic	Treatment Group Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Baseline	N	162	155	317
	MEAN	29.5	30.8	30.1
	MEDIAN	27.0	27.0	27.0
	STDDEV	10.43	11.90	11.17
	MINIMUM	17	17	17
	MAXIMUM	65	75	75
	MISSING	1	0	1

Note: MISSING row indicates number of patients with either missing data at baseline or insufficient data to calculate total

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Table 13.16.1.1

Psychoactive Medication History by Pharmacotherapy Class Identification and Generic Term

Intention-To-Treat Population

Age Group : Children

Psychoactive Class	Generic Term(s)	Treatment Group Paroxetine (N=46)	Placebo (N=45)	Total (N=91)
SSRI	Total	0	2(4.4%)	2(2.2%)
	FLUOXETINE	0	1(2.2%)	1(1.1%)
	SERTRALINE HYDROCHLORIDE	0	1(2.2%)	1(1.1%)
MAOI	Total	0	0	0
TCA	Total	1(2.2%)	0	1(1.1%)
	IMIPRAMINE	1(2.2%)	0	1(1.1%)
Benzodiazepines	Total	0	1(2.2%)	1(1.1%)
	DIAZEPAM	0	1(2.2%)	1(1.1%)
Other psychoactive medications	Total	3(6.5%)	5(11.1%)	8(8.8%)
	AMPHETAMINE ASPARTATE	1(2.2%)	1(2.2%)	2(2.2%)
	AMPHETAMINE SULFATE	1(2.2%)	1(2.2%)	2(2.2%)
	DEXTROAMPHETAMINE SACCHARATE	1(2.2%)	1(2.2%)	2(2.2%)
	DEXTROAMPHETAMINE SULFATE	1(2.2%)	1(2.2%)	2(2.2%)
	METHYLPHENIDATE HYDROCHLORIDE	2(4.3%)	5(11.1%)	7(7.7%)
	OXYBUTYNIN	1(2.2%)	0	1(1.1%)
Total *		4(8.7%)	8(17.8%)	12(13.2%)
None		42(91.3%)	37(82.2%)	79(86.8%)

* Total number of patients in one or more psychoactive class
Note that this tabulates medication taken during the year prior to screening

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Table 13.16.1.1

Psychoactive Medication History by Pharmacotherapy Class Identification and Generic Term

Intention-To-Treat Population

Age Group : Adolescents

Psychoactive Class	Generic Term(s)	Treatment Group Paroxetine (N=117)	Placebo (N=111)	Total (N=228)
SSRI	Total	10(8.5%)	10(9.0%)	20(8.8%)
	CITALOPRAM	0	2(1.8%)	2(0.9%)
	FLUOXETINE	2(1.7%)	3(2.7%)	5(2.2%)
	FLUVOXAMINE MALEATE	0	1(0.9%)	1(0.4%)
	PAROXETINE	4(3.4%)	6(5.4%)	10(4.4%)
	SERTRALINE	1(0.9%)	0	1(0.4%)
	SERTRALINE HYDROCHLORIDE	4(3.4%)	1(0.9%)	5(2.2%)
MAOI	Total	0	0	0
TCA	Total	4(3.4%)	1(0.9%)	5(2.2%)
	DOXEPIN	1(0.9%)	0	1(0.4%)
	IMIPRAMINE	2(1.7%)	1(0.9%)	3(1.3%)
	IMIPRAMINE HYDROCHLORIDE	1(0.9%)	0	1(0.4%)
Benzodiazepines	Total	3(2.6%)	3(2.7%)	6(2.6%)
	ALPRAZOLAM	1(0.9%)	1(0.9%)	2(0.9%)
	CLOBAZAM	0	1(0.9%)	1(0.4%)
	LORAZEPAM	2(1.7%)	0	2(0.9%)
	PRAZEPAM	0	1(0.9%)	1(0.4%)
Other psychoactive medications	Total	17(14.5%)	11(9.9%)	28(12.3%)
	AMFEBUTAMONE HYDROCHLORIDE	0	1(0.9%)	1(0.4%)
	AMPHETAMINE ASPARTATE	1(0.9%)	3(2.7%)	4(1.8%)
	AMPHETAMINE SULFATE	1(0.9%)	3(2.7%)	4(1.8%)
	CARBAMAZEPINE	0	1(0.9%)	1(0.4%)
	CLONIDINE	0	1(0.9%)	1(0.4%)
	DEXAMPHETAMINE SULFATE	1(0.9%)	1(0.9%)	2(0.9%)
	DEXTROAMPHETAMINE SACCHARATE	1(0.9%)	3(2.7%)	4(1.8%)
	DEXTROAMPHETAMINE SULFATE	1(0.9%)	3(2.7%)	4(1.8%)
	FLUPENTIXOL DIHYDROCHLORIDE	1(0.9%)	0	1(0.4%)
	HYDROXYZINE HYDROCHLORIDE	1(0.9%)	0	1(0.4%)
	HYPERICUM EXTRACT	1(0.9%)	0	1(0.4%)
	METHYLPHENIDATE HYDROCHLORIDE	10(8.5%)	5(4.5%)	15(6.6%)
	MIRTAZAPINE	0	1(0.9%)	1(0.4%)
	NEFAZODONE	1(0.9%)	1(0.9%)	2(0.9%)
	PEMOLINE MAGNESIUM	0	1(0.9%)	1(0.4%)
	PROPRANOLOL HYDROCHLORIDE	1(0.9%)	0	1(0.4%)
	RISPERIDONE	1(0.9%)	0	1(0.4%)
	THIORIDAZINE HYDROCHLORIDE	1(0.9%)	0	1(0.4%)
	TRAZODONE HYDROCHLORIDE	1(0.9%)	1(0.9%)	2(0.9%)

* Total number of patients in one or more psychoactive class
Note that this tabulates medication taken during the year prior to screening

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Table 13.16.1.1

Psychoactive Medication History by Pharmacotherapy Class Identification and Generic Term

Intention-To-Treat Population

Age Group : Adolescents

Psychoactive Class	Generic Term(s)	Treatment Group Paroxetine (N=117)	Placebo (N=111)	Total (N=228)
Total *		26(22.2%)	22(19.8%)	48(21.1%)
None		91(77.8%)	89(80.2%)	180(78.9%)

* Total number of patients in one or more psychoactive class
Note that this tabulates medication taken during the year prior to screening

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Table 13.16.1.1

Psychoactive Medication History by Pharmacotherapy Class Identification and Generic Term

Intention-To-Treat Population

Age Group : Total

Psychoactive Class	Generic Term(s)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
SSRI	Total	10(6.1%)	12(7.7%)	22(6.9%)
	CITALOPRAM	0	2(1.3%)	2(0.6%)
	FLUOXETINE	2(1.2%)	4(2.6%)	6(1.9%)
	FLUVOXAMINE MALEATE	0	1(0.6%)	1(0.3%)
	PAROXETINE	4(2.5%)	6(3.8%)	10(3.1%)
	SERTRALINE	1(0.6%)	0	1(0.3%)
	SERTRALINE HYDROCHLORIDE	4(2.5%)	2(1.3%)	6(1.9%)
MAOI	Total	0	0	0
TCA	Total	5(3.1%)	1(0.6%)	6(1.9%)
	DOXEPIN	1(0.6%)	0	1(0.3%)
	IMIPRAMINE	3(1.8%)	1(0.6%)	4(1.3%)
	IMIPRAMINE HYDROCHLORIDE	1(0.6%)	0	1(0.3%)
Benzodiazepines	Total	3(1.8%)	4(2.6%)	7(2.2%)
	ALPRAZOLAM	1(0.6%)	1(0.6%)	2(0.6%)
	CLOBAZAM	0	1(0.6%)	1(0.3%)
	DIAZEPAM	0	1(0.6%)	1(0.3%)
	LORAZEPAM	2(1.2%)	0	2(0.6%)
	PRAZEPAM	0	1(0.6%)	1(0.3%)
Other psychoactive medications	Total	20(12.3%)	16(10.3%)	36(11.3%)
	AMFEBUTAMONE HYDROCHLORIDE	0	1(0.6%)	1(0.3%)
	AMPHETAMINE ASPARTATE	2(1.2%)	4(2.6%)	6(1.9%)
	AMPHETAMINE SULFATE	2(1.2%)	4(2.6%)	6(1.9%)
	CARBAMAZEPINE	0	1(0.6%)	1(0.3%)
	CLONIDINE	0	1(0.6%)	1(0.3%)
	DEXAMPHETAMINE SULFATE	1(0.6%)	1(0.6%)	2(0.6%)
	DEXTROAMPHETAMINE SACCHARATE	2(1.2%)	4(2.6%)	6(1.9%)
	DEXTROAMPHETAMINE SULFATE	2(1.2%)	4(2.6%)	6(1.9%)
	FLUPENTIXOL DIHYDROCHLORIDE	1(0.6%)	0	1(0.3%)
	HYDROXYZINE HYDROCHLORIDE	1(0.6%)	0	1(0.3%)
	HYPERICUM EXTRACT	1(0.6%)	0	1(0.3%)
	METHYLPHENIDATE HYDROCHLORIDE	12(7.4%)	10(6.4%)	22(6.9%)
	MIRTAZAPINE	0	1(0.6%)	1(0.3%)
	NEFAZODONE	1(0.6%)	1(0.6%)	2(0.6%)
	OXYBUTYNIN	1(0.6%)	0	1(0.3%)
	PEMOLINE MAGNESIUM	0	1(0.6%)	1(0.3%)
	PROPRANOLOL HYDROCHLORIDE	1(0.6%)	0	1(0.3%)
	RISPERIDONE	1(0.6%)	0	1(0.3%)

* Total number of patients in one or more psychoactive class
Note that this tabulates medication taken during the year prior to screening

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Table 13.16.1.1

Psychoactive Medication History by Pharmacotherapy Class Identification and Generic Term

Intention-To-Treat Population

Age Group : Total

Psychoactive Class	Generic Term(s)	Treatment Group Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Other psychoactive medications	THIORIDAZINE HYDROCHLORIDE	1(0.6%)	0	1(0.3%)
	TRAZODONE HYDROCHLORIDE	1(0.6%)	1(0.6%)	2(0.6%)
Total *		30(18.4%)	30(19.2%)	60(18.8%)
None		133(81.6%)	126(80.8%)	259(81.2%)

* Total number of patients in one or more psychoactive class
Note that this tabulates medication taken during the year prior to screening

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Table 13.16.1.2

Number (%) of Patients with Prior Psychoactive Medication by Generic Term Ordered by Decreasing Frequency

Intention-To-Treat Population

Generic Term	Treatment Group Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Total number of patients with at least one prior psychoactive medication	30 (18.4%)	30 (19.2%)	60 (18.8%)
METHYLPHENIDATE HYDROCHLORIDE	12 (7.4%)	10 (6.4%)	22 (6.9%)
PAROXETINE	4 (2.5%)	6 (3.8%)	10 (3.1%)
SERTRALINE HYDROCHLORIDE	4 (2.5%)	2 (1.3%)	6 (1.9%)
IMIPRAMINE	3 (1.8%)	1 (0.6%)	4 (1.3%)
AMPHETAMINE ASPARTATE	2 (1.2%)	4 (2.6%)	6 (1.9%)
AMPHETAMINE SULFATE	2 (1.2%)	4 (2.6%)	6 (1.9%)
DEXTROAMPHETAMINE SACCHARATE	2 (1.2%)	4 (2.6%)	6 (1.9%)
DEXTROAMPHETAMINE SULFATE	2 (1.2%)	4 (2.6%)	6 (1.9%)
FLUOXETINE	2 (1.2%)	4 (2.6%)	6 (1.9%)
LORAZEPAM	2 (1.2%)	0	2 (0.6%)
ALPRAZOLAM	1 (0.6%)	1 (0.6%)	2 (0.6%)
DEXAMPHETAMINE SULFATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
NEFAZODONE	1 (0.6%)	1 (0.6%)	2 (0.6%)
TRAZODONE HYDROCHLORIDE	1 (0.6%)	1 (0.6%)	2 (0.6%)
DOXEPIN	1 (0.6%)	0	1 (0.3%)
FLUPENTIXOL DIHYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
HYDROXYZINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
HYPERICUM EXTRACT	1 (0.6%)	0	1 (0.3%)
IMIPRAMINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
OXYBUTYNIN	1 (0.6%)	0	1 (0.3%)
PROPRANOLOL HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
RISPERIDONE	1 (0.6%)	0	1 (0.3%)
SERTRALINE	1 (0.6%)	0	1 (0.3%)
THIORIDAZINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
CITALOPRAM	0	2 (1.3%)	2 (0.6%)
AMFEBUTAMONE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
CARBAMAZEPINE	0	1 (0.6%)	1 (0.3%)
CLOBAZAM	0	1 (0.6%)	1 (0.3%)
CLONIDINE	0	1 (0.6%)	1 (0.3%)
DIAZEPAM	0	1 (0.6%)	1 (0.3%)
FLUVOXAMINE MALEATE	0	1 (0.6%)	1 (0.3%)
MIRTAZAPINE	0	1 (0.6%)	1 (0.3%)
PEMOLINE MAGNESIUM	0	1 (0.6%)	1 (0.3%)
PRAZEPAM	0	1 (0.6%)	1 (0.3%)

Note that this tabulates medication taken during the year prior to screening

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Table 13.16.2.1

Number (%) of Patients with Prior Non-Psychoactive Medication by ATC Classification and Generic Term

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Total number of patients with at least one prior non-psychoactive medication	Total	73 (44.8%)	62 (39.7%)	135 (42.3%)
ALIMENTARY TRACT/METAB	Total	17 (10.4%)	11 (7.1%)	28 (8.8%)
	ACETYLSALICYLIC ACID	1 (0.6%)	0	1 (0.3%)
	ALUMINIUM HYDROXIDE	1 (0.6%)	0	1 (0.3%)
	BISACODYL	1 (0.6%)	0	1 (0.3%)
	CALCIUM CARBONATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	CATHINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
	CIMETIDINE	1 (0.6%)	0	1 (0.3%)
	FAMOTIDINE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	FLUORIDE NOS	1 (0.6%)	0	1 (0.3%)
	INSULIN	1 (0.6%)	1 (0.6%)	2 (0.6%)
	MAGNESIUM HYDROXIDE	1 (0.6%)	0	1 (0.3%)
	METOCLOPRAMIDE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
	PARAFFIN, LIQUID	2 (1.2%)	1 (0.6%)	3 (0.9%)
	PSYLLIUM HYDROPHILIC MUCILLOID	0	1 (0.6%)	1 (0.3%)
	RANITIDINE HYDROCHLORIDE	2 (1.2%)	1 (0.6%)	3 (0.9%)
	RETINOL PALMITATE	1 (0.6%)	0	1 (0.3%)
	SENNA FRUIT	0	1 (0.6%)	1 (0.3%)
	TOCOPHEROL	1 (0.6%)	0	1 (0.3%)
	TRIAMCINOLONE ACETONIDE	1 (0.6%)	0	1 (0.3%)
	VITAMINS NOS	8 (4.9%)	4 (2.6%)	12 (3.8%)
	ZINC	0	1 (0.6%)	1 (0.3%)
ANTIINFECTIVES,SYSTEMIC	Total	13 (8.0%)	14 (9.0%)	27 (8.5%)
	AMOXICILLIN	1 (0.6%)	0	1 (0.3%)
	AMOXICILLIN TRIHYDRATE	1 (0.6%)	3 (1.9%)	4 (1.3%)
	AMPICILLIN	1 (0.6%)	0	1 (0.3%)
	AZITHROMYCIN	1 (0.6%)	0	1 (0.3%)
	CEFACLOR	1 (0.6%)	0	1 (0.3%)
	CEFALEXIN	1 (0.6%)	0	1 (0.3%)
	CEFPROZIL MONOHYDRATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	CEFUROXIME AXETIL	1 (0.6%)	0	1 (0.3%)
	CLARITHROMYCIN	0	1 (0.6%)	1 (0.3%)
	CLAVULANIC ACID	1 (0.6%)	1 (0.6%)	2 (0.6%)
	CLINDAMYCIN PHOSPHATE	0	1 (0.6%)	1 (0.3%)
	DOXYCYCLINE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
	ERYTHROMYCIN	0	1 (0.6%)	1 (0.3%)
	INFLUENZA VIRUS VACCINE POLYVALENT	0	1 (0.6%)	1 (0.3%)
	MINOCYCLINE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	MINOCYCLINE HYDROCHLORIDE	1 (0.6%)	2 (1.3%)	3 (0.9%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.16.2.1

Number (%) of Patients with Prior Non-Psychoactive Medication by ATC Classification and Generic Term

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
ANTIINFECTIVES,SYSTEMIC	OXYTETRACYCLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
	SULFAMETHOXAZOLE	0	1 (0.6%)	1 (0.3%)
	TETRACYCLINE	1 (0.6%)	2 (1.3%)	3 (0.9%)
	TETRACYCLINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
	TRIMETHOPRIM	0	1 (0.6%)	1 (0.3%)
ANTINEOPLASTIC & IMMUNOSUP	Total	1 (0.6%)	3 (1.9%)	4 (1.3%)
	DIETHYLSTILBESTROL DIPROPIONATE	0	1 (0.6%)	1 (0.3%)
	LEUPRORELIN ACETATE	0	1 (0.6%)	1 (0.3%)
	TRETINOIN	1 (0.6%)	1 (0.6%)	2 (0.6%)
BLOOD/BLOOD FORM ORGANS	Total	1 (0.6%)	2 (1.3%)	3 (0.9%)
	ACETYLSALICYLIC ACID	1 (0.6%)	0	1 (0.3%)
	AMINO ACIDS NOS	0	1 (0.6%)	1 (0.3%)
	ATORVASTATIN CALCIUM	0	1 (0.6%)	1 (0.3%)
CARDIOVASCULAR	Total	0	1 (0.6%)	1 (0.3%)
	ETILEFRINE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
CENTRAL NERVOUS SYSTEM	Total	23 (14.1%)	23 (14.7%)	46 (14.4%)
	ACETYLSALICYLIC ACID	2 (1.2%)	1 (0.6%)	3 (0.9%)
	CAFFEINE	1 (0.6%)	2 (1.3%)	3 (0.9%)
	CHLORPHENAMINE MALEATE	1 (0.6%)	0	1 (0.3%)
	CODEINE PHOSPHATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	DIPHENHYDRAMINE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
	HYDROXYZINE	0	1 (0.6%)	1 (0.3%)
	IBUPROFEN	11 (6.7%)	8 (5.1%)	19 (6.0%)
	LIDOCAINE	2 (1.2%)	4 (2.6%)	6 (1.9%)
	MEPYRAMINE MALEATE	0	2 (1.3%)	2 (0.6%)
	PAMABROM	0	2 (1.3%)	2 (0.6%)
	PARACETAMOL	12 (7.4%)	16 (10.3%)	28 (8.8%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
	PRILOCAINE	2 (1.2%)	4 (2.6%)	6 (1.9%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
	SALSALATE	0	1 (0.6%)	1 (0.3%)
DERMATOLOGICALS	Total	24 (14.7%)	21 (13.5%)	45 (14.1%)
	ADAPALENE	0	1 (0.6%)	1 (0.3%)
	BENZOYL PEROXIDE	1 (0.6%)	0	1 (0.3%)
	BETAMETHASONE ACETATE	0	1 (0.6%)	1 (0.3%)
	BETAMETHASONE DIPROPIONATE	0	1 (0.6%)	1 (0.3%)
	BETAMETHASONE SODIUM PHOSPHATE	0	2 (1.3%)	2 (0.6%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.16.2.1

Number (%) of Patients with Prior Non-Psychoactive Medication by ATC Classification and Generic Term

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
DERMATOLOGICALS	BUDESONIDE	2 (1.2%)	2 (1.3%)	4 (1.3%)
	CLINDAMYCIN PHOSPHATE	0	1 (0.6%)	1 (0.3%)
	DIPHENHYDRAMINE HYDROCHLORIDE	3 (1.8%)	1 (0.6%)	4 (1.3%)
	ERYTHROMYCIN	1 (0.6%)	1 (0.6%)	2 (0.6%)
	FLUOCINONIDE	1 (0.6%)	0	1 (0.3%)
	FLUTICASONE PROPIONATE	5 (3.1%)	3 (1.9%)	8 (2.5%)
	HYDROCORTISONE	1 (0.6%)	0	1 (0.3%)
	LIDOCAINE	2 (1.2%)	4 (2.6%)	6 (1.9%)
	MOMETASONE FUROATE	1 (0.6%)	4 (2.6%)	5 (1.6%)
	OXYTETRACYCLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
	PARAFFIN, LIQUID	2 (1.2%)	1 (0.6%)	3 (0.9%)
	PRILOCAINE	2 (1.2%)	4 (2.6%)	6 (1.9%)
	RETINOL PALMITATE	1 (0.6%)	0	1 (0.3%)
	TAZAROTENE	1 (0.6%)	0	1 (0.3%)
	TETRACYCLINE	1 (0.6%)	2 (1.3%)	3 (0.9%)
	TETRACYCLINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
	TOCOPHEROL	1 (0.6%)	0	1 (0.3%)
	TOPICAL ANTIBIOTIC	0	1 (0.6%)	1 (0.3%)
	TRETINOIN	1 (0.6%)	1 (0.6%)	2 (0.6%)
	TRIAMCINOLONE ACETONIDE	1 (0.6%)	0	1 (0.3%)
	TRICLOSAN	0	1 (0.6%)	1 (0.3%)
GU SYSTEM/SEX HORMONES	Total	10 (6.1%)	2 (1.3%)	12 (3.8%)
	CYPROTERONE ACETATE	1 (0.6%)	0	1 (0.3%)
	DIETHYLSTILBESTROL DIPROPIONATE	0	1 (0.6%)	1 (0.3%)
	ETHINYLESTRADIOL	8 (4.9%)	1 (0.6%)	9 (2.8%)
	GESTODENE	1 (0.6%)	0	1 (0.3%)
	LEVONORGESTREL	2 (1.2%)	1 (0.6%)	3 (0.9%)
	NORETHISTERONE	1 (0.6%)	0	1 (0.3%)
	NORGESTIMATE	3 (1.8%)	0	3 (0.9%)
	OXYTETRACYCLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
	PROGESTERONE	1 (0.6%)	0	1 (0.3%)
MUSCULO-SKELETAL	Total	10 (6.1%)	8 (5.1%)	18 (5.6%)
	IBUPROFEN	10 (6.1%)	7 (4.5%)	17 (5.3%)
	NAPROXEN	0	1 (0.6%)	1 (0.3%)
	NAPROXEN SODIUM	0	1 (0.6%)	1 (0.3%)
PARASITOLOGY	Total	1 (0.6%)	0	1 (0.3%)
	MEFLOQUINE	1 (0.6%)	0	1 (0.3%)
RESPIRATORY	Total	27 (16.6%)	26 (16.7%)	53 (16.6%)
	ACETYLSALICYLIC ACID	1 (0.6%)	0	1 (0.3%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.16.2.1

Number (%) of Patients with Prior Non-Psychoactive Medication by ATC Classification and Generic Term

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
RESPIRATORY	AMMONIUM CHLORIDE	0	1 (0.6%)	1 (0.3%)
	ASCORBIC ACID	1 (0.6%)	0	1 (0.3%)
	BECLOMETASONE DIPROPIONATE	1 (0.6%)	0	1 (0.3%)
	BROMHEXINE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
	BROMPHENIRAMINE MALEATE	2 (1.2%)	2 (1.3%)	4 (1.3%)
	BUDESONIDE	2 (1.2%)	2 (1.3%)	4 (1.3%)
	CAFFEINE	0	1 (0.6%)	1 (0.3%)
	CETIRIZINE HYDROCHLORIDE	3 (1.8%)	3 (1.9%)	6 (1.9%)
	CHLORPHENAMINE MALEATE	3 (1.8%)	1 (0.6%)	4 (1.3%)
	CHLORPHENAMINE TANNATE	1 (0.6%)	0	1 (0.3%)
	CLEMASTINE FUMARATE	1 (0.6%)	0	1 (0.3%)
	CODEINE PHOSPHATE	0	1 (0.6%)	1 (0.3%)
	CROMOGLICATE SODIUM	1 (0.6%)	0	1 (0.3%)
	DEXCHLORPHENIRAMINE MALEATE	1 (0.6%)	0	1 (0.3%)
	DIPHENHYDRAMINE HYDROCHLORIDE	3 (1.8%)	3 (1.9%)	6 (1.9%)
	EPHEDRINE SULFATE	1 (0.6%)	0	1 (0.3%)
	FENOTEROL HYDROBROMIDE	0	1 (0.6%)	1 (0.3%)
	FEXOFENADINE HYDROCHLORIDE	0	5 (3.2%)	5 (1.6%)
	FLUTICASONE PROPIONATE	5 (3.1%)	3 (1.9%)	8 (2.5%)
	GUAIFENESIN	1 (0.6%)	0	1 (0.3%)
	IPRATROPIUM BROMIDE	0	1 (0.6%)	1 (0.3%)
	LORATADINE	3 (1.8%)	5 (3.2%)	8 (2.5%)
	MEPYRAMINE TANNATE	1 (0.6%)	0	1 (0.3%)
	MOMETASONE FUROATE	1 (0.6%)	4 (2.6%)	5 (1.6%)
	MONTELUKAST SODIUM	0	1 (0.6%)	1 (0.3%)
	MOROXYDINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
	NASAL SPRAY	1 (0.6%)	0	1 (0.3%)
	ORCIPRENALINE SULFATE	0	1 (0.6%)	1 (0.3%)
	PARACETAMOL	2 (1.2%)	1 (0.6%)	3 (0.9%)
	PHENYLEPHRINE HYDROCHLORIDE	3 (1.8%)	2 (1.3%)	5 (1.6%)
	PHENYLEPHRINE TANNATE	1 (0.6%)	0	1 (0.3%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	4 (2.5%)	3 (1.9%)	7 (2.2%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	6 (3.7%)	4 (2.6%)	10 (3.1%)
	PSEUDOEPHEDRINE SULFATE	0	1 (0.6%)	1 (0.3%)
	SALBUTAMOL	3 (1.8%)	6 (3.8%)	9 (2.8%)
	SALMETEROL HYDROXYNAPHTHOATE	1 (0.6%)	0	1 (0.3%)
	SODIUM CITRATE	0	1 (0.6%)	1 (0.3%)
	TERBUTALINE SULFATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	TRIAMCINOLONE ACETONIDE	1 (0.6%)	0	1 (0.3%)
	TRIPROLIDINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
SENSORY ORGANS	Total	8 (4.9%)	2 (1.3%)	10 (3.1%)
	CROMOGLICATE SODIUM	1 (0.6%)	0	1 (0.3%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.16.2.1

Number (%) of Patients with Prior Non-Psychoactive Medication by ATC Classification and Generic Term

Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
SENSORY ORGANS	DEXAMETHASONE	1 (0.6%)	0	1 (0.3%)
	ERYTHROMYCIN	0	1 (0.6%)	1 (0.3%)
	HYDROCORTISONE	1 (0.6%)	0	1 (0.3%)
	OXYTETRACYCLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
	TETRACYCLINE	1 (0.6%)	2 (1.3%)	3 (0.9%)
	TETRACYCLINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
	TRIAMCINOLONE ACETONIDE	1 (0.6%)	0	1 (0.3%)
SYSTEMIC HORMONAL	Total	4 (2.5%)	4 (2.6%)	8 (2.5%)
	BETAMETHASONE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	BETAMETHASONE SODIUM PHOSPHATE	0	1 (0.6%)	1 (0.3%)
	CHLORPHENAMINE MALEATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	DEXAMETHASONE	1 (0.6%)	0	1 (0.3%)
	HYDROCORTISONE	1 (0.6%)	0	1 (0.3%)
	LEVOTHYROXINE SODIUM	0	2 (1.3%)	2 (0.6%)
	TRIAMCINOLONE ACETONIDE	1 (0.6%)	0	1 (0.3%)
VARIOUS	Total	2 (1.2%)	5 (3.2%)	7 (2.2%)
	ALLERGENIC EXTRACT, NOS	0	2 (1.3%)	2 (0.6%)
	AMINO ACIDS NOS	0	1 (0.6%)	1 (0.3%)
	HERBAL MEDICATION	1 (0.6%)	0	1 (0.3%)
	NUTRITIONAL SUPPLEMENT NOS	1 (0.6%)	1 (0.6%)	2 (0.6%)
	PROTEINS NOS	0	1 (0.6%)	1 (0.3%)
	SPIRULINA	0	1 (0.6%)	1 (0.3%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.16.2.2

Number (%) of Patients with Prior Non-Psychoactive Medication by Generic Term Ordered by Decreasing Frequency

Intention-To-Treat Population

Generic Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Total number of patients with at least one prior non-psychoactive medication	73 (44.8%)	62 (39.7%)	135 (42.3%)
PARACETAMOL	12 (7.4%)	16 (10.3%)	28 (8.8%)
IBUPROFEN	11 (6.7%)	8 (5.1%)	19 (6.0%)
VITAMINS NOS	8 (4.9%)	4 (2.6%)	12 (3.8%)
ETHINYLESTRADIOL	8 (4.9%)	1 (0.6%)	9 (2.8%)
PSEUDOEPHEDRINE HYDROCHLORIDE	6 (3.7%)	4 (2.6%)	10 (3.1%)
FLUTICASONE PROPIONATE	5 (3.1%)	3 (1.9%)	8 (2.5%)
PHENYLPROPANOLAMINE HYDROCHLORIDE	4 (2.5%)	3 (1.9%)	7 (2.2%)
CHLORPHENAMINE MALEATE	4 (2.5%)	2 (1.3%)	6 (1.9%)
SALBUTAMOL	3 (1.8%)	6 (3.8%)	9 (2.8%)
LORATADINE	3 (1.8%)	5 (3.2%)	8 (2.5%)
CETIRIZINE HYDROCHLORIDE	3 (1.8%)	3 (1.9%)	6 (1.9%)
DIPHENHYDRAMINE HYDROCHLORIDE	3 (1.8%)	3 (1.9%)	6 (1.9%)
PHENYLEPHRINE HYDROCHLORIDE	3 (1.8%)	2 (1.3%)	5 (1.6%)
ACETYLSALICYLIC ACID	3 (1.8%)	1 (0.6%)	4 (1.3%)
NORGESTIMATE	3 (1.8%)	0	3 (0.9%)
LIDOCAINE	2 (1.2%)	4 (2.6%)	6 (1.9%)
PRILOCAINE	2 (1.2%)	4 (2.6%)	6 (1.9%)
BROMPHENIRAMINE MALEATE	2 (1.2%)	2 (1.3%)	4 (1.3%)
BUDESONIDE	2 (1.2%)	2 (1.3%)	4 (1.3%)
LEVONORGESTREL	2 (1.2%)	1 (0.6%)	3 (0.9%)
PARAFFIN, LIQUID	2 (1.2%)	1 (0.6%)	3 (0.9%)
RANITIDINE HYDROCHLORIDE	2 (1.2%)	1 (0.6%)	3 (0.9%)
TETRACYCLINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
MOMETASONE FUROATE	1 (0.6%)	4 (2.6%)	5 (1.6%)
AMOXICILLIN TRIHYDRATE	1 (0.6%)	3 (1.9%)	4 (1.3%)
CAFFEINE	1 (0.6%)	2 (1.3%)	3 (0.9%)
MINOCYCLINE HYDROCHLORIDE	1 (0.6%)	2 (1.3%)	3 (0.9%)
TETRACYCLINE	1 (0.6%)	2 (1.3%)	3 (0.9%)
BETAMETHASONE	1 (0.6%)	1 (0.6%)	2 (0.6%)
CALCIUM CARBONATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
CEFPROZIL MONOHYDRATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
CLAVULANIC ACID	1 (0.6%)	1 (0.6%)	2 (0.6%)
CODEINE PHOSPHATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
ERYTHROMYCIN	1 (0.6%)	1 (0.6%)	2 (0.6%)
FAMOTIDINE	1 (0.6%)	1 (0.6%)	2 (0.6%)
INSULIN	1 (0.6%)	1 (0.6%)	2 (0.6%)
MINOCYCLINE	1 (0.6%)	1 (0.6%)	2 (0.6%)
NUTRITIONAL SUPPLEMENT NOS	1 (0.6%)	1 (0.6%)	2 (0.6%)
TERBUTALINE SULFATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
TRETINOIN	1 (0.6%)	1 (0.6%)	2 (0.6%)
ALUMINIUM HYDROXIDE	1 (0.6%)	0	1 (0.3%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.16.2.2

Number (%) of Patients with Prior Non-Psychoactive Medication by Generic Term Ordered by Decreasing Frequency

Intention-To-Treat Population

Generic Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
AMOXICILLIN	1 (0.6%)	0	1 (0.3%)
AMPICILLIN	1 (0.6%)	0	1 (0.3%)
ASCORBIC ACID	1 (0.6%)	0	1 (0.3%)
AZITHROMYCIN	1 (0.6%)	0	1 (0.3%)
BECLOMETASONE DIPROPIONATE	1 (0.6%)	0	1 (0.3%)
BENZOYL PEROXIDE	1 (0.6%)	0	1 (0.3%)
BISACODYL	1 (0.6%)	0	1 (0.3%)
CATHINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
CEFACLOR	1 (0.6%)	0	1 (0.3%)
CEFALEXIN	1 (0.6%)	0	1 (0.3%)
CEFUROXIME AXETIL	1 (0.6%)	0	1 (0.3%)
CHLORPHENAMINE TANNATE	1 (0.6%)	0	1 (0.3%)
CIMETIDINE	1 (0.6%)	0	1 (0.3%)
CLEMASTINE FUMARATE	1 (0.6%)	0	1 (0.3%)
CROMOGLICATE SODIUM	1 (0.6%)	0	1 (0.3%)
CYPROTERONE ACETATE	1 (0.6%)	0	1 (0.3%)
DEXAMETHASONE	1 (0.6%)	0	1 (0.3%)
DEXCHLORPHENIRAMINE MALEATE	1 (0.6%)	0	1 (0.3%)
EPHEDRINE SULFATE	1 (0.6%)	0	1 (0.3%)
FLUOCINONIDE	1 (0.6%)	0	1 (0.3%)
FLUORIDE NOS	1 (0.6%)	0	1 (0.3%)
GESTODENE	1 (0.6%)	0	1 (0.3%)
GUAIFENESIN	1 (0.6%)	0	1 (0.3%)
HERBAL MEDICATION	1 (0.6%)	0	1 (0.3%)
HYDROCORTISONE	1 (0.6%)	0	1 (0.3%)
MAGNESIUM HYDROXIDE	1 (0.6%)	0	1 (0.3%)
MEFLOQUINE	1 (0.6%)	0	1 (0.3%)
MEPYRAMINE TANNATE	1 (0.6%)	0	1 (0.3%)
MOROXYDINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
NASAL SPRAY	1 (0.6%)	0	1 (0.3%)
NORETHISTERONE	1 (0.6%)	0	1 (0.3%)
OXYTETRACYCLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
PHENYLEPHRINE TANNATE	1 (0.6%)	0	1 (0.3%)
PROGESTERONE	1 (0.6%)	0	1 (0.3%)
RETINOL PALMITATE	1 (0.6%)	0	1 (0.3%)
SALMETEROL HYDROXYNAPHTHOATE	1 (0.6%)	0	1 (0.3%)
TAZAROTENE	1 (0.6%)	0	1 (0.3%)
TOCOPHEROL	1 (0.6%)	0	1 (0.3%)
TRIAMCINOLONE ACETONIDE	1 (0.6%)	0	1 (0.3%)
TRIPROLIDINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
FEXOFENADINE HYDROCHLORIDE	0	5 (3.2%)	5 (1.6%)
ALLERGENIC EXTRACT, NOS	0	2 (1.3%)	2 (0.6%)
BETAMETHASONE SODIUM PHOSPHATE	0	2 (1.3%)	2 (0.6%)
LEVOTHYROXINE SODIUM	0	2 (1.3%)	2 (0.6%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.16.2.2

Number (%) of Patients with Prior Non-Psychoactive Medication by Generic Term Ordered by Decreasing Frequency

Intention-To-Treat Population

Generic Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
MEPYRAMINE MALEATE	0	2 (1.3%)	2 (0.6%)
PAMABROM	0	2 (1.3%)	2 (0.6%)
ADAPALENE	0	1 (0.6%)	1 (0.3%)
AMINO ACIDS NOS	0	1 (0.6%)	1 (0.3%)
AMMONIUM CHLORIDE	0	1 (0.6%)	1 (0.3%)
ATORVASTATIN CALCIUM	0	1 (0.6%)	1 (0.3%)
BETAMETHASONE ACETATE	0	1 (0.6%)	1 (0.3%)
BETAMETHASONE DIPROPIONATE	0	1 (0.6%)	1 (0.3%)
BROMHEXINE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
CLARITHROMYCIN	0	1 (0.6%)	1 (0.3%)
CLINDAMYCIN PHOSPHATE	0	1 (0.6%)	1 (0.3%)
DIETHYLSTILBESTROL DIPROPIONATE	0	1 (0.6%)	1 (0.3%)
DOXYCYCLINE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
ETILEFRINE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
FENOTEROL HYDROBROMIDE	0	1 (0.6%)	1 (0.3%)
HYDROXYZINE	0	1 (0.6%)	1 (0.3%)
INFLUENZA VIRUS VACCINE POLYVALENT	0	1 (0.6%)	1 (0.3%)
IPRATROPIUM BROMIDE	0	1 (0.6%)	1 (0.3%)
LEUPRORELIN ACETATE	0	1 (0.6%)	1 (0.3%)
METOCLOPRAMIDE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
MONTELUKAST SODIUM	0	1 (0.6%)	1 (0.3%)
NAPROXEN	0	1 (0.6%)	1 (0.3%)
NAPROXEN SODIUM	0	1 (0.6%)	1 (0.3%)
ORCIPRENALINE SULFATE	0	1 (0.6%)	1 (0.3%)
PROTEINS NOS	0	1 (0.6%)	1 (0.3%)
PSEUDOEPHEDRINE SULFATE	0	1 (0.6%)	1 (0.3%)
PSYLLIUM HYDROPHILIC MUCILLOID	0	1 (0.6%)	1 (0.3%)
SALSALATE	0	1 (0.6%)	1 (0.3%)
SENNA FRUIT	0	1 (0.6%)	1 (0.3%)
SODIUM CITRATE	0	1 (0.6%)	1 (0.3%)
SPIRULINA	0	1 (0.6%)	1 (0.3%)
SULFAMETHOXAZOLE	0	1 (0.6%)	1 (0.3%)
TOPICAL ANTIBIOTIC	0	1 (0.6%)	1 (0.3%)
TRICLOSAN	0	1 (0.6%)	1 (0.3%)
TRIMETHOPRIM	0	1 (0.6%)	1 (0.3%)
ZINC	0	1 (0.6%)	1 (0.3%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.16.2.3

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)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Total number of patients with at least one concomitant medication	Total	129 (79.1%)	111 (71.2%)	240 (75.2%)
ALIMENTARY TRACT/METAB	Total	48 (29.4%)	31 (19.9%)	79 (24.8%)
	ACETYLSALICYLIC ACID	11 (6.7%)	9 (5.8%)	20 (6.3%)
	ALGIN	2 (1.2%)	0	2 (0.6%)
	ALGINIC ACID	2 (1.2%)	0	2 (0.6%)
	ALUMINIUM HYDROXIDE	6 (3.7%)	0	6 (1.9%)
	AMINOPENTAMIDE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	ANISEED OIL	0	1 (0.6%)	1 (0.3%)
	ASCORBIC ACID	1 (0.6%)	2 (1.3%)	3 (0.9%)
	ATROPINE SULFATE	0	1 (0.6%)	1 (0.3%)
	ATTAPULGITE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	BENZOIC ACID	0	1 (0.6%)	1 (0.3%)
	BISACODYL	1 (0.6%)	0	1 (0.3%)
	BISMUTH SUBCARBONATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	BISMUTH SUBSALICYLATE	2 (1.2%)	5 (3.2%)	7 (2.2%)
	CALCIUM	2 (1.2%)	1 (0.6%)	3 (0.9%)
	CALCIUM CARBONATE	4 (2.5%)	4 (2.6%)	8 (2.5%)
	CAMPHOR	0	1 (0.6%)	1 (0.3%)
	CHLORPHENAMINE MALEATE	0	1 (0.6%)	1 (0.3%)
	CYCLIZINE HYDROCHLORIDE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	DIPHENOXYLATE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
	ETHER	0	1 (0.6%)	1 (0.3%)
	FAMOTIDINE	2 (1.2%)	1 (0.6%)	3 (0.9%)
	FLUORIDE NOS	1 (0.6%)	0	1 (0.3%)
	GLYCEROL	0	1 (0.6%)	1 (0.3%)
	HYDROGEN PEROXIDE	1 (0.6%)	0	1 (0.3%)
	HYOSCINE BUTYLBROMIDE	5 (3.1%)	0	5 (1.6%)
	INSULIN	1 (0.6%)	1 (0.6%)	2 (0.6%)
	KANAMYCIN SULFATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	KAOLIN	1 (0.6%)	2 (1.3%)	3 (0.9%)
	LOPERAMIDE HYDROCHLORIDE	1 (0.6%)	2 (1.3%)	3 (0.9%)
	MAGNESIUM HYDROXIDE	6 (3.7%)	0	6 (1.9%)
	MAGNESIUM NOS	1 (0.6%)	0	1 (0.3%)
	MAGNESIUM TRISILICATE	2 (1.2%)	0	2 (0.6%)
	MECLOZINE	0	1 (0.6%)	1 (0.3%)
	METAMIZOLE SODIUM	1 (0.6%)	0	1 (0.3%)
	METOCLOPRAMIDE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
	MINERALS NOS	1 (0.6%)	0	1 (0.3%)
	MULTIVITAMINS, NOS	1 (0.6%)	0	1 (0.3%)
	NEOMYCIN	0	1 (0.6%)	1 (0.3%)
	NYSTATIN	2 (1.2%)	0	2 (0.6%)
	OXETACAINE	1 (0.6%)	0	1 (0.3%)
	PARAFFIN, LIQUID	2 (1.2%)	1 (0.6%)	3 (0.9%)
	PECTIN	2 (1.2%)	3 (1.9%)	5 (1.6%)

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Table 13.16.2.3

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)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
ALIMENTARY TRACT/METAB	PEPPERMINT OIL	0	1 (0.6%)	1 (0.3%)
	POTASSIUM CHLORIDE	0	1 (0.6%)	1 (0.3%)
	POTASSIUM NITRATE	0	1 (0.6%)	1 (0.3%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
	PSYLLIUM HYDROPHILIC MUCILLOID	0	1 (0.6%)	1 (0.3%)
	RANITIDINE HYDROCHLORIDE	4 (2.5%)	1 (0.6%)	5 (1.6%)
	RETINOL	1 (0.6%)	0	1 (0.3%)
	RETINOL PALMITATE	1 (0.6%)	0	1 (0.3%)
	SODIUM BICARBONATE	2 (1.2%)	0	2 (0.6%)
	SODIUM CHLORIDE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	SODIUM LACTATE	0	1 (0.6%)	1 (0.3%)
	TOCOPHEROL	1 (0.6%)	0	1 (0.3%)
	TRIAMCINOLONE ACETONIDE	2 (1.2%)	2 (1.3%)	4 (1.3%)
	VITAMINS NOS	10 (6.1%)	5 (3.2%)	15 (4.7%)
	ZINC	1 (0.6%)	1 (0.6%)	2 (0.6%)
ANTIINFECTIVES,SYSTEMIC	Total	45 (27.6%)	48 (30.8%)	93 (29.2%)
	AMOXICILLIN	4 (2.5%)	5 (3.2%)	9 (2.8%)
	AMOXICILLIN TRIHYDRATE	9 (5.5%)	12 (7.7%)	21 (6.6%)
	AMPICILLIN	1 (0.6%)	0	1 (0.3%)
	AZITHROMYCIN	5 (3.1%)	2 (1.3%)	7 (2.2%)
	CEFADROXIL MONOHYDRATE	1 (0.6%)	0	1 (0.3%)
	CEFALEXIN	2 (1.2%)	0	2 (0.6%)
	CEFALEXIN MONOHYDRATE	0	3 (1.9%)	3 (0.9%)
	CEFDINIR	0	1 (0.6%)	1 (0.3%)
	CEFIXIME	2 (1.2%)	0	2 (0.6%)
	CEFPODOXIME	1 (0.6%)	0	1 (0.3%)
	CEFPROZIL MONOHYDRATE	2 (1.2%)	1 (0.6%)	3 (0.9%)
	CEFRADINE	1 (0.6%)	0	1 (0.3%)
	CEFUROXIME AXETIL	1 (0.6%)	3 (1.9%)	4 (1.3%)
	CIPROFLOXACIN	1 (0.6%)	0	1 (0.3%)
	CLARITHROMYCIN	0	2 (1.3%)	2 (0.6%)
	CLAVULANIC ACID	5 (3.1%)	4 (2.6%)	9 (2.8%)
	CLINDAMYCIN PHOSPHATE	0	1 (0.6%)	1 (0.3%)
	CLOXACILLIN	1 (0.6%)	0	1 (0.3%)
	DOXYCYCLINE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	DOXYCYCLINE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
	ERYTHROMYCIN	2 (1.2%)	2 (1.3%)	4 (1.3%)
	FLUCONAZOLE	0	1 (0.6%)	1 (0.3%)
	FUSIDIC ACID	1 (0.6%)	0	1 (0.3%)
	HEPATITIS B VACCINE	2 (1.2%)	1 (0.6%)	3 (0.9%)
	HEPATITIS VACCINE, NOS	1 (0.6%)	0	1 (0.3%)
	INFLUENZA VIRUS VACCINE POLYVALENT	2 (1.2%)	2 (1.3%)	4 (1.3%)
	ITRACONAZOLE	1 (0.6%)	0	1 (0.3%)
	LORACARBEF	0	2 (1.3%)	2 (0.6%)

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Table 13.16.2.3

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)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
ANTIINFECTIVES,SYSTEMIC	MINOCYCLINE	2 (1.2%)	1 (0.6%)	3 (0.9%)
	MINOCYCLINE HYDROCHLORIDE	2 (1.2%)	4 (2.6%)	6 (1.9%)
	MUPIROCIN	1 (0.6%)	0	1 (0.3%)
	NEOMYCIN	0	1 (0.6%)	1 (0.3%)
	OFLOXACIN	1 (0.6%)	0	1 (0.3%)
	OXYTETRACYCLINE	0	1 (0.6%)	1 (0.3%)
	OXYTETRACYCLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
	PENICILLIN NOS	2 (1.2%)	2 (1.3%)	4 (1.3%)
	PHENOXYMETHYLPENICILLIN POTASSIUM	1 (0.6%)	0	1 (0.3%)
	PROCAINE BENZYLPENICILLIN	1 (0.6%)	0	1 (0.3%)
	RIFAMPICIN	1 (0.6%)	0	1 (0.3%)
	SULFAMETHOXAZOLE	4 (2.5%)	5 (3.2%)	9 (2.8%)
	TETANUS TOXOID	1 (0.6%)	0	1 (0.3%)
	TETRACYCLINE	1 (0.6%)	2 (1.3%)	3 (0.9%)
	TETRACYCLINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
	TRIMETHOPRIM	4 (2.5%)	5 (3.2%)	9 (2.8%)
ANTINEOPLASTIC & IMMUNOSUP	Total	1 (0.6%)	4 (2.6%)	5 (1.6%)
	DIETHYLSTILBESTROL DIPROPIONATE	0	1 (0.6%)	1 (0.3%)
	LEUPRORELIN ACETATE	0	1 (0.6%)	1 (0.3%)
	MEDROXYPROGESTERONE ACETATE	0	1 (0.6%)	1 (0.3%)
	TRETINOIN	1 (0.6%)	1 (0.6%)	2 (0.6%)
BLOOD/BLOOD FORM ORGANS	Total	13 (8.0%)	10 (6.4%)	23 (7.2%)
	ACETYLSALICYLIC ACID	11 (6.7%)	8 (5.1%)	19 (6.0%)
	AMINO ACIDS NOS	0	1 (0.6%)	1 (0.3%)
	ASCORBIC ACID	1 (0.6%)	0	1 (0.3%)
	ATORVASTATIN CALCIUM	0	1 (0.6%)	1 (0.3%)
	CYANOCOBALAMIN	1 (0.6%)	0	1 (0.3%)
	FERROUS FUMARATE	1 (0.6%)	0	1 (0.3%)
	FOLIC ACID	1 (0.6%)	0	1 (0.3%)
	INTRINSIC FACTOR	1 (0.6%)	0	1 (0.3%)
	SODIUM CHLORIDE	1 (0.6%)	0	1 (0.3%)
CARDIOVASCULAR	Total	5 (3.1%)	3 (1.9%)	8 (2.5%)
	BISMUTH SUBGALLATE	1 (0.6%)	0	1 (0.3%)
	ETILEFRINE HYDROCHLORIDE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	LIDOCAINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
	PREDNISOLONE SODIUM PHOSPHATE	0	1 (0.6%)	1 (0.3%)
	THEOPHYLLINE	1 (0.6%)	1 (0.6%)	2 (0.6%)
CENTRAL NERVOUS SYSTEM	Total	88 (54.0%)	72 (46.2%)	160 (50.2%)
	ACETYLSALICYLATE CALCIUM	1 (0.6%)	0	1 (0.3%)
	ACETYLSALICYLIC ACID	16 (9.8%)	15 (9.6%)	31 (9.7%)

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Table 13.16.2.3

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)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
CENTRAL NERVOUS SYSTEM	ANESTHESIA, NOS	1 (0.6%)	0	1 (0.3%)
	ASCORBIC ACID	1 (0.6%)	2 (1.3%)	3 (0.9%)
	BIPERIDEN HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
	CAFFEINE	8 (4.9%)	8 (5.1%)	16 (5.0%)
	CHLORPHENAMINE MALEATE	3 (1.8%)	5 (3.2%)	8 (2.5%)
	CINNAMEDRINE HYDROCHLORIDE	1 (0.6%)	2 (1.3%)	3 (0.9%)
	CODEINE PHOSPHATE	8 (4.9%)	3 (1.9%)	11 (3.4%)
	DEXTROMETHORPHAN HYDROBROMIDE	2 (1.2%)	5 (3.2%)	7 (2.2%)
	DEXTROPROPOXYPHENE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
	DIPHENHYDRAMINE HYDROCHLORIDE	3 (1.8%)	2 (1.3%)	5 (1.6%)
	DOXYLAMINE SUCCINATE	2 (1.2%)	4 (2.6%)	6 (1.9%)
	HYDROCODONE BITARTRATE	0	1 (0.6%)	1 (0.3%)
	HYDROXYZINE	1 (0.6%)	0	1 (0.3%)
	IBUPROFEN	34 (20.9%)	22 (14.1%)	56 (17.6%)
	LEVOGLUTAMIDE	1 (0.6%)	0	1 (0.3%)
	LIDOCAINE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	LIDOCAINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
	LORAZEPAM	1 (0.6%)	0	1 (0.3%)
	MENTHOL	1 (0.6%)	1 (0.6%)	2 (0.6%)
	MEPROBAMATE	1 (0.6%)	0	1 (0.3%)
	MEPYRAMINE MALEATE	0	3 (1.9%)	3 (0.9%)
	NITROUS OXIDE	0	1 (0.6%)	1 (0.3%)
	ORPHENADRINE CITRATE	0	2 (1.3%)	2 (0.6%)
	PAMABROM	0	3 (1.9%)	3 (0.9%)
	PARACETAMOL	64 (39.3%)	52 (33.3%)	116 (36.4%)
	PAROXETINE	4 (2.5%)	2 (1.3%)	6 (1.9%)
	PEMOLINE	1 (0.6%)	0	1 (0.3%)
	PHENACETIN	1 (0.6%)	0	1 (0.3%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	2 (1.2%)	2 (1.3%)	4 (1.3%)
	PHENYLTOLOXAMINE CITRATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	PRILOCAINE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	PROCAINE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
	PROMETHAZINE	0	1 (0.6%)	1 (0.3%)
	PROMETHAZINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	7 (4.3%)	8 (5.1%)	15 (4.7%)
	SALSALATE	0	1 (0.6%)	1 (0.3%)
DERMATOLOGICALS	Total	39 (23.9%)	36 (23.1%)	75 (23.5%)
	ADAPALENE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	BACITRACIN	0	1 (0.6%)	1 (0.3%)
	BENTONITE	1 (0.6%)	0	1 (0.3%)
	BENZALKONIUM CHLORIDE	0	2 (1.3%)	2 (0.6%)
	BENZOIC ACID	1 (0.6%)	0	1 (0.3%)
	BENZOXONIUM CHLORIDE	1 (0.6%)	0	1 (0.3%)

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Table 13.16.2.3

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)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
DERMATOLOGICALS	BENZOYL PEROXIDE	1 (0.6%)	0	1 (0.3%)
	BETAMETHASONE DIPROPIONATE	0	1 (0.6%)	1 (0.3%)
	BETAMETHASONE SODIUM PHOSPHATE	0	1 (0.6%)	1 (0.3%)
	BETAMETHASONE VALERATE	0	2 (1.3%)	2 (0.6%)
	BUDESONIDE	2 (1.2%)	1 (0.6%)	3 (0.9%)
	CALAMINE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	CAMPHOR	0	1 (0.6%)	1 (0.3%)
	CETRIMONIUM BROMIDE	0	1 (0.6%)	1 (0.3%)
	CETYLPYRIDINIUM CHLORIDE	1 (0.6%)	0	1 (0.3%)
	CHINOFORM	0	1 (0.6%)	1 (0.3%)
	CLINDAMYCIN PHOSPHATE	0	1 (0.6%)	1 (0.3%)
	CLOTRIMAZOLE	0	1 (0.6%)	1 (0.3%)
	DIFLUCORTOLONE VALERATE	0	1 (0.6%)	1 (0.3%)
	DIPHENHYDRAMINE	0	1 (0.6%)	1 (0.3%)
	DIPHENHYDRAMINE HYDROCHLORIDE	10 (6.1%)	3 (1.9%)	13 (4.1%)
	ERYTHROMYCIN	2 (1.2%)	2 (1.3%)	4 (1.3%)
	FLUOCINONIDE	1 (0.6%)	0	1 (0.3%)
	FLUTICASONE PROPIONATE	5 (3.1%)	5 (3.2%)	10 (3.1%)
	FUSIDIC ACID	1 (0.6%)	0	1 (0.3%)
	GENTAMICIN SULFATE	0	1 (0.6%)	1 (0.3%)
	GLYCEROL	1 (0.6%)	1 (0.6%)	2 (0.6%)
	HYDROCORTISONE	2 (1.2%)	3 (1.9%)	5 (1.6%)
	HYDROGEN PEROXIDE	1 (0.6%)	0	1 (0.3%)
	ISOCONAZOLE NITRATE	0	1 (0.6%)	1 (0.3%)
	LIDOCAINE	1 (0.6%)	2 (1.3%)	3 (0.9%)
	LIDOCAINE HYDROCHLORIDE	3 (1.8%)	0	3 (0.9%)
	MALIC ACID	1 (0.6%)	0	1 (0.3%)
	METHYLPREDNISOLONE ACETATE	0	1 (0.6%)	1 (0.3%)
	MICONAZOLE NITRATE	1 (0.6%)	0	1 (0.3%)
	MOMETASONE FUROATE	2 (1.2%)	5 (3.2%)	7 (2.2%)
	MUPIROCIN	1 (0.6%)	0	1 (0.3%)
	NEOMYCIN	0	1 (0.6%)	1 (0.3%)
	NEOMYCIN SULFATE	0	1 (0.6%)	1 (0.3%)
	NYSTATIN	2 (1.2%)	0	2 (0.6%)
	OXYTETRACYCLINE	0	1 (0.6%)	1 (0.3%)
	OXYTETRACYCLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
	PARAFFIN, LIQUID	2 (1.2%)	1 (0.6%)	3 (0.9%)
	PHENOL	1 (0.6%)	1 (0.6%)	2 (0.6%)
	PHENOL, LIQUEFIED	1 (0.6%)	0	1 (0.3%)
	POLYMYXIN B SULFATE	0	1 (0.6%)	1 (0.3%)
	PREDNISOLONE SODIUM PHOSPHATE	0	1 (0.6%)	1 (0.3%)
	PRILOCAINE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	PROPYLENE GLYCOL	1 (0.6%)	0	1 (0.3%)
	RETINOL	1 (0.6%)	0	1 (0.3%)
	RETINOL PALMITATE	1 (0.6%)	0	1 (0.3%)
	SALICYLIC ACID	1 (0.6%)	0	1 (0.3%)

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Table 13.16.2.3

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)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
DERMATOLOGICALS	SODIUM CITRATE	1 (0.6%)	0	1 (0.3%)
	TAZAROTENE	1 (0.6%)	0	1 (0.3%)
	TERBINAFINE	1 (0.6%)	0	1 (0.3%)
	TETRACYCLINE	1 (0.6%)	2 (1.3%)	3 (0.9%)
	TETRACYCLINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
	TOCOPHEROL	1 (0.6%)	0	1 (0.3%)
	TOLNAFTATE	0	1 (0.6%)	1 (0.3%)
	TOPICAL ANTIBIOTIC	0	1 (0.6%)	1 (0.3%)
	TRETINOIN	1 (0.6%)	1 (0.6%)	2 (0.6%)
	TRIAMCINOLONE ACETONIDE	2 (1.2%)	4 (2.6%)	6 (1.9%)
	TRICLOSAN	0	1 (0.6%)	1 (0.3%)
	TYROTHRICIN	0	1 (0.6%)	1 (0.3%)
	ZINC ACETATE	1 (0.6%)	0	1 (0.3%)
	ZINC OXIDE	1 (0.6%)	0	1 (0.3%)
GU SYSTEM/SEX HORMONES	Total	13 (8.0%)	6 (3.8%)	19 (6.0%)
	CIPROFLOXACIN	1 (0.6%)	0	1 (0.3%)
	CLOTRIMAZOLE	0	1 (0.6%)	1 (0.3%)
	CYPROTERONE ACETATE	1 (0.6%)	0	1 (0.3%)
	DESOGESTREL	0	1 (0.6%)	1 (0.3%)
	DIETHYLSTILBESTROL DIPROPIONATE	0	1 (0.6%)	1 (0.3%)
	ETHINYLESTRADIOL	8 (4.9%)	2 (1.3%)	10 (3.1%)
	GESTODENE	1 (0.6%)	0	1 (0.3%)
	LEVONORGESTREL	2 (1.2%)	1 (0.6%)	3 (0.9%)
	MEDROXYPROGESTERONE ACETATE	0	1 (0.6%)	1 (0.3%)
	NORETHISTERONE	1 (0.6%)	0	1 (0.3%)
	NORFLOXACIN	1 (0.6%)	0	1 (0.3%)
	NORGESTIMATE	3 (1.8%)	0	3 (0.9%)
	NYSTATIN	2 (1.2%)	0	2 (0.6%)
	OFLOXACIN	1 (0.6%)	0	1 (0.3%)
	OXYTETRACYCLINE	0	1 (0.6%)	1 (0.3%)
	OXYTETRACYCLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
MUSCULO-SKELETAL	Total	40 (24.5%)	30 (19.2%)	70 (21.9%)
	CASEIN	1 (0.6%)	0	1 (0.3%)
	DICLOFENAC POTASSIUM	1 (0.6%)	0	1 (0.3%)
	DICLOFENAC SODIUM	3 (1.8%)	0	3 (0.9%)
	EUCALYPTUS OIL	1 (0.6%)	0	1 (0.3%)
	GLYCERYL MONOOLEATE	1 (0.6%)	0	1 (0.3%)
	IBUPROFEN	32 (19.6%)	23 (14.7%)	55 (17.2%)
	MEFENAMIC ACID	1 (0.6%)	3 (1.9%)	4 (1.3%)
	MELOXICAM	1 (0.6%)	0	1 (0.3%)
	MENTHOL	1 (0.6%)	0	1 (0.3%)
	METAXALONE	0	1 (0.6%)	1 (0.3%)
	NABUMETONE	0	1 (0.6%)	1 (0.3%)

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Table 13.16.2.3

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)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
MUSCULO-SKELETAL	NAPROXEN	1 (0.6%)	0	1 (0.3%)
	NAPROXEN SODIUM	5 (3.1%)	2 (1.3%)	7 (2.2%)
	ORPHENADRINE CITRATE	0	2 (1.3%)	2 (0.6%)
	PSEUDOEPHEDRINE	0	1 (0.6%)	1 (0.3%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
	SODIUM GLYCEROPHOSPHATE	1 (0.6%)	0	1 (0.3%)
PARASITOLOGY	Total	1 (0.6%)	2 (1.3%)	3 (0.9%)
	ALBENDAZOLE	0	1 (0.6%)	1 (0.3%)
	MEFLOQUINE	1 (0.6%)	0	1 (0.3%)
	PIPERONYL BUTOXIDE	0	1 (0.6%)	1 (0.3%)
	PYRETHRINS	0	1 (0.6%)	1 (0.3%)
	PYRETHRUM EXTRACT	0	1 (0.6%)	1 (0.3%)
RESPIRATORY	Total	68 (41.7%)	68 (43.6%)	136 (42.6%)
	ACETYLSALICYLIC ACID	3 (1.8%)	2 (1.3%)	5 (1.6%)
	AMBUPHYLLINE	0	1 (0.6%)	1 (0.3%)
	AMINOACETIC ACID	1 (0.6%)	1 (0.6%)	2 (0.6%)
	AMMONIUM CHLORIDE	2 (1.2%)	5 (3.2%)	7 (2.2%)
	AMYLMETACRESOL	2 (1.2%)	1 (0.6%)	3 (0.9%)
	ANISEED OIL	0	1 (0.6%)	1 (0.3%)
	ARISTOLOCHIC ACID	0	1 (0.6%)	1 (0.3%)
	ASCORBIC ACID	4 (2.5%)	3 (1.9%)	7 (2.2%)
	ATROPINE SULFATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	BALSAM SULPHURIS	0	1 (0.6%)	1 (0.3%)
	BECLOMETASONE DIPROPIONATE	2 (1.2%)	0	2 (0.6%)
	BENZALKONIUM CHLORIDE	1 (0.6%)	3 (1.9%)	4 (1.3%)
	BENZOIC ACID	0	1 (0.6%)	1 (0.3%)
	BENZOXONIUM CHLORIDE	1 (0.6%)	0	1 (0.3%)
	BROMHEXINE HYDROCHLORIDE	3 (1.8%)	4 (2.6%)	7 (2.2%)
	BROMPHENIRAMINE MALEATE	6 (3.7%)	6 (3.8%)	12 (3.8%)
	BUCHU	0	1 (0.6%)	1 (0.3%)
	BUDESONIDE	2 (1.2%)	1 (0.6%)	3 (0.9%)
	CAFFEINE	6 (3.7%)	5 (3.2%)	11 (3.4%)
	CAMPHOR	0	2 (1.3%)	2 (0.6%)
	CETIRIZINE	0	2 (1.3%)	2 (0.6%)
	CETIRIZINE HYDROCHLORIDE	5 (3.1%)	6 (3.8%)	11 (3.4%)
	CETRIMONIUM BROMIDE	0	1 (0.6%)	1 (0.3%)
	CETYLPYRIDINIUM CHLORIDE	1 (0.6%)	0	1 (0.3%)
	CHLOROFORM	0	1 (0.6%)	1 (0.3%)
	CHLORPHENAMINE MALEATE	16 (9.8%)	12 (7.7%)	28 (8.8%)
	CHLORPHENAMINE TANNATE	1 (0.6%)	0	1 (0.3%)
	CINCHONA BARK	0	1 (0.6%)	1 (0.3%)
	CLEMASTINE FUMARATE	1 (0.6%)	0	1 (0.3%)
	CODEINE PHOSPHATE	2 (1.2%)	2 (1.3%)	4 (1.3%)
	COUGH COLD PREPARATIONS NOS	0	1 (0.6%)	1 (0.3%)

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Table 13.16.2.3

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)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
RESPIRATORY	COUGH SYRUP/MED	2 (1.2%)	1 (0.6%)	3 (0.9%)
	CROMOGLICATE SODIUM	1 (0.6%)	0	1 (0.3%)
	CYCLIZINE HYDROCHLORIDE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	DECONGESTANT NOS	1 (0.6%)	0	1 (0.3%)
	DEXTROMETHORPHAN	1 (0.6%)	3 (1.9%)	4 (1.3%)
	DEXTROMETHORPHAN HYDROBROMIDE	5 (3.1%)	7 (4.5%)	12 (3.8%)
	DICHLOROBENZYL ALCOHOL	2 (1.2%)	1 (0.6%)	3 (0.9%)
	DIMENHYDRINATE	2 (1.2%)	0	2 (0.6%)
	DIMETOTIAZINE	1 (0.6%)	0	1 (0.3%)
	DIPHENHYDRAMINE	0	1 (0.6%)	1 (0.3%)
	DIPHENHYDRAMINE HYDROCHLORIDE	13 (8.0%)	7 (4.5%)	20 (6.3%)
	DIPHENYLPYRALINE HYDROCHLORIDE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	DOXYLAMINE SUCCINATE	1 (0.6%)	4 (2.6%)	5 (1.6%)
	EPHEDRINE HYDROCHLORIDE	3 (1.8%)	1 (0.6%)	4 (1.3%)
	ETAFEDRINE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
	ETHANOL	0	1 (0.6%)	1 (0.3%)
	ETHER	0	1 (0.6%)	1 (0.3%)
	ETOFYLLINE	0	1 (0.6%)	1 (0.3%)
	EUCALYPTUS OIL	1 (0.6%)	0	1 (0.3%)
	FENOTEROL HYDROBROMIDE	0	1 (0.6%)	1 (0.3%)
	FEXOFENADINE HYDROCHLORIDE	1 (0.6%)	6 (3.8%)	7 (2.2%)
	FLUTICASONE PROPIONATE	5 (3.1%)	5 (3.2%)	10 (3.1%)
	FUSAFUNGINE	1 (0.6%)	0	1 (0.3%)
	GLYCEROL	0	1 (0.6%)	1 (0.3%)
	GUAIFENESIN	3 (1.8%)	12 (7.7%)	15 (4.7%)
	HYDROCODONE BITARTRATE	0	2 (1.3%)	2 (0.6%)
	HYDROXYETHYL THEOPHYLLINE	0	1 (0.6%)	1 (0.3%)
	HYOSCINE METHONITRATE	1 (0.6%)	0	1 (0.3%)
	IBUPROFEN	1 (0.6%)	1 (0.6%)	2 (0.6%)
	IODINATED GLYCEROL	0	1 (0.6%)	1 (0.3%)
	IPRATROPIUM BROMIDE	0	1 (0.6%)	1 (0.3%)
	LIDOCAINE	0	1 (0.6%)	1 (0.3%)
	LIDOCAINE HYDROCHLORIDE	3 (1.8%)	0	3 (0.9%)
	LORATADINE	8 (4.9%)	8 (5.1%)	16 (5.0%)
	MECLOZINE	0	1 (0.6%)	1 (0.3%)
	MENTHOL	2 (1.2%)	1 (0.6%)	3 (0.9%)
	MEPYRAMINE MALEATE	1 (0.6%)	3 (1.9%)	4 (1.3%)
	MEPYRAMINE TANNATE	1 (0.6%)	0	1 (0.3%)
	MOMETASONE FUROATE	2 (1.2%)	5 (3.2%)	7 (2.2%)
	MONTELUKAST SODIUM	0	1 (0.6%)	1 (0.3%)
	MOROXYDINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
	NAPHAZOLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
	NASAL SPRAY	1 (0.6%)	1 (0.6%)	2 (0.6%)
	ORCIPRENALINE SULFATE	1 (0.6%)	2 (1.3%)	3 (0.9%)
	OXYMETAZOLINE HYDROCHLORIDE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	PARACETAMOL	13 (8.0%)	16 (10.3%)	29 (9.1%)

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Table 13.16.2.3

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)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
RESPIRATORY	PEPPERMINT OIL	0	1 (0.6%)	1 (0.3%)
	PHENIRAMINE MALEATE	0	3 (1.9%)	3 (0.9%)
	PHENYLEPHRINE	2 (1.2%)	0	2 (0.6%)
	PHENYLEPHRINE HYDROCHLORIDE	9 (5.5%)	8 (5.1%)	17 (5.3%)
	PHENYLEPHRINE TANNATE	1 (0.6%)	0	1 (0.3%)
	PHENYLMERCURIC ACETATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	PHENYLPROPANOLAMINE	1 (0.6%)	0	1 (0.3%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	10 (6.1%)	12 (7.7%)	22 (6.9%)
	PHENYLTOLOXAMINE	1 (0.6%)	0	1 (0.3%)
	POLYGALA SENEGA	0	1 (0.6%)	1 (0.3%)
	POTASSIUM NITRATE	0	1 (0.6%)	1 (0.3%)
	PREDNISONE	1 (0.6%)	2 (1.3%)	3 (0.9%)
	PROMETHAZINE	0	1 (0.6%)	1 (0.3%)
	PROMETHAZINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
	PSEUDOEPHEDRINE	0	2 (1.3%)	2 (0.6%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	18 (11.0%)	17 (10.9%)	35 (11.0%)
	PSEUDOEPHEDRINE SULFATE	0	2 (1.3%)	2 (0.6%)
	SALBUTAMOL	5 (3.1%)	6 (3.8%)	11 (3.4%)
	SALICYLAMIDE	2 (1.2%)	0	2 (0.6%)
	SALMETEROL HYDROXYNAPHTHOATE	2 (1.2%)	1 (0.6%)	3 (0.9%)
	SODIUM CHLORIDE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	SODIUM CITRATE	2 (1.2%)	2 (1.3%)	4 (1.3%)
	SORBITOL	1 (0.6%)	1 (0.6%)	2 (0.6%)
	TERBUTALINE SULFATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
	THEOPHYLLINE	2 (1.2%)	2 (1.3%)	4 (1.3%)
	TRIAMCINOLONE ACETONIDE	2 (1.2%)	4 (2.6%)	6 (1.9%)
	TRIPROLIDINE	0	1 (0.6%)	1 (0.3%)
	TRIPROLIDINE HYDROCHLORIDE	2 (1.2%)	1 (0.6%)	3 (0.9%)
	TYROTHRICIN	0	1 (0.6%)	1 (0.3%)
	XYLOMETAZOLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
SENSORY ORGANS	Total	21 (12.9%)	13 (8.3%)	34 (10.7%)
	BROMPHENIRAMINE MALEATE	2 (1.2%)	1 (0.6%)	3 (0.9%)
	CIPROFLOXACIN	1 (0.6%)	0	1 (0.3%)
	CROMOGLICATE SODIUM	1 (0.6%)	0	1 (0.3%)
	DICLOFENAC SODIUM	3 (1.8%)	0	3 (0.9%)
	ERYTHROMYCIN	2 (1.2%)	2 (1.3%)	4 (1.3%)
	FUSIDIC ACID	1 (0.6%)	0	1 (0.3%)
	HYDROCORTISONE	2 (1.2%)	3 (1.9%)	5 (1.6%)
	LIDOCAINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
	NAPHAZOLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
	NEOMYCIN	0	1 (0.6%)	1 (0.3%)
	NEOMYCIN SULFATE	1 (0.6%)	0	1 (0.3%)
	OFLOXACIN	1 (0.6%)	0	1 (0.3%)
	OXYTETRACYCLINE	0	1 (0.6%)	1 (0.3%)

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Table 13.16.2.3

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)	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
SENSORY ORGANS	OXYTETRACYCLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	2 (1.2%)	1 (0.6%)	3 (0.9%)
	POLYMYXIN B SULFATE	2 (1.2%)	0	2 (0.6%)
	PREDNISOLONE SODIUM PHOSPHATE	0	1 (0.6%)	1 (0.3%)
	SODIUM CHLORIDE	1 (0.6%)	0	1 (0.3%)
	TETRACYCLINE	1 (0.6%)	2 (1.3%)	3 (0.9%)
	TETRACYCLINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
	TRIAMCINOLONE ACETONIDE	2 (1.2%)	2 (1.3%)	4 (1.3%)
	TRIMETHOPRIM SULFATE	1 (0.6%)	0	1 (0.3%)
	XYLOMETAZOLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
SYSTEMIC HORMONAL	Total	8 (4.9%)	12 (7.7%)	20 (6.3%)
	BETAMETHASONE	3 (1.8%)	2 (1.3%)	5 (1.6%)
	BETAMETHASONE SODIUM PHOSPHATE	0	1 (0.6%)	1 (0.3%)
	CHLORPHENAMINE MALEATE	3 (1.8%)	2 (1.3%)	5 (1.6%)
	DESMOPRESSIN	1 (0.6%)	0	1 (0.3%)
	HYDROCORTISONE	1 (0.6%)	3 (1.9%)	4 (1.3%)
	LEVOTHYROXINE SODIUM	0	2 (1.3%)	2 (0.6%)
	METHYLPREDNISOLONE ACETATE	0	1 (0.6%)	1 (0.3%)
	PREDNISOLONE SODIUM PHOSPHATE	0	1 (0.6%)	1 (0.3%)
	PREDNISONE	1 (0.6%)	2 (1.3%)	3 (0.9%)
	SOMATROPIN	0	1 (0.6%)	1 (0.3%)
	TRIAMCINOLONE ACETONIDE	2 (1.2%)	2 (1.3%)	4 (1.3%)
VARIOUS	Total	5 (3.1%)	4 (2.6%)	9 (2.8%)
	ALLERGENIC EXTRACT, NOS	0	2 (1.3%)	2 (0.6%)
	AMINO ACIDS NOS	1 (0.6%)	1 (0.6%)	2 (0.6%)
	ECHINACEA EXTRACT	1 (0.6%)	0	1 (0.3%)
	GASTRIC MUCOSA EXTRACTS	1 (0.6%)	0	1 (0.3%)
	HERBAL MEDICATION	1 (0.6%)	0	1 (0.3%)
	HOMEOPATHIC PREPARATIONS	1 (0.6%)	0	1 (0.3%)
	LIVER EXTRACTS	1 (0.6%)	0	1 (0.3%)
	MINERALS NOS	1 (0.6%)	0	1 (0.3%)
	NUTRITIONAL SUPPLEMENT NOS	1 (0.6%)	1 (0.6%)	2 (0.6%)
	SPIRULINA	0	1 (0.6%)	1 (0.3%)
	SPLEEN EXTRACTS	1 (0.6%)	0	1 (0.3%)
	VITAMIN B SUBSTANCES	1 (0.6%)	0	1 (0.3%)

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Table 13.16.2.4

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Excluding Taper Phase
Intention-To-Treat Population

Generic Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
Total number of patients with at least one concomitant medication	129 (79.1%)	111 (71.2%)	240 (75.2%)
PARACETAMOL	67 (41.1%)	55 (35.3%)	122 (38.2%)
IBUPROFEN	35 (21.5%)	23 (14.7%)	58 (18.2%)
CHLORPHENAMINE MALEATE	19 (11.7%)	14 (9.0%)	33 (10.3%)
PSEUDOEPHEDRINE HYDROCHLORIDE	18 (11.0%)	17 (10.9%)	35 (11.0%)
ACETYLSALICYLIC ACID	18 (11.0%)	15 (9.6%)	33 (10.3%)
DIPHENHYDRAMINE HYDROCHLORIDE	14 (8.6%)	8 (5.1%)	22 (6.9%)
CAFFEINE	12 (7.4%)	11 (7.1%)	23 (7.2%)
PHENYLPROPANOLAMINE HYDROCHLORIDE	11 (6.7%)	13 (8.3%)	24 (7.5%)
VITAMINS NOS	10 (6.1%)	5 (3.2%)	15 (4.7%)
AMOXICILLIN TRIHYDRATE	9 (5.5%)	12 (7.7%)	21 (6.6%)
PHENYLEPHRINE HYDROCHLORIDE	9 (5.5%)	8 (5.1%)	17 (5.3%)
LORATADINE	8 (4.9%)	8 (5.1%)	16 (5.0%)
CODEINE PHOSPHATE	8 (4.9%)	3 (1.9%)	11 (3.4%)
ETHINYLESTRADIOL	8 (4.9%)	2 (1.3%)	10 (3.1%)
BROMPHENIRAMINE MALEATE	6 (3.7%)	6 (3.8%)	12 (3.8%)
ALUMINIUM HYDROXIDE	6 (3.7%)	0	6 (1.9%)
MAGNESIUM HYDROXIDE	6 (3.7%)	0	6 (1.9%)
DEXTROMETHORPHAN HYDROBROMIDE	5 (3.1%)	8 (5.1%)	13 (4.1%)
CETIRIZINE HYDROCHLORIDE	5 (3.1%)	6 (3.8%)	11 (3.4%)
SALBUTAMOL	5 (3.1%)	6 (3.8%)	11 (3.4%)
FLUTICASONE PROPIONATE	5 (3.1%)	5 (3.2%)	10 (3.1%)
ASCORBIC ACID	5 (3.1%)	4 (2.6%)	9 (2.8%)
CLAVULANIC ACID	5 (3.1%)	4 (2.6%)	9 (2.8%)
AZITHROMYCIN	5 (3.1%)	2 (1.3%)	7 (2.2%)
NAPROXEN SODIUM	5 (3.1%)	2 (1.3%)	7 (2.2%)
HYOSCINE BUTYLBROMIDE	5 (3.1%)	0	5 (1.6%)
AMOXICILLIN	4 (2.5%)	5 (3.2%)	9 (2.8%)
SULFAMETHOXAZOLE	4 (2.5%)	5 (3.2%)	9 (2.8%)
TRIMETHOPRIM	4 (2.5%)	5 (3.2%)	9 (2.8%)
CALCIUM CARBONATE	4 (2.5%)	4 (2.6%)	8 (2.5%)
PAROXETINE	4 (2.5%)	2 (1.3%)	6 (1.9%)
RANITIDINE HYDROCHLORIDE	4 (2.5%)	1 (0.6%)	5 (1.6%)
GUAIFENESIN	3 (1.8%)	12 (7.7%)	15 (4.7%)
BROMHEXINE HYDROCHLORIDE	3 (1.8%)	4 (2.6%)	7 (2.2%)
HYDROCORTISONE	3 (1.8%)	3 (1.9%)	6 (1.9%)
BETAMETHASONE	3 (1.8%)	2 (1.3%)	5 (1.6%)
SODIUM CITRATE	3 (1.8%)	2 (1.3%)	5 (1.6%)
EPHEDRINE HYDROCHLORIDE	3 (1.8%)	1 (0.6%)	4 (1.3%)
DICLOFENAC SODIUM	3 (1.8%)	0	3 (0.9%)
LIDOCAINE HYDROCHLORIDE	3 (1.8%)	0	3 (0.9%)
NORGESTIMATE	3 (1.8%)	0	3 (0.9%)
AMMONIUM CHLORIDE	2 (1.2%)	5 (3.2%)	7 (2.2%)
BISMUTH SUBSALICYLATE	2 (1.2%)	5 (3.2%)	7 (2.2%)

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Table 13.16.2.4

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Excluding Taper Phase
Intention-To-Treat Population

Generic Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
DOXYLAMINE SUCCINATE	2 (1.2%)	5 (3.2%)	7 (2.2%)
MOMETASONE FUROATE	2 (1.2%)	5 (3.2%)	7 (2.2%)
MINOCYCLINE HYDROCHLORIDE	2 (1.2%)	4 (2.6%)	6 (1.9%)
TRIAMCINOLONE ACETONIDE	2 (1.2%)	4 (2.6%)	6 (1.9%)
PECTIN	2 (1.2%)	3 (1.9%)	5 (1.6%)
ERYTHROMYCIN	2 (1.2%)	2 (1.3%)	4 (1.3%)
INFLUENZA VIRUS VACCINE POLYVALENT	2 (1.2%)	2 (1.3%)	4 (1.3%)
PENICILLIN NOS	2 (1.2%)	2 (1.3%)	4 (1.3%)
THEOPHYLLINE	2 (1.2%)	2 (1.3%)	4 (1.3%)
AMYLMETACRESOL	2 (1.2%)	1 (0.6%)	3 (0.9%)
BUDESONIDE	2 (1.2%)	1 (0.6%)	3 (0.9%)
CALCIUM	2 (1.2%)	1 (0.6%)	3 (0.9%)
CEFPROZIL MONOHYDRATE	2 (1.2%)	1 (0.6%)	3 (0.9%)
COUGH SYRUP/MED	2 (1.2%)	1 (0.6%)	3 (0.9%)
DICHLOROBENZYL ALCOHOL	2 (1.2%)	1 (0.6%)	3 (0.9%)
FAMOTIDINE	2 (1.2%)	1 (0.6%)	3 (0.9%)
HEPATITIS B VACCINE	2 (1.2%)	1 (0.6%)	3 (0.9%)
LEVONORGESTREL	2 (1.2%)	1 (0.6%)	3 (0.9%)
MENTHOL	2 (1.2%)	1 (0.6%)	3 (0.9%)
MINOCYCLINE	2 (1.2%)	1 (0.6%)	3 (0.9%)
PARAFFIN, LIQUID	2 (1.2%)	1 (0.6%)	3 (0.9%)
POLYMYXIN B SULFATE	2 (1.2%)	1 (0.6%)	3 (0.9%)
SALMETEROL HYDROXYNAPHTHOATE	2 (1.2%)	1 (0.6%)	3 (0.9%)
TRIPROLIDINE HYDROCHLORIDE	2 (1.2%)	1 (0.6%)	3 (0.9%)
ALGIN	2 (1.2%)	0	2 (0.6%)
ALGINIC ACID	2 (1.2%)	0	2 (0.6%)
BECLOMETASONE DIPROPIONATE	2 (1.2%)	0	2 (0.6%)
CEFALEXIN	2 (1.2%)	0	2 (0.6%)
CEFIXIME	2 (1.2%)	0	2 (0.6%)
DIMENHYDRINATE	2 (1.2%)	0	2 (0.6%)
MAGNESIUM TRISILICATE	2 (1.2%)	0	2 (0.6%)
MINERALS NOS	2 (1.2%)	0	2 (0.6%)
MOROXYDINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
NYSTATIN	2 (1.2%)	0	2 (0.6%)
PHENYLEPHRINE	2 (1.2%)	0	2 (0.6%)
PROMETHAZINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
SALICYLAMIDE	2 (1.2%)	0	2 (0.6%)
SODIUM BICARBONATE	2 (1.2%)	0	2 (0.6%)
TETRACYCLINE HYDROCHLORIDE	2 (1.2%)	0	2 (0.6%)
FEXOFENADINE HYDROCHLORIDE	1 (0.6%)	6 (3.8%)	7 (2.2%)
MEPYRAMINE MALEATE	1 (0.6%)	6 (3.8%)	7 (2.2%)
BENZALKONIUM CHLORIDE	1 (0.6%)	3 (1.9%)	4 (1.3%)
CEFUROXIME AXETIL	1 (0.6%)	3 (1.9%)	4 (1.3%)
DEXTROMETHORPHAN	1 (0.6%)	3 (1.9%)	4 (1.3%)
MEFENAMIC ACID	1 (0.6%)	3 (1.9%)	4 (1.3%)
ATROPINE SULFATE	1 (0.6%)	2 (1.3%)	3 (0.9%)

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Table 13.16.2.4

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Excluding Taper Phase
Intention-To-Treat Population

Generic Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
CINNAMEDRINE HYDROCHLORIDE	1 (0.6%)	2 (1.3%)	3 (0.9%)
GLYCEROL	1 (0.6%)	2 (1.3%)	3 (0.9%)
KAOLIN	1 (0.6%)	2 (1.3%)	3 (0.9%)
LIDOCAINE	1 (0.6%)	2 (1.3%)	3 (0.9%)
LOPERAMIDE HYDROCHLORIDE	1 (0.6%)	2 (1.3%)	3 (0.9%)
ORCIPRENALINE SULFATE	1 (0.6%)	2 (1.3%)	3 (0.9%)
PREDNISONE	1 (0.6%)	2 (1.3%)	3 (0.9%)
SODIUM CHLORIDE	1 (0.6%)	2 (1.3%)	3 (0.9%)
TETRACYCLINE	1 (0.6%)	2 (1.3%)	3 (0.9%)
ADAPALENE	1 (0.6%)	1 (0.6%)	2 (0.6%)
AMINO ACIDS NOS	1 (0.6%)	1 (0.6%)	2 (0.6%)
AMINOACETIC ACID	1 (0.6%)	1 (0.6%)	2 (0.6%)
AMINOPENTAMIDE	1 (0.6%)	1 (0.6%)	2 (0.6%)
ATTAPULGITE	1 (0.6%)	1 (0.6%)	2 (0.6%)
BENZOIC ACID	1 (0.6%)	1 (0.6%)	2 (0.6%)
BISMUTH SUBCARBONATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
CALAMINE	1 (0.6%)	1 (0.6%)	2 (0.6%)
CYCLIZINE HYDROCHLORIDE	1 (0.6%)	1 (0.6%)	2 (0.6%)
DIPHENYLPYRALINE HYDROCHLORIDE	1 (0.6%)	1 (0.6%)	2 (0.6%)
DOXYCYCLINE	1 (0.6%)	1 (0.6%)	2 (0.6%)
ETILEFRINE HYDROCHLORIDE	1 (0.6%)	1 (0.6%)	2 (0.6%)
INSULIN	1 (0.6%)	1 (0.6%)	2 (0.6%)
KANAMYCIN SULFATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
NASAL SPRAY	1 (0.6%)	1 (0.6%)	2 (0.6%)
NEOMYCIN SULFATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
NUTRITIONAL SUPPLEMENT NOS	1 (0.6%)	1 (0.6%)	2 (0.6%)
OXYMETAZOLINE HYDROCHLORIDE	1 (0.6%)	1 (0.6%)	2 (0.6%)
PHENOL	1 (0.6%)	1 (0.6%)	2 (0.6%)
PHENYLMERCURIC ACETATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
PHENYLTOLOXAMINE CITRATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
PRILOCAINE	1 (0.6%)	1 (0.6%)	2 (0.6%)
SORBITOL	1 (0.6%)	1 (0.6%)	2 (0.6%)
TERBUTALINE SULFATE	1 (0.6%)	1 (0.6%)	2 (0.6%)
TRETINOIN	1 (0.6%)	1 (0.6%)	2 (0.6%)
ZINC	1 (0.6%)	1 (0.6%)	2 (0.6%)
ACETYLSALICYLATE CALCIUM	1 (0.6%)	0	1 (0.3%)
AMPICILLIN	1 (0.6%)	0	1 (0.3%)
ANESTHESIA, NOS	1 (0.6%)	0	1 (0.3%)
BENTONITE	1 (0.6%)	0	1 (0.3%)
BENZOXONIUM CHLORIDE	1 (0.6%)	0	1 (0.3%)
BENZOYL PEROXIDE	1 (0.6%)	0	1 (0.3%)
BISACODYL	1 (0.6%)	0	1 (0.3%)
BISMUTH SUBGALLATE	1 (0.6%)	0	1 (0.3%)
CASEIN	1 (0.6%)	0	1 (0.3%)
CEFADROXIL MONOHYDRATE	1 (0.6%)	0	1 (0.3%)
CEFPODOXIME	1 (0.6%)	0	1 (0.3%)

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Table 13.16.2.4

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Excluding Taper Phase
Intention-To-Treat Population

Generic Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
CEFRADINE	1 (0.6%)	0	1 (0.3%)
CETYLPYRIDINIUM CHLORIDE	1 (0.6%)	0	1 (0.3%)
CHLORPHENAMINE TANNATE	1 (0.6%)	0	1 (0.3%)
CIPROFLOXACIN	1 (0.6%)	0	1 (0.3%)
CLEMASTINE FUMARATE	1 (0.6%)	0	1 (0.3%)
CLOXACILLIN	1 (0.6%)	0	1 (0.3%)
CROMOGLICATE SODIUM	1 (0.6%)	0	1 (0.3%)
CYANOCOBALAMIN	1 (0.6%)	0	1 (0.3%)
CYPROTERONE ACETATE	1 (0.6%)	0	1 (0.3%)
DECONGESTANT NOS	1 (0.6%)	0	1 (0.3%)
DESMOPRESSIN	1 (0.6%)	0	1 (0.3%)
DEXTROPROPOXYPHENE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
DICLOFENAC POTASSIUM	1 (0.6%)	0	1 (0.3%)
DIMETOTIAZINE	1 (0.6%)	0	1 (0.3%)
ECHINACEA EXTRACT	1 (0.6%)	0	1 (0.3%)
EUCALYPTUS OIL	1 (0.6%)	0	1 (0.3%)
FERROUS FUMARATE	1 (0.6%)	0	1 (0.3%)
FLUOCINONIDE	1 (0.6%)	0	1 (0.3%)
FLUORIDE NOS	1 (0.6%)	0	1 (0.3%)
FOLIC ACID	1 (0.6%)	0	1 (0.3%)
FUSAFUNGINE	1 (0.6%)	0	1 (0.3%)
FUSIDIC ACID	1 (0.6%)	0	1 (0.3%)
GASTRIC MUCOSA EXTRACTS	1 (0.6%)	0	1 (0.3%)
GESTODENE	1 (0.6%)	0	1 (0.3%)
GLYCERYL MONOOLEATE	1 (0.6%)	0	1 (0.3%)
HEPATITIS VACCINE, NOS	1 (0.6%)	0	1 (0.3%)
HERBAL MEDICATION	1 (0.6%)	0	1 (0.3%)
HOMEOPATHIC PREPARATIONS	1 (0.6%)	0	1 (0.3%)
HYDROGEN PEROXIDE	1 (0.6%)	0	1 (0.3%)
HYDROXYZINE	1 (0.6%)	0	1 (0.3%)
HYOSCINE METHONITRATE	1 (0.6%)	0	1 (0.3%)
INTRINSIC FACTOR	1 (0.6%)	0	1 (0.3%)
ITRACONAZOLE	1 (0.6%)	0	1 (0.3%)
LEVOGLUTAMIDE	1 (0.6%)	0	1 (0.3%)
LIVER EXTRACTS	1 (0.6%)	0	1 (0.3%)
LORAZEPAM	1 (0.6%)	0	1 (0.3%)
MAGNESIUM NOS	1 (0.6%)	0	1 (0.3%)
MALIC ACID	1 (0.6%)	0	1 (0.3%)
MEFLOQUINE	1 (0.6%)	0	1 (0.3%)
MELOXICAM	1 (0.6%)	0	1 (0.3%)
MEPROBAMATE	1 (0.6%)	0	1 (0.3%)
MEPYRAMINE TANNATE	1 (0.6%)	0	1 (0.3%)
METAMIZOLE SODIUM	1 (0.6%)	0	1 (0.3%)
MICONAZOLE NITRATE	1 (0.6%)	0	1 (0.3%)
MULTIVITAMINS, NOS	1 (0.6%)	0	1 (0.3%)
MUPIROCIN	1 (0.6%)	0	1 (0.3%)

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Table 13.16.2.4

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Excluding Taper Phase
Intention-To-Treat Population

Generic Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
NAPHAZOLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
NAPROXEN	1 (0.6%)	0	1 (0.3%)
NORETHISTERONE	1 (0.6%)	0	1 (0.3%)
NORFLOXACIN	1 (0.6%)	0	1 (0.3%)
OFLOXACIN	1 (0.6%)	0	1 (0.3%)
OXETACAINE	1 (0.6%)	0	1 (0.3%)
OXYTETRACYCLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
PEMOLINE	1 (0.6%)	0	1 (0.3%)
PHENACETIN	1 (0.6%)	0	1 (0.3%)
PHENOL, LIQUEFIED	1 (0.6%)	0	1 (0.3%)
PHENOXYMETHYLPENICILLIN POTASSIUM	1 (0.6%)	0	1 (0.3%)
PHENYLEPHRINE TANNATE	1 (0.6%)	0	1 (0.3%)
PHENYLPROPANOLAMINE	1 (0.6%)	0	1 (0.3%)
PHENYLTOLOXAMINE	1 (0.6%)	0	1 (0.3%)
PROCAINE BENZYLPENICILLIN	1 (0.6%)	0	1 (0.3%)
PROPYLENE GLYCOL	1 (0.6%)	0	1 (0.3%)
RETINOL	1 (0.6%)	0	1 (0.3%)
RETINOL PALMITATE	1 (0.6%)	0	1 (0.3%)
RIFAMPICIN	1 (0.6%)	0	1 (0.3%)
SALICYLIC ACID	1 (0.6%)	0	1 (0.3%)
SODIUM GLYCEROPHOSPHATE	1 (0.6%)	0	1 (0.3%)
SPLEEN EXTRACTS	1 (0.6%)	0	1 (0.3%)
TAZAROTENE	1 (0.6%)	0	1 (0.3%)
TERBINAFINE	1 (0.6%)	0	1 (0.3%)
TETANUS TOXOID	1 (0.6%)	0	1 (0.3%)
TOCOPHEROL	1 (0.6%)	0	1 (0.3%)
TRIMETHOPRIM SULFATE	1 (0.6%)	0	1 (0.3%)
VITAMIN B SUBSTANCES	1 (0.6%)	0	1 (0.3%)
XYLOMETAZOLINE HYDROCHLORIDE	1 (0.6%)	0	1 (0.3%)
ZINC ACETATE	1 (0.6%)	0	1 (0.3%)
ZINC OXIDE	1 (0.6%)	0	1 (0.3%)
CAMPHOR	0	3 (1.9%)	3 (0.9%)
CEFALEXIN MONOHYDRATE	0	3 (1.9%)	3 (0.9%)
PAMABROM	0	3 (1.9%)	3 (0.9%)
PHENIRAMINE MALEATE	0	3 (1.9%)	3 (0.9%)
ALLERGENIC EXTRACT, NOS	0	2 (1.3%)	2 (0.6%)
BETAMETHASONE VALERATE	0	2 (1.3%)	2 (0.6%)
CETIRIZINE	0	2 (1.3%)	2 (0.6%)
CLARITHROMYCIN	0	2 (1.3%)	2 (0.6%)
HYDROCODONE BITARTRATE	0	2 (1.3%)	2 (0.6%)
LEVOTHYROXINE SODIUM	0	2 (1.3%)	2 (0.6%)
LORACARBEF	0	2 (1.3%)	2 (0.6%)
ORPHENADRINE CITRATE	0	2 (1.3%)	2 (0.6%)
PSEUDOEPHEDRINE	0	2 (1.3%)	2 (0.6%)
PSEUDOEPHEDRINE SULFATE	0	2 (1.3%)	2 (0.6%)
ALBENDAZOLE	0	1 (0.6%)	1 (0.3%)

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Table 13.16.2.4

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Excluding Taper Phase
Intention-To-Treat Population

Generic Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
AMBUPHYLLINE	0	1 (0.6%)	1 (0.3%)
ANISEED OIL	0	1 (0.6%)	1 (0.3%)
ARISTOLOCHIC ACID	0	1 (0.6%)	1 (0.3%)
ATORVASTATIN CALCIUM	0	1 (0.6%)	1 (0.3%)
BACITRACIN	0	1 (0.6%)	1 (0.3%)
BALSAM SULPHURIS	0	1 (0.6%)	1 (0.3%)
BETAMETHASONE DIPROPIONATE	0	1 (0.6%)	1 (0.3%)
BETAMETHASONE SODIUM PHOSPHATE	0	1 (0.6%)	1 (0.3%)
BIPERIDEN HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
BUCHU	0	1 (0.6%)	1 (0.3%)
CEFDINIR	0	1 (0.6%)	1 (0.3%)
CETRIMONIUM BROMIDE	0	1 (0.6%)	1 (0.3%)
CHINOFORM	0	1 (0.6%)	1 (0.3%)
CHLOROFORM	0	1 (0.6%)	1 (0.3%)
CINCHONA BARK	0	1 (0.6%)	1 (0.3%)
CLINDAMYCIN PHOSPHATE	0	1 (0.6%)	1 (0.3%)
CLOTRIMAZOLE	0	1 (0.6%)	1 (0.3%)
COUGH COLD PREPARATIONS NOS	0	1 (0.6%)	1 (0.3%)
DESOGESTREL	0	1 (0.6%)	1 (0.3%)
DIETHYLSTILBESTROL DIPROPIONATE	0	1 (0.6%)	1 (0.3%)
DIFLUCORTOLONE VALERATE	0	1 (0.6%)	1 (0.3%)
DIPHENHYDRAMINE	0	1 (0.6%)	1 (0.3%)
DIPHENOXYLATE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
DOXYCYCLINE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
ETAFEDRINE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
ETHANOL	0	1 (0.6%)	1 (0.3%)
ETHER	0	1 (0.6%)	1 (0.3%)
ETOFYLLINE	0	1 (0.6%)	1 (0.3%)
FENOTEROL HYDROBROMIDE	0	1 (0.6%)	1 (0.3%)
FLUCONAZOLE	0	1 (0.6%)	1 (0.3%)
GENTAMICIN SULFATE	0	1 (0.6%)	1 (0.3%)
HYDROXYETHYL THEOPHYLLINE	0	1 (0.6%)	1 (0.3%)
IODINATED GLYCEROL	0	1 (0.6%)	1 (0.3%)
IPRATROPIUM BROMIDE	0	1 (0.6%)	1 (0.3%)
ISOCONAZOLE NITRATE	0	1 (0.6%)	1 (0.3%)
LEUPRORELIN ACETATE	0	1 (0.6%)	1 (0.3%)
MECLOZINE	0	1 (0.6%)	1 (0.3%)
MEDROXYPROGESTERONE ACETATE	0	1 (0.6%)	1 (0.3%)
METAXALONE	0	1 (0.6%)	1 (0.3%)
METHYLPREDNISOLONE ACETATE	0	1 (0.6%)	1 (0.3%)
METOCLOPRAMIDE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
MONTELUKAST SODIUM	0	1 (0.6%)	1 (0.3%)
NABUMETONE	0	1 (0.6%)	1 (0.3%)
NEOMYCIN	0	1 (0.6%)	1 (0.3%)
NITROUS OXIDE	0	1 (0.6%)	1 (0.3%)
OXYTETRACYCLINE	0	1 (0.6%)	1 (0.3%)

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Table 13.16.2.4

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Excluding Taper Phase
Intention-To-Treat Population

Generic Term	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
PEPPERMINT OIL	0	1 (0.6%)	1 (0.3%)
PIPERONYL BUTOXIDE	0	1 (0.6%)	1 (0.3%)
POLYGALA SENEGA	0	1 (0.6%)	1 (0.3%)
POTASSIUM CHLORIDE	0	1 (0.6%)	1 (0.3%)
POTASSIUM NITRATE	0	1 (0.6%)	1 (0.3%)
PREDNISOLONE SODIUM PHOSPHATE	0	1 (0.6%)	1 (0.3%)
PROCAINE HYDROCHLORIDE	0	1 (0.6%)	1 (0.3%)
PROMETHAZINE	0	1 (0.6%)	1 (0.3%)
PSYLLIUM HYDROPHILIC MUCILLOID	0	1 (0.6%)	1 (0.3%)
PYRETHRINS	0	1 (0.6%)	1 (0.3%)
PYRETHRUM EXTRACT	0	1 (0.6%)	1 (0.3%)
SALSALATE	0	1 (0.6%)	1 (0.3%)
SODIUM LACTATE	0	1 (0.6%)	1 (0.3%)
SOMATROPIN	0	1 (0.6%)	1 (0.3%)
SPIRULINA	0	1 (0.6%)	1 (0.3%)
TOLNAFTATE	0	1 (0.6%)	1 (0.3%)
TOPICAL ANTIBIOTIC	0	1 (0.6%)	1 (0.3%)
TRICLOSAN	0	1 (0.6%)	1 (0.3%)
TRIPROLIDINE	0	1 (0.6%)	1 (0.3%)
TYROTHRICIN	0	1 (0.6%)	1 (0.3%)

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Table 13.16.2.5

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase Or Follow-up Phase
Intention-To-Treat Population Entering Taper Phase or Follow-Up Phase

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=144)	Placebo (N=129)	Total (N=273)
Total number of patients with at least one concomitant medication during taper or follow-up	Total	97 (67.4%)	83 (64.3%)	180 (65.9%)
ALIMENTARY TRACT/METAB	Total	28 (19.4%)	17 (13.2%)	45 (16.5%)
	ACETYLSALICYLIC ACID	4 (2.8%)	3 (2.3%)	7 (2.6%)
	ALGIN	1 (0.7%)	0	1 (0.4%)
	ALGINIC ACID	1 (0.7%)	0	1 (0.4%)
	ALUMINIUM HYDROXIDE	2 (1.4%)	0	2 (0.7%)
	ASCORBIC ACID	1 (0.7%)	1 (0.8%)	2 (0.7%)
	BISACODYL	1 (0.7%)	0	1 (0.4%)
	BISMUTH SUBSALICYLATE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	CALCIUM	0	1 (0.8%)	1 (0.4%)
	CALCIUM CARBONATE	1 (0.7%)	3 (2.3%)	4 (1.5%)
	CYCLIZINE HYDROCHLORIDE	2 (1.4%)	0	2 (0.7%)
	DICYCLOVERINE	1 (0.7%)	0	1 (0.4%)
	DOMPERIDONE	2 (1.4%)	0	2 (0.7%)
	FAMOTIDINE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	FLUORIDE NOS	1 (0.7%)	0	1 (0.4%)
	GINGER	0	1 (0.8%)	1 (0.4%)
	INSULIN	1 (0.7%)	1 (0.8%)	2 (0.7%)
	KAOLIN	1 (0.7%)	0	1 (0.4%)
	MAGNESIUM HYDROXIDE	1 (0.7%)	0	1 (0.4%)
	MAGNESIUM TRISILICATE	1 (0.7%)	0	1 (0.4%)
	MEBEVERINE	1 (0.7%)	0	1 (0.4%)
	MINERALS NOS	1 (0.7%)	0	1 (0.4%)
	PARAFFIN, LIQUID	2 (1.4%)	1 (0.8%)	3 (1.1%)
	PECTIN	1 (0.7%)	1 (0.8%)	2 (0.7%)
	PROMETHAZINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
	PSYLLIUM HYDROPHILIC MUCILLOID	0	1 (0.8%)	1 (0.4%)
	RANITIDINE HYDROCHLORIDE	2 (1.4%)	1 (0.8%)	3 (1.1%)
	RETINOL	1 (0.7%)	0	1 (0.4%)
	RETINOL PALMITATE	1 (0.7%)	0	1 (0.4%)
	SENNA FRUIT	1 (0.7%)	0	1 (0.4%)
	SODIUM BICARBONATE	1 (0.7%)	0	1 (0.4%)
	SODIUM CHLORIDE	1 (0.7%)	0	1 (0.4%)
	TOCOPHEROL	1 (0.7%)	0	1 (0.4%)
	TRIAMCINOLONE ACETONIDE	2 (1.4%)	2 (1.6%)	4 (1.5%)
	VITAMINS NOS	8 (5.6%)	4 (3.1%)	12 (4.4%)
	ZINC	0	1 (0.8%)	1 (0.4%)
ANTIINFECTIVES,SYSTEMIC	Total	17 (11.8%)	20 (15.5%)	37 (13.6%)

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 subjects 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 13.16.2.5

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase Or Follow-up Phase
Intention-To-Treat Population Entering Taper Phase or Follow-Up Phase

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=144)	Placebo (N=129)	Total (N=273)
ANTIINFECTIVES,SYSTEMIC	AMOXICILLIN	3 (2.1%)	2 (1.6%)	5 (1.8%)
	AMOXICILLIN TRIHYDRATE	2 (1.4%)	3 (2.3%)	5 (1.8%)
	AZITHROMYCIN	1 (0.7%)	1 (0.8%)	2 (0.7%)
	CEFALEXIN	1 (0.7%)	0	1 (0.4%)
	CEFIXIME	1 (0.7%)	0	1 (0.4%)
	CEFPROZIL MONOHYDRATE	1 (0.7%)	0	1 (0.4%)
	CEFUROXIME AXETIL	0	1 (0.8%)	1 (0.4%)
	CLAVULANIC ACID	0	3 (2.3%)	3 (1.1%)
	CLINDAMYCIN PHOSPHATE	0	1 (0.8%)	1 (0.4%)
	DOXYCYCLINE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	DOXYCYCLINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
	ERYTHROMYCIN	1 (0.7%)	0	1 (0.4%)
	FLUCONAZOLE	0	1 (0.8%)	1 (0.4%)
	MINOCYCLINE	2 (1.4%)	1 (0.8%)	3 (1.1%)
	MINOCYCLINE HYDROCHLORIDE	2 (1.4%)	4 (3.1%)	6 (2.2%)
	OXYTETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
	PENICILLIN NOS	0	1 (0.8%)	1 (0.4%)
	PHENOXYMETHYLPENICILLIN POTASSIUM	2 (1.4%)	0	2 (0.7%)
	PIVAMPICILLIN HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
	SULFAMETHOXAZOLE	0	2 (1.6%)	2 (0.7%)
	TETRACYCLINE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	TETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
	TRIMETHOPRIM	0	2 (1.6%)	2 (0.7%)
ANTINEOPLASTIC & IMMUNOSUP	Total	1 (0.7%)	3 (2.3%)	4 (1.5%)
	DIETHYLSTILBESTROL DIPROPIONATE	0	1 (0.8%)	1 (0.4%)
	LEUPRORELIN ACETATE	0	1 (0.8%)	1 (0.4%)
	TRETINOIN	1 (0.7%)	1 (0.8%)	2 (0.7%)
BLOOD/BLOOD FORM ORGANS	Total	6 (4.2%)	5 (3.9%)	11 (4.0%)
	ACETYLSALICYLIC ACID	4 (2.8%)	3 (2.3%)	7 (2.6%)
	AMINO ACIDS NOS	0	1 (0.8%)	1 (0.4%)
	ATORVASTATIN CALCIUM	0	1 (0.8%)	1 (0.4%)
	FERROUS SULFATE	1 (0.7%)	0	1 (0.4%)
	SODIUM CHLORIDE	1 (0.7%)	0	1 (0.4%)
CARDIOVASCULAR	Total	1 (0.7%)	1 (0.8%)	2 (0.7%)
	ETILEFRINE HYDROCHLORIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
CENTRAL NERVOUS SYSTEM	Total	64 (44.4%)	52 (40.3%)	116 (42.5%)

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 subjects 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 13.16.2.5

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase Or Follow-up Phase
Intention-To-Treat Population Entering Taper Phase or Follow-Up Phase

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=144)	Placebo (N=129)	Total (N=273)
CENTRAL NERVOUS SYSTEM	ACETYLSALICYLIC ACID	6 (4.2%)	5 (3.9%)	11 (4.0%)
	AMFEBUTAMONE HYDROCHLORIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	AMPHETAMINE ASPARTATE	1 (0.7%)	0	1 (0.4%)
	AMPHETAMINE SULFATE	1 (0.7%)	0	1 (0.4%)
	CAFFEINE	3 (2.1%)	2 (1.6%)	5 (1.8%)
	CANNABIS	1 (0.7%)	0	1 (0.4%)
	CHLORPHENAMINE MALEATE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	CINNAMEDRINE HYDROCHLORIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	CITALOPRAM	0	1 (0.8%)	1 (0.4%)
	CODEINE PHOSPHATE	1 (0.7%)	2 (1.6%)	3 (1.1%)
	DEXTROAMPHETAMINE SACCHARATE	1 (0.7%)	0	1 (0.4%)
	DEXTROAMPHETAMINE SULFATE	1 (0.7%)	0	1 (0.4%)
	DEXTROMETHORPHAN HYDROBROMIDE	1 (0.7%)	0	1 (0.4%)
	DIPHENHYDRAMINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
	DOXYLAMINE SUCCINATE	1 (0.7%)	0	1 (0.4%)
	IBUPROFEN	17 (11.8%)	12 (9.3%)	29 (10.6%)
	LORAZEPAM	1 (0.7%)	1 (0.8%)	2 (0.7%)
	MEPROBAMATE	1 (0.7%)	0	1 (0.4%)
	MEPYRAMINE MALEATE	0	3 (2.3%)	3 (1.1%)
	METHYLPHENIDATE HYDROCHLORIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	PAMABROM	0	3 (2.3%)	3 (1.1%)
	PARACETAMOL	21 (14.6%)	20 (15.5%)	41 (15.0%)
	PAROXETINE	34 (23.6%)	23 (17.8%)	57 (20.9%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	PHENYLTOLOXAMINE CITRATE	0	1 (0.8%)	1 (0.4%)
	PROCHLORPERAZINE	1 (0.7%)	0	1 (0.4%)
	PROMETHAZINE HYDROCHLORIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	2 (1.4%)	3 (2.3%)	5 (1.8%)
	RISPERIDONE	1 (0.7%)	0	1 (0.4%)
	SALICYLATES	1 (0.7%)	0	1 (0.4%)
	SALSALATE	0	1 (0.8%)	1 (0.4%)
	SERTRALINE HYDROCHLORIDE	0	2 (1.6%)	2 (0.7%)
	VALPROATE SEMISODIUM	1 (0.7%)	0	1 (0.4%)
DERMATOLOGICALS	Total	21 (14.6%)	20 (15.5%)	41 (15.0%)
	ADAPALENE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	BENZALKONIUM CHLORIDE	0	1 (0.8%)	1 (0.4%)
	BETAMETHASONE DIPROPIONATE	0	1 (0.8%)	1 (0.4%)
	BETAMETHASONE VALERATE	0	1 (0.8%)	1 (0.4%)
	BUDESONIDE	2 (1.4%)	1 (0.8%)	3 (1.1%)
	CALAMINE	0	1 (0.8%)	1 (0.4%)

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 subjects 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 13.16.2.5

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase Or Follow-up Phase
Intention-To-Treat Population Entering Taper Phase or Follow-Up Phase

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=144)	Placebo (N=129)	Total (N=273)
DERMATOLOGICALS	CAMPHOR	0	1 (0.8%)	1 (0.4%)
	CHINOFORM	0	1 (0.8%)	1 (0.4%)
	CLINDAMYCIN PHOSPHATE	0	1 (0.8%)	1 (0.4%)
	DIPHENHYDRAMINE	0	1 (0.8%)	1 (0.4%)
	DIPHENHYDRAMINE HYDROCHLORIDE	2 (1.4%)	2 (1.6%)	4 (1.5%)
	ERYTHROMYCIN	1 (0.7%)	0	1 (0.4%)
	FLUTICASONE PROPIONATE	5 (3.5%)	4 (3.1%)	9 (3.3%)
	GENTAMICIN SULFATE	0	1 (0.8%)	1 (0.4%)
	GLYCEROL	0	1 (0.8%)	1 (0.4%)
	MOMETASONE FUROATE	0	4 (3.1%)	4 (1.5%)
	OXYTETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
	PARAFFIN, LIQUID	2 (1.4%)	1 (0.8%)	3 (1.1%)
	PHENOL	1 (0.7%)	0	1 (0.4%)
	PROMETHAZINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
	PROMETHAZINE TEOCLATE	1 (0.7%)	0	1 (0.4%)
	RETINOL	1 (0.7%)	0	1 (0.4%)
	RETINOL PALMITATE	1 (0.7%)	0	1 (0.4%)
	TETRACYCLINE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	TETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
	TOCOPHEROL	1 (0.7%)	0	1 (0.4%)
	TOLNAFTATE	0	1 (0.8%)	1 (0.4%)
	TOPICAL ANTIBIOTIC	0	1 (0.8%)	1 (0.4%)
	TRETINOIN	1 (0.7%)	1 (0.8%)	2 (0.7%)
	TRIAMCINOLONE ACETONIDE	2 (1.4%)	3 (2.3%)	5 (1.8%)
	TRICLOSAN	0	1 (0.8%)	1 (0.4%)
GU SYSTEM/SEX HORMONES	Total	10 (6.9%)	2 (1.6%)	12 (4.4%)
	CYPROTERONE ACETATE	1 (0.7%)	0	1 (0.4%)
	DIETHYLSTILBESTROL DIPROPIONATE	0	1 (0.8%)	1 (0.4%)
	ETHINYLESTRADIOL	9 (6.3%)	1 (0.8%)	10 (3.7%)
	GESTODENE	1 (0.7%)	0	1 (0.4%)
	LEVONORGESTREL	2 (1.4%)	1 (0.8%)	3 (1.1%)
	NORETHISTERONE	1 (0.7%)	0	1 (0.4%)
	NORGESTIMATE	4 (2.8%)	0	4 (1.5%)
	OXYTETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
MUSCULO-SKELETAL	Total	19 (13.2%)	14 (10.9%)	33 (12.1%)
	EUCALYPTUS OIL	1 (0.7%)	0	1 (0.4%)
	IBUPROFEN	17 (11.8%)	13 (10.1%)	30 (11.0%)
	MEFENAMIC ACID	0	1 (0.8%)	1 (0.4%)
	MENTHOL	1 (0.7%)	0	1 (0.4%)

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 subjects 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 13.16.2.5

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase Or Follow-up Phase
Intention-To-Treat Population Entering Taper Phase or Follow-Up Phase

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=144)	Placebo (N=129)	Total (N=273)
MUSCULO-SKELETAL	NAPROXEN	1 (0.7%)	0	1 (0.4%)
	NAPROXEN SODIUM	2 (1.4%)	1 (0.8%)	3 (1.1%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
PARASITOLOGY	Total	1 (0.7%)	0	1 (0.4%)
	MEFLOQUINE	1 (0.7%)	0	1 (0.4%)
RESPIRATORY	Total	40 (27.8%)	31 (24.0%)	71 (26.0%)
	ACETYLSALICYLIC ACID	1 (0.7%)	0	1 (0.4%)
	AMINOACETIC ACID	1 (0.7%)	0	1 (0.4%)
	AMMONIUM CHLORIDE	1 (0.7%)	0	1 (0.4%)
	ASCORBIC ACID	2 (1.4%)	1 (0.8%)	3 (1.1%)
	BECLOMETASONE DIPROPIONATE	1 (0.7%)	0	1 (0.4%)
	BENZALKONIUM CHLORIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	BROMPHENIRAMINE MALEATE	3 (2.1%)	2 (1.6%)	5 (1.8%)
	BUDESONIDE	2 (1.4%)	1 (0.8%)	3 (1.1%)
	CAFFEINE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	CETIRIZINE HYDROCHLORIDE	3 (2.1%)	4 (3.1%)	7 (2.6%)
	CHLORPHENAMINE MALEATE	6 (4.2%)	3 (2.3%)	9 (3.3%)
	CHLORPHENAMINE TANNATE	1 (0.7%)	0	1 (0.4%)
	CLEMASTINE FUMARATE	1 (0.7%)	0	1 (0.4%)
	CODEINE PHOSPHATE	0	1 (0.8%)	1 (0.4%)
	CROMOGLICATE SODIUM	2 (1.4%)	0	2 (0.7%)
	CYCLIZINE HYDROCHLORIDE	2 (1.4%)	0	2 (0.7%)
	DEXTROMETHORPHAN HYDROBROMIDE	2 (1.4%)	0	2 (0.7%)
	DIMENHYDRINATE	1 (0.7%)	0	1 (0.4%)
	DIPHENHYDRAMINE	0	1 (0.8%)	1 (0.4%)
	DIPHENHYDRAMINE HYDROCHLORIDE	3 (2.1%)	2 (1.6%)	5 (1.8%)
	DOXYLAMINE SUCCINATE	1 (0.7%)	0	1 (0.4%)
	ETOFYLLINE	0	1 (0.8%)	1 (0.4%)
	EUCALYPTUS OIL	1 (0.7%)	0	1 (0.4%)
	FENOTEROL HYDROBROMIDE	0	1 (0.8%)	1 (0.4%)
	FEXOFENADINE HYDROCHLORIDE	0	4 (3.1%)	4 (1.5%)
	FLUTICASONE PROPIONATE	5 (3.5%)	4 (3.1%)	9 (3.3%)
	GUAIFENESIN	1 (0.7%)	6 (4.7%)	7 (2.6%)
	HYDROCODONE	1 (0.7%)	0	1 (0.4%)
	HYDROCODONE BITARTRATE	0	1 (0.8%)	1 (0.4%)
	IBUPROFEN	0	1 (0.8%)	1 (0.4%)
	IPRATROPIUM BROMIDE	0	1 (0.8%)	1 (0.4%)
	LORATADINE	8 (5.6%)	7 (5.4%)	15 (5.5%)
	MENTHOL	1 (0.7%)	0	1 (0.4%)
	MEPYRAMINE MALEATE	1 (0.7%)	0	1 (0.4%)

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 subjects 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 13.16.2.5

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase Or Follow-up Phase
Intention-To-Treat Population Entering Taper Phase or Follow-Up Phase

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=144)	Placebo (N=129)	Total (N=273)
RESPIRATORY	MEPYRAMINE TANNATE	1 (0.7%)	0	1 (0.4%)
	MOMETASONE FUROATE	0	4 (3.1%)	4 (1.5%)
	MONTELUKAST SODIUM	0	1 (0.8%)	1 (0.4%)
	MOROXYDINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
	OXYMETAZOLINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
	PARACETAMOL	5 (3.5%)	4 (3.1%)	9 (3.3%)
	PHENIRAMINE MALEATE	1 (0.7%)	0	1 (0.4%)
	PHENYLEPHRINE	0	1 (0.8%)	1 (0.4%)
	PHENYLEPHRINE HYDROCHLORIDE	4 (2.8%)	5 (3.9%)	9 (3.3%)
	PHENYLEPHRINE TANNATE	1 (0.7%)	0	1 (0.4%)
	PHENYLMERCURIC ACETATE	1 (0.7%)	0	1 (0.4%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	6 (4.2%)	6 (4.7%)	12 (4.4%)
	PROMETHAZINE HYDROCHLORIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	PROMETHAZINE TEOCLATE	1 (0.7%)	0	1 (0.4%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	5 (3.5%)	7 (5.4%)	12 (4.4%)
	PSEUDOEPHEDRINE SULFATE	0	2 (1.6%)	2 (0.7%)
	SALBUTAMOL	3 (2.1%)	5 (3.9%)	8 (2.9%)
	SALICYLAMIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	SALMETEROL HYDROXYNAPHTHOATE	2 (1.4%)	1 (0.8%)	3 (1.1%)
	SODIUM CHLORIDE	1 (0.7%)	0	1 (0.4%)
	SODIUM CITRATE	1 (0.7%)	0	1 (0.4%)
	SORBITOL	1 (0.7%)	0	1 (0.4%)
	TERBUTALINE SULFATE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	THEOPHYLLINE	0	1 (0.8%)	1 (0.4%)
	TRIAMCINOLONE ACETONIDE	2 (1.4%)	3 (2.3%)	5 (1.8%)
SENSORY ORGANS	Total	11 (7.6%)	4 (3.1%)	15 (5.5%)
	BROMPHENIRAMINE MALEATE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	CROMOGLICATE SODIUM	2 (1.4%)	0	2 (0.7%)
	ERYTHROMYCIN	1 (0.7%)	0	1 (0.4%)
	NEOMYCIN SULFATE	1 (0.7%)	0	1 (0.4%)
	OXYTETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	POLYMYXIN B SULFATE	1 (0.7%)	0	1 (0.4%)
	SODIUM CHLORIDE	1 (0.7%)	0	1 (0.4%)
	TETRACYCLINE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	TETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
	TRIAMCINOLONE ACETONIDE	2 (1.4%)	2 (1.6%)	4 (1.5%)
SYSTEMIC HORMONAL	Total	3 (2.1%)	5 (3.9%)	8 (2.9%)

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 subjects 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 13.16.2.5

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase Or Follow-up Phase
Intention-To-Treat Population Entering Taper Phase or Follow-Up Phase

		Treatment Group		
ATC Code Level 1	Generic Term(s)	Paroxetine (N=144)	Placebo (N=129)	Total (N=273)
SYSTEMIC HORMONAL	BETAMETHASONE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	CHLORPHENAMINE MALEATE	1 (0.7%)	1 (0.8%)	2 (0.7%)
	LEVOTHYROXINE SODIUM	0	2 (1.6%)	2 (0.7%)
	TRIAMCINOLONE ACETONIDE	2 (1.4%)	2 (1.6%)	4 (1.5%)
VARIOUS	Total	4 (2.8%)	5 (3.9%)	9 (3.3%)
	ALLERGENIC EXTRACT, NOS	0	2 (1.6%)	2 (0.7%)
	AMINO ACIDS NOS	0	1 (0.8%)	1 (0.4%)
	ECHINACEA EXTRACT	1 (0.7%)	0	1 (0.4%)
	GINGER	0	1 (0.8%)	1 (0.4%)
	HERBAL MEDICATION	2 (1.4%)	0	2 (0.7%)
	NUTRITIONAL SUPPLEMENT NOS	1 (0.7%)	1 (0.8%)	2 (0.7%)
	SPIRULINA	0	1 (0.8%)	1 (0.4%)

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 subjects 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 13.16.2.6

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase Or Follow-up Phase
Intention-To-Treat Population Entering Taper Phase or Follow-Up Phase

Generic Term	Treatment Group: Paroxetine (N=144)	Placebo (N=129)	Total (N=273)
Total number of patients with at least one concomitant medication during taper or follow-up	97 (67.4%)	83 (64.3%)	180 (65.9%)
PAROXETINE	34 (23.6%)	23 (17.8%)	57 (20.9%)
PARACETAMOL	23 (16.0%)	21 (16.3%)	44 (16.1%)
IBUPROFEN	17 (11.8%)	13 (10.1%)	30 (11.0%)
ETHINYLESTRADIOL	9 (6.3%)	1 (0.8%)	10 (3.7%)
LORATADINE	8 (5.6%)	7 (5.4%)	15 (5.5%)
VITAMINS NOS	8 (5.6%)	4 (3.1%)	12 (4.4%)
ACETYLSALICYLIC ACID	7 (4.9%)	5 (3.9%)	12 (4.4%)
CHLORPHENAMINE MALEATE	7 (4.9%)	4 (3.1%)	11 (4.0%)
PHENYLPROPANOLAMINE HYDROCHLORIDE	6 (4.2%)	6 (4.7%)	12 (4.4%)
PSEUDOEPHEDRINE HYDROCHLORIDE	5 (3.5%)	7 (5.4%)	12 (4.4%)
FLUTICASONE PROPIONATE	5 (3.5%)	4 (3.1%)	9 (3.3%)
PHENYLEPHRINE HYDROCHLORIDE	4 (2.8%)	5 (3.9%)	9 (3.3%)
CAFFEINE	4 (2.8%)	3 (2.3%)	7 (2.6%)
NORGESTIMATE	4 (2.8%)	0	4 (1.5%)
SALBUTAMOL	3 (2.1%)	5 (3.9%)	8 (2.9%)
CETIRIZINE HYDROCHLORIDE	3 (2.1%)	4 (3.1%)	7 (2.6%)
AMOXICILLIN	3 (2.1%)	2 (1.6%)	5 (1.8%)
BROMPHENIRAMINE MALEATE	3 (2.1%)	2 (1.6%)	5 (1.8%)
DIPHENHYDRAMINE HYDROCHLORIDE	3 (2.1%)	2 (1.6%)	5 (1.8%)
MINOCYCLINE HYDROCHLORIDE	2 (1.4%)	4 (3.1%)	6 (2.2%)
AMOXICILLIN TRIHYDRATE	2 (1.4%)	3 (2.3%)	5 (1.8%)
TRIAMCINOLONE ACETONIDE	2 (1.4%)	3 (2.3%)	5 (1.8%)
ASCORBIC ACID	2 (1.4%)	2 (1.6%)	4 (1.5%)
BUDESONIDE	2 (1.4%)	1 (0.8%)	3 (1.1%)
LEVONORGESTREL	2 (1.4%)	1 (0.8%)	3 (1.1%)
MINOCYCLINE	2 (1.4%)	1 (0.8%)	3 (1.1%)
NAPROXEN SODIUM	2 (1.4%)	1 (0.8%)	3 (1.1%)
PARAFFIN, LIQUID	2 (1.4%)	1 (0.8%)	3 (1.1%)
RANITIDINE HYDROCHLORIDE	2 (1.4%)	1 (0.8%)	3 (1.1%)
SALMETEROL HYDROXYNAPHTHOATE	2 (1.4%)	1 (0.8%)	3 (1.1%)
ALUMINIUM HYDROXIDE	2 (1.4%)	0	2 (0.7%)
CROMOGLICATE SODIUM	2 (1.4%)	0	2 (0.7%)
CYCLIZINE HYDROCHLORIDE	2 (1.4%)	0	2 (0.7%)
DEXTROMETHORPHAN HYDROBROMIDE	2 (1.4%)	0	2 (0.7%)
DOMPERIDONE	2 (1.4%)	0	2 (0.7%)
HERBAL MEDICATION	2 (1.4%)	0	2 (0.7%)
PHENOXYMETHYLPENICILLIN POTASSIUM	2 (1.4%)	0	2 (0.7%)
GUAIFENESIN	1 (0.7%)	6 (4.7%)	7 (2.6%)
CALCIUM CARBONATE	1 (0.7%)	3 (2.3%)	4 (1.5%)

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 subjects 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 13.16.2.6

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase Or Follow-up Phase
Intention-To-Treat Population Entering Taper Phase or Follow-Up Phase

Generic Term	Treatment Group: Paroxetine (N=144)	Placebo (N=129)	Total (N=273)
MEPYRAMINE MALEATE	1 (0.7%)	3 (2.3%)	4 (1.5%)
CODEINE PHOSPHATE	1 (0.7%)	2 (1.6%)	3 (1.1%)
ADAPALENE	1 (0.7%)	1 (0.8%)	2 (0.7%)
AMFEBUTAMONE HYDROCHLORIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
AZITHROMYCIN	1 (0.7%)	1 (0.8%)	2 (0.7%)
BENZALKONIUM CHLORIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
BETAMETHASONE	1 (0.7%)	1 (0.8%)	2 (0.7%)
BISMUTH SUBSALICYLATE	1 (0.7%)	1 (0.8%)	2 (0.7%)
CINNAMEDRINE HYDROCHLORIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
DOXYCYCLINE	1 (0.7%)	1 (0.8%)	2 (0.7%)
ETILEFRINE HYDROCHLORIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
FAMOTIDINE	1 (0.7%)	1 (0.8%)	2 (0.7%)
INSULIN	1 (0.7%)	1 (0.8%)	2 (0.7%)
LORAZEPAM	1 (0.7%)	1 (0.8%)	2 (0.7%)
METHYLPHENIDATE HYDROCHLORIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
NUTRITIONAL SUPPLEMENT NOS	1 (0.7%)	1 (0.8%)	2 (0.7%)
PECTIN	1 (0.7%)	1 (0.8%)	2 (0.7%)
PROMETHAZINE HYDROCHLORIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
SALICYLAMIDE	1 (0.7%)	1 (0.8%)	2 (0.7%)
TERBUTALINE SULFATE	1 (0.7%)	1 (0.8%)	2 (0.7%)
TETRACYCLINE	1 (0.7%)	1 (0.8%)	2 (0.7%)
TRETINOIN	1 (0.7%)	1 (0.8%)	2 (0.7%)
ALGIN	1 (0.7%)	0	1 (0.4%)
ALGINIC ACID	1 (0.7%)	0	1 (0.4%)
AMINOACETIC ACID	1 (0.7%)	0	1 (0.4%)
AMMONIUM CHLORIDE	1 (0.7%)	0	1 (0.4%)
AMPHETAMINE ASPARTATE	1 (0.7%)	0	1 (0.4%)
AMPHETAMINE SULFATE	1 (0.7%)	0	1 (0.4%)
BECLOMETASONE DIPROPIONATE	1 (0.7%)	0	1 (0.4%)
BISACODYL	1 (0.7%)	0	1 (0.4%)
CANNABIS	1 (0.7%)	0	1 (0.4%)
CEFALEXIN	1 (0.7%)	0	1 (0.4%)
CEFIXIME	1 (0.7%)	0	1 (0.4%)
CEFPROZIL MONOHYDRATE	1 (0.7%)	0	1 (0.4%)
CHLORPHENAMINE TANNATE	1 (0.7%)	0	1 (0.4%)
CLEMASTINE FUMARATE	1 (0.7%)	0	1 (0.4%)
CYPROTERONE ACETATE	1 (0.7%)	0	1 (0.4%)
DEXTROAMPHETAMINE SACCHARATE	1 (0.7%)	0	1 (0.4%)
DEXTROAMPHETAMINE SULFATE	1 (0.7%)	0	1 (0.4%)
DICYCLOVERINE	1 (0.7%)	0	1 (0.4%)
DIMENHYDRINATE	1 (0.7%)	0	1 (0.4%)
DOXYLAMINE SUCCINATE	1 (0.7%)	0	1 (0.4%)

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 subjects 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 13.16.2.6

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase Or Follow-up Phase
Intention-To-Treat Population Entering Taper Phase or Follow-Up Phase

Generic Term	Treatment Group: Paroxetine (N=144)	Placebo (N=129)	Total (N=273)
ECHINACEA EXTRACT	1 (0.7%)	0	1 (0.4%)
ERYTHROMYCIN	1 (0.7%)	0	1 (0.4%)
EUCALYPTUS OIL	1 (0.7%)	0	1 (0.4%)
FERROUS SULFATE	1 (0.7%)	0	1 (0.4%)
FLUORIDE NOS	1 (0.7%)	0	1 (0.4%)
GESTODENE	1 (0.7%)	0	1 (0.4%)
HYDROCODONE	1 (0.7%)	0	1 (0.4%)
KAOLIN	1 (0.7%)	0	1 (0.4%)
MAGNESIUM HYDROXIDE	1 (0.7%)	0	1 (0.4%)
MAGNESIUM TRISILICATE	1 (0.7%)	0	1 (0.4%)
MEBEVERINE	1 (0.7%)	0	1 (0.4%)
MEFLOQUINE	1 (0.7%)	0	1 (0.4%)
MENTHOL	1 (0.7%)	0	1 (0.4%)
MEPROBAMATE	1 (0.7%)	0	1 (0.4%)
MEPYRAMINE TANNATE	1 (0.7%)	0	1 (0.4%)
MINERALS NOS	1 (0.7%)	0	1 (0.4%)
MOROXYDINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
NAPROXEN	1 (0.7%)	0	1 (0.4%)
NEOMYCIN SULFATE	1 (0.7%)	0	1 (0.4%)
NORETHISTERONE	1 (0.7%)	0	1 (0.4%)
OXYMETAZOLINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
OXYTETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
PHENIRAMINE MALEATE	1 (0.7%)	0	1 (0.4%)
PHENOL	1 (0.7%)	0	1 (0.4%)
PHENYLEPHRINE TANNATE	1 (0.7%)	0	1 (0.4%)
PHENYLMERCURIC ACETATE	1 (0.7%)	0	1 (0.4%)
POLYMYXIN B SULFATE	1 (0.7%)	0	1 (0.4%)
PROCHLORPERAZINE	1 (0.7%)	0	1 (0.4%)
PROMETHAZINE TEOCLATE	1 (0.7%)	0	1 (0.4%)
RETINOL	1 (0.7%)	0	1 (0.4%)
RETINOL PALMITATE	1 (0.7%)	0	1 (0.4%)
RISPERIDONE	1 (0.7%)	0	1 (0.4%)
SALICYLATES	1 (0.7%)	0	1 (0.4%)
SENNA FRUIT	1 (0.7%)	0	1 (0.4%)
SODIUM BICARBONATE	1 (0.7%)	0	1 (0.4%)
SODIUM CHLORIDE	1 (0.7%)	0	1 (0.4%)
SODIUM CITRATE	1 (0.7%)	0	1 (0.4%)
SORBITOL	1 (0.7%)	0	1 (0.4%)
TETRACYCLINE HYDROCHLORIDE	1 (0.7%)	0	1 (0.4%)
TOCOPHEROL	1 (0.7%)	0	1 (0.4%)
VALPROATE SEMISODIUM	1 (0.7%)	0	1 (0.4%)
FEXOFENADINE HYDROCHLORIDE	0	4 (3.1%)	4 (1.5%)

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 subjects 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 13.16.2.6

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase Or Follow-up Phase
Intention-To-Treat Population Entering Taper Phase or Follow-Up Phase

Generic Term	Treatment Group: Paroxetine (N=144)	Placebo (N=129)	Total (N=273)
MOMETASONE FUROATE	0	4 (3.1%)	4 (1.5%)
CLAVULANIC ACID	0	3 (2.3%)	3 (1.1%)
PAMABROM	0	3 (2.3%)	3 (1.1%)
ALLERGENIC EXTRACT, NOS	0	2 (1.6%)	2 (0.7%)
LEVOTHYROXINE SODIUM	0	2 (1.6%)	2 (0.7%)
PSEUDOEPHEDRINE SULFATE	0	2 (1.6%)	2 (0.7%)
SERTRALINE HYDROCHLORIDE	0	2 (1.6%)	2 (0.7%)
SULFAMETHOXAZOLE	0	2 (1.6%)	2 (0.7%)
TRIMETHOPRIM	0	2 (1.6%)	2 (0.7%)
AMINO ACIDS NOS	0	1 (0.8%)	1 (0.4%)
ATORVASTATIN CALCIUM	0	1 (0.8%)	1 (0.4%)
BETAMETHASONE DIPROPIONATE	0	1 (0.8%)	1 (0.4%)
BETAMETHASONE VALERATE	0	1 (0.8%)	1 (0.4%)
CALAMINE	0	1 (0.8%)	1 (0.4%)
CALCIUM	0	1 (0.8%)	1 (0.4%)
CAMPHOR	0	1 (0.8%)	1 (0.4%)
CEFUROXIME AXETIL	0	1 (0.8%)	1 (0.4%)
CHINOFORM	0	1 (0.8%)	1 (0.4%)
CITALOPRAM	0	1 (0.8%)	1 (0.4%)
CLINDAMYCIN PHOSPHATE	0	1 (0.8%)	1 (0.4%)
DIETHYLSTILBESTROL DIPROPIONATE	0	1 (0.8%)	1 (0.4%)
DIPHENHYDRAMINE	0	1 (0.8%)	1 (0.4%)
DOXYCYCLINE HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
ETOFYLLINE	0	1 (0.8%)	1 (0.4%)
FENOTEROL HYDROBROMIDE	0	1 (0.8%)	1 (0.4%)
FLUCONAZOLE	0	1 (0.8%)	1 (0.4%)
GENTAMICIN SULFATE	0	1 (0.8%)	1 (0.4%)
GINGER	0	1 (0.8%)	1 (0.4%)
GLYCEROL	0	1 (0.8%)	1 (0.4%)
HYDROCODONE BITARTRATE	0	1 (0.8%)	1 (0.4%)
IPRATROPIUM BROMIDE	0	1 (0.8%)	1 (0.4%)
LEUPRORELIN ACETATE	0	1 (0.8%)	1 (0.4%)
MEFENAMIC ACID	0	1 (0.8%)	1 (0.4%)
MONTELUKAST SODIUM	0	1 (0.8%)	1 (0.4%)
PENICILLIN NOS	0	1 (0.8%)	1 (0.4%)
PHENYLEPHRINE	0	1 (0.8%)	1 (0.4%)
PHENYLTOLOXAMINE CITRATE	0	1 (0.8%)	1 (0.4%)
PIVAMPICILLIN HYDROCHLORIDE	0	1 (0.8%)	1 (0.4%)
PSYLLIUM HYDROPHILIC MUCILLOID	0	1 (0.8%)	1 (0.4%)
SALSALATE	0	1 (0.8%)	1 (0.4%)
SPIRULINA	0	1 (0.8%)	1 (0.4%)
THEOPHYLLINE	0	1 (0.8%)	1 (0.4%)

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 subjects 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 13.16.2.6

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase Or Follow-up Phase
Intention-To-Treat Population Entering Taper Phase or Follow-Up Phase

Generic Term	Treatment Group: Paroxetine (N=144)	Placebo (N=129)	Total (N=273)
TOLNAFTATE	0	1 (0.8%)	1 (0.4%)
TOPICAL ANTIBIOTIC	0	1 (0.8%)	1 (0.4%)
TRICLOSAN	0	1 (0.8%)	1 (0.4%)
ZINC	0	1 (0.8%)	1 (0.4%)

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 subjects 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 13.17.1

Number (%) of Patients who missed more than three consecutive days of study medication at each visit and overall

Intention-To-Treat Population

Age Group : Children

	Treatment Group: Paroxetine (N = 46)		Placebo (N = 45)		Total (N = 91)	
Visit	Missed > 3 Consecutive Days: No	Yes *	No	Yes *	No	Yes *
Week 1	46 (100.0%)	0	45 (100.0%)	0	91 (100.0%)	0
Week 2	46 (100.0%)	0	45 (100.0%)	0	91 (100.0%)	0
Week 3	45 (97.8%)	1 (2.2%)	45 (100.0%)	0	90 (98.9%)	1 (1.1%)
Week 4	43 (100.0%)	0	43 (100.0%)	0	86 (100.0%)	0
Week 6	42 (100.0%)	0	39 (95.1%)	2 (4.9%)	81 (97.6%)	2 (2.4%)
Week 8	39 (95.1%)	2 (4.9%)	37 (97.4%)	1 (2.6%)	76 (96.2%)	3 (3.8%)
Week 10	38 (97.4%)	1 (2.6%)	33 (97.1%)	1 (2.9%)	71 (97.3%)	2 (2.7%)
Week 12	35 (100.0%)	0	31 (100.0%)	0	66 (100.0%)	0
Week 16	32 (94.1%)	2 (5.9%)	27 (87.1%)	4 (12.9%)	59 (90.8%)	6 (9.2%)
Overall **	41 (89.1%)	5 (10.9%)	37 (82.2%)	8 (17.8%)	78 (85.7%)	13 (14.3%)

* Patients who have missed more than 3 consecutive days of study medication are considered non-compliant
Note: Percentages are out of number of patients in each treatment group who have this study medication information on the relevant eCRF panel, patients with unknown compliance and duration of study medication > 3 days at that visit are considered non-compliant
**Overall=Number of patients who miss more than 3 consecutive days at any point in the study.
Patients who miss more than 3 consecutive days on more than one occasion are only counted once
Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

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Table 13.17.1

Number (%) of Patients who missed more than three consecutive days of study medication at each visit and overall

Intention-To-Treat Population

Age Group : Adolescents

	Treatment Group					
	Paroxetine (N = 117)		Placebo (N = 111)		Total (N = 228)	
	Missed > 3 Consecutive Days		Missed > 3 Consecutive Days		Missed > 3 Consecutive Days	
Visit	No	Yes *	No	Yes *	No	Yes *
Week 1	113(97.4%)	3 (2.6%)	109(99.1%)	1 (0.9%)	222(98.2%)	4 (1.8%)
Week 2	114(100.0%)	0	106(100.0%)	0	220(100.0%)	0
Week 3	113(100.0%)	0	104(100.0%)	0	217(100.0%)	0
Week 4	112(100.0%)	0	98 (99.0%)	1 (1.0%)	210(99.5%)	1 (0.5%)
Week 6	106(95.5%)	5 (4.5%)	98 (98.0%)	2 (2.0%)	204(96.7%)	7 (3.3%)
Week 8	101(99.0%)	1 (1.0%)	87 (93.5%)	6 (6.5%)	188(96.4%)	7 (3.6%)
Week 10	96 (96.0%)	4 (4.0%)	78 (94.0%)	5 (6.0%)	174(95.1%)	9 (4.9%)
Week 12	96 (100.0%)	0	77 (97.5%)	2 (2.5%)	173(98.9%)	2 (1.1%)
Week 16	92 (96.8%)	3 (3.2%)	71 (92.2%)	6 (7.8%)	163(94.8%)	9 (5.2%)
Overall **	102(87.9%)	14 (12.1%)	91 (82.7%)	19 (17.3%)	193(85.4%)	33 (14.6%)

* Patients who have missed more than 3 consecutive days of study medication are considered non-compliant
Note: Percentages are out of number of patients in each treatment group who have this study medication information on the relevant eCRF panel, patients with unknown compliance and duration of study medication > 3 days at that visit are considered non-compliant
**Overall=Number of patients who miss more than 3 consecutive days at any point in the study.
Patients who miss more than 3 consecutive days on more than one occasion are only counted once
Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

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Table 13.17.1

Number (%) of Patients who missed more than three consecutive days of study medication at each visit and overall

Intention-To-Treat Population

Age Group : Total

	Treatment Group					
	Paroxetine (N = 163)		Placebo (N = 156)		Total (N = 319)	
	Missed > 3 Consecutive Days		Missed > 3 Consecutive Days		Missed > 3 Consecutive Days	
Visit	No	Yes *	No	Yes *	No	Yes *
Week 1	159(98.1%)	3 (1.9%)	154(99.4%)	1 (0.6%)	313(98.7%)	4 (1.3%)
Week 2	160(100.0%)	0	151(100.0%)	0	311(100.0%)	0
Week 3	158(99.4%)	1 (0.6%)	149(100.0%)	0	307(99.7%)	1 (0.3%)
Week 4	155(100.0%)	0	141(99.3%)	1 (0.7%)	296(99.7%)	1 (0.3%)
Week 6	148(96.7%)	5 (3.3%)	137(97.2%)	4 (2.8%)	285(96.9%)	9 (3.1%)
Week 8	140(97.9%)	3 (2.1%)	124(94.7%)	7 (5.3%)	264(96.4%)	10 (3.6%)
Week 10	134(96.4%)	5 (3.6%)	111(94.9%)	6 (5.1%)	245(95.7%)	11 (4.3%)
Week 12	131(100.0%)	0	108(98.2%)	2 (1.8%)	239(99.2%)	2 (0.8%)
Week 16	124(96.1%)	5 (3.9%)	98 (90.7%)	10 (9.3%)	222(93.7%)	15 (6.3%)
Overall **	143(88.3%)	19 (11.7%)	128(82.6%)	27 (17.4%)	271(85.5%)	46 (14.5%)

* Patients who have missed more than 3 consecutive days of study medication are considered non-compliant
Note: Percentages are out of number of patients in each treatment group who have this study medication information on the relevant eCRF panel, patients with unknown compliance and duration of study medication > 3 days at that visit are considered non-compliant
**Overall=Number of patients who miss more than 3 consecutive days at any point in the study.
Patients who miss more than 3 consecutive days on more than one occasion are only counted once
Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

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Table 13.17.2

Tablet Accountability (number (%) of patients) at Each Visit and Overall

Intention-To-Treat Population

Age Group: Children

Study Treatment Group

	Paroxetine N=46 Accountable*		Placebo N=45 Accountable*		Total N=91 Accountable*	
	Yes	No	Yes	No	Yes	No
Week 1	40 (87.0%)	6 (13.0%)	40 (88.9%)	5 (11.1%)	80 (87.9%)	11 (12.1%)
Week 2	42 (91.3%)	4 (8.7%)	39 (86.7%)	6 (13.3%)	81 (89.0%)	10 (11.0%)
Week 3	43 (93.5%)	3 (6.5%)	40 (88.9%)	5 (11.1%)	83 (91.2%)	8 (8.8%)
Week 4	37 (86.0%)	6 (14.0%)	36 (83.7%)	7 (16.3%)	73 (84.9%)	13 (15.1%)
Week 6	29 (69.0%)	13 (31.0%)	31 (77.5%)	9 (22.5%)	60 (73.2%)	22 (26.8%)
Week 8	31 (77.5%)	9 (22.5%)	34 (89.5%)	4 (10.5%)	65 (83.3%)	13 (16.7%)
Week 10	32 (82.1%)	7 (17.9%)	26 (76.5%)	8 (23.5%)	58 (79.5%)	15 (20.5%)
Week 12	29 (82.9%)	6 (17.1%)	26 (83.9%)	5 (16.1%)	55 (83.3%)	11 (16.7%)
Week 16	28 (80.0%)	7 (20.0%)	28 (90.3%)	3 (9.7%)	56 (84.8%)	10 (15.2%)
Overall**	43 (95.6%)	2 (4.4%)	41 (93.2%)	3 (6.8%)	84 (94.4%)	5 (5.6%)

* Accountability at each visit is defined as the result of the following calculation falling within the 80%-120% band:
[(No. of Capsules Dispensed - No. of Capsules Returned) / (No. of Days * 2)] * 100
** Accountability overall is defined as the result of the following calculation falling within the 80%-120% band:
[(Total No. of Capsules Dispensed - Total No. of Capsules Returned) / (Total No. of Days * 2)] * 100
Note: No. of Days = Stop Date - Start Date + 1
Note: Percentages are out of number of patients in each treatment group who have this study medication information on the relevant eCRF panel
Note: Accountability and Overall Accountability are only calculated if all data needed is present
Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but is in Listing 13.17.1

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Table 13.17.2

Tablet Accountability (number (%) of patients) at Each Visit and Overall

Intention-To-Treat Population

Age Group: Adolescents

Study Treatment Group

	Paroxetine N=117 Accountable*		Placebo N=111 Accountable*		Total N=228 Accountable*	
	Yes	No	Yes	No	Yes	No
Week 1	103 (90.4%)	11 (9.6%)	96 (88.1%)	13 (11.9%)	199 (89.2%)	24 (10.8%)
Week 2	107 (93.9%)	7 (6.1%)	95 (89.6%)	11 (10.4%)	202 (91.8%)	18 (8.2%)
Week 3	104 (92.0%)	9 (8.0%)	94 (91.3%)	9 (8.7%)	198 (91.7%)	18 (8.3%)
Week 4	100 (90.1%)	11 (9.9%)	84 (85.7%)	14 (14.3%)	184 (88.0%)	25 (12.0%)
Week 6	88 (80.7%)	21 (19.3%)	85 (85.9%)	14 (14.1%)	173 (83.2%)	35 (16.8%)
Week 8	92 (89.3%)	11 (10.7%)	81 (90.0%)	9 (10.0%)	173 (89.6%)	20 (10.4%)
Week 10	84 (84.8%)	15 (15.2%)	68 (87.2%)	10 (12.8%)	152 (85.9%)	25 (14.1%)
Week 12	83 (86.5%)	13 (13.5%)	69 (89.6%)	8 (10.4%)	152 (87.9%)	21 (12.1%)
Week 16	84 (88.4%)	11 (11.6%)	68 (91.9%)	6 (8.1%)	152 (89.9%)	17 (10.1%)
Overall**	100 (90.1%)	11 (9.9%)	93 (94.9%)	5 (5.1%)	193 (92.3%)	16 (7.7%)

* Accountability at each visit is defined as the result of the following calculation falling within the 80%-120% band:
[(No. of Capsules Dispensed - No. of Capsules Returned) / (No. of Days * 2)] * 100
** Accountability overall is defined as the result of the following calculation falling within the 80%-120% band:
[(Total No. of Capsules Dispensed - Total No. of Capsules Returned) / (Total No. of Days * 2)] * 100
Note: No. of Days = Stop Date - Start Date + 1
Note: Percentages are out of number of patients in each treatment group who have this study medication information on the relevant eCRF panel
Note: Accountability and Overall Accountability are only calculated if all data needed is present
Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but is in Listing 13.17.1

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Table 13.17.2

Tablet Accountability (number (%) of patients) at Each Visit and Overall

Intention-To-Treat Population

Age Group: Total

Study Treatment Group

	Paroxetine N=163 Accountable*		Placebo N=156 Accountable*		Total N=319 Accountable*	
	Yes	No	Yes	No	Yes	No
Week 1	143 (89.4%)	17 (10.6%)	136 (88.3%)	18 (11.7%)	279 (88.9%)	35 (11.1%)
Week 2	149 (93.1%)	11 (6.9%)	134 (88.7%)	17 (11.3%)	283 (91.0%)	28 (9.0%)
Week 3	147 (92.5%)	12 (7.5%)	134 (90.5%)	14 (9.5%)	281 (91.5%)	26 (8.5%)
Week 4	137 (89.0%)	17 (11.0%)	120 (85.1%)	21 (14.9%)	257 (87.1%)	38 (12.9%)
Week 6	117 (77.5%)	34 (22.5%)	116 (83.5%)	23 (16.5%)	233 (80.3%)	57 (19.7%)
Week 8	123 (86.0%)	20 (14.0%)	115 (89.8%)	13 (10.2%)	238 (87.8%)	33 (12.2%)
Week 10	116 (84.1%)	22 (15.9%)	94 (83.9%)	18 (16.1%)	210 (84.0%)	40 (16.0%)
Week 12	112 (85.5%)	19 (14.5%)	95 (88.0%)	13 (12.0%)	207 (86.6%)	32 (13.4%)
Week 16	112 (86.2%)	18 (13.8%)	96 (91.4%)	9 (8.6%)	208 (88.5%)	27 (11.5%)
Overall**	143 (91.7%)	13 (8.3%)	134 (94.4%)	8 (5.6%)	277 (93.0%)	21 (7.0%)

* Accountability at each visit is defined as the result of the following calculation falling within the 80%-120% band:
[(No. of Capsules Dispensed - No. of Capsules Returned) / (No. of Days * 2)] * 100
** Accountability overall is defined as the result of the following calculation falling within the 80%-120% band:
[(Total No. of Capsules Dispensed - Total No. of Capsules Returned) / (Total No. of Days * 2)] * 100
Note: No. of Days = Stop Date - Start Date + 1
Note: Percentages are out of number of patients in each treatment group who have this study medication information on the relevant eCRF panel
Note: Accountability and Overall Accountability are only calculated if all data needed is present
Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but is in Listing 13.17.1

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Table 13.17.3

Number (%) of Patients Exposed to each Study Medication Dose Level

Intention-To-Treat Population

Age Group: Children

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	46	100.0	0	0.0	0	0.0	0	0.0	0	0.0	46	100.0
Week 2	23	50.0	23	50.0	0	0.0	0	0.0	0	0.0	46	100.0
Week 3	15	32.6	20	43.5	11	23.9	0	0.0	0	0.0	46	100.0
Week 4	11	25.6	15	34.9	11	25.6	6	14.0	0	0.0	43	100.0
Week 6	10	23.8	13	31.0	9	21.4	6	14.3	4	9.5	42	100.0
Week 8	7	17.1	16	39.0	6	14.6	8	19.5	4	9.8	41	100.0
Week 10	6	15.4	13	33.3	6	15.4	8	20.5	6	15.4	39	100.0
Week 12	4	11.4	12	34.3	8	22.9	5	14.3	6	17.1	35	100.0
Week 16	5	14.3	10	28.6	9	25.7	5	14.3	6	17.1	35	100.0

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

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Table 13.17.3

Number (%) of Patients Exposed to each Study Medication Dose Level

Intention-To-Treat Population

Age Group: Adolescents

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	116	100.0	0	0.0	0	0.0	0	0.0	0	0.0	116	100.0
Week 2	39	34.2	75	65.8	0	0.0	0	0.0	0	0.0	114	100.0
Week 3	15	13.3	64	56.6	34	30.1	0	0.0	0	0.0	113	100.0
Week 4	9	8.0	46	41.1	36	32.1	21	18.8	0	0.0	112	100.0
Week 6	8	7.1	27	24.1	40	35.7	22	19.6	15	13.4	112	100.0
Week 8	6	5.8	23	22.3	26	25.2	27	26.2	21	20.4	103	100.0
Week 10	6	6.0	19	19.0	20	20.0	29	29.0	26	26.0	100	100.0
Week 12	7	7.3	16	16.7	19	19.8	28	29.2	26	27.1	96	100.0
Week 16	7	7.4	16	16.8	16	16.8	28	29.5	28	29.5	95	100.0

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

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Table 13.17.3

Number (%) of Patients Exposed to each Study Medication Dose Level

Intention-To-Treat Population

Age Group: Total

	Daily Dosage of Paroxetine N(%)											
	10mg		20mg		30mg		40mg		50mg		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	162	100.0	0	0.0	0	0.0	0	0.0	0	0.0	162	100.0
Week 2	62	38.8	98	61.3	0	0.0	0	0.0	0	0.0	160	100.0
Week 3	30	18.9	84	52.8	45	28.3	0	0.0	0	0.0	159	100.0
Week 4	20	12.9	61	39.4	47	30.3	27	17.4	0	0.0	155	100.0
Week 6	18	11.7	40	26.0	49	31.8	28	18.2	19	12.3	154	100.0
Week 8	13	9.0	39	27.1	32	22.2	35	24.3	25	17.4	144	100.0
Week 10	12	8.6	32	23.0	26	18.7	37	26.6	32	23.0	139	100.0
Week 12	11	8.4	28	21.4	27	20.6	33	25.2	32	24.4	131	100.0
Week 16	12	9.2	26	20.0	25	19.2	33	25.4	34	26.2	130	100.0

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

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Table 13.17.3

Number (%) of Patients Exposed to each Study Medication Dose Level

Intention-To-Treat Population

Age Group: Children

	Daily Dose Level of Placebo N(%)											
	1		2		3		4		5		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	45	100.0	0	0.0	0	0.0	0	0.0	0	0.0	45	100.0
Week 2	22	48.9	23	51.1	0	0.0	0	0.0	0	0.0	45	100.0
Week 3	11	24.4	17	37.8	17	37.8	0	0.0	0	0.0	45	100.0
Week 4	5	11.6	15	34.9	9	20.9	14	32.6	0	0.0	43	100.0
Week 6	3	7.3	13	31.7	7	17.1	8	19.5	10	24.4	41	100.0
Week 8	3	7.7	11	28.2	4	10.3	8	20.5	13	33.3	39	100.0
Week 10	2	5.9	10	29.4	4	11.8	6	17.6	12	35.3	34	100.0
Week 12	2	6.5	9	29.0	5	16.1	4	12.9	11	35.5	31	100.0
Week 16	2	6.5	8	25.8	4	12.9	6	19.4	11	35.5	31	100.0

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

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Table 13.17.3

Number (%) of Patients Exposed to each Study Medication Dose Level

Intention-To-Treat Population

Age Group: Adolescents

	Daily Dose Level of Placebo N(%)											
	1		2		3		4		5		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	111	100.0	0	0.0	0	0.0	0	0.0	0	0.0	111	100.0
Week 2	40	37.7	66	62.3	0	0.0	0	0.0	0	0.0	106	100.0
Week 3	12	11.5	51	49.0	41	39.4	0	0.0	0	0.0	104	100.0
Week 4	8	8.0	29	29.0	32	32.0	31	31.0	0	0.0	100	100.0
Week 6	5	5.0	17	17.0	28	28.0	28	28.0	22	22.0	100	100.0
Week 8	4	4.3	9	9.7	15	16.1	35	37.6	30	32.3	93	100.0
Week 10	3	3.6	9	10.7	9	10.7	25	29.8	38	45.2	84	100.0
Week 12	2	2.5	8	10.1	9	11.4	16	20.3	44	55.7	79	100.0
Week 16	2	2.6	7	9.1	7	9.1	14	18.2	47	61.0	77	100.0

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

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Table 13.17.3

Number (%) of Patients Exposed to each Study Medication Dose Level

Intention-To-Treat Population

Age Group: Total

	Daily Dose Level of Placebo N(%)											
	1		2		3		4		5		Total	
	n	%	n	%	n	%	n	%	n	%	n	%
Visit												
Week 1	156	100.0	0	0.0	0	0.0	0	0.0	0	0.0	156	100.0
Week 2	62	41.1	89	58.9	0	0.0	0	0.0	0	0.0	151	100.0
Week 3	23	15.4	68	45.6	58	38.9	0	0.0	0	0.0	149	100.0
Week 4	13	9.1	44	30.8	41	28.7	45	31.5	0	0.0	143	100.0
Week 6	8	5.7	30	21.3	35	24.8	36	25.5	32	22.7	141	100.0
Week 8	7	5.3	20	15.2	19	14.4	43	32.6	43	32.6	132	100.0
Week 10	5	4.2	19	16.1	13	11.0	31	26.3	50	42.4	118	100.0
Week 12	4	3.6	17	15.5	14	12.7	20	18.2	55	50.0	110	100.0
Week 16	4	3.7	15	13.9	11	10.2	20	18.5	58	53.7	108	100.0

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

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Table 13.17.4

Number (%) of Patients by Maximum Daily Dose Level of Study Medication At Any Time During The Study

Intention-To-Treat Population

Age Group: Children

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
6 (13.0%)	14 (30.4%)	10 (21.7%)	10 (21.7%)	6 (13.0%)	46 (100.0%)

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

Table 13.17.4

Number (%) of Patients by Maximum Daily Dose Level of Study Medication At Any Time During The Study

Intention-To-Treat Population

Age Group: Adolescents

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
5 (4.3%)	20 (17.2%)	23 (19.8%)	31 (26.7%)	37 (31.9%)	116 (100.0%)

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

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Table 13.17.4

Number (%) of Patients by Maximum Daily Dose Level of Study Medication At Any Time During The Study

Intention-To-Treat Population

Age Group: Total

Paroxetine					
10mg	20mg	30mg	40mg	50mg	Total
11 (6.8%)	34 (21.0%)	33 (20.4%)	41 (25.3%)	43 (26.5%)	162 (100.0%)

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

Table 13.17.4

Number (%) of Patients by Maximum Daily Dose Level of Study Medication At Any Time During The Study

Intention-To-Treat Population

Age Group: Children

Placebo					
1	2	3	4	5	Total
3 (6.7%)	9 (20.0%)	6 (13.3%)	10 (22.2%)	17 (37.8%)	45 (100.0%)

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

Table 13.17.4

Number (%) of Patients by Maximum Daily Dose Level of Study Medication At Any Time During The Study

Intention-To-Treat Population

Age Group: Adolescents

Placebo					
1	2	3	4	5	Total
6 (5.4%)	14 (12.6%)	8 (7.2%)	23 (20.7%)	60 (54.1%)	111 (100.0%)

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

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Table 13.17.4

Number (%) of Patients by Maximum Daily Dose Level of Study Medication At Any Time During The Study

Intention-To-Treat Population

Age Group: Total

Placebo					
1	2	3	4	5	Total
9 (5.8%)	23 (14.7%)	14 (9.0%)	33 (21.2%)	77 (49.4%)	156 (100.0%)

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

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Table 13.17.5.1

Overall duration of Exposure to Study Medication (Excluding Taper Medication)

Intention-To-Treat Population

Age Group: Children

Days	Paroxetine (N=46)	Placebo (N=45)	Total (N=91)
	----------Treatment Group----------		
>= 1	46 (100.0%)	45 (100.0%)	91 (100.0%)
> 7	46 (100.0%)	45 (100.0%)	91 (100.0%)
> 14	46 (100.0%)	45 (100.0%)	91 (100.0%)
> 21	43 (93.5%)	45 (100.0%)	88 (96.7%)
> 28	42 (91.3%)	44 (97.8%)	86 (94.5%)
> 42	42 (91.3%)	39 (86.7%)	81 (89.0%)
> 56	40 (87.0%)	35 (77.8%)	75 (82.4%)
> 70	35 (76.1%)	34 (75.6%)	69 (75.8%)
> 84	35 (76.1%)	31 (68.9%)	66 (72.5%)
> 98	33 (71.7%)	30 (66.7%)	63 (69.2%)
> 112	17 (37.0%)	19 (42.2%)	36 (39.6%)
Overall Mean	97.6	94.7	96.2
Minimum	16	26	16
Maximum	132	132	132

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

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Table 13.17.5.1

Overall duration of Exposure to Study Medication (Excluding Taper Medication)

Intention-To-Treat Population

Age Group: Adolescents

Days	Paroxetine (N=117)	Placebo (N=111)	Total (N=228)
	----------Treatment Group----------		
>= 1	116 (100.0%)	110 (100.0%)	226 (100.0%)
> 7	115 (99.1%)	108 (98.2%)	223 (98.7%)
> 14	113 (97.4%)	104 (94.5%)	217 (96.0%)
> 21	113 (97.4%)	103 (93.6%)	216 (95.6%)
> 28	111 (95.7%)	100 (90.9%)	211 (93.4%)
> 42	104 (89.7%)	96 (87.3%)	200 (88.5%)
> 56	101 (87.1%)	89 (80.9%)	190 (84.1%)
> 70	98 (84.5%)	81 (73.6%)	179 (79.2%)
> 84	95 (81.9%)	80 (72.7%)	175 (77.4%)
> 98	94 (81.0%)	75 (68.2%)	169 (74.8%)
> 112	62 (53.4%)	37 (33.6%)	99 (43.8%)
Overall Mean	102.4	93.1	97.9
Minimum	1	2	1
Maximum	147	138	147

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

BRL 29060 - 676

Table 13.17.5.1

Overall duration of Exposure to Study Medication (Excluding Taper Medication)

Intention-To-Treat Population

Age Group: Total

Days	Treatment Group: Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
>= 1	162 (100.0%)	155 (100.0%)	317 (100.0%)
> 7	161 (99.4%)	153 (98.7%)	314 (99.1%)
> 14	159 (98.1%)	149 (96.1%)	308 (97.2%)
> 21	156 (96.3%)	148 (95.5%)	304 (95.9%)
> 28	153 (94.4%)	144 (92.9%)	297 (93.7%)
> 42	146 (90.1%)	135 (87.1%)	281 (88.6%)
> 56	141 (87.0%)	124 (80.0%)	265 (83.6%)
> 70	133 (82.1%)	115 (74.2%)	248 (78.2%)
> 84	130 (80.2%)	111 (71.6%)	241 (76.0%)
> 98	127 (78.4%)	105 (67.7%)	232 (73.2%)
> 112	79 (48.8%)	56 (36.1%)	135 (42.6%)
Overall Mean	101.0	93.6	97.4
Minimum	1	2	1
Maximum	147	138	147

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

BRL 29060 - 676

Table 13.17.5.2

Overall duration of Exposure to Study Medication (Including Taper Medication)

Intention-To-Treat Population

Age Group: Children

Days	Paroxetine (N=46)	Placebo (N=45)	Total (N=91)
	----------Treatment Group----------		
>= 1	46 (100.0%)	45 (100.0%)	91 (100.0%)
> 7	46 (100.0%)	45 (100.0%)	91 (100.0%)
> 14	46 (100.0%)	45 (100.0%)	91 (100.0%)
> 21	43 (93.5%)	45 (100.0%)	88 (96.7%)
> 28	42 (91.3%)	44 (97.8%)	86 (94.5%)
> 42	42 (91.3%)	40 (88.9%)	82 (90.1%)
> 56	40 (87.0%)	36 (80.0%)	76 (83.5%)
> 70	35 (76.1%)	36 (80.0%)	71 (78.0%)
> 84	35 (76.1%)	33 (73.3%)	68 (74.7%)
> 98	33 (71.7%)	30 (66.7%)	63 (69.2%)
> 112	30 (65.2%)	29 (64.4%)	59 (64.8%)
> 140	4 (8.7%)	8 (17.8%)	12 (13.2%)
Overall Mean	106.2	108.7	107.4
Minimum	16	26	16
Maximum	148	171	171

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

BRL 29060 - 676

Table 13.17.5.2

Overall duration of Exposure to Study Medication (Including Taper Medication)

Intention-To-Treat Population

Age Group: Adolescents

Days	Treatment Group: Paroxetine (N=117)	Placebo (N=111)	Total (N=228)
>= 1	116 (100.0%)	110 (100.0%)	226 (100.0%)
> 7	115 (99.1%)	108 (98.2%)	223 (98.7%)
> 14	113 (97.4%)	104 (94.5%)	217 (96.0%)
> 21	113 (97.4%)	103 (93.6%)	216 (95.6%)
> 28	111 (95.7%)	101 (91.8%)	212 (93.8%)
> 42	104 (89.7%)	98 (89.1%)	202 (89.4%)
> 56	102 (87.9%)	93 (84.5%)	195 (86.3%)
> 70	99 (85.3%)	86 (78.2%)	185 (81.9%)
> 84	96 (82.8%)	86 (78.2%)	182 (80.5%)
> 98	95 (81.9%)	78 (70.9%)	173 (76.5%)
> 112	86 (74.1%)	70 (63.6%)	156 (69.0%)
> 140	25 (21.6%)	22 (20.0%)	47 (20.8%)
Overall Mean	115.7	109.8	112.8
Minimum	1	2	1
Maximum	166	168	168

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

BRL 29060 - 676

Table 13.17.5.2

Overall duration of Exposure to Study Medication (Including Taper Medication)

Intention-To-Treat Population

Age Group: Total

Days	Paroxetine (N=163)	Placebo (N=156)	Total (N=319)
		Treatment Group	
>= 1	162 (100.0%)	155 (100.0%)	317 (100.0%)
> 7	161 (99.4%)	153 (98.7%)	314 (99.1%)
> 14	159 (98.1%)	149 (96.1%)	308 (97.2%)
> 21	156 (96.3%)	148 (95.5%)	304 (95.9%)
> 28	153 (94.4%)	145 (93.5%)	298 (94.0%)
> 42	146 (90.1%)	138 (89.0%)	284 (89.6%)
> 56	142 (87.7%)	129 (83.2%)	271 (85.5%)
> 70	134 (82.7%)	122 (78.7%)	256 (80.8%)
> 84	131 (80.9%)	119 (76.8%)	250 (78.9%)
> 98	128 (79.0%)	108 (69.7%)	236 (74.4%)
> 112	116 (71.6%)	99 (63.9%)	215 (67.8%)
> 140	29 (17.9%)	30 (19.4%)	59 (18.6%)
Overall Mean	113.0	109.5	111.3
Minimum	1	2	1
Maximum	166	171	171

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

BRL 29060 - 676

Table 13.17.6

Mean Daily Dosage (mg) of Paroxetine / Mean Daily Dose Level of Placebo by Visit and Overall

Intention-To-Treat Population
Age Group : Children
Mean Daily Dosage (mg) of Paroxetine

Visit	N	Mean (mg)	Std Dev
Week 1	46	10.0	0.00
Week 2	46	15.0	5.06
Week 3	46	19.1	7.55
Week 4	43	22.8	10.08
Week 6	42	25.5	12.73
Week 8	41	26.6	12.57
Week 10	39	28.7	13.41
Week 12	35	29.1	12.92
Week 16	35	29.1	13.14
Patient Mean	46	21.7	8.85

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

BRL 29060 - 676

Table 13.17.6

Mean Daily Dosage (mg) of Paroxetine / Mean Daily Dose Level of Placebo by Visit and Overall

Intention-To-Treat Population
Age Group : Adolescents
Mean Daily Dosage (mg) of Paroxetine

Visit	N	Mean (mg)	Std Dev
Week 1	116	10.0	0.00
Week 2	114	16.6	4.77
Week 3	113	21.7	6.40
Week 4	112	26.2	8.83
Week 6	112	30.8	11.24
Week 8	103	33.3	12.00
Week 10	100	35.0	12.35
Week 12	96	35.2	12.56
Week 16	95	35.7	12.77
Patient Mean	116	26.1	8.09

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

BRL 29060 - 676

Table 13.17.6

Mean Daily Dosage (mg) of Paroxetine / Mean Daily Dose Level of Placebo by Visit and Overall

Intention-To-Treat Population
Age Group : Total
Mean Daily Dosage (mg) of Paroxetine

Visit	N	Mean (mg)	Std Dev
Week 1	162	10.0	0.00
Week 2	160	16.1	4.89
Week 3	159	20.9	6.82
Week 4	155	25.2	9.28
Week 6	154	29.4	11.86
Week 8	144	31.4	12.49
Week 10	139	33.2	12.92
Week 12	131	33.6	12.89
Week 16	130	33.9	13.15
Patient Mean	162	24.8	8.51

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

BRL 29060 - 676

Table 13.17.6

Mean Daily Dosage (mg) of Paroxetine / Mean Daily Dose Level of Placebo by Visit and Overall

Intention-To-Treat Population
Age Group : Children
Mean Daily Dose Level of Placebo

Visit	N	Mean	Std Dev
Week 1	45	1.0	0.00
Week 2	45	1.5	0.51
Week 3	45	2.1	0.79
Week 4	43	2.7	1.05
Week 6	41	3.2	1.33
Week 8	39	3.4	1.41
Week 10	34	3.5	1.40
Week 12	31	3.4	1.41
Week 16	31	3.5	1.39
Patient Mean	45	2.6	0.89

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

Table 13.17.6

Mean Daily Dosage (mg) of Paroxetine / Mean Daily Dose Level of Placebo by Visit and Overall

Intention-To-Treat Population
Age Group : Adolescents
Mean Daily Dose Level of Placebo

Visit	N	Mean	Std Dev
Week 1	111	1.0	0.00
Week 2	106	1.6	0.49
Week 3	104	2.3	0.66
Week 4	100	2.9	0.95
Week 6	100	3.5	1.16
Week 8	93	3.8	1.12
Week 10	84	4.0	1.15
Week 12	79	4.2	1.14
Week 16	77	4.3	1.12
Patient Mean	111	2.8	0.85

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

BRL 29060 - 676

Table 13.17.6

Mean Daily Dosage (mg) of Paroxetine / Mean Daily Dose Level of Placebo by Visit and Overall

Intention-To-Treat Population
Age Group : Total
Mean Daily Dose Level of Placebo

Visit	N	Mean	Std Dev
Week 1	156	1.0	0.00
Week 2	151	1.6	0.49
Week 3	149	2.2	0.70
Week 4	143	2.8	0.98
Week 6	141	3.4	1.21
Week 8	132	3.7	1.22
Week 10	118	3.9	1.25
Week 12	110	4.0	1.26
Week 16	108	4.0	1.24
Patient Mean	156	2.7	0.87

Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

Table 13.17.7

Mean Daily Dosage (mg) of Paroxetine / Mean Daily Dose Level of Placebo at Week 16 LOCF Endpoint for CGI Global Improvement

Intention-To-Treat Population

Treatment Group:Paroxetine

Week 16 LOCF Endpoint	N	Mean	Std Dev
Children	46	26.5	13.20
Adolescents	115	35.0	13.07
Total	161	32.6	13.63

Summary Statistics for the visit making up each patients LOCF assessment for CGI Global Improvement
Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

Table 13.17.7

Mean Daily Dosage (mg) of Paroxetine / Mean Daily Dose Level of Placebo at Week 16 LOCF Endpoint for CGI Global Improvement

Intention-To-Treat Population

Treatment Group:Placebo

Week 16 LOCF Endpoint	N	Mean	Std Dev
Children	45	3.6	1.36
Adolescents	109	4.0	1.29
Total	154	3.9	1.32

Summary Statistics for the visit making up each patients LOCF assessment for CGI Global Improvement
Data for PID 676.021.24565 is not included in this table due to irreconcilable dosing data but it is in Listing 13.17.1

12 Source Tables: Efficacy

Table 14.1.1b

Number and Percentage of Patients in Each Category of CGI Global Improvement

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
Week 1	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much improved (1)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Much Improved (2)	4	9.3	5	4.4	9	5.7	3	7.0	1	1.0	4	2.7
	Minimally improved (3)	17	39.5	29	25.4	46	29.3	12	27.9	17	16.2	29	19.6
	No change (4)	22	51.2	75	65.8	97	61.8	28	65.1	85	81.0	113	76.4
	Minimally worse (5)	0	0.0	5	4.4	5	3.2	0	0.0	2	1.9	2	1.4
	Much worse (6)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	43	100.0	114	100.0	157	100.0	43	100.0	105	100.0	148	100.0
Week 2	Not assessed (0)	0	0.0	1	0.9	1	0.6	0	0.0	0	0.0	0	0.0
	Very much improved (1)	2	4.4	2	1.8	4	2.6	2	4.5	0	0.0	2	1.4
	Much Improved (2)	9	20.0	12	10.8	21	13.5	4	9.1	5	5.0	9	6.3
	Minimally improved (3)	22	48.9	43	38.7	65	41.7	15	34.1	35	35.0	50	34.7
	No change (4)	12	26.7	51	45.9	63	40.4	23	52.3	58	58.0	81	56.3
	Minimally worse (5)	0	0.0	2	1.8	2	1.3	0	0.0	2	2.0	2	1.4
	Much worse (6)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	45	100.0	111	100.0	156	100.0	44	100.0	100	100.0	144	100.0
Week 3	Not assessed (0)	0	0.0	1	1.0	1	0.7	0	0.0	1	1.0	1	0.7

(CONTINUED)

Table 14.1.1b

Number and Percentage of Patients in Each Category of CGI Global Improvement

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
Week 3	Very much improved (1)	3	7.5	5	4.8	8	5.5	2	5.1	0	0.0	2	1.4
	Much Improved (2)	13	32.5	22	21.0	35	24.1	5	12.8	9	9.1	14	10.1
	Minimally improved (3)	20	50.0	47	44.8	67	46.2	19	48.7	35	35.4	54	39.1
	No change (4)	4	10.0	29	27.6	33	22.8	13	33.3	50	50.5	63	45.7
	Minimally worse (5)	0	0.0	1	1.0	1	0.7	0	0.0	4	4.0	4	2.9
	Much worse (6)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	40	100.0	105	100.0	145	100.0	39	100.0	99	100.0	138	100.0
Week 4	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much improved (1)	4	9.3	15	13.4	19	12.3	1	2.3	2	2.0	3	2.1
	Much Improved (2)	18	41.9	41	36.6	59	38.1	6	13.6	19	18.8	25	17.2
	Minimally improved (3)	15	34.9	29	25.9	44	28.4	21	47.7	37	36.6	58	40.0
	No change (4)	6	14.0	24	21.4	30	19.4	16	36.4	41	40.6	57	39.3
	Minimally worse (5)	0	0.0	1	0.9	1	0.6	0	0.0	2	2.0	2	1.4
	Much worse (6)	0	0.0	2	1.8	2	1.3	0	0.0	0	0.0	0	0.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	43	100.0	112	100.0	155	100.0	44	100.0	101	100.0	145	100.0
Week 6	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much improved (1)	7	16.7	19	18.6	26	18.1	4	10.3	3	3.1	7	5.1

(CONTINUED)

Table 14.1.1b

Number and Percentage of Patients in Each Category of CGI Global Improvement

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
Week 6	Much Improved (2)	17	40.5	40	39.2	57	39.6	9	23.1	25	25.5	34	24.8
	Minimally improved (3)	15	35.7	27	26.5	42	29.2	14	35.9	37	37.8	51	37.2
	No change (4)	3	7.1	13	12.7	16	11.1	12	30.8	31	31.6	43	31.4
	Minimally worse (5)	0	0.0	2	2.0	2	1.4	0	0.0	2	2.0	2	1.5
	Much worse (6)	0	0.0	1	1.0	1	0.7	0	0.0	0	0.0	0	0.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	42	100.0	102	100.0	144	100.0	39	100.0	98	100.0	137	100.0
Week 8	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much improved (1)	9	22.0	28	28.3	37	26.4	3	7.9	8	9.1	11	8.7
	Much Improved (2)	20	48.8	42	42.4	62	44.3	11	28.9	27	30.7	38	30.2
	Minimally improved (3)	10	24.4	19	19.2	29	20.7	14	36.8	25	28.4	39	31.0
	No change (4)	2	4.9	9	9.1	11	7.9	10	26.3	26	29.5	36	28.6
	Minimally worse (5)	0	0.0	1	1.0	1	0.7	0	0.0	1	1.1	1	0.8
	Much worse (6)	0	0.0	0	0.0	0	0.0	0	0.0	1	1.1	1	0.8
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	41	100.0	99	100.0	140	100.0	38	100.0	88	100.0	126	100.0
Week 10	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much improved (1)	12	37.5	36	37.1	48	37.2	4	11.8	14	17.7	18	15.9
	Much Improved (2)	12	37.5	37	38.1	49	38.0	16	47.1	19	24.1	35	31.0

(CONTINUED)

Table 14.1.1b

Number and Percentage of Patients in Each Category of CGI Global Improvement

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
Week 10	Minimally improved (3)	7	21.9	16	16.5	23	17.8	7	20.6	24	30.4	31	27.4
	No change (4)	1	3.1	7	7.2	8	6.2	6	17.6	22	27.8	28	24.8
	Minimally worse (5)	0	0.0	1	1.0	1	0.8	1	2.9	0	0.0	1	0.9
	Much worse (6)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	32	100.0	97	100.0	129	100.0	34	100.0	79	100.0	113	100.0
Week 12	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much improved (1)	15	42.9	41	42.3	56	42.4	5	16.1	15	19.2	20	18.3
	Much Improved (2)	12	34.3	36	37.1	48	36.4	12	38.7	19	24.4	31	28.4
	Minimally improved (3)	6	17.1	13	13.4	19	14.4	6	19.4	22	28.2	28	25.7
	No change (4)	2	5.7	4	4.1	6	4.5	8	25.8	20	25.6	28	25.7
	Minimally worse (5)	0	0.0	1	1.0	1	0.8	0	0.0	2	2.6	2	1.8
	Much worse (6)	0	0.0	2	2.1	2	1.5	0	0.0	0	0.0	0	0.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	35	100.0	97	100.0	132	100.0	31	100.0	78	100.0	109	100.0
Week 16	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	2	2.8	2	2.0
	Very much improved (1)	18	56.3	51	55.4	69	55.6	6	20.7	14	19.4	20	19.8
	Much Improved (2)	8	25.0	29	31.5	37	29.8	12	41.4	19	26.4	31	30.7
	Minimally improved (3)	4	12.5	10	10.9	14	11.3	3	10.3	21	29.2	24	23.8

(CONTINUED)

Table 14.1.1b

Number and Percentage of Patients in Each Category of CGI Global Improvement

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
Week 16	No change (4)	2	6.3	1	1.1	3	2.4	6	20.7	16	22.2	22	21.8
	Minimally worse (5)	0	0.0	0	0.0	0	0.0	1	3.4	0	0.0	1	1.0
	Much worse (6)	0	0.0	1	1.1	1	0.8	1	3.4	0	0.0	1	1.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	32	100.0	92	100.0	124	100.0	29	100.0	72	100.0	101	100.0
Week 16 LOCF	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much improved (1)	24	52.2	53	45.7	77	47.5	6	13.3	17	15.6	23	14.9
	Much Improved (2)	13	28.3	36	31.0	49	30.2	15	33.3	21	19.3	36	23.4
	Minimally improved (3)	5	10.9	14	12.1	19	11.7	6	13.3	34	31.2	40	26.0
	No change (4)	4	8.7	8	6.9	12	7.4	16	35.6	34	31.2	50	32.5
	Minimally worse (5)	0	0.0	1	0.9	1	0.6	1	2.2	3	2.8	4	2.6
	Much worse (6)	0	0.0	4	3.4	4	2.5	1	2.2	0	0.0	1	0.6
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	46	100.0	116	100.0	162	100.0	45	100.0	109	100.0	154	100.0

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Table 14.1.1c

Number and Percentage of Patients in Each Category of CGI Global Improvement

Per-Protocol Population

		Treatment Group											
		Paroxetine (N = 124)						Placebo (N = 110)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
Week 1	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much improved (1)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Much Improved (2)	3	9.7	5	5.5	8	6.6	0	0.0	1	1.3	1	0.9
	Minimally improved (3)	11	35.5	24	26.4	35	28.7	10	32.3	12	16.0	22	20.8
	No change (4)	17	54.8	59	64.8	76	62.3	21	67.7	60	80.0	81	76.4
	Minimally worse (5)	0	0.0	3	3.3	3	2.5	0	0.0	2	2.7	2	1.9
	Much worse (6)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	31	100.0	91	100.0	122	100.0	31	100.0	75	100.0	106	100.0
Week 2	Not assessed (0)	0	0.0	1	1.1	1	0.8	0	0.0	0	0.0	0	0.0
	Very much improved (1)	1	3.1	2	2.2	3	2.5	0	0.0	0	0.0	0	0.0
	Much Improved (2)	7	21.9	12	13.5	19	15.7	4	12.9	2	2.7	6	5.7
	Minimally improved (3)	16	50.0	35	39.3	51	42.1	9	29.0	28	37.3	37	34.9
	No change (4)	8	25.0	38	42.7	46	38.0	18	58.1	45	60.0	63	59.4
	Minimally worse (5)	0	0.0	1	1.1	1	0.8	0	0.0	0	0.0	0	0.0
	Much worse (6)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	32	100.0	89	100.0	121	100.0	31	100.0	75	100.0	106	100.0
Week 3	Not assessed (0)	0	0.0	1	1.2	1	0.9	0	0.0	0	0.0	0	0.0

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Table 14.1.1c

Number and Percentage of Patients in Each Category of CGI Global Improvement

Per-Protocol Population

		Treatment Group											
		Paroxetine (N = 124)						Placebo (N = 110)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
Week 3	Very much improved (1)	1	3.7	5	5.8	6	5.3	0	0.0	0	0.0	0	0.0
	Much Improved (2)	11	40.7	18	20.9	29	25.7	4	13.8	7	9.3	11	10.6
	Minimally improved (3)	13	48.1	39	45.3	52	46.0	13	44.8	27	36.0	40	38.5
	No change (4)	2	7.4	23	26.7	25	22.1	12	41.4	38	50.7	50	48.1
	Minimally worse (5)	0	0.0	0	0.0	0	0.0	0	0.0	3	4.0	3	2.9
	Much worse (6)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	27	100.0	86	100.0	113	100.0	29	100.0	75	100.0	104	100.0
Week 4	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much improved (1)	3	9.4	14	15.4	17	13.8	0	0.0	2	2.6	2	1.8
	Much Improved (2)	15	46.9	31	34.1	46	37.4	5	15.6	12	15.6	17	15.6
	Minimally improved (3)	10	31.3	25	27.5	35	28.5	14	43.8	31	40.3	45	41.3
	No change (4)	4	12.5	19	20.9	23	18.7	13	40.6	30	39.0	43	39.4
	Minimally worse (5)	0	0.0	1	1.1	1	0.8	0	0.0	2	2.6	2	1.8
	Much worse (6)	0	0.0	1	1.1	1	0.8	0	0.0	0	0.0	0	0.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	32	100.0	91	100.0	123	100.0	32	100.0	77	100.0	109	100.0
Week 6	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much improved (1)	6	18.8	17	19.5	23	19.3	2	7.1	3	3.9	5	4.8

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Table 14.1.1c

Number and Percentage of Patients in Each Category of CGI Global Improvement

Per-Protocol Population

		Treatment Group											
		Paroxetine (N = 124)						Placebo (N = 110)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
Week 6	Much Improved (2)	14	43.8	34	39.1	48	40.3	8	28.6	17	22.4	25	24.0
	Minimally improved (3)	10	31.3	23	26.4	33	27.7	9	32.1	30	39.5	39	37.5
	No change (4)	2	6.3	10	11.5	12	10.1	9	32.1	25	32.9	34	32.7
	Minimally worse (5)	0	0.0	2	2.3	2	1.7	0	0.0	1	1.3	1	1.0
	Much worse (6)	0	0.0	1	1.1	1	0.8	0	0.0	0	0.0	0	0.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	32	100.0	87	100.0	119	100.0	28	100.0	76	100.0	104	100.0
Week 8	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much improved (1)	8	25.8	22	26.5	30	26.3	1	3.6	6	8.6	7	7.1
	Much Improved (2)	17	54.8	38	45.8	55	48.2	8	28.6	23	32.9	31	31.6
	Minimally improved (3)	4	12.9	17	20.5	21	18.4	10	35.7	20	28.6	30	30.6
	No change (4)	2	6.5	5	6.0	7	6.1	9	32.1	20	28.6	29	29.6
	Minimally worse (5)	0	0.0	1	1.2	1	0.9	0	0.0	0	0.0	0	0.0
	Much worse (6)	0	0.0	0	0.0	0	0.0	0	0.0	1	1.4	1	1.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	31	100.0	83	100.0	114	100.0	28	100.0	70	100.0	98	100.0
Week 10	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much improved (1)	9	37.5	29	35.4	38	35.8	1	4.0	11	16.9	12	13.3
	Much Improved (2)	11	45.8	33	40.2	44	41.5	13	52.0	17	26.2	30	33.3

(CONTINUED)

Table 14.1.1c

Number and Percentage of Patients in Each Category of CGI Global Improvement

Per-Protocol Population

		Treatment Group											
		Paroxetine (N = 124)						Placebo (N = 110)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
Week 10	Minimally improved (3)	3	12.5	15	18.3	18	17.0	5	20.0	19	29.2	24	26.7
	No change (4)	1	4.2	4	4.9	5	4.7	5	20.0	18	27.7	23	25.6
	Minimally worse (5)	0	0.0	1	1.2	1	0.9	1	4.0	0	0.0	1	1.1
	Much worse (6)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	24	100.0	82	100.0	106	100.0	25	100.0	65	100.0	90	100.0
Week 12	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much improved (1)	12	42.9	36	43.9	48	43.6	2	8.3	11	17.5	13	14.9
	Much Improved (2)	11	39.3	28	34.1	39	35.5	11	45.8	17	27.0	28	32.2
	Minimally improved (3)	3	10.7	13	15.9	16	14.5	4	16.7	18	28.6	22	25.3
	No change (4)	2	7.1	3	3.7	5	4.5	7	29.2	16	25.4	23	26.4
	Minimally worse (5)	0	0.0	1	1.2	1	0.9	0	0.0	1	1.6	1	1.1
	Much worse (6)	0	0.0	1	1.2	1	0.9	0	0.0	0	0.0	0	0.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	28	100.0	82	100.0	110	100.0	24	100.0	63	100.0	87	100.0
Week 16	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	2	3.2	2	2.3
	Very much improved (1)	16	59.3	43	55.1	59	56.2	3	12.5	12	19.0	15	17.2
	Much Improved (2)	8	29.6	24	30.8	32	30.5	11	45.8	16	25.4	27	31.0
	Minimally improved (3)	1	3.7	10	12.8	11	10.5	3	12.5	20	31.7	23	26.4

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Table 14.1.1c

Number and Percentage of Patients in Each Category of CGI Global Improvement

Per-Protocol Population

		Treatment Group											
		Paroxetine (N = 124)						Placebo (N = 110)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
Week 16	No change (4)	2	7.4	1	1.3	3	2.9	5	20.8	13	20.6	18	20.7
	Minimally worse (5)	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	1	1.1
	Much worse (6)	0	0.0	0	0.0	0	0.0	1	4.2	0	0.0	1	1.1
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	27	100.0	78	100.0	105	100.0	24	100.0	63	100.0	87	100.0
Week 16 LOCF	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much improved (1)	18	56.3	44	47.8	62	50.0	3	9.4	13	16.7	16	14.5
	Much Improved (2)	10	31.3	29	31.5	39	31.5	11	34.4	16	20.5	27	24.5
	Minimally improved (3)	1	3.1	12	13.0	13	10.5	3	9.4	27	34.6	30	27.3
	No change (4)	3	9.4	4	4.3	7	5.6	13	40.6	21	26.9	34	30.9
	Minimally worse (5)	0	0.0	1	1.1	1	0.8	1	3.1	1	1.3	2	1.8
	Much worse (6)	0	0.0	2	2.2	2	1.6	1	3.1	0	0.0	1	0.9
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	32	100.0	92	100.0	124	100.0	32	100.0	78	100.0	110	100.0

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Table 14.1.2b

Summary of Analysis for CGI Global Improvement - Proportion of Responders
Adjusted for Country Grouping, Baseline Score, Age Group and Gender
Intention-To-Treat Population

	Paroxetine			Placebo			Treatment Comparisons *			
	n	%	N	n	%	N	Odds Ratio	Lower 95% CI Limit	Upper 95% CI Limit	p-value
Week 1	9	5.7	157	4	2.7	148				
Week 2	24	15.6	154	11	7.6	144				
Week 3	42	29.4	143	16	11.7	137				
Week 4	77	50.0	154	28	19.3	145				
Week 6	82	57.3	143	41	29.9	137				
Week 8	98	70.5	139	49	38.9	126				
Week 10	97	75.2	129	53	46.9	113				
Week 12	104	78.8	132	51	46.8	109				
Week 16	106	85.5	124	51	51.5	99	6.56	3.29	13.05	<0.001
Week 16 LOCF Endpoint	125	77.6	161	59	38.3	154	7.02	4.07	12.11	<0.001
70% LOCF Endpoint	118	73.3	161	57	37.0	154	5.37	3.21	8.98	<0.001

* The odds ratios represent the odds of improving with paroxetine relative to that with placebo
Note : Responders are patients who have a score of 1 or 2
Note: 'Baseline Score' refers to Severity of Illness for CGI
Note: Percentage of responders is unadjusted, whilst the odds ratio is adjusted for the terms in the model
Due to insuffucient observations, the observed CGI Severity of Illness baseline scores had to be recatagorised as 'Mildly or Moderately ill', 'Markedly ill' or 'Severely or Most Extremely ill'
Note : Due to insufficient observations, South Africa and Belgium were combined to form one country group.
Note: 70% LOCF visit is Week 12

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Table 14.1.2.1

Summary of Analysis for CGI Global Improvement - Proportion of Responders
Covariate significance, Week 16 LOCF
Intention-To-Treat Population

	Change in Deviance*	Change in Degrees of Freedom**	P-Value ***
Term in Model:			
Country Grouping	25.53	2	<0.001
Baseline CGI-S Score	2.76	2	0.251
Age Group (Children, Adolescents)	3.29	1	0.070
Gender	0.25	1	0.619

* Increase in deviance from removing the term from the full model
** Increase in degrees of freedom from removing the term from the full model
*** By comparison to the chi-squared distribution
Due to insuffucient observations, the observed CGI Severity of Illness baseline scores had to be recatagorised as 'Mildly or Moderately ill', 'Markedly ill' or 'Severely or Most Extremely ill'
Note : Due to insufficient observations, South Africa and Belgium were combined to form one country group.

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Table 14.1.2bZ

Summary of Analysis for CGI Global Improvement - Proportion of Responders (Excluding Centre 001)
Adjusted for Country Grouping, Baseline Score, Age Group and Gender
Intention-To-Treat Population

	Paroxetine			Placebo			Treatment Comparisons *			
	n	%	N	n	%	N	Odds Ratio	Lower 95% CI Limit	Upper 95% CI Limit	p-value
Week 16	105	86.1	122	51	52.6	97	6.67	3.31	13.47	<0.001
Week 16 LOCF Endpoint	124	78.0	159	59	38.8	152	7.07	4.07	12.29	<0.001
70% LOCF Endpoint	117	73.6	159	56	36.8	152	5.60	3.32	9.44	<0.001

* The odds ratios represent the odds of improving with paroxetine relative to that with placebo
Note : Responders are patients who have a score of 1 or 2
Note: 'Baseline Score' refers to Severity of Illness for CGI
Note: Percentage of responders is unadjusted, whilst the odds ratio is adjusted for the terms in the model
Due to insuffucient observations, the observed CGI Severity of Illness baseline scores had to be recatagorised as 'Mildly or Moderately ill', 'Markedly ill' or 'Severely or Most Extremely ill'
Note : Due to insufficient observations, South Africa and Belgium were combined to form one country group.
Note: 70% LOCF visit is Week 12

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Table 14.1.2c

Summary of Analysis for CGI Global Improvement - Proportion of Responders
Adjusted for Country Grouping, Baseline Score, Age Group and Gender
Per-Protocol Population

	Paroxetine			Placebo			Treatment Comparisons *			
	n	%	N	n	%	N	Odds Ratio	Lower 95% CI Limit	Upper 95% CI Limit	p-value
Week 1	8	6.6	122	1	0.9	106				
Week 2	22	18.3	120	6	5.7	106				
Week 3	35	31.3	112	11	10.6	104				
Week 4	63	51.2	123	19	17.4	109				
Week 6	71	59.7	119	30	28.8	104				
Week 8	85	74.6	114	38	38.8	98				
Week 10	82	77.4	106	42	46.7	90				
Week 12	87	79.1	110	41	47.1	87				
Week 16	91	86.7	105	42	49.4	85	7.80	3.60	16.90	<0.001
Week 16 LOCF Endpoint	101	81.5	124	43	39.1	110	8.41	4.36	16.21	<0.001
70% LOCF Endpoint	94	75.8	124	42	38.2	110	5.53	3.03	10.07	<0.001

* The odds ratios represent the odds of improving with paroxetine relative to that with placebo
Note : Responders are patients who have a score of 1 or 2
Note: 'Baseline Score' refers to Severity of Illness for CGI
Note: Country Grouping term has three groups - 'USA', 'Canada' and 'South Africa and Belgium'.
Note: Percentage of responders is unadjusted, whilst the odds ratio is adjusted for the terms in the model
Due to insuffucient observations, the observed CGI Severity of Illness baseline scores had to be recatagorised as 'Mildly or Moderately ill', 'Markedly ill' or 'Severely or Most Extremely ill'
Note: 70% LOCF visit is Week 12

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Table 14.2.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit	Severity												
Baseline	Not assessed (0)	0	0	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	0	0	0
	Borderline mentally ill (2)	0	0	0	0	0	0	0	0	0	0	0	0
	Mildly ill (3)	1	2.2	3	2.6	4	2.5	3	6.7	3	2.7	6	3.9
	Moderately ill (4)	25	55.6	49	41.9	74	45.7	20	44.4	49	44.5	69	44.5
	Markedly ill (5)	16	35.6	45	38.5	61	37.7	20	44.4	41	37.3	61	39.4
	Severely ill (6)	3	6.7	18	15.4	21	13.0	2	4.4	15	13.6	17	11.0
	Among the most extremely ill patients (7)	0	0	2	1.7	2	1.2	0	0	2	1.8	2	1.3
	Total	45	100.0	117	100.0	162	100.0	45	100.0	110	100.0	155	100.0
Week 1	Severity												
	Not assessed (0)	0	0	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	0	0	0
	Borderline mentally ill (2)	1	2.3	0	0	1	0.6	0	0	0	0	0	0
	Mildly ill (3)	1	2.3	9	7.9	10	6.3	6	14.0	4	3.8	10	6.8
	Moderately ill (4)	30	68.2	49	43.0	79	50.0	21	48.8	49	46.7	70	47.3
	Markedly ill (5)	10	22.7	42	36.8	52	32.9	14	32.6	43	41.0	57	38.5
	Severely ill (6)	2	4.5	13	11.4	15	9.5	2	4.7	9	8.6	11	7.4
	Among the most extremely ill patients (7)	0	0	1	0.9	1	0.6	0	0	0	0	0	0

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Table 14.2.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit	Total												
Week 1		44	100.0	114	100.0	158	100.0	43	100.0	105	100.0	148	100.0
Week 2	Severity												
	Not assessed (0)	0	0	1	0.9	1	0.6	0	0	0	0	0	0
	Normal, not at all ill (1)	0	0	1	0.9	1	0.6	2	4.5	0	0	2	1.4
	Borderline mentally ill (2)	2	4.4	0	0	2	1.3	1	2.3	0	0	1	0.7
	Mildly ill (3)	10	22.2	16	14.4	26	16.7	6	13.6	9	9.0	15	10.4
	Moderately ill (4)	22	48.9	52	46.8	74	47.4	18	40.9	47	47.0	65	45.1
	Markedly ill (5)	10	22.2	32	28.8	42	26.9	16	36.4	36	36.0	52	36.1
	Severely ill (6)	1	2.2	9	8.1	10	6.4	1	2.3	7	7.0	8	5.6
	Among the most extremely ill patients (7)	0	0	0	0	0	0	0	0	1	1.0	1	0.7
	Total	45	100.0	111	100.0	156	100.0	44	100.0	100	100.0	144	100.0
Week 3	Severity												
	Not assessed (0)	0	0	1	1.0	1	0.7	0	0	1	1.0	1	0.7
	Normal, not at all ill (1)	1	2.5	1	1.0	2	1.4	3	7.7	0	0	3	2.2
	Borderline mentally ill (2)	2	5.0	5	4.8	7	4.8	0	0	2	2.0	2	1.4
	Mildly ill (3)	13	32.5	18	17.1	31	21.4	7	17.9	8	8.1	15	10.9
	Moderately ill (4)	18	45.0	51	48.6	69	47.6	17	43.6	45	45.5	62	44.9
	Markedly ill (5)	6	15.0	23	21.9	29	20.0	11	28.2	35	35.4	46	33.3

(CONTINUED)

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Table 14.2.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit	Severity												
Week 3	Severely ill (6)	0	0	5	4.8	5	3.4	1	2.6	7	7.1	8	5.8
	Among the most extremely ill patients (7)	0	0	1	1.0	1	0.7	0	0	1	1.0	1	0.7
	Total	40	100.0	105	100.0	145	100.0	39	100.0	99	100.0	138	100.0
Week 4	Severity												
	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Normal, not at all ill (1)	1	2.3	1	0.9	2	1.3	2	4.5	1	1.0	3	2.1
	Borderline mentally ill (2)	2	4.7	8	7.1	10	6.5	1	2.3	2	2.0	3	2.1
	Mildly ill (3)	15	34.9	36	32.1	51	32.9	6	13.6	17	16.8	23	15.9
	Moderately ill (4)	20	46.5	50	44.6	70	45.2	23	52.3	46	45.5	69	47.6
	Markedly ill (5)	5	11.6	13	11.6	18	11.6	10	22.7	31	30.7	41	28.3
	Severely ill (6)	0	0	4	3.6	4	2.6	2	4.5	4	4.0	6	4.1
	Among the most extremely ill patients (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	43	100.0	112	100.0	155	100.0	44	100.0	101	100.0	145	100.0
Week 6	Severity												
	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Normal, not at all ill (1)	3	7.1	4	3.9	7	4.9	2	5.1	1	1.0	3	2.2
	Borderline mentally ill (2)	2	4.8	15	14.7	17	11.8	4	10.3	4	4.1	8	5.8
	Mildly ill (3)	16	38.1	32	31.4	48	33.3	8	20.5	18	18.4	26	19.0

(CONTINUED)

Table 14.2.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit	Severity												
Week 6	Moderately ill (4)	18	42.9	38	37.3	56	38.9	14	35.9	47	48.0	61	44.5
	Markedly ill (5)	3	7.1	10	9.8	13	9.0	10	25.6	25	25.5	35	25.5
	Severely ill (6)	0	0	3	2.9	3	2.1	1	2.6	3	3.1	4	2.9
	Among the most extremely ill patients (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	42	100.0	102	100.0	144	100.0	39	100.0	98	100.0	137	100.0
Week 8	Severity												
	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Normal, not at all ill (1)	1	2.4	6	6.1	7	5.0	3	7.9	0	0	3	2.4
	Borderline mentally ill (2)	5	12.2	19	19.2	24	17.1	3	7.9	9	10.2	12	9.5
	Mildly ill (3)	18	43.9	38	38.4	56	40.0	8	21.1	21	23.9	29	23.0
	Moderately ill (4)	14	34.1	26	26.3	40	28.6	17	44.7	41	46.6	58	46.0
	Markedly ill (5)	3	7.3	8	8.1	11	7.9	6	15.8	14	15.9	20	15.9
	Severely ill (6)	0	0	2	2.0	2	1.4	1	2.6	3	3.4	4	3.2
	Among the most extremely ill patients (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	41	100.0	99	100.0	140	100.0	38	100.0	88	100.0	126	100.0
Week 10	Severity												
	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Normal, not at all ill (1)	2	6.3	12	12.4	14	10.9	4	11.8	3	3.8	7	6.2

(CONTINUED)

Table 14.2.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit	Severity												
Week 10	Borderline mentally ill (2)	6	18.8	22	22.7	28	21.7	3	8.8	10	12.7	13	11.5
	Mildly ill (3)	15	46.9	36	37.1	51	39.5	12	35.3	18	22.8	30	26.5
	Moderately ill (4)	7	21.9	17	17.5	24	18.6	11	32.4	33	41.8	44	38.9
	Markedly ill (5)	2	6.3	8	8.2	10	7.8	4	11.8	12	15.2	16	14.2
	Severely ill (6)	0	0	2	2.1	2	1.6	0	0	3	3.8	3	2.7
	Among the most extremely ill patients (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	32	100.0	97	100.0	129	100.0	34	100.0	79	100.0	113	100.0
Week 12	Severity												
	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Normal, not at all ill (1)	5	14.3	15	15.5	20	15.2	4	12.9	3	3.8	7	6.4
	Borderline mentally ill (2)	8	22.9	28	28.9	36	27.3	3	9.7	17	21.8	20	18.3
	Mildly ill (3)	15	42.9	30	30.9	45	34.1	10	32.3	10	12.8	20	18.3
	Moderately ill (4)	4	11.4	20	20.6	24	18.2	10	32.3	36	46.2	46	42.2
	Markedly ill (5)	3	8.6	3	3.1	6	4.5	4	12.9	8	10.3	12	11.0
	Severely ill (6)	0	0	1	1.0	1	0.8	0	0	4	5.1	4	3.7
	Among the most extremely ill patients (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	35	100.0	97	100.0	132	100.0	31	100.0	78	100.0	109	100.0

(CONTINUED)

Table 14.2.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit	Severity												
Week 16	Not assessed (0)	0	0	0	0	0	0	0	0	1	1.4	1	1.0
	Normal, not at all ill (1)	6	18.8	28	30.4	34	27.4	5	17.2	5	6.9	10	9.9
	Borderline mentally ill (2)	13	40.6	25	27.2	38	30.6	4	13.8	16	22.2	20	19.8
	Mildly ill (3)	7	21.9	22	23.9	29	23.4	8	27.6	14	19.4	22	21.8
	Moderately ill (4)	3	9.4	14	15.2	17	13.7	10	34.5	29	40.3	39	38.6
	Markedly ill (5)	3	9.4	2	2.2	5	4.0	2	6.9	4	5.6	6	5.9
	Severely ill (6)	0	0	1	1.1	1	0.8	0	0	3	4.2	3	3.0
	Among the most extremely ill patients (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	32	100.0	92	100.0	124	100.0	29	100.0	72	100.0	101	100.0
Week 16 LOCF	Severity												
	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Normal, not at all ill (1)	8	17.4	28	24.1	36	22.2	5	11.1	6	5.5	11	7.1
	Borderline mentally ill (2)	15	32.6	26	22.4	41	25.3	5	11.1	16	14.7	21	13.6
	Mildly ill (3)	13	28.3	29	25.0	42	25.9	10	22.2	16	14.7	26	16.9
	Moderately ill (4)	7	15.2	21	18.1	28	17.3	12	26.7	46	42.2	58	37.7
	Markedly ill (5)	3	6.5	9	7.8	12	7.4	12	26.7	18	16.5	30	19.5
	Severely ill (6)	0	0	3	2.6	3	1.9	1	2.2	7	6.4	8	5.2
	Among the most extremely ill patients (7)	0	0	0	0	0	0	0	0	0	0	0	0

(CONTINUED)

Table 14.2.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit	Total												
Week 16 LOCF		46	100.0	116	100.0	162	100.0	45	100.0	109	100.0	154	100.0

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Table 14.2.2

Number and Percentage of Patients by Change in CGI Severity of Illness from Baseline

Intention-To-Treat Population

		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Change from Baseline to:	Change in Severity												
Week 1	-3	1	2.3	1	0.9	2	1.3	0	0	1	1.0	1	0.7
	-2	1	2.3	1	0.9	2	1.3	1	2.3	0	0	1	0.7
	-1	5	11.4	16	14.0	21	13.3	6	14.0	8	7.6	14	9.5
	0	36	81.8	95	83.3	131	82.9	35	81.4	95	90.5	130	87.8
	1	0	0	1	0.9	1	0.6	1	2.3	1	1.0	2	1.4
	Missing	1	2.3	0	0	1	0.6	0	0	0	0	0	0
	Total	44	100.0	114	100.0	158	100.0	43	100.0	105	100.0	148	100.0
Week 2	Change in Severity												
	-4	0	0	0	0	0	0	1	2.3	0	0	1	0.7
	-3	2	4.4	2	1.8	4	2.6	1	2.3	1	1.0	2	1.4
	-2	2	4.4	3	2.7	5	3.2	0	0	2	2.0	2	1.4
	-1	12	26.7	32	28.8	44	28.2	9	20.5	17	17.0	26	18.1
	0	28	62.2	72	64.9	100	64.1	33	75.0	80	80.0	113	78.5
	1	0	0	1	0.9	1	0.6	0	0	0	0	0	0
	Missing	1	2.2	1	0.9	2	1.3	0	0	0	0	0	0
	Total	45	100.0	111	100.0	156	100.0	44	100.0	100	100.0	144	100.0
Week 3	Change in Severity												
	-4	1	2.5	1	1.0	2	1.4	1	2.6	0	0	1	0.7

(CONTINUED)

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Table 14.2.2

Number and Percentage of Patients by Change in CGI Severity of Illness from Baseline

Intention-To-Treat Population

		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Change from Baseline to:	Change in Severity												
Week 3	-3	1	2.5	2	1.9	3	2.1	2	5.1	1	1.0	3	2.2
	-2	5	12.5	13	12.4	18	12.4	1	2.6	4	4.0	5	3.6
	-1	14	35.0	36	34.3	50	34.5	8	20.5	17	17.2	25	18.1
	0	18	45.0	51	48.6	69	47.6	27	69.2	75	75.8	102	73.9
	1	0	0	1	1.0	1	0.7	0	0	1	1.0	1	0.7
	Missing	1	2.5	1	1.0	2	1.4	0	0	1	1.0	1	0.7
	Total	40	100.0	105	100.0	145	100.0	39	100.0	99	100.0	138	100.0
Week 4	Change in Severity												
	-5	0	0	1	0.9	1	0.6	0	0	0	0	0	0
	-4	1	2.3	0	0	1	0.6	0	0	1	1.0	1	0.7
	-3	2	4.7	4	3.6	6	3.9	2	4.5	0	0	2	1.4
	-2	5	11.6	30	26.8	35	22.6	0	0	8	7.9	8	5.5
	-1	16	37.2	36	32.1	52	33.5	15	34.1	33	32.7	48	33.1
	0	18	41.9	40	35.7	58	37.4	27	61.4	59	58.4	86	59.3
	2	0	0	1	0.9	1	0.6	0	0	0	0	0	0
	Missing	1	2.3	0	0	1	0.6	0	0	0	0	0	0
	Total	43	100.0	112	100.0	155	100.0	44	100.0	101	100.0	145	100.0

(CONTINUED)

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Table 14.2.2

Number and Percentage of Patients by Change in CGI Severity of Illness from Baseline

Intention-To-Treat Population

		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Change from Baseline to:	Change in Severity												
Week 6	-4	2	4.8	2	2.0	4	2.8	1	2.6	2	2.0	3	2.2
	-3	1	2.4	10	9.8	11	7.6	1	2.6	0	0	1	0.7
	-2	9	21.4	28	27.5	37	25.7	3	7.7	13	13.3	16	11.7
	-1	15	35.7	32	31.4	47	32.6	14	35.9	29	29.6	43	31.4
	0	14	33.3	30	29.4	44	30.6	20	51.3	53	54.1	73	53.3
	1	0	0	0	0	0	0	0	0	1	1.0	1	0.7
	Missing	1	2.4	0	0	1	0.7	0	0	0	0	0	0
	Total	42	100.0	102	100.0	144	100.0	39	100.0	98	100.0	137	100.0
Week 8	Change in Severity												
	-5	0	0	1	1.0	1	0.7	0	0	0	0	0	0
	-4	0	0	1	1.0	1	0.7	1	2.6	2	2.3	3	2.4
	-3	4	9.8	16	16.2	20	14.3	2	5.3	2	2.3	4	3.2
	-2	10	24.4	35	35.4	45	32.1	2	5.3	15	17.0	17	13.5
	-1	13	31.7	18	18.2	31	22.1	15	39.5	32	36.4	47	37.3
	0	13	31.7	28	28.3	41	29.3	18	47.4	37	42.0	55	43.7
	Missing	1	2.4	0	0	1	0.7	0	0	0	0	0	0
	Total	41	100.0	99	100.0	140	100.0	38	100.0	88	100.0	126	100.0

(CONTINUED)

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Table 14.2.2

Number and Percentage of Patients by Change in CGI Severity of Illness from Baseline

Intention-To-Treat Population

		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Change from Baseline to:	Change in Severity												
Week 10	-5	0	0	4	4.1	4	3.1	0	0	0	0	0	0
	-4	1	3.1	3	3.1	4	3.1	1	2.9	2	2.5	3	2.7
	-3	4	12.5	17	17.5	21	16.3	3	8.8	5	6.3	8	7.1
	-2	10	31.3	32	33.0	42	32.6	4	11.8	13	16.5	17	15.0
	-1	12	37.5	22	22.7	34	26.4	16	47.1	28	35.4	44	38.9
	0	5	15.6	18	18.6	23	17.8	10	29.4	31	39.2	41	36.3
	1	0	0	1	1.0	1	0.8	0	0	0	0	0	0
	Total	32	100.0	97	100.0	129	100.0	34	100.0	79	100.0	113	100.0
Week 12	Change in Severity												
	-5	0	0	2	2.1	2	1.5	0	0	0	0	0	0
	-4	5	14.3	4	4.1	9	6.8	1	3.2	4	5.1	5	4.6
	-3	4	11.4	28	28.9	32	24.2	3	9.7	6	7.7	9	8.3
	-2	6	17.1	31	32.0	37	28.0	4	12.9	16	20.5	20	18.3
	-1	15	42.9	20	20.6	35	26.5	13	41.9	22	28.2	35	32.1
	0	5	14.3	10	10.3	15	11.4	10	32.3	30	38.5	40	36.7
	1	0	0	2	2.1	2	1.5	0	0	0	0	0	0
	Total	35	100.0	97	100.0	132	100.0	31	100.0	78	100.0	109	100.0

(CONTINUED)

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Table 14.2.2

Number and Percentage of Patients by Change in CGI Severity of Illness from Baseline

Intention-To-Treat Population

		Paroxetine (N = 163)						Placebo (N = 156)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Change from Baseline to:	Change in Severity												
Week 16	-5	1	3.1	3	3.3	4	3.2	0	0	2	2.8	2	2.0
	-4	3	9.4	11	12.0	14	11.3	1	3.4	1	1.4	2	2.0
	-3	5	15.6	33	35.9	38	30.6	4	13.8	8	11.1	12	11.9
	-2	13	40.6	22	23.9	35	28.2	6	20.7	17	23.6	23	22.8
	-1	5	15.6	15	16.3	20	16.1	11	37.9	23	31.9	34	33.7
	0	5	15.6	6	6.5	11	8.9	6	20.7	20	27.8	26	25.7
	1	0	0	2	2.2	2	1.6	1	3.4	0	0	1	1.0
	Missing	0	0	0	0	0	0	0	0	1	1.4	1	1.0
	Total	32	100.0	92	100.0	124	100.0	29	100.0	72	100.0	101	100.0
Week 16 LOCF	Change in Severity												
	-5	1	2.2	3	2.6	4	2.5	0	0	2	1.8	2	1.3
	-4	4	8.7	11	9.5	15	9.3	1	2.2	2	1.8	3	1.9
	-3	6	13.0	34	29.3	40	24.7	4	8.9	8	7.3	12	7.8
	-2	17	37.0	27	23.3	44	27.2	6	13.3	19	17.4	25	16.2
	-1	11	23.9	22	19.0	33	20.4	15	33.3	28	25.7	43	27.9
	0	6	13.0	15	12.9	21	13.0	18	40.0	50	45.9	68	44.2
	1	0	0	4	3.4	4	2.5	1	2.2	0	0	1	0.6
	Missing	1	2.2	0	0	1	0.6	0	0	0	0	0	0
	Total	46	100.0	116	100.0	162	100.0	45	100.0	109	100.0	154	100.0

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Table 14.2.3

Summary of Analysis of Change from Baseline for CGI Severity of Illness Score

Intention-To-Treat Population
Age Group : Children

	Paroxetine					Placebo					Treatment Comparisons	
	Mean	Median	Minimum	Maximum	N	Mean	Median	Minimum	Maximum	N	Median Difference	p-value*
Baseline	4.5	4.0	3	6	45	4.5	4.0	3	6	45		
Change from baseline to:												
Week 1	-0.2	0.0	-3	0	43	-0.2	0.0	-2	1	43		
Week 2	-0.5	0.0	-3	0	44	-0.4	0.0	-4	0	44		
Week 3	-0.8	-1.0	-4	0	39	-0.5	0.0	-4	0	39		
Week 4	-0.9	-1.0	-4	0	42	-0.5	0.0	-3	0	44		
Week 6	-1.1	-1.0	-4	0	41	-0.7	0.0	-4	0	39		
Week 8	-1.1	-1.0	-3	0	40	-0.8	-1.0	-4	0	38		
Week 10	-1.5	-1.0	-4	0	32	-1.1	-1.0	-4	0	34		
Week 12	-1.7	-1.0	-4	0	35	-1.1	-1.0	-4	0	31		
Week 16	-2.0	-2.0	-5	0	32	-1.3	-1.0	-4	1	29	-1.0	0.044
Week 16 LOCF Endpoint	-1.9	-2.0	-5	0	45	-0.9	-1.0	-4	1	45	-1.0	<0.001
70% LOCF Endpoint	-1.6	-1.0	-4	0	45	-0.8	-1.0	-4	0	45	-1.0	<0.001

* P-value from Wilcoxon Rank Sum Test
Note: 70% LOCF visit is Week 12

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Table 14.2.3

Summary of Analysis of Change from Baseline for CGI Severity of Illness Score

Intention-To-Treat Population
Age Group : Adolescents

	Paroxetine					Placebo					Treatment Comparisons	
	Mean	Median	Minimum	Maximum	N	Mean	Median	Minimum	Maximum	N	Median Difference	p-value*
Baseline	4.7	5.0	3	7	117	4.7	5.0	3	7	110		
Change from Baseline to:												
Week 1	-0.2	0.0	-3	1	114	-0.1	0.0	-3	1	105		
Week 2	-0.4	0.0	-3	1	110	-0.2	0.0	-3	0	100		
Week 3	-0.7	-0.5	-4	1	104	-0.3	0.0	-3	1	98		
Week 4	-1.0	-1.0	-5	2	112	-0.5	0.0	-4	0	101		
Week 6	-1.2	-1.0	-4	0	102	-0.6	0.0	-4	1	98		
Week 8	-1.5	-2.0	-5	0	99	-0.9	-1.0	-4	0	88		
Week 10	-1.7	-2.0	-5	1	97	-1.0	-1.0	-4	0	79		
Week 12	-2.0	-2.0	-5	1	97	-1.1	-1.0	-4	0	78		
Week 16	-2.3	-3.0	-5	1	92	-1.3	-1.0	-5	0	71	-1.0	<0.001
Week 16 LOCF Endpoint	-2.0	-2.0	-5	1	116	-1.0	-1.0	-5	0	109	-1.0	<0.001
70% LOCF Endpoint	-1.8	-2.0	-5	1	116	-0.9	0.0	-4	0	109	-1.0	<0.001

* P-value from Wilcoxon Rank Sum Test
Note: 70% LOCF visit is Week 12

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Table 14.3.1

Summary Statistics for LSAS-CA Total Score

Intention-To-Treat Population

		Paroxetine (N=163)			Placebo (N=156)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Baseline	N	44	117	161	45	110	155
	MEAN	70.7	80.3	77.6	71.2	80.3	77.7
	MEDIAN	71.5	79.0	79.0	69.0	84.0	80.0
	STDDEV	31.00	27.49	28.72	28.65	26.04	27.05
	MINIMUM	1	22	1	9	26	9
	MAXIMUM	127	133	133	132	130	132
	MISSING	2	0	2	0	0	0
Week 4	N	41	109	150	42	98	140
	MEAN	43.6	57.0	53.3	62.5	67.1	65.7
	MEDIAN	38.0	52.0	49.5	61.5	66.0	64.0
	STDDEV	30.05	30.87	31.12	27.09	29.97	29.12
	MINIMUM	3	0	0	14	11	11
	MAXIMUM	114	138	138	130	134	134
	MISSING	2	5	7	3	4	7
Week 8	N	39	95	134	33	86	119
	MEAN	31.9	41.5	38.7	49.7	60.4	57.4
	MEDIAN	28.0	36.0	33.0	46.0	62.5	58.0
	STDDEV	25.55	28.15	27.67	28.82	30.06	29.99
	MINIMUM	0	0	0	6	4	4
	MAXIMUM	112	108	112	106	134	134
	MISSING	3	8	11	5	7	12
Week 12	N	35	94	129	30	75	105
	MEAN	23.6	35.2	32.1	45.5	57.3	53.9
	MEDIAN	16.0	34.0	25.0	41.0	58.0	54.0
	STDDEV	27.31	26.02	26.78	28.89	29.98	30.01
	MINIMUM	0	0	0	2	3	2
	MAXIMUM	126	101	126	111	123	123
	MISSING	0	5	5	3	5	8
Week 16	N	32	92	124	29	72	101
	MEAN	21.7	27.5	26.0	42.0	52.5	49.5
	MEDIAN	12.0	24.5	20.5	41.0	48.0	47.0
	STDDEV	23.67	22.74	23.03	26.99	28.63	28.44
	MINIMUM	0	0	0	0	0	0
	MAXIMUM	94	88	94	104	119	119
	MISSING	1	3	4	1	3	4
Week 16 LOCF	N	45	115	160	45	105	150

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

Summary Statistics for LSAS-CA Total Score

Intention-To-Treat Population

		Paroxetine (N=163)			Placebo (N=156)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 16 LOCF	MEAN	20.5	36.5	32.0	49.2	58.2	55.5
	MEDIAN	12.0	30.0	24.5	46.0	60.0	56.0
	STDDEV	21.81	31.55	29.95	28.53	31.88	31.09
	MINIMUM	0	0	0	0	0	0
	MAXIMUM	94	138	138	111	134	134
	MISSING	1	2	3	0	6	6

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

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Table 14.3.2

Summary of Analysis for Change from Baseline in LSAS-CA Total score
Adjusted for Country Grouping, Baseline Score, Age Group and Gender
Intention-To-Treat Population

	Paroxetine			Placebo			Treatment Comparisons *			
	Least Square Mean+	s.e+	N	Least Square Mean+	s.e+	N	Difference	Lower 95% CI Limit	Upper 95% CI Limit	p-value
Baseline	77.63	28.72	161	77.66	27.05	155				
Change from baseline to:										
Week 4	-24.76	2.38	150	-12.31	2.41	140				
Week 8	-35.98	2.53	134	-16.55	2.66	119				
Week 12	-43.91	2.78	129	-21.70	2.91	105				
Week 16	-49.03	2.64	124	-25.72	2.75	101	-23.31	-29.59	-17.03	<0.001
Week 16 LOCF Endpoint	-48.01	2.64	159	-24.25	2.67	150	-23.75	-29.77	-17.74	<0.001
70% LOCF Endpoint	-44.31	2.59	159	-22.23	2.63	150	-22.08	-27.99	-16.16	<0.001

* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
+ Note that for Baseline, raw means not Least Square means and Standard Deviations not Standard Errors are presented
Note: LOCF Endpoint may have more patients than the first post-baseline visit as
early withdrawal data at unscheduled visits is not tabulated but is carried forward for LOCF endpoint
Note: Country Grouping term has been carried forward from the primary analysis. It has three groups
'USA', 'Canada' and 'South Africa and Belgium'.
Note: 70% LOCF is Week 12

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Table 14.3.3

Summary Statistics for Change from Baseline in LSAS-CA Total score

Intention-To-Treat Population

		Paroxetine (N=163)			Placebo (N=156)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Baseline	N	44	117	161	45	110	155
	MEAN	70.7	80.3	77.6	71.2	80.3	77.7
	MEDIAN	71.5	79.0	79.0	69.0	84.0	80.0
	STDDEV	31.00	27.49	28.72	28.65	26.04	27.05
	MINIMUM	1	22	1	9	26	9
	MAXIMUM	127	133	133	132	130	132
	MISSING	2	0	2	0	0	0
Week 4	N	41	109	150	42	98	140
	MEAN	-27.7	-22.6	-24.0	-7.6	-14.2	-12.2
	MEDIAN	-25.0	-19.0	-19.0	-7.5	-9.0	-9.0
	STDDEV	26.69	26.32	26.43	20.36	23.40	22.66
	MINIMUM	-105	-98	-105	-53	-112	-112
	MAXIMUM	7	50	50	48	34	48
	MISSING	2	5	7	3	4	7
Week 8	N	39	95	134	33	86	119
	MEAN	-37.1	-36.7	-36.8	-17.5	-18.2	-18.0
	MEDIAN	-34.0	-34.0	-34.0	-15.0	-15.5	-15.0
	STDDEV	28.31	31.17	30.26	19.95	24.05	22.91
	MINIMUM	-111	-129	-129	-61	-105	-105
	MAXIMUM	7	48	48	10	34	34
	MISSING	3	8	11	5	7	12
Week 12	N	35	94	129	30	75	105
	MEAN	-44.7	-41.8	-42.6	-21.3	-20.7	-20.9
	MEDIAN	-38.0	-41.0	-41.0	-20.5	-16.0	-20.0
	STDDEV	32.84	34.46	33.93	25.50	24.65	24.77
	MINIMUM	-127	-124	-127	-88	-81	-88
	MAXIMUM	14	39	39	9	35	35
	MISSING	0	5	5	3	5	8
Week 16	N	32	92	124	29	72	101
	MEAN	-46.4	-50.4	-49.3	-25.4	-26.9	-26.5
	MEDIAN	-40.0	-50.0	-48.0	-15.0	-21.0	-21.0
	STDDEV	33.83	31.55	32.06	30.83	28.85	29.28
	MINIMUM	-126	-132	-132	-91	-112	-112
	MAXIMUM	36	22	36	18	33	33
	MISSING	1	3	4	1	3	4
Week 16 LOCF	N	44	115	159	45	105	150
	MEAN	-50.2	-43.8	-45.6	-22.0	-21.9	-21.9
	MEDIAN	-47.0	-46.0	-47.0	-14.0	-16.0	-15.5
	STDDEV	31.98	34.54	33.87	28.44	27.42	27.63

Table 14.3.3

Summary Statistics for Change from Baseline in LSAS-CA Total score

Intention-To-Treat Population

		Paroxetine (N=163)			Placebo (N=156)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 16 LOCF	MINIMUM	-126	-132	-132	-91	-112	-112
	MAXIMUM	36	39	39	18	33	33
	MISSING	2	2	4	0	6	6

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Table 14.4.1

Summary Statistics for D-GSADS-A Total Score

Intention-To-Treat Population
(>= 11 years)

Visit	Statistic	Treatment Group Paroxetine	Placebo
Baseline	N	126	125
	MEAN	84.4	81.9
	MEDIAN	85.0	85.0
	STDDEV	25.42	26.25
	MINIMUM	18	15
	MAXIMUM	129	131
Week 4	N	118	110
	MEAN	60.3	68.0
	MEDIAN	60.0	67.5
	STDDEV	29.04	27.20
	MINIMUM	7	4
	MAXIMUM	127	126
Week 8	N	103	97
	MEAN	46.0	62.3
	MEDIAN	45.0	64.0
	STDDEV	29.32	28.19
	MINIMUM	0	2
	MAXIMUM	111	127
Week 12	N	103	88
	MEAN	37.5	59.3
	MEDIAN	35.0	61.0
	STDDEV	26.82	28.87
	MINIMUM	0	3
	MAXIMUM	103	126
Week 16	N	98	84
	MEAN	32.8	54.6
	MEDIAN	32.5	54.0
	STDDEV	24.84	29.21
	MINIMUM	0	0
	MAXIMUM	101	114
Week 16 LOCF	N	125	120
	MEAN	40.2	59.9
	MEDIAN	36.0	60.0
	STDDEV	31.42	30.13
	MINIMUM	0	0
	MAXIMUM	127	126

The table includes patients 11 years or older

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Table 14.4.2

Summary of Analysis for Change from Baseline in D-GSADS-A Total score
Adjusted for Country Grouping, Baseline Score and Gender
Intention-To-Treat Population

	Paroxetine			Placebo			Treatment Comparisons *			
	Least Square Mean+	s.e+	N	Least Square Mean+	s.e+	N	Difference	Lower 95% CI Limit	Upper 95% CI Limit	p-value
Baseline	84.44	25.42	126	81.93	26.25	125				
Change from baseline to:										
Week 4	-22.42	2.01	117	-12.66	2.06	110				
Week 8	-34.45	2.57	102	-15.00	2.66	97				
Week 12	-42.66	2.73	102	-18.83	2.86	88				
Week 16	-46.75	2.76	97	-23.49	2.90	84	-23.26	-30.51	-16.01	<0.001
Week 16 LOCF Endpoint	-42.94	2.66	124	-21.08	2.71	120	-21.86	-28.56	-15.16	<0.001
70% Endpoint	-40.06	2.52	124	-18.53	2.57	120	-21.53	-27.88	-15.17	<0.001

* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
+ Note that for Baseline, raw means not Least Square means and Standard Deviations not Standard Errors are presented
The table includes patients 11 years or older
Note: LOCF Endpoint may have more patients than first post-baseline visit as
early withdrawal data at unscheduled visits is not tabulated but is carried forward for LOCF endpoint
Note: Country Grouping term has been carried forward from the primary analysis. It has three groups
'USA', 'Canada' and 'South Africa and Belgium'.
Note: 70% LOCF visit is Week 12

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Table 14.5.1

Summary Statistics for SPAI-C Total Score

Intention-To-Treat Population

Visit	Statistic	Treatment Group Paroxetine	Placebo
Baseline	N	71	66
	MEAN	28.1	29.5
	MEDIAN	28.0	30.0
	STDDEV	11.71	11.06
	MINIMUM	2	3
	MAXIMUM	51	51
Week 4	N	63	60
	MEAN	18.4	25.3
	MEDIAN	17.0	24.5
	STDDEV	12.24	10.92
	MINIMUM	0	4
	MAXIMUM	50	49
Week 8	N	59	47
	MEAN	13.4	23.5
	MEDIAN	11.0	22.0
	STDDEV	11.49	12.44
	MINIMUM	0	2
	MAXIMUM	45	47
Week 12	N	58	40
	MEAN	10.4	19.6
	MEDIAN	9.5	16.5
	STDDEV	10.27	11.98
	MINIMUM	0	0
	MAXIMUM	42	46
Week 16	N	51	41
	MEAN	9.3	19.2
	MEDIAN	6.0	18.0
	STDDEV	9.98	10.77
	MINIMUM	0	0
	MAXIMUM	38	44
Week 16 LOCF	N	72	66
	MEAN	11.2	21.1
	MEDIAN	7.5	19.0
	STDDEV	11.75	12.52
	MINIMUM	0	0
	MAXIMUM	50	47

The table includes patients 13 years or younger, however it may also include some patients aged 14 and 15 years old (see clinical report for details)

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Table 14.5.2

Summary of Analysis for Change from Baseline in SPAI-C Total Score
Adjusted for Country Grouping, Baseline Score and Gender
Intention-To-Treat Population

	Paroxetine			Placebo			Treatment Comparisons *			
	Least Square Mean+	s.e+	N	Least Square Mean+	s.e+	N	Difference	Lower 95% CI Limit	Upper 95% CI Limit	p-value
Baseline	28.06	11.71	71	29.52	11.06	66				
Change from baseline to:										
Week 4	-9.43	1.50	63	-3.23	1.53	60				
Week 8	-13.82	1.61	59	-4.44	1.76	47				
Week 12	-16.67	1.60	57	-7.96	1.82	40				
Week 16	-18.06	1.64	51	-8.69	1.75	41	-9.36	-13.55	-5.17	<0.001
Week 16 LOCF Endpoint	-17.55	1.59	69	-8.11	1.62	66	-9.44	-13.19	-5.69	<0.001
70% LOCF Endpoint	-16.79	1.57	69	-8.05	1.60	66	-8.75	-12.44	-5.05	<0.001

* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
+ Note that for Baseline, raw means not Least Square means and Standard Deviations not Standard Errors are presented
The table includes patients 13 years or younger, however it may also include some patients aged 14 and 15 years old (see clinical report for details)
Note: LOCF Endpoint may have more patients than first post-baseline visit as early withdrawal data at unscheduled visits is not tabulated but is carried forward for LOCF endpoint
Note: Country Grouping term has been carried forward from the primary analysis. It has three groups 'USA', 'Canada' and 'South Africa and Belgium'.
Note: 70% LOCF is Week 12

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Table 14.6.1

Summary Statistics for SPAI Difference Score

Intention-To-Treat Population

Visit	Statistic	Treatment Group Paroxetine	Placebo
Baseline	N	81	84
	MEAN	98.7	90.9
	MEDIAN	102.0	92.5
	STDDEV	31.56	32.23
	MINIMUM	19	11
	MAXIMUM	157	144
Week 4	N	76	77
	MEAN	73.6	83.4
	MEDIAN	67.0	84.0
	STDDEV	31.76	35.03
	MINIMUM	6	2
	MAXIMUM	157	153
Week 8	N	65	66
	MEAN	59.5	74.9
	MEDIAN	57.0	80.0
	STDDEV	34.46	35.04
	MINIMUM	0	4
	MAXIMUM	141	154
Week 12	N	63	60
	MEAN	46.3	72.5
	MEDIAN	42.0	78.5
	STDDEV	33.27	37.30
	MINIMUM	0	2
	MAXIMUM	130	154
Week 16	N	62	54
	MEAN	37.8	66.2
	MEDIAN	34.0	66.0
	STDDEV	34.23	38.12
	MINIMUM	-3	-1
	MAXIMUM	155	148
Week 16 LOCF	N	79	82
	MEAN	42.3	72.5
	MEDIAN	38.0	74.0
	STDDEV	35.98	39.68
	MINIMUM	-3	-1
	MAXIMUM	155	156

The table includes patients 14 years or older, however it may also include some patients aged 13 years old (see clinical report for details)

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Table 14.6.2

Summary of Analysis for Change from Baseline in SPAI Difference Score
Adjusted for Country Grouping, Baseline Score and Gender
Intention-To-Treat Population

	Paroxetine			Placebo			Treatment Comparisons *			
	Least Square Mean+	s.e+	N	Least Square Mean+	s.e+	N	Difference	Lower 95% CI Limit	Upper 95% CI Limit	p-value
Baseline	98.70	31.56	81	90.94	32.23	84				
Change from baseline to:										
Week 4	-21.53	3.54	74	-7.36	3.46	76				
Week 8	-31.49	4.35	63	-11.33	4.12	66				
Week 12	-48.44	4.71	62	-17.73	4.54	60				
Week 16	-56.00	4.98	61	-24.63	4.95	54	-31.37	-43.62	-19.12	<0.001
Week 16 LOCF Endpoint	-51.85	4.53	77	-19.05	4.40	81	-32.80	-43.57	-22.03	<0.001
70% LOCF Endpoint	-47.20	4.19	77	-16.85	4.07	81	-30.35	-40.30	-20.40	<0.001

* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
+ Note that for Baseline, raw means not Least Square means and Standard Deviations not Standard Errors are presented
The table includes patients 14 years or older, however it may also include some patients aged 13 years old (see clinical report for details)
Note: LOCF Endpoint may have more patients than first post-baseline visit as early withdrawal data at unscheduled visits is not tabulated but is carried forward for LOCF endpoint
Note: Country Grouping term has been carried forward from the primary analysis. It has three groups 'USA', 'Canada' and 'South Africa and Belgium'.
Note: 70% LOCF is Week 12

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Table 14.7.1

Summary Statistics for GAF Score

Intention-To-Treat Population

		Paroxetine (N=163)			Placebo (N=156)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Baseline	N	45	117	162	45	110	155
	MEAN	53.0	52.9	53.0	55.0	52.8	53.5
	MEDIAN	55.0	51.0	53.0	55.0	52.0	55.0
	STDDEV	6.30	7.07	6.85	7.70	7.38	7.51
	MINIMUM	31	31	31	31	31	31
	MAXIMUM	65	72	72	70	78	78
	MISSING	1	0	1	0	0	0
Week 4	N	41	109	150	42	98	140
	MEAN	61.1	60.5	60.7	58.1	57.2	57.5
	MEDIAN	61.0	60.0	60.0	58.0	57.5	58.0
	STDDEV	7.49	8.96	8.56	10.15	7.37	8.27
	MINIMUM	45	36	36	31	40	31
	MAXIMUM	80	95	95	95	80	95
	MISSING	2	5	7	3	4	7
Week 8	N	40	94	134	33	87	120
	MEAN	64.7	66.3	65.8	63.2	60.4	61.1
	MEDIAN	63.5	65.0	65.0	61.0	60.0	60.0
	STDDEV	9.83	9.83	9.82	10.79	8.54	9.25
	MINIMUM	50	48	48	39	43	39
	MAXIMUM	90	91	91	89	80	89
	MISSING	2	9	11	5	6	11
Week 12	N	35	94	129	30	76	106
	MEAN	70.5	71.1	71.0	64.4	62.6	63.1
	MEDIAN	70.0	70.0	70.0	62.0	61.5	62.0
	STDDEV	12.59	10.78	11.25	10.37	9.61	9.82
	MINIMUM	50	43	43	45	47	45
	MAXIMUM	95	95	95	89	85	89
	MISSING	0	5	5	3	4	7
Week 16	N	32	92	124	29	72	101
	MEAN	75.5	73.7	74.2	66.3	65.0	65.4
	MEDIAN	79.0	74.5	75.0	65.0	65.0	65.0
	STDDEV	12.66	11.41	11.72	11.80	11.48	11.53
	MINIMUM	51	51	51	45	32	32
	MAXIMUM	95	95	95	90	90	90
	MISSING	1	3	4	1	3	4
Week 16 LOCF	N	45	115	160	45	106	151

Note: 'MISSING' row indicates number of patients with missing data or inadequate information at that visit (but still in the study or withdrawing that week)

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Table 14.7.1

Summary Statistics for GAF Score

Intention-To-Treat Population

		Paroxetine (N=163)			Placebo (N=156)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 16 LOCF	MEAN	71.9	70.0	70.5	62.3	61.8	62.0
	MEDIAN	70.0	70.0	70.0	60.0	60.0	60.0
	STDDEV	12.71	13.36	13.17	12.01	11.77	11.80
	MINIMUM	50	36	36	39	32	32
	MAXIMUM	95	95	95	90	90	90
	MISSING	1	2	3	0	5	5

Note: 'MISSING' row indicates number of patients with missing data or inadequate information at that visit (but still in the study or withdrawing that week)

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Table 14.7.2

Summary of Analysis for Change from Baseline in GAF score
Adjusted for Country Grouping, Baseline Score, Age Group and Gender
Intention-To-Treat Population

	Paroxetine			Placebo			Treatment Comparisons *			
	Least Square Mean+	s.e+	N	Least Square Mean+	s.e+	N	Difference	Lower 95% CI Limit	Upper 95% CI Limit	p-value
Baseline	52.97	6.85	162	53.48	7.51	155				
Change from baseline to:										
Week 4	7.41	0.71	150	3.88	0.72	140				
Week 8	11.82	0.95	134	6.62	1.00	120				
Week 12	16.25	1.11	129	8.22	1.16	106				
Week 16	19.54	1.24	124	10.37	1.30	101	9.17	6.21	12.13	<0.001
Week 16 LOCF Endpoint	17.11	1.14	159	8.37	1.15	151	8.74	6.15	11.34	<0.001
70% LOCF Endpoint	15.01	1.01	159	7.43	1.02	151	7.58	5.28	9.88	<0.001

* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
+ Note that for Baseline, raw means not Least Square means and Standard Deviations not Standard Errors are presented
Note: LOCF Endpoint may have more patients than first post-baseline visit as
early withdrawal data at unscheduled visits is not tabulated but is carried forward for LOCF endpoint
Note: Country Grouping term has been carried forward from the primary analysis. It has three groups
'USA', 'Canada' and 'South Africa and Belgium'.
Note: 70% LOCF is Week 12

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Table 14.7.3

Summary Statistics for Change from Baseline in GAF score

Intention-To-Treat Population

		Paroxetine (N=163)			Placebo (N=156)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Baseline	N	45	117	162	45	110	155
	MEAN	53.0	52.9	53.0	55.0	52.8	53.5
	MEDIAN	55.0	51.0	53.0	55.0	52.0	55.0
	STDDEV	6.30	7.07	6.85	7.70	7.38	7.51
	MINIMUM	31	31	31	31	31	31
	MAXIMUM	65	72	72	70	78	78
	MISSING	1	0	1	0	0	0
Week 4	N	41	109	150	42	98	140
	MEAN	8.5	7.5	7.7	2.7	4.6	4.0
	MEDIAN	7.0	7.0	7.0	1.0	4.5	3.0
	STDDEV	6.60	8.59	8.09	7.41	6.05	6.52
	MINIMUM	0	-17	-17	-15	-8	-15
	MAXIMUM	25	40	40	35	25	35
	MISSING	2	5	7	3	4	7
Week 8	N	40	94	134	33	87	120
	MEAN	11.7	13.0	12.6	6.5	7.0	6.9
	MEDIAN	10.0	11.0	10.0	3.0	5.0	5.0
	STDDEV	10.72	10.68	10.67	8.55	9.08	8.91
	MINIMUM	-5	-10	-10	-5	-24	-24
	MAXIMUM	37	46	46	30	35	35
	MISSING	2	9	11	5	6	11
Week 12	N	35	94	129	30	76	106
	MEAN	16.7	17.6	17.4	7.3	9.2	8.6
	MEDIAN	14.0	19.0	17.0	5.0	8.0	7.0
	STDDEV	12.78	11.62	11.90	9.05	9.94	9.69
	MINIMUM	-3	-12	-12	-3	-10	-10
	MAXIMUM	50	50	50	34	34	34
	MISSING	0	5	5	3	4	7
Week 16	N	32	92	124	29	72	101
	MEAN	21.5	20.8	21.0	9.0	11.0	10.4
	MEDIAN	22.5	20.0	20.0	5.0	10.0	10.0
	STDDEV	13.24	11.54	11.95	10.84	12.76	12.22
	MINIMUM	0	-9	-9	-8	-43	-43
	MAXIMUM	50	48	50	35	45	45
	MISSING	1	3	4	1	3	4
Week 16 LOCF	N	44	115	159	45	106	151
	MEAN	18.9	17.0	17.5	7.2	8.9	8.4
	MEDIAN	16.0	15.0	16.0	5.0	8.0	6.0
	STDDEV	12.36	13.27	13.01	9.67	11.77	11.18

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Table 14.7.3

Summary Statistics for Change from Baseline in GAF score

Intention-To-Treat Population

		Paroxetine (N=163)			Placebo (N=156)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 16 LOCF	MINIMUM	0	-12	-12	-8	-43	-43
	MAXIMUM	50	48	50	35	45	45
	MISSING	2	2	4	0	5	5

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Table 14.8.1

Summary Statistics for CDRS-R Total Score

Intention-To-Treat Population

		Paroxetine (N=163)			Placebo (N=156)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Baseline	N	45	117	162	45	110	155
	MEAN	29.4	29.6	29.5	29.5	31.3	30.8
	MEDIAN	26.0	28.0	27.0	26.0	27.5	27.0
	STDDEV	10.05	10.62	10.43	10.58	12.41	11.90
	MINIMUM	17	17	17	17	17	17
	MAXIMUM	56	65	65	50	75	75
	MISSING	1	0	1	0	0	0
Week 16	N	32	92	124	29	71	100
	MEAN	21.9	22.2	22.1	27.2	25.9	26.3
	MEDIAN	20.0	20.0	20.0	23.0	23.0	23.0
	STDDEV	5.65	7.45	7.01	10.43	9.25	9.57
	MINIMUM	17	17	17	17	17	17
	MAXIMUM	41	58	58	58	54	58
	MISSING	1	3	4	1	4	5
Week 16 LOCF	N	40	106	146	39	87	126
	MEAN	22.7	24.7	24.1	28.7	27.2	27.6
	MEDIAN	20.0	20.0	20.0	25.0	23.0	23.0
	STDDEV	6.60	11.76	10.61	10.92	10.99	10.94
	MINIMUM	17	17	17	17	17	17
	MAXIMUM	41	78	78	58	68	68
	MISSING	6	11	17	6	24	30

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

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Table 14.8.2

Summary of Analysis for Change from Baseline in CDRS-R Total Score
Adjusted for Country Grouping, Baseline Score, Age Group and Gender
Intention-To-Treat Population

	Paroxetine			Placebo			Treatment Comparisons *			
	Least Square Mean+	s.e+	N	Least Square Mean+	s.e+	N	Difference	Lower 95% CI Limit	Upper 95% CI Limit	p-value
Baseline	29.51	10.43	162	30.77	11.90	155				
Change from baseline to:										
Week 16	-6.16	0.79	124	-2.13	0.83	100	-4.03	-5.91	-2.15	<0.001
Week 16 LOCF Endpoint	-4.75	0.97	145	-1.14	1.00	126	-3.61	-5.88	-1.34	0.002

* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
+ Note that for Baseline, raw means not Least Square means and Standard Deviations not Standard Errors are presented

Note: LOCF Endpoint may have more patients than first post-baseline visit as
early withdrawal data at unscheduled visits is not tabulated but is carried forward for LOCF endpoint
Note: Country Grouping term has been carried forward from the primary analysis. It has three groups
'USA', 'Canada' and 'South Africa and Belgium'.

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Table 14.8.3

Summary Statistics for Change from Baseline in CDRS-R Total Score

Intention-To-Treat Population

		Paroxetine (N=163)			Placebo (N=156)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Baseline	N	45	117	162	45	110	155
	MEAN	29.4	29.6	29.5	29.5	31.3	30.8
	MEDIAN	26.0	28.0	27.0	26.0	27.5	27.0
	STDDEV	10.05	10.62	10.43	10.58	12.41	11.90
	MINIMUM	17	17	17	17	17	17
	MAXIMUM	56	65	65	50	75	75
	MISSING	1	0	1	0	0	0
Week 16	N	32	92	124	29	71	100
	MEAN	-6.8	-6.2	-6.4	-1.4	-3.0	-2.5
	MEDIAN	-4.5	-5.5	-5.0	0.0	-2.0	-2.0
	STDDEV	8.33	8.52	8.44	13.15	8.54	10.05
	MINIMUM	-25	-30	-30	-31	-24	-31
	MAXIMUM	7	30	30	41	17	41
	MISSING	1	3	4	1	4	5
Week 16 LOCF	N	39	106	145	39	87	126
	MEAN	-7.1	-4.4	-5.1	-1.1	-2.3	-1.9
	MEDIAN	-4.0	-5.0	-5.0	0.0	-2.0	-1.0
	STDDEV	9.24	11.80	11.20	12.83	8.94	10.27
	MINIMUM	-38	-30	-38	-31	-24	-31
	MAXIMUM	7	56	56	41	22	41
	MISSING	7	11	18	6	24	30

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

13 Source Tables: Safety

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Table 15.1.1.0

Number (%) of Patients With Adverse Experiences Prior to Start of Treatment
By Body System
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=163)	Placebo (N=156)
TOTAL	TOTAL	20 (12.3%)	24 (15.4%)
Body as a Whole	TOTAL	9 (5.5%)	15 (9.6%)
	HEADACHE	5 (3.1%)	8 (5.1%)
	ALLERGIC REACTION	2 (1.2%)	1 (0.6%)
	INFECTION	1 (0.6%)	2 (1.3%)
	TRAUMA	1 (0.6%)	2 (1.3%)
	ABDOMINAL PAIN	0	1 (0.6%)
	ASTHENIA	0	1 (0.6%)
	FLU SYNDROME	0	1 (0.6%)
	PAIN	0	1 (0.6%)
Respiratory System	TOTAL	6 (3.7%)	7 (4.5%)
	RESPIRATORY DISORDER	3 (1.8%)	3 (1.9%)
	COUGH INCREASED	1 (0.6%)	1 (0.6%)
	RHINITIS	1 (0.6%)	1 (0.6%)
	ASTHMA	1 (0.6%)	0
	PHARYNGITIS	0	2 (1.3%)
Digestive System	TOTAL	2 (1.2%)	3 (1.9%)
	NAUSEA	1 (0.6%)	3 (1.9%)
	GASTROINTESTINAL DISORDER	1 (0.6%)	0
Metabolic and Nutritional Disorders	TOTAL	2 (1.2%)	0
	BILIRUBINEMIA	1 (0.6%)	0
	HYPERNATREMIA	1 (0.6%)	0
Cardiovascular System	TOTAL	1 (0.6%)	0
	SYNCOPE	1 (0.6%)	0
Musculoskeletal System	TOTAL	1 (0.6%)	0
	MYALGIA	1 (0.6%)	0
Nervous System	TOTAL	1 (0.6%)	1 (0.6%)
	NERVOUSNESS	1 (0.6%)	0
	TREMOR	0	1 (0.6%)
Skin and Appendages	TOTAL	1 (0.6%)	1 (0.6%)
	MACULOPAPULAR RASH	1 (0.6%)	0
	RASH	0	1 (0.6%)
Hemic and Lymphatic System	TOTAL	0	1 (0.6%)
	EOSINOPHILIA	0	1 (0.6%)

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Table 15.1.1.0

Number (%) of Patients With Adverse Experiences Prior to Start of Treatment
By Body System
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=163)	Placebo (N=156)
Body System	Preferred Term		
Special Senses	TOTAL	0	1 (0.6%)
	CONJUNCTIVITIS	0	1 (0.6%)

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Table 15.1.1.0

Number (%) of Patients With Adverse Experiences Prior to Start of Treatment
By Body System
Intention-To-Treat Population
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=71)	Placebo (N=89)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.1.0

Number (%) of Patients With Adverse Experiences Prior to Start of Treatment
By Body System
Intention-To-Treat Population
Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=92)	Placebo (N=67)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=46)	Placebo (N=45)
TOTAL	TOTAL	41 (89.1%)	35 (77.8%)
Body as a Whole	TOTAL	28 (60.9%)	24 (53.3%)
	HEADACHE	15 (32.6%)	11 (24.4%)
	ABDOMINAL PAIN	10 (21.7%)	5 (11.1%)
	INFECTION	6 (13.0%)	8 (17.8%)
	TRAUMA	5 (10.9%)	4 (8.9%)
	ASTHENIA	3 (6.5%)	1 (2.2%)
	ALLERGIC REACTION	2 (4.3%)	2 (4.4%)
	FEVER	2 (4.3%)	1 (2.2%)
	BACK PAIN	1 (2.2%)	1 (2.2%)
	ABNORMAL LABORATORY VALUE	0	1 (2.2%)
	CHEST PAIN	0	1 (2.2%)
	PAIN	0	1 (2.2%)
Nervous System	TOTAL	23 (50.0%)	10 (22.2%)
	NERVOUSNESS	7 (15.2%)	2 (4.4%)
	INSOMNIA	6 (13.0%)	3 (6.7%)
	SOMNOLENCE	4 (8.7%)	5 (11.1%)
	HYPERKINESIA	4 (8.7%)	0
	HOSTILITY	3 (6.5%)	0
	CONCENTRATION IMPAIRED	1 (2.2%)	2 (4.4%)
	DIZZINESS	1 (2.2%)	1 (2.2%)
	LACK OF EMOTION	1 (2.2%)	0
	MANIC REACTION	1 (2.2%)	0
	NEUROSIS	1 (2.2%)	0
	SPEECH DISORDER	1 (2.2%)	0
	AGITATION	0	1 (2.2%)
	INCOORDINATION	0	1 (2.2%)
Digestive System	TOTAL	13 (28.3%)	14 (31.1%)
	DECREASED APPETITE	3 (6.5%)	2 (4.4%)
	VOMITING	3 (6.5%)	2 (4.4%)
	DIARRHEA	2 (4.3%)	4 (8.9%)
	NAUSEA	2 (4.3%)	4 (8.9%)
	DYSPEPSIA	2 (4.3%)	2 (4.4%)
	FECAL INCONTINENCE	2 (4.3%)	1 (2.2%)
	FLATULENCE	2 (4.3%)	0
	CONSTIPATION	1 (2.2%)	1 (2.2%)
	INCREASED APPETITE	1 (2.2%)	0
	ULCERATIVE STOMATITIS	1 (2.2%)	0
	GASTROENTERITIS	0	2 (4.4%)
	TOOTH CARIES	0	1 (2.2%)
	TOOTH DISORDER	0	1 (2.2%)

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=45)
Respiratory System	TOTAL	13 (28.3%)	20 (44.4%)
	RESPIRATORY DISORDER	7 (15.2%)	3 (6.7%)
	COUGH INCREASED	3 (6.5%)	5 (11.1%)
	PHARYNGITIS	2 (4.3%)	7 (15.6%)
	SINUSITIS	2 (4.3%)	3 (6.7%)
	RHINITIS	1 (2.2%)	7 (15.6%)
	EPISTAXIS	1 (2.2%)	1 (2.2%)
	ASTHMA	1 (2.2%)	0
	BRONCHITIS	0	1 (2.2%)
Special Senses	TOTAL	9 (19.6%)	2 (4.4%)
	OTITIS MEDIA	5 (10.9%)	1 (2.2%)
	CONJUNCTIVITIS	3 (6.5%)	0
	EAR PAIN	1 (2.2%)	1 (2.2%)
	OTITIS EXTERNA	1 (2.2%)	0
Skin and Appendages	TOTAL	8 (17.4%)	5 (11.1%)
	RASH	5 (10.9%)	2 (4.4%)
	CONTACT DERMATITIS	2 (4.3%)	0
	NAIL DISORDER	1 (2.2%)	0
	PRURITUS	1 (2.2%)	0
	SWEATING	1 (2.2%)	0
	ECZEMA	0	1 (2.2%)
	FUNGAL DERMATITIS	0	1 (2.2%)
	PHOTOSENSITIVITY	0	1 (2.2%)
Urogenital System	TOTAL	5 (10.9%)	1 (2.2%)
	URINARY INCONTINENCE	5 (10.9%)	0
	ALBUMINURIA	1 (2.2%)	0
	URINARY RETENTION	0	1 (2.2%)
Cardiovascular System	TOTAL	2 (4.3%)	1 (2.2%)
	VASODILATATION	2 (4.3%)	0
	TACHYCARDIA	0	1 (2.2%)
Musculoskeletal System	TOTAL	2 (4.3%)	1 (2.2%)
	ARTHRALGIA	1 (2.2%)	1 (2.2%)
	MYALGIA	1 (2.2%)	0
Hemic and Lymphatic System	TOTAL	1 (2.2%)	0
	PURPURA	1 (2.2%)	0
Metabolic and Nutritional Disorders	TOTAL	1 (2.2%)	1 (2.2%)

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=46)	Treatment Group Placebo (N=45)
Metabolic and Nutritional Disorders	WEIGHT GAIN	1 (2.2%)	0
	HYPONATREMIA	0	1 (2.2%)

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Children, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=23)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Children, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=21)	Placebo (N=22)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=117)	 Placebo (N=111)
TOTAL	TOTAL	103 (88.0%)	90 (81.1%)
Body as a Whole	TOTAL	78 (66.7%)	60 (54.1%)
	HEADACHE	47 (40.2%)	31 (27.9%)
	INFECTION	27 (23.1%)	17 (15.3%)
	ASTHENIA	21 (17.9%)	11 (9.9%)
	ABDOMINAL PAIN	14 (12.0%)	10 (9.0%)
	TRAUMA	9 (7.7%)	8 (7.2%)
	ALLERGIC REACTION	5 (4.3%)	2 (1.8%)
	FLU SYNDROME	4 (3.4%)	3 (2.7%)
	FEVER	4 (3.4%)	2 (1.8%)
	BACK PAIN	2 (1.7%)	6 (5.4%)
	PAIN	2 (1.7%)	1 (0.9%)
	MONILIASIS	2 (1.7%)	0
	CELLULITIS	1 (0.9%)	0
	RHEUMATOID ARTHRITIS	1 (0.9%)	0
	CHILLS	0	1 (0.9%)
	NEOPLASM	0	1 (0.9%)
Digestive System	TOTAL	47 (40.2%)	22 (19.8%)
	NAUSEA	15 (12.8%)	8 (7.2%)
	DYSPEPSIA	10 (8.5%)	4 (3.6%)
	DECREASED APPETITE	10 (8.5%)	3 (2.7%)
	VOMITING	8 (6.8%)	1 (0.9%)
	DRY MOUTH	4 (3.4%)	5 (4.5%)
	DIARRHEA	4 (3.4%)	3 (2.7%)
	INCREASED APPETITE	4 (3.4%)	2 (1.8%)
	STOMATITIS	2 (1.7%)	1 (0.9%)
	GINGIVITIS	1 (0.9%)	1 (0.9%)
	TOOTH DISORDER	1 (0.9%)	1 (0.9%)
	GASTRITIS	1 (0.9%)	0
	GASTROINTESTINAL DISORDER	1 (0.9%)	0
	RECTAL DISORDER	1 (0.9%)	0
	GASTROENTERITIS	0	2 (1.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (0.9%)
	ULCERATIVE STOMATITIS	0	1 (0.9%)
Nervous System	TOTAL	46 (39.3%)	26 (23.4%)
	SOMNOLENCE	17 (14.5%)	8 (7.2%)
	INSOMNIA	17 (14.5%)	6 (5.4%)
	DIZZINESS	7 (6.0%)	9 (8.1%)
	NERVOUSNESS	7 (6.0%)	7 (6.3%)
	EMOTIONAL LABILITY	4 (3.4%)	2 (1.8%)
	AGITATION	3 (2.6%)	1 (0.9%)

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=117)	Treatment Group: Placebo (N=111)
Nervous System	ABNORMAL DREAMS	3 (2.6%)	0
	DEPRESSION	3 (2.6%)	0
	TREMOR	3 (2.6%)	0
	HOSTILITY	2 (1.7%)	2 (1.8%)
	HYPERKINESIA	2 (1.7%)	0
	MANIC REACTION	2 (1.7%)	0
	AMNESIA	1 (0.9%)	0
	CONCENTRATION IMPAIRED	1 (0.9%)	0
	DEPERSONALIZATION	1 (0.9%)	0
	LACK OF EMOTION	1 (0.9%)	0
	LIBIDO DECREASED	1 (0.9%)	0
	MYOCLONUS	1 (0.9%)	0
	NEUROSIS	1 (0.9%)	0
	ANXIETY	0	1 (0.9%)
	EXTRAPYRAMIDAL SYNDROME	0	1 (0.9%)
	HYPERTONIA	0	1 (0.9%)
	VERTIGO	0	1 (0.9%)
Respiratory System	TOTAL	42 (35.9%)	44 (39.6%)
	RESPIRATORY DISORDER	18 (15.4%)	17 (15.3%)
	RHINITIS	16 (13.7%)	18 (16.2%)
	PHARYNGITIS	11 (9.4%)	7 (6.3%)
	COUGH INCREASED	6 (5.1%)	6 (5.4%)
	SINUSITIS	6 (5.1%)	4 (3.6%)
	BRONCHITIS	3 (2.6%)	2 (1.8%)
	YAWN	3 (2.6%)	1 (0.9%)
	ASTHMA	2 (1.7%)	1 (0.9%)
	EPISTAXIS	2 (1.7%)	0
	PNEUMONIA	0	1 (0.9%)
Skin and Appendages	TOTAL	10 (8.5%)	8 (7.2%)
	RASH	3 (2.6%)	2 (1.8%)
	SWEATING	3 (2.6%)	1 (0.9%)
	CONTACT DERMATITIS	2 (1.7%)	0
	ACNE	1 (0.9%)	3 (2.7%)
	HERPES SIMPLEX	1 (0.9%)	1 (0.9%)
	VESICULOBULLOUS RASH	1 (0.9%)	0
	ECZEMA	0	1 (0.9%)
Musculoskeletal System	TOTAL	8 (6.8%)	8 (7.2%)
	MYALGIA	5 (4.3%)	5 (4.5%)
	ARTHRALGIA	3 (2.6%)	3 (2.7%)
	ARTHROSIS	0	1 (0.9%)

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=117)	Treatment Group: Placebo (N=111)
Special Senses	TOTAL	8 (6.8%)	5 (4.5%)
	CONJUNCTIVITIS	3 (2.6%)	1 (0.9%)
	EAR PAIN	3 (2.6%)	0
	OTITIS MEDIA	1 (0.9%)	1 (0.9%)
	MYDRIASIS	1 (0.9%)	0
	ABNORMAL VISION	0	1 (0.9%)
	OTITIS EXTERNA	0	1 (0.9%)
	PHOTOPHOBIA	0	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	7 (6.0%)	6 (5.4%)
	WEIGHT GAIN	3 (2.6%)	3 (2.7%)
	THIRST	1 (0.9%)	1 (0.9%)
	WEIGHT LOSS	1 (0.9%)	1 (0.9%)
	HYPERKALEMIA	1 (0.9%)	0
	KETOSIS	1 (0.9%)	0
	BILIRUBINEMIA	0	1 (0.9%)
Cardiovascular System	TOTAL	5 (4.3%)	4 (3.6%)
	HYPOTENSION	1 (0.9%)	2 (1.8%)
	SYNCOPE	1 (0.9%)	2 (1.8%)
	VASODILATATION	1 (0.9%)	1 (0.9%)
	MIGRAINE	1 (0.9%)	0
	QT INTERVAL PROLONGED	1 (0.9%)	0
Hemic and Lymphatic System	TOTAL	5 (4.3%)	2 (1.8%)
	PURPURA	3 (2.6%)	0
	LEUKOPENIA	1 (0.9%)	1 (0.9%)
	ANEMIA	1 (0.9%)	0
	LEUKOCYTOSIS	1 (0.9%)	0
	EOSINOPHILIA	0	1 (0.9%)
	POLYCYTHEMIA	0	1 (0.9%)
Urogenital System	TOTAL	2 (1.7%)	5 (4.5%)
	ALBUMINURIA	1 (0.9%)	2 (1.8%)
	URINARY FREQUENCY	1 (0.9%)	1 (0.9%)
	URINE ABNORMALITY	1 (0.9%)	0
	URINARY TRACT INFECTION	0	2 (1.8%)
	CYSTITIS	0	1 (0.9%)

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Male Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=46)	Placebo (N=66)
TOTAL	TOTAL	1 (2.2%)	0
Urogenital System	TOTAL	1 (2.2%)	0
	ABNORMAL EJACULATION	1 (2.2%)	0

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=71)	 Placebo (N=45)
TOTAL	TOTAL	6 (8.5%)	4 (8.9%)
Urogenital System	TOTAL	6 (8.5%)	4 (8.9%)
	DYSMENORRHEA	5 (7.0%)	4 (8.9%)
	AMENORRHEA	1 (1.4%)	0

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=163)	 Placebo (N=156)
TOTAL	TOTAL	144 (88.3%)	125 (80.1%)
Body as a Whole	TOTAL	106 (65.0%)	84 (53.8%)
	HEADACHE	62 (38.0%)	42 (26.9%)
	INFECTION	33 (20.2%)	25 (16.0%)
	ABDOMINAL PAIN	24 (14.7%)	15 (9.6%)
	ASTHENIA	24 (14.7%)	12 (7.7%)
	TRAUMA	14 (8.6%)	12 (7.7%)
	ALLERGIC REACTION	7 (4.3%)	4 (2.6%)
	FEVER	6 (3.7%)	3 (1.9%)
	FLU SYNDROME	4 (2.5%)	3 (1.9%)
	BACK PAIN	3 (1.8%)	7 (4.5%)
	PAIN	2 (1.2%)	2 (1.3%)
	MONILIASIS	2 (1.2%)	0
	CELLULITIS	1 (0.6%)	0
	RHEUMATOID ARTHRITIS	1 (0.6%)	0
	ABNORMAL LABORATORY VALUE	0	1 (0.6%)
	CHEST PAIN	0	1 (0.6%)
	CHILLS	0	1 (0.6%)
	NEOPLASM	0	1 (0.6%)
Nervous System	TOTAL	69 (42.3%)	36 (23.1%)
	INSOMNIA	23 (14.1%)	9 (5.8%)
	SOMNOLENCE	21 (12.9%)	13 (8.3%)
	NERVOUSNESS	14 (8.6%)	9 (5.8%)
	DIZZINESS	8 (4.9%)	10 (6.4%)
	HYPERKINESIA	6 (3.7%)	0
	HOSTILITY	5 (3.1%)	2 (1.3%)
	EMOTIONAL LABILITY	4 (2.5%)	2 (1.3%)
	AGITATION	3 (1.8%)	2 (1.3%)
	ABNORMAL DREAMS	3 (1.8%)	0
	DEPRESSION	3 (1.8%)	0
	MANIC REACTION	3 (1.8%)	0
	TREMOR	3 (1.8%)	0
	CONCENTRATION IMPAIRED	2 (1.2%)	2 (1.3%)
	LACK OF EMOTION	2 (1.2%)	0
	NEUROSIS	2 (1.2%)	0
	AMNESIA	1 (0.6%)	0
	DEPERSONALIZATION	1 (0.6%)	0
	LIBIDO DECREASED	1 (0.6%)	0
	MYOCLONUS	1 (0.6%)	0
	SPEECH DISORDER	1 (0.6%)	0
	ANXIETY	0	1 (0.6%)
	EXTRAPYRAMIDAL SYNDROME	0	1 (0.6%)

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=163)	Placebo (N=156)
Nervous System	HYPERTONIA	0	1 (0.6%)
	INCOORDINATION	0	1 (0.6%)
	VERTIGO	0	1 (0.6%)
Digestive System	TOTAL	60 (36.8%)	36 (23.1%)
	NAUSEA	17 (10.4%)	12 (7.7%)
	DECREASED APPETITE	13 (8.0%)	5 (3.2%)
	DYSPEPSIA	12 (7.4%)	6 (3.8%)
	VOMITING	11 (6.7%)	3 (1.9%)
	DIARRHEA	6 (3.7%)	7 (4.5%)
	INCREASED APPETITE	5 (3.1%)	2 (1.3%)
	DRY MOUTH	4 (2.5%)	5 (3.2%)
	FECAL INCONTINENCE	2 (1.2%)	1 (0.6%)
	STOMATITIS	2 (1.2%)	1 (0.6%)
	FLATULENCE	2 (1.2%)	0
	TOOTH DISORDER	1 (0.6%)	2 (1.3%)
	CONSTIPATION	1 (0.6%)	1 (0.6%)
	GINGIVITIS	1 (0.6%)	1 (0.6%)
	ULCERATIVE STOMATITIS	1 (0.6%)	1 (0.6%)
	GASTRITIS	1 (0.6%)	0
	GASTROINTESTINAL DISORDER	1 (0.6%)	0
	RECTAL DISORDER	1 (0.6%)	0
	GASTROENTERITIS	0	4 (2.6%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (0.6%)
	TOOTH CARIES	0	1 (0.6%)
Respiratory System	TOTAL	55 (33.7%)	64 (41.0%)
	RESPIRATORY DISORDER	25 (15.3%)	20 (12.8%)
	RHINITIS	17 (10.4%)	25 (16.0%)
	PHARYNGITIS	13 (8.0%)	14 (9.0%)
	COUGH INCREASED	9 (5.5%)	11 (7.1%)
	SINUSITIS	8 (4.9%)	7 (4.5%)
	BRONCHITIS	3 (1.8%)	3 (1.9%)
	ASTHMA	3 (1.8%)	1 (0.6%)
	EPISTAXIS	3 (1.8%)	1 (0.6%)
	YAWN	3 (1.8%)	1 (0.6%)
	PNEUMONIA	0	1 (0.6%)
Skin and Appendages	TOTAL	18 (11.0%)	13 (8.3%)
	RASH	8 (4.9%)	4 (2.6%)
	SWEATING	4 (2.5%)	1 (0.6%)
	CONTACT DERMATITIS	4 (2.5%)	0
	ACNE	1 (0.6%)	3 (1.9%)
	HERPES SIMPLEX	1 (0.6%)	1 (0.6%)

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=163)	Placebo (N=156)
Skin and Appendages	NAIL DISORDER	1 (0.6%)	0
	PRURITUS	1 (0.6%)	0
	VESICULOBULLOUS RASH	1 (0.6%)	0
	ECZEMA	0	2 (1.3%)
	FUNGAL DERMATITIS	0	1 (0.6%)
	PHOTOSENSITIVITY	0	1 (0.6%)
Special Senses	TOTAL	17 (10.4%)	7 (4.5%)
	OTITIS MEDIA	6 (3.7%)	2 (1.3%)
	CONJUNCTIVITIS	6 (3.7%)	1 (0.6%)
	EAR PAIN	4 (2.5%)	1 (0.6%)
	OTITIS EXTERNA	1 (0.6%)	1 (0.6%)
	MYDRIASIS	1 (0.6%)	0
	ABNORMAL VISION	0	1 (0.6%)
	PHOTOPHOBIA	0	1 (0.6%)
Musculoskeletal System	TOTAL	10 (6.1%)	9 (5.8%)
	MYALGIA	6 (3.7%)	5 (3.2%)
	ARTHRALGIA	4 (2.5%)	4 (2.6%)
	ARTHROSIS	0	1 (0.6%)
Metabolic and Nutritional Disorders	TOTAL	8 (4.9%)	7 (4.5%)
	WEIGHT GAIN	4 (2.5%)	3 (1.9%)
	THIRST	1 (0.6%)	1 (0.6%)
	WEIGHT LOSS	1 (0.6%)	1 (0.6%)
	HYPERKALEMIA	1 (0.6%)	0
	KETOSIS	1 (0.6%)	0
	BILIRUBINEMIA	0	1 (0.6%)
	HYPONATREMIA	0	1 (0.6%)
Cardiovascular System	TOTAL	7 (4.3%)	5 (3.2%)
	VASODILATATION	3 (1.8%)	1 (0.6%)
	HYPOTENSION	1 (0.6%)	2 (1.3%)
	SYNCOPE	1 (0.6%)	2 (1.3%)
	MIGRAINE	1 (0.6%)	0
	QT INTERVAL PROLONGED	1 (0.6%)	0
	TACHYCARDIA	0	1 (0.6%)
Urogenital System	TOTAL	7 (4.3%)	6 (3.8%)
	URINARY INCONTINENCE	5 (3.1%)	0
	ALBUMINURIA	2 (1.2%)	2 (1.3%)
	URINARY FREQUENCY	1 (0.6%)	1 (0.6%)
	URINE ABNORMALITY	1 (0.6%)	0

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=163)	Placebo (N=156)
Urogenital System	URINARY TRACT INFECTION	0	2 (1.3%)
	CYSTITIS	0	1 (0.6%)
	URINARY RETENTION	0	1 (0.6%)
Hemic and Lymphatic System	TOTAL	6 (3.7%)	2 (1.3%)
	PURPURA	4 (2.5%)	0
	LEUKOPENIA	1 (0.6%)	1 (0.6%)
	ANEMIA	1 (0.6%)	0
	LEUKOCYTOSIS	1 (0.6%)	0
	EOSINOPHILIA	0	1 (0.6%)
	POLYCYTHEMIA	0	1 (0.6%)

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Total, Male Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=71)	 Placebo (N=89)
TOTAL	TOTAL	1 (1.4%)	0
Urogenital System	TOTAL	1 (1.4%)	0
	ABNORMAL EJACULATION	1 (1.4%)	0

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Table 15.1.1.1

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Total, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=92)	 Placebo (N=67)
TOTAL	TOTAL	6 (6.5%)	4 (6.0%)
Urogenital System	TOTAL	6 (6.5%)	4 (6.0%)
	DYSMENORRHEA	5 (5.4%)	4 (6.0%)
	AMENORRHEA	1 (1.1%)	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 Treatment Phase
by Descending Order
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=45)
TOTAL	41 (89.1%)	34 (75.6%)
HEADACHE	15 (32.6%)	11 (24.4%)
ABDOMINAL PAIN	10 (21.7%)	5 (11.1%)
RESPIRATORY DISORDER	7 (15.2%)	3 (6.7%)
NERVOUSNESS	7 (15.2%)	2 (4.4%)
INFECTION	6 (13.0%)	8 (17.8%)
INSOMNIA	6 (13.0%)	3 (6.7%)
TRAUMA	5 (10.9%)	4 (8.9%)
RASH	5 (10.9%)	2 (4.4%)
OTITIS MEDIA	5 (10.9%)	1 (2.2%)
URINARY INCONTINENCE	5 (10.9%)	0
SOMNOLENCE	4 (8.7%)	5 (11.1%)
HYPERKINESIA	4 (8.7%)	0
COUGH INCREASED	3 (6.5%)	5 (11.1%)
DECREASED APPETITE	3 (6.5%)	2 (4.4%)
VOMITING	3 (6.5%)	2 (4.4%)
ASTHENIA	3 (6.5%)	1 (2.2%)
CONJUNCTIVITIS	3 (6.5%)	0
HOSTILITY	3 (6.5%)	0
PHARYNGITIS	2 (4.3%)	7 (15.6%)
DIARRHEA	2 (4.3%)	4 (8.9%)
NAUSEA	2 (4.3%)	4 (8.9%)
SINUSITIS	2 (4.3%)	3 (6.7%)
ALLERGIC REACTION	2 (4.3%)	2 (4.4%)
DYSPEPSIA	2 (4.3%)	2 (4.4%)
FECAL INCONTINENCE	2 (4.3%)	1 (2.2%)
FEVER	2 (4.3%)	1 (2.2%)
CONTACT DERMATITIS	2 (4.3%)	0
FLATULENCE	2 (4.3%)	0
VASODILATATION	2 (4.3%)	0
RHINITIS	1 (2.2%)	7 (15.6%)
CONCENTRATION IMPAIRED	1 (2.2%)	2 (4.4%)
ARTHRALGIA	1 (2.2%)	1 (2.2%)
BACK PAIN	1 (2.2%)	1 (2.2%)
DIZZINESS	1 (2.2%)	1 (2.2%)
EAR PAIN	1 (2.2%)	1 (2.2%)
EPISTAXIS	1 (2.2%)	1 (2.2%)
ALBUMINURIA	1 (2.2%)	0
ASTHMA	1 (2.2%)	0
INCREASED APPETITE	1 (2.2%)	0
LACK OF EMOTION	1 (2.2%)	0
MANIC REACTION	1 (2.2%)	0
MYALGIA	1 (2.2%)	0
NEUROSIS	1 (2.2%)	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 Treatment Phase
by Descending Order
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=45)
PURPURA	1 (2.2%)	0
SWEATING	1 (2.2%)	0
WEIGHT GAIN	1 (2.2%)	0
GASTROENTERITIS	0	2 (4.4%)
AGITATION	0	1 (2.2%)
BRONCHITIS	0	1 (2.2%)
ECZEMA	0	1 (2.2%)
PAIN	0	1 (2.2%)
TOOTH DISORDER	0	1 (2.2%)

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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 Treatment Phase
by Descending Order
Intention-To-Treat Population
Age Group : Children, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=25)	 Placebo (N=23)
TOTAL	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 Treatment Phase
by Descending Order
Intention-To-Treat Population
Age Group : Children, Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=21)	 Placebo (N=22)
TOTAL	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 Treatment Phase
by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=117)	 Placebo (N=111)
TOTAL	102 (87.2%)	88 (79.3%)
HEADACHE	47 (40.2%)	31 (27.9%)
INFECTION	27 (23.1%)	17 (15.3%)
ASTHENIA	21 (17.9%)	11 (9.9%)
RESPIRATORY DISORDER	18 (15.4%)	17 (15.3%)
SOMNOLENCE	17 (14.5%)	8 (7.2%)
INSOMNIA	17 (14.5%)	6 (5.4%)
RHINITIS	16 (13.7%)	18 (16.2%)
NAUSEA	15 (12.8%)	8 (7.2%)
ABDOMINAL PAIN	14 (12.0%)	10 (9.0%)
PHARYNGITIS	11 (9.4%)	7 (6.3%)
DYSPEPSIA	10 (8.5%)	4 (3.6%)
DECREASED APPETITE	10 (8.5%)	3 (2.7%)
TRAUMA	9 (7.7%)	8 (7.2%)
VOMITING	8 (6.8%)	1 (0.9%)
DIZZINESS	7 (6.0%)	9 (8.1%)
NERVOUSNESS	7 (6.0%)	7 (6.3%)
COUGH INCREASED	6 (5.1%)	6 (5.4%)
SINUSITIS	6 (5.1%)	4 (3.6%)
MYALGIA	5 (4.3%)	5 (4.5%)
ALLERGIC REACTION	5 (4.3%)	2 (1.8%)
DRY MOUTH	4 (3.4%)	5 (4.5%)
DIARRHEA	4 (3.4%)	3 (2.7%)
FLU SYNDROME	4 (3.4%)	3 (2.7%)
EMOTIONAL LABILITY	4 (3.4%)	2 (1.8%)
FEVER	4 (3.4%)	2 (1.8%)
INCREASED APPETITE	4 (3.4%)	2 (1.8%)
ARTHRALGIA	3 (2.6%)	3 (2.7%)
WEIGHT GAIN	3 (2.6%)	3 (2.7%)
BRONCHITIS	3 (2.6%)	2 (1.8%)
RASH	3 (2.6%)	2 (1.8%)
AGITATION	3 (2.6%)	1 (0.9%)
CONJUNCTIVITIS	3 (2.6%)	1 (0.9%)
SWEATING	3 (2.6%)	1 (0.9%)
YAWN	3 (2.6%)	1 (0.9%)
ABNORMAL DREAMS	3 (2.6%)	0
DEPRESSION	3 (2.6%)	0
EAR PAIN	3 (2.6%)	0
PURPURA	3 (2.6%)	0
TREMOR	3 (2.6%)	0
BACK PAIN	2 (1.7%)	6 (5.4%)
HOSTILITY	2 (1.7%)	2 (1.8%)
ASTHMA	2 (1.7%)	1 (0.9%)
PAIN	2 (1.7%)	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 Treatment Phase
by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=117)	 Placebo (N=111)
STOMATITIS	2 (1.7%)	1 (0.9%)
CONTACT DERMATITIS	2 (1.7%)	0
EPISTAXIS	2 (1.7%)	0
HYPERKINESIA	2 (1.7%)	0
MANIC REACTION	2 (1.7%)	0
MONILIASIS	2 (1.7%)	0
ACNE	1 (0.9%)	3 (2.7%)
ALBUMINURIA	1 (0.9%)	2 (1.8%)
HYPOTENSION	1 (0.9%)	2 (1.8%)
SYNCOPE	1 (0.9%)	2 (1.8%)
OTITIS MEDIA	1 (0.9%)	1 (0.9%)
TOOTH DISORDER	1 (0.9%)	1 (0.9%)
VASODILATATION	1 (0.9%)	1 (0.9%)
CONCENTRATION IMPAIRED	1 (0.9%)	0
LACK OF EMOTION	1 (0.9%)	0
NEUROSIS	1 (0.9%)	0
GASTROENTERITIS	0	2 (1.8%)
URINARY TRACT INFECTION	0	2 (1.8%)
ECZEMA	0	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 Treatment Phase
by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=66)
TOTAL	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 Treatment Phase
by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=71)	 Placebo (N=45)
TOTAL	5 (7.0%)	4 (8.9%)
DYSMENORRHEA	5 (7.0%)	4 (8.9%)

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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 Treatment Phase
by Descending Order
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=163)	 Placebo (N=156)
TOTAL	143 (87.7%)	122 (78.2%)
HEADACHE	62 (38.0%)	42 (26.9%)
INFECTION	33 (20.2%)	25 (16.0%)
RESPIRATORY DISORDER	25 (15.3%)	20 (12.8%)
ABDOMINAL PAIN	24 (14.7%)	15 (9.6%)
ASTHENIA	24 (14.7%)	12 (7.7%)
INSOMNIA	23 (14.1%)	9 (5.8%)
SOMNOLENCE	21 (12.9%)	13 (8.3%)
RHINITIS	17 (10.4%)	25 (16.0%)
NAUSEA	17 (10.4%)	12 (7.7%)
TRAUMA	14 (8.6%)	12 (7.7%)
NERVOUSNESS	14 (8.6%)	9 (5.8%)
PHARYNGITIS	13 (8.0%)	14 (9.0%)
DECREASED APPETITE	13 (8.0%)	5 (3.2%)
DYSPEPSIA	12 (7.4%)	6 (3.8%)
VOMITING	11 (6.7%)	3 (1.9%)
COUGH INCREASED	9 (5.5%)	11 (7.1%)
DIZZINESS	8 (4.9%)	10 (6.4%)
SINUSITIS	8 (4.9%)	7 (4.5%)
RASH	8 (4.9%)	4 (2.6%)
ALLERGIC REACTION	7 (4.3%)	4 (2.6%)
DIARRHEA	6 (3.7%)	7 (4.5%)
MYALGIA	6 (3.7%)	5 (3.2%)
FEVER	6 (3.7%)	3 (1.9%)
OTITIS MEDIA	6 (3.7%)	2 (1.3%)
CONJUNCTIVITIS	6 (3.7%)	1 (0.6%)
HYPERKINESIA	6 (3.7%)	0
HOSTILITY	5 (3.1%)	2 (1.3%)
INCREASED APPETITE	5 (3.1%)	2 (1.3%)
URINARY INCONTINENCE	5 (3.1%)	0
DRY MOUTH	4 (2.5%)	5 (3.2%)
ARTHRALGIA	4 (2.5%)	4 (2.6%)
FLU SYNDROME	4 (2.5%)	3 (1.9%)
WEIGHT GAIN	4 (2.5%)	3 (1.9%)
EMOTIONAL LABILITY	4 (2.5%)	2 (1.3%)
EAR PAIN	4 (2.5%)	1 (0.6%)
SWEATING	4 (2.5%)	1 (0.6%)
CONTACT DERMATITIS	4 (2.5%)	0
PURPURA	4 (2.5%)	0
BACK PAIN	3 (1.8%)	7 (4.5%)
BRONCHITIS	3 (1.8%)	3 (1.9%)
AGITATION	3 (1.8%)	2 (1.3%)
ASTHMA	3 (1.8%)	1 (0.6%)
EPISTAXIS	3 (1.8%)	1 (0.6%)

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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 Treatment Phase
by Descending Order
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=163)	 Placebo (N=156)
VASODILATATION	3 (1.8%)	1 (0.6%)
YAWN	3 (1.8%)	1 (0.6%)
ABNORMAL DREAMS	3 (1.8%)	0
DEPRESSION	3 (1.8%)	0
MANIC REACTION	3 (1.8%)	0
TREMOR	3 (1.8%)	0
ALBUMINURIA	2 (1.2%)	2 (1.3%)
CONCENTRATION IMPAIRED	2 (1.2%)	2 (1.3%)
PAIN	2 (1.2%)	2 (1.3%)
FECAL INCONTINENCE	2 (1.2%)	1 (0.6%)
STOMATITIS	2 (1.2%)	1 (0.6%)
FLATULENCE	2 (1.2%)	0
LACK OF EMOTION	2 (1.2%)	0
MONILIASIS	2 (1.2%)	0
NEUROSIS	2 (1.2%)	0
ACNE	1 (0.6%)	3 (1.9%)
HYPOTENSION	1 (0.6%)	2 (1.3%)
SYNCOPE	1 (0.6%)	2 (1.3%)
TOOTH DISORDER	1 (0.6%)	2 (1.3%)
GASTROENTERITIS	0	4 (2.6%)
ECZEMA	0	2 (1.3%)
URINARY TRACT INFECTION	0	2 (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 Treatment Phase
by Descending Order
Intention-To-Treat Population
Age Group : Total, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=71)	 Placebo (N=89)
TOTAL	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 Treatment Phase
by Descending Order
Intention-To-Treat Population
Age Group : Total, Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=92)	 Placebo (N=67)
TOTAL	5 (5.4%)	4 (6.0%)
DYSMENORRHEA	5 (5.4%)	4 (6.0%)

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
By Body System
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=25)	Placebo (N=29)
TOTAL	TOTAL	10 (40.0%)	6 (20.7%)
Body as a Whole	TOTAL	5 (20.0%)	1 (3.4%)
	HEADACHE	3 (12.0%)	1 (3.4%)
	TRAUMA	2 (8.0%)	0
	ABDOMINAL PAIN	1 (4.0%)	0
	FLU SYNDROME	1 (4.0%)	0
Nervous System	TOTAL	3 (12.0%)	1 (3.4%)
	DIZZINESS	1 (4.0%)	0
	INSOMNIA	1 (4.0%)	0
	NERVOUSNESS	1 (4.0%)	0
	ANXIETY	0	1 (3.4%)
Digestive System	TOTAL	2 (8.0%)	0
	DIARRHEA	1 (4.0%)	0
	NAUSEA	1 (4.0%)	0
Respiratory System	TOTAL	2 (8.0%)	3 (10.3%)
	RHINITIS	1 (4.0%)	1 (3.4%)
	SINUSITIS	1 (4.0%)	0
	COUGH INCREASED	0	1 (3.4%)
	PHARYNGITIS	0	1 (3.4%)
	RESPIRATORY DISORDER	0	1 (3.4%)
Urogenital System	TOTAL	0	1 (3.4%)
	PYURIA	0	1 (3.4%)

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
By Body System
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=12)	Placebo (N=15)
Body System	Preferred Term		
TOTAL	TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=13)	Placebo (N=14)
Body System	Preferred Term		
TOTAL	TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=81)	Placebo (N=79)
TOTAL	TOTAL	23 (28.4%)	16 (20.3%)
Body as a Whole	TOTAL	11 (13.6%)	12 (15.2%)
	HEADACHE	5 (6.2%)	7 (8.9%)
	ABDOMINAL PAIN	3 (3.7%)	2 (2.5%)
	ASTHENIA	1 (1.2%)	1 (1.3%)
	INFECTION	1 (1.2%)	1 (1.3%)
	TRAUMA	1 (1.2%)	1 (1.3%)
	ALLERGIC REACTION	1 (1.2%)	0
	BACK PAIN	0	1 (1.3%)
Nervous System	TOTAL	9 (11.1%)	2 (2.5%)
	DIZZINESS	4 (4.9%)	0
	NERVOUSNESS	3 (3.7%)	1 (1.3%)
	SOMNOLENCE	2 (2.5%)	0
	EMOTIONAL LABILITY	1 (1.2%)	0
	MYOCLONUS	1 (1.2%)	0
	VERTIGO	1 (1.2%)	0
	ANXIETY	0	1 (1.3%)
Digestive System	TOTAL	3 (3.7%)	0
	NAUSEA	3 (3.7%)	0
Respiratory System	TOTAL	3 (3.7%)	5 (6.3%)
	RESPIRATORY DISORDER	1 (1.2%)	3 (3.8%)
	PHARYNGITIS	1 (1.2%)	0
	SINUSITIS	1 (1.2%)	0
	LARYNX DISORDER	0	2 (2.5%)
	COUGH INCREASED	0	1 (1.3%)
Cardiovascular System	TOTAL	1 (1.2%)	0
	HYPOTENSION	1 (1.2%)	0
Special Senses	TOTAL	1 (1.2%)	0
	ABNORMAL VISION	1 (1.2%)	0

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
By Body System
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=30)	Placebo (N=48)
Body System	Preferred Term		
TOTAL	TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=51)	Placebo (N=31)
Body System	Preferred Term		
TOTAL	TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=106)	Placebo (N=108)
TOTAL	TOTAL	33 (31.1%)	22 (20.4%)
Body as a Whole	TOTAL	16 (15.1%)	13 (12.0%)
	HEADACHE	8 (7.5%)	8 (7.4%)
	ABDOMINAL PAIN	4 (3.8%)	2 (1.9%)
	TRAUMA	3 (2.8%)	1 (0.9%)
	ASTHENIA	1 (0.9%)	1 (0.9%)
	INFECTION	1 (0.9%)	1 (0.9%)
	ALLERGIC REACTION	1 (0.9%)	0
	FLU SYNDROME	1 (0.9%)	0
	BACK PAIN	0	1 (0.9%)
Nervous System	TOTAL	12 (11.3%)	3 (2.8%)
	DIZZINESS	5 (4.7%)	0
	NERVOUSNESS	4 (3.8%)	1 (0.9%)
	SOMNOLENCE	2 (1.9%)	0
	EMOTIONAL LABILITY	1 (0.9%)	0
	INSOMNIA	1 (0.9%)	0
	MYOCLONUS	1 (0.9%)	0
	VERTIGO	1 (0.9%)	0
	ANXIETY	0	2 (1.9%)
Digestive System	TOTAL	5 (4.7%)	0
	NAUSEA	4 (3.8%)	0
	DIARRHEA	1 (0.9%)	0
Respiratory System	TOTAL	5 (4.7%)	8 (7.4%)
	SINUSITIS	2 (1.9%)	0
	RESPIRATORY DISORDER	1 (0.9%)	4 (3.7%)
	PHARYNGITIS	1 (0.9%)	1 (0.9%)
	RHINITIS	1 (0.9%)	1 (0.9%)
	COUGH INCREASED	0	2 (1.9%)
	LARYNX DISORDER	0	2 (1.9%)
Cardiovascular System	TOTAL	1 (0.9%)	0
	HYPOTENSION	1 (0.9%)	0
Special Senses	TOTAL	1 (0.9%)	0
	ABNORMAL VISION	1 (0.9%)	0
Urogenital System	TOTAL	0	1 (0.9%)
	PYURIA	0	1 (0.9%)

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
By Body System
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=42)	Placebo (N=63)
Body System	Preferred Term		
TOTAL	TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=64)	Placebo (N=45)
Body System	Preferred Term		
TOTAL	TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=25)	 Placebo (N=29)
TOTAL	7 (28.0%)	4 (13.8%)
HEADACHE	3 (12.0%)	1 (3.4%)
TRAUMA	2 (8.0%)	0
ABDOMINAL PAIN	1 (4.0%)	0
DIZZINESS	1 (4.0%)	0
NAUSEA	1 (4.0%)	0
NERVOUSNESS	1 (4.0%)	0
SINUSITIS	1 (4.0%)	0
ANXIETY	0	1 (3.4%)
COUGH INCREASED	0	1 (3.4%)
RESPIRATORY DISORDER	0	1 (3.4%)

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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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=12)	Treatment Group: Placebo (N=15)
TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=13)	Treatment Group: Placebo (N=14)
TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=81)	 Placebo (N=79)
TOTAL	19 (23.5%)	14 (17.7%)
HEADACHE	5 (6.2%)	7 (8.9%)
DIZZINESS	4 (4.9%)	0
ABDOMINAL PAIN	3 (3.7%)	2 (2.5%)
NERVOUSNESS	3 (3.7%)	1 (1.3%)
NAUSEA	3 (3.7%)	0
SOMNOLENCE	2 (2.5%)	0
RESPIRATORY DISORDER	1 (1.2%)	3 (3.8%)
TRAUMA	1 (1.2%)	1 (1.3%)
SINUSITIS	1 (1.2%)	0
LARYNX DISORDER	0	2 (2.5%)
ANXIETY	0	1 (1.3%)
COUGH INCREASED	0	1 (1.3%)

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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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=30)	 Placebo (N=48)
TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=51)	Treatment Group: Placebo (N=31)
TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=106)	 Placebo (N=108)
TOTAL	26 (24.5%)	18 (16.7%)
HEADACHE	8 (7.5%)	8 (7.4%)
DIZZINESS	5 (4.7%)	0
ABDOMINAL PAIN	4 (3.8%)	2 (1.9%)
NERVOUSNESS	4 (3.8%)	1 (0.9%)
NAUSEA	4 (3.8%)	0
TRAUMA	3 (2.8%)	1 (0.9%)
SINUSITIS	2 (1.9%)	0
SOMNOLENCE	2 (1.9%)	0
RESPIRATORY DISORDER	1 (0.9%)	4 (3.7%)
ANXIETY	0	2 (1.9%)
COUGH INCREASED	0	2 (1.9%)
LARYNX DISORDER	0	2 (1.9%)

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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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=42)	Treatment Group: Placebo (N=63)
TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=64)	Treatment Group: Placebo (N=45)
TOTAL	0	0

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase or Taper Phase
By Body System
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
TOTAL	TOTAL	145 (89.0%)	125 (80.1%)
Body as a Whole	TOTAL	110 (67.5%)	86 (55.1%)
	HEADACHE	67 (41.1%)	45 (28.8%)
	INFECTION	34 (20.9%)	26 (16.7%)
	ABDOMINAL PAIN	28 (17.2%)	16 (10.3%)
	ASTHENIA	25 (15.3%)	12 (7.7%)
	TRAUMA	17 (10.4%)	13 (8.3%)
	ALLERGIC REACTION	8 (4.9%)	4 (2.6%)
	FEVER	6 (3.7%)	3 (1.9%)
	FLU SYNDROME	5 (3.1%)	3 (1.9%)
	BACK PAIN	3 (1.8%)	8 (5.1%)
	PAIN	2 (1.2%)	2 (1.3%)
	MONILIASIS	2 (1.2%)	0
	CELLULITIS	1 (0.6%)	0
	RHEUMATOID ARTHRITIS	1 (0.6%)	0
	ABNORMAL LABORATORY VALUE	0	1 (0.6%)
	CHEST PAIN	0	1 (0.6%)
	CHILLS	0	1 (0.6%)
	NEOPLASM	0	1 (0.6%)
Nervous System	TOTAL	75 (46.0%)	38 (24.4%)
	INSOMNIA	24 (14.7%)	9 (5.8%)
	SOMNOLENCE	23 (14.1%)	13 (8.3%)
	NERVOUSNESS	15 (9.2%)	10 (6.4%)
	DIZZINESS	13 (8.0%)	10 (6.4%)
	HYPERKINESIA	6 (3.7%)	0
	EMOTIONAL LABILITY	5 (3.1%)	2 (1.3%)
	HOSTILITY	5 (3.1%)	2 (1.3%)
	AGITATION	3 (1.8%)	2 (1.3%)
	ABNORMAL DREAMS	3 (1.8%)	0
	DEPRESSION	3 (1.8%)	0
	MANIC REACTION	3 (1.8%)	0
	TREMOR	3 (1.8%)	0
	CONCENTRATION IMPAIRED	2 (1.2%)	2 (1.3%)
	LACK OF EMOTION	2 (1.2%)	0
	MYOCLONUS	2 (1.2%)	0
	NEUROSIS	2 (1.2%)	0
	VERTIGO	1 (0.6%)	1 (0.6%)
	AMNESIA	1 (0.6%)	0
	DEPERSONALIZATION	1 (0.6%)	0
	LIBIDO DECREASED	1 (0.6%)	0
	SPEECH DISORDER	1 (0.6%)	0
	ANXIETY	0	3 (1.9%)

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase or Taper Phase
By Body System
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
Nervous System	EXTRAPYRAMIDAL SYNDROME	0	1 (0.6%)
	HYPERTONIA	0	1 (0.6%)
	INCOORDINATION	0	1 (0.6%)
Digestive System	TOTAL	62 (38.0%)	36 (23.1%)
	NAUSEA	21 (12.9%)	12 (7.7%)
	DECREASED APPETITE	13 (8.0%)	5 (3.2%)
	DYSPEPSIA	12 (7.4%)	6 (3.8%)
	VOMITING	11 (6.7%)	3 (1.9%)
	DIARRHEA	6 (3.7%)	7 (4.5%)
	INCREASED APPETITE	5 (3.1%)	2 (1.3%)
	DRY MOUTH	4 (2.5%)	5 (3.2%)
	FECAL INCONTINENCE	2 (1.2%)	1 (0.6%)
	STOMATITIS	2 (1.2%)	1 (0.6%)
	FLATULENCE	2 (1.2%)	0
	TOOTH DISORDER	1 (0.6%)	2 (1.3%)
	CONSTIPATION	1 (0.6%)	1 (0.6%)
	GINGIVITIS	1 (0.6%)	1 (0.6%)
	ULCERATIVE STOMATITIS	1 (0.6%)	1 (0.6%)
	GASTRITIS	1 (0.6%)	0
	GASTROINTESTINAL DISORDER	1 (0.6%)	0
	RECTAL DISORDER	1 (0.6%)	0
	GASTROENTERITIS	0	4 (2.6%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (0.6%)
	TOOTH CARIES	0	1 (0.6%)
Respiratory System	TOTAL	60 (36.8%)	69 (44.2%)
	RESPIRATORY DISORDER	26 (16.0%)	24 (15.4%)
	RHINITIS	18 (11.0%)	26 (16.7%)
	PHARYNGITIS	14 (8.6%)	14 (9.0%)
	SINUSITIS	10 (6.1%)	7 (4.5%)
	COUGH INCREASED	9 (5.5%)	13 (8.3%)
	BRONCHITIS	3 (1.8%)	3 (1.9%)
	ASTHMA	3 (1.8%)	1 (0.6%)
	EPISTAXIS	3 (1.8%)	1 (0.6%)
	YAWN	3 (1.8%)	1 (0.6%)
	LARYNX DISORDER	0	2 (1.3%)
	PNEUMONIA	0	1 (0.6%)
Skin and Appendages	TOTAL	18 (11.0%)	13 (8.3%)
	RASH	8 (4.9%)	4 (2.6%)
	SWEATING	4 (2.5%)	1 (0.6%)
	CONTACT DERMATITIS	4 (2.5%)	0
	ACNE	1 (0.6%)	3 (1.9%)

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase or Taper Phase
By Body System
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
Skin and Appendages	HERPES SIMPLEX	1 (0.6%)	1 (0.6%)
	NAIL DISORDER	1 (0.6%)	0
	PRURITUS	1 (0.6%)	0
	VESICULOBULLOUS RASH	1 (0.6%)	0
	ECZEMA	0	2 (1.3%)
	FUNGAL DERMATITIS	0	1 (0.6%)
	PHOTOSENSITIVITY	0	1 (0.6%)
Special Senses	TOTAL	18 (11.0%)	7 (4.5%)
	OTITIS MEDIA	6 (3.7%)	2 (1.3%)
	CONJUNCTIVITIS	6 (3.7%)	1 (0.6%)
	EAR PAIN	4 (2.5%)	1 (0.6%)
	ABNORMAL VISION	1 (0.6%)	1 (0.6%)
	OTITIS EXTERNA	1 (0.6%)	1 (0.6%)
	MYDRIASIS	1 (0.6%)	0
	PHOTOPHOBIA	0	1 (0.6%)
Musculoskeletal System	TOTAL	10 (6.1%)	9 (5.8%)
	MYALGIA	6 (3.7%)	5 (3.2%)
	ARTHRALGIA	4 (2.5%)	4 (2.6%)
	ARTHROSIS	0	1 (0.6%)
Metabolic and Nutritional Disorders	TOTAL	8 (4.9%)	7 (4.5%)
	WEIGHT GAIN	4 (2.5%)	3 (1.9%)
	THIRST	1 (0.6%)	1 (0.6%)
	WEIGHT LOSS	1 (0.6%)	1 (0.6%)
	HYPERKALEMIA	1 (0.6%)	0
	KETOSIS	1 (0.6%)	0
	BILIRUBINEMIA	0	1 (0.6%)
	HYPONATREMIA	0	1 (0.6%)
Cardiovascular System	TOTAL	7 (4.3%)	5 (3.2%)
	VASODILATATION	3 (1.8%)	1 (0.6%)
	HYPOTENSION	1 (0.6%)	2 (1.3%)
	SYNCOPE	1 (0.6%)	2 (1.3%)
	MIGRAINE	1 (0.6%)	0
	QT INTERVAL PROLONGED	1 (0.6%)	0
	TACHYCARDIA	0	1 (0.6%)
Urogenital System	TOTAL	7 (4.3%)	7 (4.5%)
	URINARY INCONTINENCE	5 (3.1%)	0
	ALBUMINURIA	2 (1.2%)	2 (1.3%)
	URINARY FREQUENCY	1 (0.6%)	1 (0.6%)

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase or Taper Phase
By Body System
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=163)	Placebo (N=156)
Urogenital System	URINE ABNORMALITY	1 (0.6%)	0
	URINARY TRACT INFECTION	0	2 (1.3%)
	CYSTITIS	0	1 (0.6%)
	PYURIA	0	1 (0.6%)
	URINARY RETENTION	0	1 (0.6%)
Hemic and Lymphatic System	TOTAL	6 (3.7%)	2 (1.3%)
	PURPURA	4 (2.5%)	0
	LEUKOPENIA	1 (0.6%)	1 (0.6%)
	ANEMIA	1 (0.6%)	0
	LEUKOCYTOSIS	1 (0.6%)	0
	EOSINOPHILIA	0	1 (0.6%)
	POLYCYTHEMIA	0	1 (0.6%)

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase or Taper Phase
By Body System
Intention-To-Treat Population
Male Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=71)	Treatment Group: Placebo (N=89)
TOTAL	TOTAL	1 (1.4%)	0
Urogenital System	TOTAL	1 (1.4%)	0
	ABNORMAL EJACULATION	1 (1.4%)	0

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Table 15.1.1.3

Number (%) of Patients With Emergent Adverse Experiences During the Treatment Phase or Taper Phase
By Body System
Intention-To-Treat Population
Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=92)	Treatment Group: Placebo (N=67)
TOTAL	TOTAL	6 (6.5%)	4 (6.0%)
Urogenital System	TOTAL	6 (6.5%)	4 (6.0%)
	DYSMENORRHEA	5 (5.4%)	4 (6.0%)
	AMENORRHEA	1 (1.1%)	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 Treatment Phase or Taper Phase by Descending Order
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
TOTAL	144 (88.3%)	122 (78.2%)
HEADACHE	67 (41.1%)	45 (28.8%)
INFECTION	34 (20.9%)	26 (16.7%)
ABDOMINAL PAIN	28 (17.2%)	16 (10.3%)
RESPIRATORY DISORDER	26 (16.0%)	24 (15.4%)
ASTHENIA	25 (15.3%)	12 (7.7%)
INSOMNIA	24 (14.7%)	9 (5.8%)
SOMNOLENCE	23 (14.1%)	13 (8.3%)
NAUSEA	21 (12.9%)	12 (7.7%)
RHINITIS	18 (11.0%)	26 (16.7%)
TRAUMA	17 (10.4%)	13 (8.3%)
NERVOUSNESS	15 (9.2%)	10 (6.4%)
PHARYNGITIS	14 (8.6%)	14 (9.0%)
DIZZINESS	13 (8.0%)	10 (6.4%)
DECREASED APPETITE	13 (8.0%)	5 (3.2%)
DYSPEPSIA	12 (7.4%)	6 (3.8%)
VOMITING	11 (6.7%)	3 (1.9%)
SINUSITIS	10 (6.1%)	7 (4.5%)
COUGH INCREASED	9 (5.5%)	13 (8.3%)
ALLERGIC REACTION	8 (4.9%)	4 (2.6%)
RASH	8 (4.9%)	4 (2.6%)
DIARRHEA	6 (3.7%)	7 (4.5%)
MYALGIA	6 (3.7%)	5 (3.2%)
FEVER	6 (3.7%)	3 (1.9%)
OTITIS MEDIA	6 (3.7%)	2 (1.3%)
CONJUNCTIVITIS	6 (3.7%)	1 (0.6%)
HYPERKINESIA	6 (3.7%)	0
FLU SYNDROME	5 (3.1%)	3 (1.9%)
EMOTIONAL LABILITY	5 (3.1%)	2 (1.3%)
HOSTILITY	5 (3.1%)	2 (1.3%)
INCREASED APPETITE	5 (3.1%)	2 (1.3%)
URINARY INCONTINENCE	5 (3.1%)	0
DRY MOUTH	4 (2.5%)	5 (3.2%)
ARTHRALGIA	4 (2.5%)	4 (2.6%)
WEIGHT GAIN	4 (2.5%)	3 (1.9%)
EAR PAIN	4 (2.5%)	1 (0.6%)
SWEATING	4 (2.5%)	1 (0.6%)
CONTACT DERMATITIS	4 (2.5%)	0
PURPURA	4 (2.5%)	0
BACK PAIN	3 (1.8%)	8 (5.1%)
BRONCHITIS	3 (1.8%)	3 (1.9%)
AGITATION	3 (1.8%)	2 (1.3%)
ASTHMA	3 (1.8%)	1 (0.6%)
EPISTAXIS	3 (1.8%)	1 (0.6%)

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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 Treatment Phase or Taper Phase by Descending Order
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
VASODILATATION	3 (1.8%)	1 (0.6%)
YAWN	3 (1.8%)	1 (0.6%)
ABNORMAL DREAMS	3 (1.8%)	0
DEPRESSION	3 (1.8%)	0
MANIC REACTION	3 (1.8%)	0
TREMOR	3 (1.8%)	0
ALBUMINURIA	2 (1.2%)	2 (1.3%)
CONCENTRATION IMPAIRED	2 (1.2%)	2 (1.3%)
PAIN	2 (1.2%)	2 (1.3%)
FECAL INCONTINENCE	2 (1.2%)	1 (0.6%)
STOMATITIS	2 (1.2%)	1 (0.6%)
FLATULENCE	2 (1.2%)	0
LACK OF EMOTION	2 (1.2%)	0
MONILIASIS	2 (1.2%)	0
MYOCLONUS	2 (1.2%)	0
NEUROSIS	2 (1.2%)	0
ACNE	1 (0.6%)	3 (1.9%)
HYPOTENSION	1 (0.6%)	2 (1.3%)
SYNCOPE	1 (0.6%)	2 (1.3%)
TOOTH DISORDER	1 (0.6%)	2 (1.3%)
GASTROENTERITIS	0	4 (2.6%)
ANXIETY	0	3 (1.9%)
ECZEMA	0	2 (1.3%)
LARYNX DISORDER	0	2 (1.3%)
URINARY TRACT INFECTION	0	2 (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 Treatment Phase or Taper Phase by Descending Order
Intention-To-Treat Population
Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=71)	Treatment Group: Placebo (N=89)
TOTAL	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 Treatment Phase or Taper Phase by Descending Order
Intention-To-Treat Population
Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=92)	Treatment Group: Placebo (N=67)
TOTAL	5 (5.4%)	4 (6.0%)
DYSMENORRHEA	5 (5.4%)	4 (6.0%)

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-up Phase
By Body System
Intention-To-Treat Population Entering The Follow-Up Phase
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=118)	Placebo (N=100)
TOTAL	TOTAL	54 (45.8%)	27 (27.0%)
Body as a Whole	TOTAL	25 (21.2%)	12 (12.0%)
	HEADACHE	16 (13.6%)	7 (7.0%)
	ABDOMINAL PAIN	6 (5.1%)	1 (1.0%)
	ASTHENIA	4 (3.4%)	1 (1.0%)
	INFECTION	2 (1.7%)	3 (3.0%)
	TRAUMA	1 (0.8%)	1 (1.0%)
	FEVER	1 (0.8%)	0
	FLU SYNDROME	1 (0.8%)	0
Nervous System	TOTAL	25 (21.2%)	6 (6.0%)
	DIZZINESS	13 (11.0%)	2 (2.0%)
	ANXIETY	4 (3.4%)	1 (1.0%)
	EMOTIONAL LABILITY	3 (2.5%)	0
	NERVOUSNESS	3 (2.5%)	0
	INSOMNIA	2 (1.7%)	1 (1.0%)
	DEPRESSION	2 (1.7%)	0
	SOMNOLENCE	1 (0.8%)	1 (1.0%)
	TREMOR	1 (0.8%)	1 (1.0%)
	HYPERKINESIA	1 (0.8%)	0
	LACK OF EMOTION	1 (0.8%)	0
	MYOCLONUS	1 (0.8%)	0
	WITHDRAWAL SYNDROME	1 (0.8%)	0
	AGITATION	0	1 (1.0%)
Digestive System	TOTAL	18 (15.3%)	6 (6.0%)
	NAUSEA	12 (10.2%)	3 (3.0%)
	VOMITING	3 (2.5%)	1 (1.0%)
	DYSPEPSIA	2 (1.7%)	0
	DECREASED APPETITE	1 (0.8%)	1 (1.0%)
	DIARRHEA	1 (0.8%)	0
	FLATULENCE	1 (0.8%)	0
	DRY MOUTH	0	1 (1.0%)
	GINGIVITIS	0	1 (1.0%)
Respiratory System	TOTAL	7 (5.9%)	6 (6.0%)
	RESPIRATORY DISORDER	3 (2.5%)	3 (3.0%)
	PHARYNGITIS	1 (0.8%)	2 (2.0%)
	RHINITIS	1 (0.8%)	2 (2.0%)
	ASTHMA	1 (0.8%)	0
	SINUSITIS	1 (0.8%)	0
Cardiovascular System	TOTAL	2 (1.7%)	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
Intention-To-Treat Population Entering The Follow-Up Phase
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=118)	Placebo (N=100)
Cardiovascular System	PALPITATION	1 (0.8%)	0
	SYNCOPE	1 (0.8%)	0
Hemic and Lymphatic System	TOTAL	2 (1.7%)	0
	HYPOCHROMIC ANEMIA	1 (0.8%)	0
	LYMPHADENOPATHY	1 (0.8%)	0
Musculoskeletal System	TOTAL	1 (0.8%)	1 (1.0%)
	MYALGIA	1 (0.8%)	1 (1.0%)
Skin and Appendages	TOTAL	1 (0.8%)	1 (1.0%)
	SWEATING	1 (0.8%)	0
	CONTACT DERMATITIS	0	1 (1.0%)
Special Senses	TOTAL	1 (0.8%)	0
	EAR PAIN	1 (0.8%)	0
Urogenital System	TOTAL	0	2 (2.0%)
	URINARY FREQUENCY	0	1 (1.0%)
	URINARY INCONTINENCE	0	1 (1.0%)
	URINARY TRACT INFECTION	0	1 (1.0%)

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-up Phase
By Body System
Intention-To-Treat Population Entering The Follow-Up Phase
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=57)
Body System	Preferred Term		
TOTAL	TOTAL	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
Intention-To-Treat Population Entering The Follow-Up Phase
Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=65)	Placebo (N=43)
Body System	Preferred Term		
TOTAL	TOTAL	0	1 (2.3%)
Urogenital System	TOTAL	0	1 (2.3%)
	DYSMENORRHEA	0	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
Intention-To-Treat Population Entering The Follow-Up Phase
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=118)	 Placebo (N=100)
TOTAL	47 (39.8%)	27 (27.0%)
HEADACHE	16 (13.6%)	7 (7.0%)
DIZZINESS	13 (11.0%)	2 (2.0%)
NAUSEA	12 (10.2%)	3 (3.0%)
ABDOMINAL PAIN	6 (5.1%)	1 (1.0%)
ANXIETY	4 (3.4%)	1 (1.0%)
ASTHENIA	4 (3.4%)	1 (1.0%)
RESPIRATORY DISORDER	3 (2.5%)	3 (3.0%)
VOMITING	3 (2.5%)	1 (1.0%)
EMOTIONAL LABILITY	3 (2.5%)	0
NERVOUSNESS	3 (2.5%)	0
INFECTION	2 (1.7%)	3 (3.0%)
INSOMNIA	2 (1.7%)	1 (1.0%)
DEPRESSION	2 (1.7%)	0
DYSPEPSIA	2 (1.7%)	0
PHARYNGITIS	1 (0.8%)	2 (2.0%)
RHINITIS	1 (0.8%)	2 (2.0%)
DECREASED APPETITE	1 (0.8%)	1 (1.0%)
MYALGIA	1 (0.8%)	1 (1.0%)
SOMNOLENCE	1 (0.8%)	1 (1.0%)
TRAUMA	1 (0.8%)	1 (1.0%)
TREMOR	1 (0.8%)	1 (1.0%)
AGITATION	0	1 (1.0%)
CONTACT DERMATITIS	0	1 (1.0%)
DRY MOUTH	0	1 (1.0%)
GINGIVITIS	0	1 (1.0%)
URINARY FREQUENCY	0	1 (1.0%)
URINARY INCONTINENCE	0	1 (1.0%)
URINARY TRACT INFECTION	0	1 (1.0%)

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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
Intention-To-Treat Population Entering The Follow-Up Phase
Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=53)	 Placebo (N=57)
TOTAL	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
Intention-To-Treat Population Entering The Follow-Up Phase
Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=65)	 Placebo (N=43)
TOTAL	0	1 (2.3%)
DYSMENORRHEA	0	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
Intention-To-Treat Population Entering The Taper Phase or Follow-Up Phase
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=144)	 Placebo (N=129)
TOTAL	TOTAL	68 (47.2%)	42 (32.6%)
Body as a Whole	TOTAL	38 (26.4%)	22 (17.1%)
	HEADACHE	22 (15.3%)	14 (10.9%)
	ABDOMINAL PAIN	10 (6.9%)	2 (1.6%)
	ASTHENIA	5 (3.5%)	2 (1.6%)
	INFECTION	3 (2.1%)	4 (3.1%)
	TRAUMA	3 (2.1%)	2 (1.6%)
	FLU SYNDROME	2 (1.4%)	0
	ALLERGIC REACTION	1 (0.7%)	0
	FEVER	1 (0.7%)	0
	BACK PAIN	0	1 (0.8%)
Nervous System	TOTAL	35 (24.3%)	9 (7.0%)
	DIZZINESS	16 (11.1%)	2 (1.6%)
	NERVOUSNESS	7 (4.9%)	1 (0.8%)
	ANXIETY	4 (2.8%)	3 (2.3%)
	EMOTIONAL LABILITY	4 (2.8%)	0
	INSOMNIA	3 (2.1%)	1 (0.8%)
	SOMNOLENCE	3 (2.1%)	1 (0.8%)
	DEPRESSION	2 (1.4%)	0
	TREMOR	1 (0.7%)	1 (0.8%)
	HYPERKINESIA	1 (0.7%)	0
	LACK OF EMOTION	1 (0.7%)	0
	MYOCLONUS	1 (0.7%)	0
	VERTIGO	1 (0.7%)	0
	WITHDRAWAL SYNDROME	1 (0.7%)	0
	AGITATION	0	1 (0.8%)
Digestive System	TOTAL	22 (15.3%)	6 (4.7%)
	NAUSEA	16 (11.1%)	3 (2.3%)
	VOMITING	3 (2.1%)	1 (0.8%)
	DIARRHEA	2 (1.4%)	0
	DYSPEPSIA	2 (1.4%)	0
	DECREASED APPETITE	1 (0.7%)	1 (0.8%)
	FLATULENCE	1 (0.7%)	0
	DRY MOUTH	0	1 (0.8%)
	GINGIVITIS	0	1 (0.8%)
Respiratory System	TOTAL	12 (8.3%)	14 (10.9%)
	RESPIRATORY DISORDER	4 (2.8%)	7 (5.4%)
	SINUSITIS	3 (2.1%)	0
	PHARYNGITIS	2 (1.4%)	3 (2.3%)
	RHINITIS	2 (1.4%)	3 (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
Intention-To-Treat Population Entering The Taper Phase or Follow-Up Phase
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=144)	Treatment Group Placebo (N=129)
Respiratory System	ASTHMA	1 (0.7%)	0
	COUGH INCREASED	0	2 (1.6%)
	LARYNX DISORDER	0	2 (1.6%)
Cardiovascular System	TOTAL	3 (2.1%)	0
	HYPOTENSION	1 (0.7%)	0
	PALPITATION	1 (0.7%)	0
	SYNCOPE	1 (0.7%)	0
Hemic and Lymphatic System	TOTAL	2 (1.4%)	0
	HYPOCHROMIC ANEMIA	1 (0.7%)	0
	LYMPHADENOPATHY	1 (0.7%)	0
Special Senses	TOTAL	2 (1.4%)	0
	ABNORMAL VISION	1 (0.7%)	0
	EAR PAIN	1 (0.7%)	0
Musculoskeletal System	TOTAL	1 (0.7%)	1 (0.8%)
	MYALGIA	1 (0.7%)	1 (0.8%)
Skin and Appendages	TOTAL	1 (0.7%)	1 (0.8%)
	SWEATING	1 (0.7%)	0
	CONTACT DERMATITIS	0	1 (0.8%)
Urogenital System	TOTAL	0	2 (1.6%)
	PYURIA	0	1 (0.8%)
	URINARY FREQUENCY	0	1 (0.8%)
	URINARY INCONTINENCE	0	1 (0.8%)
	URINARY TRACT INFECTION	0	1 (0.8%)

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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
Intention-To-Treat Population Entering The Taper Phase or Follow-Up Phase
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=63)	Placebo (N=72)
Body System	Preferred Term		
TOTAL	TOTAL	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
Intention-To-Treat Population Entering The Taper Phase or Follow-Up Phase
Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=81)	Placebo (N=57)
Body System	Preferred Term		
TOTAL	TOTAL	0	1 (1.8%)
Urogenital System	TOTAL	0	1 (1.8%)
	DYSMENORRHEA	0	1 (1.8%)

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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
Intention-To-Treat Population Entering The Taper Phase or Follow-Up Phase
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=144)	Treatment Group: Placebo (N=129)
TOTAL	65 (45.1%)	35 (27.1%)
HEADACHE	22 (15.3%)	14 (10.9%)
NAUSEA	16 (11.1%)	3 (2.3%)
DIZZINESS	16 (11.1%)	2 (1.6%)
ABDOMINAL PAIN	10 (6.9%)	2 (1.6%)
NERVOUSNESS	7 (4.9%)	1 (0.8%)
ASTHENIA	5 (3.5%)	2 (1.6%)
RESPIRATORY DISORDER	4 (2.8%)	7 (5.4%)
ANXIETY	4 (2.8%)	3 (2.3%)
EMOTIONAL LABILITY	4 (2.8%)	0
INFECTION	3 (2.1%)	4 (3.1%)
TRAUMA	3 (2.1%)	2 (1.6%)
INSOMNIA	3 (2.1%)	1 (0.8%)
SOMNOLENCE	3 (2.1%)	1 (0.8%)
VOMITING	3 (2.1%)	1 (0.8%)
SINUSITIS	3 (2.1%)	0
PHARYNGITIS	2 (1.4%)	3 (2.3%)
RHINITIS	2 (1.4%)	3 (2.3%)
DEPRESSION	2 (1.4%)	0
DIARRHEA	2 (1.4%)	0
DYSPEPSIA	2 (1.4%)	0
FLU SYNDROME	2 (1.4%)	0
COUGH INCREASED	0	2 (1.6%)
LARYNX DISORDER	0	2 (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
Intention-To-Treat Population Entering The Taper Phase or Follow-Up Phase
Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=63)	Treatment Group: Placebo (N=72)
TOTAL	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
Intention-To-Treat Population Entering The Taper Phase or Follow-Up Phase
Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=81)	Treatment Group: Placebo (N=57)
TOTAL	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
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
TOTAL	TOTAL	147 (90.2%)	127 (81.4%)
Body as a Whole	TOTAL	116 (71.2%)	88 (56.4%)
	HEADACHE	74 (45.4%)	48 (30.8%)
	INFECTION	36 (22.1%)	29 (18.6%)
	ABDOMINAL PAIN	32 (19.6%)	16 (10.3%)
	ASTHENIA	29 (17.8%)	13 (8.3%)
	TRAUMA	17 (10.4%)	14 (9.0%)
	ALLERGIC REACTION	8 (4.9%)	4 (2.6%)
	FEVER	7 (4.3%)	3 (1.9%)
	FLU SYNDROME	6 (3.7%)	3 (1.9%)
	BACK PAIN	3 (1.8%)	8 (5.1%)
	PAIN	2 (1.2%)	2 (1.3%)
	MONILIASIS	2 (1.2%)	0
	CELLULITIS	1 (0.6%)	0
	RHEUMATOID ARTHRITIS	1 (0.6%)	0
	ABNORMAL LABORATORY VALUE	0	1 (0.6%)
	CHEST PAIN	0	1 (0.6%)
	CHILLS	0	1 (0.6%)
	NEOPLASM	0	1 (0.6%)
Nervous System	TOTAL	88 (54.0%)	42 (26.9%)
	INSOMNIA	26 (16.0%)	10 (6.4%)
	SOMNOLENCE	24 (14.7%)	13 (8.3%)
	DIZZINESS	23 (14.1%)	12 (7.7%)
	NERVOUSNESS	17 (10.4%)	10 (6.4%)
	EMOTIONAL LABILITY	8 (4.9%)	2 (1.3%)
	HYPERKINESIA	7 (4.3%)	0
	HOSTILITY	5 (3.1%)	2 (1.3%)
	DEPRESSION	5 (3.1%)	0
	ANXIETY	4 (2.5%)	4 (2.6%)
	TREMOR	4 (2.5%)	1 (0.6%)
	AGITATION	3 (1.8%)	3 (1.9%)
	ABNORMAL DREAMS	3 (1.8%)	0
	LACK OF EMOTION	3 (1.8%)	0
	MANIC REACTION	3 (1.8%)	0
	CONCENTRATION IMPAIRED	2 (1.2%)	2 (1.3%)
	MYOCLONUS	2 (1.2%)	0
	NEUROSIS	2 (1.2%)	0
	VERTIGO	1 (0.6%)	1 (0.6%)
	AMNESIA	1 (0.6%)	0
	DEPERSONALIZATION	1 (0.6%)	0
	LIBIDO DECREASED	1 (0.6%)	0
	SPEECH DISORDER	1 (0.6%)	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
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
Nervous System	WITHDRAWAL SYNDROME	1 (0.6%)	0
	EXTRAPYRAMIDAL SYNDROME	0	1 (0.6%)
	HYPERTONIA	0	1 (0.6%)
	INCOORDINATION	0	1 (0.6%)
Digestive System	TOTAL	72 (44.2%)	41 (26.3%)
	NAUSEA	30 (18.4%)	15 (9.6%)
	DECREASED APPETITE	14 (8.6%)	6 (3.8%)
	DYSPEPSIA	14 (8.6%)	6 (3.8%)
	VOMITING	13 (8.0%)	4 (2.6%)
	DIARRHEA	7 (4.3%)	7 (4.5%)
	INCREASED APPETITE	5 (3.1%)	2 (1.3%)
	DRY MOUTH	4 (2.5%)	6 (3.8%)
	FLATULENCE	3 (1.8%)	0
	FECAL INCONTINENCE	2 (1.2%)	1 (0.6%)
	STOMATITIS	2 (1.2%)	1 (0.6%)
	GINGIVITIS	1 (0.6%)	2 (1.3%)
	TOOTH DISORDER	1 (0.6%)	2 (1.3%)
	CONSTIPATION	1 (0.6%)	1 (0.6%)
	ULCERATIVE STOMATITIS	1 (0.6%)	1 (0.6%)
	GASTRITIS	1 (0.6%)	0
	GASTROINTESTINAL DISORDER	1 (0.6%)	0
	RECTAL DISORDER	1 (0.6%)	0
	GASTROENTERITIS	0	4 (2.6%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (0.6%)
	TOOTH CARIES	0	1 (0.6%)
Respiratory System	TOTAL	60 (36.8%)	71 (45.5%)
	RESPIRATORY DISORDER	27 (16.6%)	25 (16.0%)
	RHINITIS	18 (11.0%)	28 (17.9%)
	PHARYNGITIS	15 (9.2%)	16 (10.3%)
	SINUSITIS	11 (6.7%)	7 (4.5%)
	COUGH INCREASED	9 (5.5%)	13 (8.3%)
	BRONCHITIS	3 (1.8%)	3 (1.9%)
	ASTHMA	3 (1.8%)	1 (0.6%)
	EPISTAXIS	3 (1.8%)	1 (0.6%)
	YAWN	3 (1.8%)	1 (0.6%)
	LARYNX DISORDER	0	2 (1.3%)
	PNEUMONIA	0	1 (0.6%)
Skin and Appendages	TOTAL	18 (11.0%)	13 (8.3%)
	RASH	8 (4.9%)	4 (2.6%)
	SWEATING	5 (3.1%)	1 (0.6%)
	CONTACT DERMATITIS	4 (2.5%)	1 (0.6%)

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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
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=163)	Placebo (N=156)
Skin and Appendages	ACNE	1 (0.6%)	3 (1.9%)
	HERPES SIMPLEX	1 (0.6%)	1 (0.6%)
	NAIL DISORDER	1 (0.6%)	0
	PRURITUS	1 (0.6%)	0
	VESICULOBULLOUS RASH	1 (0.6%)	0
	ECZEMA	0	2 (1.3%)
	FUNGAL DERMATITIS	0	1 (0.6%)
	PHOTOSENSITIVITY	0	1 (0.6%)
Special Senses	TOTAL	18 (11.0%)	7 (4.5%)
	OTITIS MEDIA	6 (3.7%)	2 (1.3%)
	CONJUNCTIVITIS	6 (3.7%)	1 (0.6%)
	EAR PAIN	5 (3.1%)	1 (0.6%)
	ABNORMAL VISION	1 (0.6%)	1 (0.6%)
	OTITIS EXTERNA	1 (0.6%)	1 (0.6%)
	MYDRIASIS	1 (0.6%)	0
	PHOTOPHOBIA	0	1 (0.6%)
Musculoskeletal System	TOTAL	11 (6.7%)	9 (5.8%)
	MYALGIA	7 (4.3%)	5 (3.2%)
	ARTHRALGIA	4 (2.5%)	4 (2.6%)
	ARTHROSIS	0	1 (0.6%)
Cardiovascular System	TOTAL	8 (4.9%)	5 (3.2%)
	VASODILATATION	3 (1.8%)	1 (0.6%)
	HYPOTENSION	1 (0.6%)	2 (1.3%)
	SYNCOPE	1 (0.6%)	2 (1.3%)
	MIGRAINE	1 (0.6%)	0
	PALPITATION	1 (0.6%)	0
	QT INTERVAL PROLONGED	1 (0.6%)	0
	TACHYCARDIA	0	1 (0.6%)
Metabolic and Nutritional Disorders	TOTAL	8 (4.9%)	7 (4.5%)
	WEIGHT GAIN	4 (2.5%)	3 (1.9%)
	THIRST	1 (0.6%)	1 (0.6%)
	WEIGHT LOSS	1 (0.6%)	1 (0.6%)
	HYPERKALEMIA	1 (0.6%)	0
	KETOSIS	1 (0.6%)	0
	BILIRUBINEMIA	0	1 (0.6%)
	HYPONATREMIA	0	1 (0.6%)
Hemic and Lymphatic System	TOTAL	7 (4.3%)	2 (1.3%)
	PURPURA	4 (2.5%)	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
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
Hemic and Lymphatic System	LEUKOPENIA	1 (0.6%)	1 (0.6%)
	ANEMIA	1 (0.6%)	0
	HYPOCHROMIC ANEMIA	1 (0.6%)	0
	LEUKOCYTOSIS	1 (0.6%)	0
	LYMPHADENOPATHY	1 (0.6%)	0
	EOSINOPHILIA	0	1 (0.6%)
	POLYCYTHEMIA	0	1 (0.6%)
Urogenital System	TOTAL	7 (4.3%)	7 (4.5%)
	URINARY INCONTINENCE	5 (3.1%)	1 (0.6%)
	ALBUMINURIA	2 (1.2%)	2 (1.3%)
	URINARY FREQUENCY	1 (0.6%)	2 (1.3%)
	URINE ABNORMALITY	1 (0.6%)	0
	URINARY TRACT INFECTION	0	3 (1.9%)
	CYSTITIS	0	1 (0.6%)
	PYURIA	0	1 (0.6%)
	URINARY RETENTION	0	1 (0.6%)

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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
Intention-To-Treat Population
Male Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=71)	 Placebo (N=89)
TOTAL	TOTAL	1 (1.4%)	0
Urogenital System	TOTAL	1 (1.4%)	0
	ABNORMAL EJACULATION	1 (1.4%)	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
Intention-To-Treat Population
Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=92)	 Placebo (N=67)
TOTAL	TOTAL	6 (6.5%)	5 (7.5%)
Urogenital System	TOTAL	6 (6.5%)	5 (7.5%)
	DYSMENORRHEA	5 (5.4%)	5 (7.5%)
	AMENORRHEA	1 (1.1%)	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
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
TOTAL	146 (89.6%)	124 (79.5%)
HEADACHE	74 (45.4%)	48 (30.8%)
INFECTION	36 (22.1%)	29 (18.6%)
ABDOMINAL PAIN	32 (19.6%)	16 (10.3%)
NAUSEA	30 (18.4%)	15 (9.6%)
ASTHENIA	29 (17.8%)	13 (8.3%)
RESPIRATORY DISORDER	27 (16.6%)	25 (16.0%)
INSOMNIA	26 (16.0%)	10 (6.4%)
SOMNOLENCE	24 (14.7%)	13 (8.3%)
DIZZINESS	23 (14.1%)	12 (7.7%)
RHINITIS	18 (11.0%)	28 (17.9%)
TRAUMA	17 (10.4%)	14 (9.0%)
NERVOUSNESS	17 (10.4%)	10 (6.4%)
PHARYNGITIS	15 (9.2%)	16 (10.3%)
DECREASED APPETITE	14 (8.6%)	6 (3.8%)
DYSPEPSIA	14 (8.6%)	6 (3.8%)
VOMITING	13 (8.0%)	4 (2.6%)
SINUSITIS	11 (6.7%)	7 (4.5%)
COUGH INCREASED	9 (5.5%)	13 (8.3%)
ALLERGIC REACTION	8 (4.9%)	4 (2.6%)
RASH	8 (4.9%)	4 (2.6%)
EMOTIONAL LABILITY	8 (4.9%)	2 (1.3%)
DIARRHEA	7 (4.3%)	7 (4.5%)
MYALGIA	7 (4.3%)	5 (3.2%)
FEVER	7 (4.3%)	3 (1.9%)
HYPERKINESIA	7 (4.3%)	0
FLU SYNDROME	6 (3.7%)	3 (1.9%)
OTITIS MEDIA	6 (3.7%)	2 (1.3%)
CONJUNCTIVITIS	6 (3.7%)	1 (0.6%)
HOSTILITY	5 (3.1%)	2 (1.3%)
INCREASED APPETITE	5 (3.1%)	2 (1.3%)
EAR PAIN	5 (3.1%)	1 (0.6%)
SWEATING	5 (3.1%)	1 (0.6%)
URINARY INCONTINENCE	5 (3.1%)	1 (0.6%)
DEPRESSION	5 (3.1%)	0
DRY MOUTH	4 (2.5%)	6 (3.8%)
ANXIETY	4 (2.5%)	4 (2.6%)
ARTHRALGIA	4 (2.5%)	4 (2.6%)
WEIGHT GAIN	4 (2.5%)	3 (1.9%)
CONTACT DERMATITIS	4 (2.5%)	1 (0.6%)
TREMOR	4 (2.5%)	1 (0.6%)
PURPURA	4 (2.5%)	0
BACK PAIN	3 (1.8%)	8 (5.1%)
AGITATION	3 (1.8%)	3 (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
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
BRONCHITIS	3 (1.8%)	3 (1.9%)
ASTHMA	3 (1.8%)	1 (0.6%)
EPISTAXIS	3 (1.8%)	1 (0.6%)
VASODILATATION	3 (1.8%)	1 (0.6%)
YAWN	3 (1.8%)	1 (0.6%)
ABNORMAL DREAMS	3 (1.8%)	0
FLATULENCE	3 (1.8%)	0
LACK OF EMOTION	3 (1.8%)	0
MANIC REACTION	3 (1.8%)	0
ALBUMINURIA	2 (1.2%)	2 (1.3%)
CONCENTRATION IMPAIRED	2 (1.2%)	2 (1.3%)
PAIN	2 (1.2%)	2 (1.3%)
FECAL INCONTINENCE	2 (1.2%)	1 (0.6%)
STOMATITIS	2 (1.2%)	1 (0.6%)
MONILIASIS	2 (1.2%)	0
MYOCLONUS	2 (1.2%)	0
NEUROSIS	2 (1.2%)	0
ACNE	1 (0.6%)	3 (1.9%)
GINGIVITIS	1 (0.6%)	2 (1.3%)
HYPOTENSION	1 (0.6%)	2 (1.3%)
SYNCOPE	1 (0.6%)	2 (1.3%)
TOOTH DISORDER	1 (0.6%)	2 (1.3%)
URINARY FREQUENCY	1 (0.6%)	2 (1.3%)
GASTROENTERITIS	0	4 (2.6%)
URINARY TRACT INFECTION	0	3 (1.9%)
ECZEMA	0	2 (1.3%)
LARYNX DISORDER	0	2 (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
Intention-To-Treat Population
Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=71)	Treatment Group: Placebo (N=89)
TOTAL	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
Intention-To-Treat Population
Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=92)	Placebo (N=67)
TOTAL	5 (5.4%)	5 (7.5%)
DYSMENORRHEA	5 (5.4%)	5 (7.5%)

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Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Treatment, Taper or Follow-up Phase
By Body System
All Patients
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=165)	Treatment Group: Placebo (N=157)
TOTAL	TOTAL	3 (1.8%)	1 (0.6%)
Body as a Whole	TOTAL	1 (0.6%)	1 (0.6%)
	TRAUMA	1 (0.6%)	0
	ABNORMAL LABORATORY VALUE	0	1 (0.6%)
Hemic and Lymphatic System	TOTAL	1 (0.6%)	0
	ANEMIA	1 (0.6%)	0
Nervous System	TOTAL	1 (0.6%)	0
	ANXIETY	1 (0.6%)	0
	DEPRESSION	1 (0.6%)	0

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Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Treatment, Taper or Follow-up Phase
By Body System
All Patients
Male Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=71)	Treatment Group: Placebo (N=90)
TOTAL	TOTAL	0	0

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Table 15.1.2.1

Number (%) of Patients with Serious Emergent Adverse Experiences During the Treatment, Taper or Follow-up Phase
By Body System
All Patients
Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=94)	Treatment Group: Placebo (N=67)
TOTAL	TOTAL	0	0

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Narratives for Patients with Serious Emergent Adverse Events

Table 15.1.2.2

Protocol No. 676

xxxx xxxxxxxx, B.S.N.

Clinical Development and Medical Affairs

SB Document Number: BRL-029060/RSD-101SWD/1

Issue Date 29 May 2002

PID: 676.202.24785

Treatment Group: No therapy

Adverse Event: MEDRA code Injury NOS [ADECS code Trauma (Concussion due to fall from bike. Symptoms: headache , nausea, vomiting. Hospitalized for two days)]

Case reference number 2000007365-1 is a clinical trial report from blinded study 29060/676 for Social Anxiety Disorder. This report refers to a 10-year-old white male (patient identification number 676.202.24785).

On 07 March 2000, during the screening phase of the study, the patient fell off his bicycle and was concussed with headache and nausea and lacerated his chin and left upper leg. The patient was treated for the event with dexamethasone, Myprodol® (codeine phosphate, paracetamol and ibuprofen) and ampicillin and underwent suture stitches on his chin and leg.

The concussion resolved on 09 March 2000 and the laceration resolved on 12 April 2000. The investigator considered these to be serious events because they resulted in hospitalization. The investigator reported the fall, laceration and concussion as unrelated to treatment with study medication.

Treatment with study medication started on 12 March 2000.

PID: 676.005.24122

Treatment Group: Paroxetine

Adverse Event: MEDRA code Fear, focus NEC, Depression [ADECS code Anxiety, Depression (hospitalization due to his fears and disease under study)]

Case report number 2000035168-1 is a clinical trial report from double-blind study 29060/676 for adolescent Social Anxiety Disorder. This case refers to a 14-year-old white male (patient identification number 676.005.24122).

The patient's medical history included spinal meningitis and asthma. Psychiatric history (measured by the ADIS C/P semi-structured interview) included an overall diagnostic label of Social Anxiety Disorder.

Concomitant medications were none.

The first dose of study medication at dose level 1 (10 mg/day) was given on 08 September 2000. The dose was gradually increased to dose level 5 (50 mg/day) on 06 October 2000, was decreased to dose level 4 (40 mg/day) on 20 October 2000 (Day 43) and increased again to level 5 on 03 November 2000 (Day 57).

On 16 Nov 2000, it was reported that the patient withdrew consent from the study and received the last dose of study medication on 16 November 2000. On 30 November 2000, 14 days after the last dose of study medication, the patient was hospitalized for fears and depression related to Social Anxiety Disorder. It was reported that the patient "felt terrible and went to a mental health resource center until 04 Dec 2000." The patient was started on 150 mg daily of Wellbutrin® (amfebutamone hydrochloride), and 15 mg daily of Risperdal® (risperidone). The event was reported as resolved on 04 Dec 2000.

The investigator reported the fears and depression as unrelated to treatment with study medication and probably associated with the patient's history of Social Anxiety Disorder and depression. The serious adverse events were considered to be moderately severe in intensity.

On 29 September 2000, the onset of mild nervousness (increased irritability) was reported. This resolved without treatment and was considered to be possibly related to treatment with study medication by the investigator.

On 10 October 2000, the onset of moderately severe asthenia (fatigue) was reported. No corrective therapy was given, but the dose of study medication was decreased as a result of this event. The event resolved in 23 days. The investigator considered asthenia to be possibly related to treatment with study medication.

PID: 676.015.24407

Treatment Group: Paroxetine

Adverse Event: MEDRA code Injury NOS [ADECS code Trauma (Fractured Arm)]

Case reference number 2001004312-1 is a clinical trial report from study 29060/676 for Social Anxiety Disorder. This report refers to a 16-year-old white male (patient identification number (676.015.24407).

The patient's medical history included tuberculosis, nocturnal enuresis, and facial acne. Psychiatric history (measured by ADIS C/P semi-structured interview) included an overall diagnostic label of enuresis, specific phobia, and Social Anxiety Disorder.

Previous medication history included the use of imipramine. Minocin® (minocycline HCl) was prescribed previously and currently for acne.

The first dose of study medication at dose level 1 (10 mg/day) was taken on 20 September 2000. The dose was gradually increased to dose level 5 (50 mg) on 02 November 2000). The last dose of study medication during the active phase of the study was taken on 16 January 2001. The final dose of taper medication was taken on 09 February 2001. The patient completed the study as planned.

On 05 February 2001, 20 days after the last dose of on-therapy study medication, the patient was in an automobile accident and was admitted to the hospital for a broken left arm. Surgery was performed to repair the break, and the patient was discharged from the hospital on 07 February 2001. The patient admitted smoking marijuana prior to the accident. On 09 February 2001, a urine drug screen was negative. Treatment medications included cephalexin and hydrocodone. At the time of the event, the patient was in the last week of his taper study medication, Week 19 dose level 1. Per information received on 27 February 2001, the event of broken arm had not resolved.

The investigator reported the broken arm as not related to treatment with study medication, and associated the event with the auto accident. The serious adverse experience of trauma (fractured arm) was judged to be severe in intensity.

On 18 February 2001, a non-serious AE of mild trauma (pain from broken arm) was reported. This resolved with treatment in one day and was considered to be unrelated to treatment with study medication.

PID: 676.205.24985

Treatment Group: Paroxetine

Adverse Event: MEDRA code Anemia NOS [ADECS code Anemia (Anemia)]

Case reference number 2001005798-1 is a clinical trial report from blinded study 29060/676 for Social Anxiety Disorder. This report refers to a 16-year-old white female (patient identification number 676.205.24985).

The patient's medical history included anemia and acne. The patient had also experienced transient left hemiparesis in 1998, which was attributed to a cephalic migraine. Psychiatric history (measured by the ADIS C/P semi-structured interview) included an overall diagnostic label of Social Anxiety Disorder. Concomitant medications included iron sulfate and Diane®-35 (cyproterone acetate / ethinylestradiol) for acne vulgaris.

The first dose of study medication, at dose level 1 (10 mg/day) was given on 08 February 2001. The dose was increased to level 2 (20 mg/day) on 01 March 2001 (Day 22). The last dose of study medication was taken on 5 March 2001 (Day 26).

On 25 February 2001, the patient developed flu and was taking unspecified "fizzy powders." The patient's doctor prescribed Flusin® effervescent (chlorpheniramine maleate, paracetamol, pseudoephedrine HCl, vitamin C) to treat the flu episode. The investigator considered this event to be unrelated to treatment with study medication.

On 04 March 2001, approximately one month after the first dose, the patient experienced two episodes of confusion and headache. The patient was reported to have walked into the kitchen, began talking incoherently and then collapsed. The patient did not experience any tonic-clonic seizures.

The patient reported headache and nausea prior to collapse, and the headache was reported to have persisted following the patient's collapse. On admission to the hospital, an electroencephalogram and electrocardiogram were normal. Magnetic resonance imaging of the brain revealed a small encephalomalatic cystic lesion involving the head of caudate nucleus on the right side and the putamen on the right side. There were no signs of expansion nor bleeding. Gastroscopy did not show any abnormalities. Laboratory measurements included hemoglobin 11.9 g/dL (normal range 12.5-16.5) and serum iron 17 umol/L (normal range 11-27).

The laboratory results indicated that the patient had an iron deficiency-induced anemia. The anemia was considered to be severe in intensity. The investigator suspected the patient had experienced temporal lobe epileptic fits and that this may be associated with the anemia. The patient was treated with intravenous iron for the anemia and commenced treatment with valproic acid.

Treatment with study medication was stopped due to this event on 05 March 2001. The patient recovered on 06 March 2001. The investigator considered the anemia to be a serious event because it was a significant hazard, contraindication, side effect or precaution and because the patient was hospitalized.

The investigator initially reported the suspected temporal lobe epilepsy to be possibly related to treatment with study medication. Following the diagnosis of anemia, the investigator confirmed that this and the suspected temporal lobe epilepsy were unrelated to treatment with study medication. These events were considered to be associated with iron deficiency.

On 06 March 2001, one day after the last dose of study medication, the anemia was reported as a non-serious AE of mild hypochromic anemia (verbatim: iron deficiency anemia–admitted for parental iron therapy). The event was treated with ferrous sulfate and resolved within 5 days. It was considered to be unrelated to treatment with study medication.

PID: 676.209.24958

Treatment Group: Placebo

Adverse Event: MEDRA code Overdose NOS [ADECS code Abnormal Laboratory Value (Unintentional Overdose of Study Medication)]

Case reference number 2000028248-1 is a clinical trial report from blinded study 29060/676 for Social Anxiety Disorder. This report refers to a 10-year-old white male (patient identification number 676.209.24958).

The patient had no previous or current significant medical history reported. No previous or concomitant medications were reported during the study. Psychiatric history (measured by the ADIS C/P semi-structured interview) included an overall diagnostic label of Social Anxiety Disorder.

The patient received the first dose of study medication at level 1 (10 mg/day) on 01 August 2000. The dose was gradually increased to level 4 (40 mg/day) on 11 September 2000 (Day 42) and remained at that dose until the start of the taper phase on 21 November 2000 (Day 113). The patient received the last dose of study medication on 11 December 2000 (Day 133).

From 11 September 2000, some 41 days after the first dose, the patient accidentally overdosed on study medication. The patient had taken four capsules daily instead of the recommended two capsules. The patient was asymptomatic. The patient did not receive any corrective therapy for the event.

Treatment with study medication was not stopped due to this event. The event resolved on 21 September 2000. The investigator considered this to be a serious event because it was an overdose.

The investigator reported the overdose to be mild in intensity and related to treatment with study medication.

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=45)
TOTAL	TOTAL	40 (87.0%)	32 (71.1%)
Body as a Whole	TOTAL	24 (52.2%)	20 (44.4%)
	HEADACHE	13 (28.3%)	9 (20.0%)
	ABDOMINAL PAIN	9 (19.6%)	4 (8.9%)
	INFECTION	4 (8.7%)	5 (11.1%)
	TRAUMA	4 (8.7%)	4 (8.9%)
	FEVER	2 (4.3%)	1 (2.2%)
	ASTHENIA	2 (4.3%)	0
	ALLERGIC REACTION	1 (2.2%)	1 (2.2%)
	BACK PAIN	1 (2.2%)	1 (2.2%)
	ABNORMAL LABORATORY VALUE	0	1 (2.2%)
	PAIN	0	1 (2.2%)
Nervous System	TOTAL	13 (28.3%)	6 (13.3%)
	NERVOUSNESS	4 (8.7%)	1 (2.2%)
	INSOMNIA	4 (8.7%)	0
	SOMNOLENCE	3 (6.5%)	3 (6.7%)
	HYPERKINESIA	2 (4.3%)	0
	HOSTILITY	1 (2.2%)	0
	SPEECH DISORDER	1 (2.2%)	0
	CONCENTRATION IMPAIRED	0	2 (4.4%)
	INCOORDINATION	0	1 (2.2%)
Digestive System	TOTAL	12 (26.1%)	12 (26.7%)
	DECREASED APPETITE	3 (6.5%)	2 (4.4%)
	NAUSEA	2 (4.3%)	3 (6.7%)
	DYSPEPSIA	2 (4.3%)	1 (2.2%)
	FECAL INCONTINENCE	2 (4.3%)	1 (2.2%)
	DIARRHEA	1 (2.2%)	2 (4.4%)
	FLATULENCE	1 (2.2%)	0
	INCREASED APPETITE	1 (2.2%)	0
	ULCERATIVE STOMATITIS	1 (2.2%)	0
	VOMITING	1 (2.2%)	0
	CONSTIPATION	0	1 (2.2%)
	GASTROENTERITIS	0	1 (2.2%)
	TOOTH CARIES	0	1 (2.2%)
	TOOTH DISORDER	0	1 (2.2%)
Respiratory System	TOTAL	11 (23.9%)	14 (31.1%)
	RESPIRATORY DISORDER	5 (10.9%)	1 (2.2%)
	COUGH INCREASED	3 (6.5%)	4 (8.9%)
	SINUSITIS	2 (4.3%)	2 (4.4%)
	RHINITIS	1 (2.2%)	6 (13.3%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=45)
Respiratory System	PHARYNGITIS	1 (2.2%)	5 (11.1%)
	EPISTAXIS	1 (2.2%)	1 (2.2%)
	ASTHMA	1 (2.2%)	0
Skin and Appendages	TOTAL	7 (15.2%)	4 (8.9%)
	RASH	4 (8.7%)	2 (4.4%)
	CONTACT DERMATITIS	2 (4.3%)	0
	NAIL DISORDER	1 (2.2%)	0
	PRURITUS	1 (2.2%)	0
	SWEATING	1 (2.2%)	0
	ECZEMA	0	1 (2.2%)
	PHOTOSENSITIVITY	0	1 (2.2%)
Special Senses	TOTAL	6 (13.0%)	0
	OTITIS MEDIA	3 (6.5%)	0
	CONJUNCTIVITIS	2 (4.3%)	0
	EAR PAIN	1 (2.2%)	0
	OTITIS EXTERNA	1 (2.2%)	0
Urogenital System	TOTAL	3 (6.5%)	0
	URINARY INCONTINENCE	3 (6.5%)	0
	ALBUMINURIA	1 (2.2%)	0
Cardiovascular System	TOTAL	2 (4.3%)	1 (2.2%)
	VASODILATATION	2 (4.3%)	0
	TACHYCARDIA	0	1 (2.2%)
Musculoskeletal System	TOTAL	2 (4.3%)	0
	ARTHRALGIA	1 (2.2%)	0
	MYALGIA	1 (2.2%)	0
Hemic and Lymphatic System	TOTAL	1 (2.2%)	0
	PURPURA	1 (2.2%)	0
Metabolic and Nutritional Disorders	TOTAL	1 (2.2%)	1 (2.2%)
	WEIGHT GAIN	1 (2.2%)	0
	HYPONATREMIA	0	1 (2.2%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=45)
TOTAL	TOTAL	20 (43.5%)	19 (42.2%)
Nervous System	TOTAL	11 (23.9%)	5 (11.1%)
	NERVOUSNESS	3 (6.5%)	1 (2.2%)
	INSOMNIA	2 (4.3%)	3 (6.7%)
	HOSTILITY	2 (4.3%)	0
	SOMNOLENCE	1 (2.2%)	2 (4.4%)
	DIZZINESS	1 (2.2%)	1 (2.2%)
	CONCENTRATION IMPAIRED	1 (2.2%)	0
	HYPERKINESIA	1 (2.2%)	0
	LACK OF EMOTION	1 (2.2%)	0
	NEUROSIS	1 (2.2%)	0
	AGITATION	0	1 (2.2%)
Body as a Whole	TOTAL	8 (17.4%)	9 (20.0%)
	HEADACHE	3 (6.5%)	3 (6.7%)
	ASTHENIA	2 (4.3%)	1 (2.2%)
	INFECTION	1 (2.2%)	3 (6.7%)
	ALLERGIC REACTION	1 (2.2%)	1 (2.2%)
	TRAUMA	1 (2.2%)	0
	ABDOMINAL PAIN	0	1 (2.2%)
	CHEST PAIN	0	1 (2.2%)
Digestive System	TOTAL	4 (8.7%)	5 (11.1%)
	VOMITING	2 (4.3%)	2 (4.4%)
	DIARRHEA	1 (2.2%)	2 (4.4%)
	NAUSEA	1 (2.2%)	2 (4.4%)
	CONSTIPATION	1 (2.2%)	0
	FLATULENCE	1 (2.2%)	0
	DYSPEPSIA	0	1 (2.2%)
	GASTROENTERITIS	0	1 (2.2%)
	TOOTH DISORDER	0	1 (2.2%)
Respiratory System	TOTAL	3 (6.5%)	6 (13.3%)
	RESPIRATORY DISORDER	2 (4.3%)	2 (4.4%)
	PHARYNGITIS	1 (2.2%)	1 (2.2%)
	SINUSITIS	0	2 (4.4%)
	BRONCHITIS	0	1 (2.2%)
	COUGH INCREASED	0	1 (2.2%)
	RHINITIS	0	1 (2.2%)
Special Senses	TOTAL	3 (6.5%)	1 (2.2%)
	OTITIS MEDIA	2 (4.3%)	1 (2.2%)
	CONJUNCTIVITIS	1 (2.2%)	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=45)
Urogenital System	TOTAL	3 (6.5%)	1 (2.2%)
	URINARY INCONTINENCE	3 (6.5%)	0
	URINARY RETENTION	0	1 (2.2%)
Hemic and Lymphatic System	TOTAL	1 (2.2%)	0
	PURPURA	1 (2.2%)	0
Skin and Appendages	TOTAL	1 (2.2%)	1 (2.2%)
	RASH	1 (2.2%)	0
	FUNGAL DERMATITIS	0	1 (2.2%)
Musculoskeletal System	TOTAL	0	1 (2.2%)
	ARTHRALGIA	0	1 (2.2%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=46)	Placebo (N=45)
TOTAL	TOTAL	5 (10.9%)	2 (4.4%)
Body as a Whole	TOTAL	3 (6.5%)	0
	INFECTION	2 (4.3%)	0
	ABDOMINAL PAIN	1 (2.2%)	0
Nervous System	TOTAL	2 (4.3%)	0
	HYPERKINESIA	1 (2.2%)	0
	MANIC REACTION	1 (2.2%)	0
Respiratory System	TOTAL	0	1 (2.2%)
	PHARYNGITIS	0	1 (2.2%)
Special Senses	TOTAL	0	1 (2.2%)
	EAR PAIN	0	1 (2.2%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=23)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=23)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=23)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=21)	Placebo (N=22)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=21)	Placebo (N=22)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=21)	Placebo (N=22)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=117)	Treatment Group: Placebo (N=111)
TOTAL	TOTAL	95 (81.2%)	77 (69.4%)
Body as a Whole	TOTAL	65 (55.6%)	43 (38.7%)
	HEADACHE	37 (31.6%)	20 (18.0%)
	INFECTION	19 (16.2%)	8 (7.2%)
	ASTHENIA	13 (11.1%)	10 (9.0%)
	ABDOMINAL PAIN	12 (10.3%)	8 (7.2%)
	TRAUMA	5 (4.3%)	2 (1.8%)
	ALLERGIC REACTION	4 (3.4%)	2 (1.8%)
	FEVER	3 (2.6%)	1 (0.9%)
	PAIN	2 (1.7%)	1 (0.9%)
	BACK PAIN	1 (0.9%)	2 (1.8%)
	FLU SYNDROME	1 (0.9%)	0
	MONILIASIS	1 (0.9%)	0
	NEOPLASM	0	1 (0.9%)
Digestive System	TOTAL	40 (34.2%)	20 (18.0%)
	NAUSEA	13 (11.1%)	6 (5.4%)
	DECREASED APPETITE	8 (6.8%)	3 (2.7%)
	VOMITING	8 (6.8%)	0
	DYSPEPSIA	7 (6.0%)	2 (1.8%)
	DRY MOUTH	4 (3.4%)	5 (4.5%)
	DIARRHEA	4 (3.4%)	2 (1.8%)
	INCREASED APPETITE	3 (2.6%)	2 (1.8%)
	STOMATITIS	2 (1.7%)	1 (0.9%)
	GASTROINTESTINAL DISORDER	1 (0.9%)	0
	GINGIVITIS	1 (0.9%)	0
	RECTAL DISORDER	1 (0.9%)	0
	GASTROENTERITIS	0	2 (1.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (0.9%)
	ULCERATIVE STOMATITIS	0	1 (0.9%)
Respiratory System	TOTAL	36 (30.8%)	34 (30.6%)
	RHINITIS	14 (12.0%)	17 (15.3%)
	RESPIRATORY DISORDER	13 (11.1%)	9 (8.1%)
	PHARYNGITIS	9 (7.7%)	5 (4.5%)
	SINUSITIS	6 (5.1%)	2 (1.8%)
	COUGH INCREASED	3 (2.6%)	4 (3.6%)
	YAWN	3 (2.6%)	1 (0.9%)
	BRONCHITIS	1 (0.9%)	2 (1.8%)
	EPISTAXIS	1 (0.9%)	0
	ASTHMA	0	1 (0.9%)
	PNEUMONIA	0	1 (0.9%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=117)	 Placebo (N=111)
Nervous System	TOTAL	32 (27.4%)	19 (17.1%)
	SOMNOLENCE	13 (11.1%)	5 (4.5%)
	INSOMNIA	9 (7.7%)	4 (3.6%)
	DIZZINESS	7 (6.0%)	9 (8.1%)
	NERVOUSNESS	5 (4.3%)	5 (4.5%)
	EMOTIONAL LABILITY	2 (1.7%)	2 (1.8%)
	ABNORMAL DREAMS	2 (1.7%)	0
	HOSTILITY	1 (0.9%)	1 (0.9%)
	AGITATION	1 (0.9%)	0
	AMNESIA	1 (0.9%)	0
	CONCENTRATION IMPAIRED	1 (0.9%)	0
	DEPRESSION	1 (0.9%)	0
	HYPERKINESIA	1 (0.9%)	0
	LACK OF EMOTION	1 (0.9%)	0
	TREMOR	1 (0.9%)	0
	ANXIETY	0	1 (0.9%)
	HYPERTONIA	0	1 (0.9%)
	VERTIGO	0	1 (0.9%)
Skin and Appendages	TOTAL	8 (6.8%)	5 (4.5%)
	RASH	3 (2.6%)	2 (1.8%)
	SWEATING	2 (1.7%)	0
	ACNE	1 (0.9%)	2 (1.8%)
	HERPES SIMPLEX	1 (0.9%)	1 (0.9%)
	VESICULOBULLOUS RASH	1 (0.9%)	0
Metabolic and Nutritional Disorders	TOTAL	7 (6.0%)	5 (4.5%)
	WEIGHT GAIN	3 (2.6%)	3 (2.7%)
	THIRST	1 (0.9%)	1 (0.9%)
	HYPERKALEMIA	1 (0.9%)	0
	KETOSIS	1 (0.9%)	0
	WEIGHT LOSS	1 (0.9%)	0
	BILIRUBINEMIA	0	1 (0.9%)
Musculoskeletal System	TOTAL	7 (6.0%)	6 (5.4%)
	MYALGIA	4 (3.4%)	4 (3.6%)
	ARTHRALGIA	3 (2.6%)	2 (1.8%)
Special Senses	TOTAL	6 (5.1%)	4 (3.6%)
	CONJUNCTIVITIS	2 (1.7%)	1 (0.9%)
	EAR PAIN	2 (1.7%)	0
	OTITIS MEDIA	1 (0.9%)	1 (0.9%)
	MYDRIASIS	1 (0.9%)	0

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=117)	 Placebo (N=111)
Special Senses	ABNORMAL VISION	0	1 (0.9%)
	PHOTOPHOBIA	0	1 (0.9%)
Cardiovascular System	TOTAL	3 (2.6%)	2 (1.8%)
	VASODILATATION	1 (0.9%)	1 (0.9%)
	MIGRAINE	1 (0.9%)	0
	QT INTERVAL PROLONGED	1 (0.9%)	0
	HYPOTENSION	0	1 (0.9%)
Hemic and Lymphatic System	TOTAL	1 (0.9%)	2 (1.8%)
	LEUKOPENIA	1 (0.9%)	1 (0.9%)
	LEUKOCYTOSIS	1 (0.9%)	0
	EOSINOPHILIA	0	1 (0.9%)
	POLYCYTHEMIA	0	1 (0.9%)
Urogenital System	TOTAL	1 (0.9%)	4 (3.6%)
	ALBUMINURIA	1 (0.9%)	2 (1.8%)
	URINE ABNORMALITY	1 (0.9%)	0
	URINARY FREQUENCY	0	1 (0.9%)
	URINARY TRACT INFECTION	0	1 (0.9%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=117)	 Placebo (N=111)
TOTAL	TOTAL	61 (52.1%)	51 (45.9%)
Body as a Whole	TOTAL	35 (29.9%)	29 (26.1%)
	HEADACHE	13 (11.1%)	12 (10.8%)
	INFECTION	8 (6.8%)	9 (8.1%)
	ASTHENIA	7 (6.0%)	2 (1.8%)
	TRAUMA	3 (2.6%)	5 (4.5%)
	FLU SYNDROME	3 (2.6%)	2 (1.8%)
	ABDOMINAL PAIN	2 (1.7%)	1 (0.9%)
	BACK PAIN	1 (0.9%)	3 (2.7%)
	FEVER	1 (0.9%)	1 (0.9%)
	ALLERGIC REACTION	1 (0.9%)	0
	CELLULITIS	1 (0.9%)	0
	MONILIASIS	1 (0.9%)	0
	RHEUMATOID ARTHRITIS	1 (0.9%)	0
Nervous System	TOTAL	21 (17.9%)	11 (9.9%)
	INSOMNIA	9 (7.7%)	3 (2.7%)
	SOMNOLENCE	4 (3.4%)	3 (2.7%)
	NERVOUSNESS	3 (2.6%)	2 (1.8%)
	AGITATION	2 (1.7%)	1 (0.9%)
	DEPRESSION	2 (1.7%)	0
	EMOTIONAL LABILITY	2 (1.7%)	0
	TREMOR	2 (1.7%)	0
	HOSTILITY	1 (0.9%)	1 (0.9%)
	DEPERSONALIZATION	1 (0.9%)	0
	HYPERKINESIA	1 (0.9%)	0
	LIBIDO DECREASED	1 (0.9%)	0
	MYOCLONUS	1 (0.9%)	0
	NEUROSIS	1 (0.9%)	0
	EXTRAPYRAMIDAL SYNDROME	0	1 (0.9%)
	VERTIGO	0	1 (0.9%)
Respiratory System	TOTAL	15 (12.8%)	16 (14.4%)
	RESPIRATORY DISORDER	6 (5.1%)	9 (8.1%)
	COUGH INCREASED	3 (2.6%)	2 (1.8%)
	PHARYNGITIS	3 (2.6%)	2 (1.8%)
	RHINITIS	2 (1.7%)	1 (0.9%)
	ASTHMA	2 (1.7%)	0
	BRONCHITIS	2 (1.7%)	0
	EPISTAXIS	1 (0.9%)	0
	SINUSITIS	0	3 (2.7%)
Digestive System	TOTAL	13 (11.1%)	8 (7.2%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=117)	Treatment Group: Placebo (N=111)
Digestive System	NAUSEA	6 (5.1%)	1 (0.9%)
	DYSPEPSIA	3 (2.6%)	2 (1.8%)
	DECREASED APPETITE	3 (2.6%)	0
	TOOTH DISORDER	1 (0.9%)	1 (0.9%)
	VOMITING	1 (0.9%)	1 (0.9%)
	INCREASED APPETITE	1 (0.9%)	0
	DIARRHEA	0	1 (0.9%)
	DRY MOUTH	0	1 (0.9%)
	GASTROENTERITIS	0	1 (0.9%)
	GINGIVITIS	0	1 (0.9%)
Cardiovascular System	TOTAL	3 (2.6%)	2 (1.8%)
	SYNCOPE	1 (0.9%)	2 (1.8%)
	HYPOTENSION	1 (0.9%)	1 (0.9%)
	MIGRAINE	1 (0.9%)	0
Hemic and Lymphatic System	TOTAL	3 (2.6%)	0
	PURPURA	3 (2.6%)	0
Skin and Appendages	TOTAL	2 (1.7%)	3 (2.7%)
	SWEATING	1 (0.9%)	1 (0.9%)
	CONTACT DERMATITIS	1 (0.9%)	0
	ACNE	0	1 (0.9%)
	ECZEMA	0	1 (0.9%)
Special Senses	TOTAL	2 (1.7%)	1 (0.9%)
	CONJUNCTIVITIS	1 (0.9%)	0
	EAR PAIN	1 (0.9%)	0
	OTITIS EXTERNA	0	1 (0.9%)
Musculoskeletal System	TOTAL	1 (0.9%)	3 (2.7%)
	MYALGIA	1 (0.9%)	1 (0.9%)
	ARTHRALGIA	0	1 (0.9%)
	ARTHROSIS	0	1 (0.9%)
Urogenital System	TOTAL	1 (0.9%)	2 (1.8%)
	URINARY FREQUENCY	1 (0.9%)	0
	CYSTITIS	0	1 (0.9%)
	URINARY TRACT INFECTION	0	1 (0.9%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (0.9%)
	WEIGHT LOSS	0	1 (0.9%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=117)	 Placebo (N=111)
TOTAL	TOTAL	14 (12.0%)	7 (6.3%)
Body as a Whole	TOTAL	7 (6.0%)	6 (5.4%)
	HEADACHE	2 (1.7%)	2 (1.8%)
	INFECTION	2 (1.7%)	0
	FLU SYNDROME	1 (0.9%)	1 (0.9%)
	TRAUMA	1 (0.9%)	1 (0.9%)
	ASTHENIA	1 (0.9%)	0
	BACK PAIN	0	2 (1.8%)
	ABDOMINAL PAIN	0	1 (0.9%)
	CHILLS	0	1 (0.9%)
Nervous System	TOTAL	3 (2.6%)	1 (0.9%)
	MANIC REACTION	2 (1.7%)	0
	ABNORMAL DREAMS	1 (0.9%)	0
	AGITATION	1 (0.9%)	0
	DIZZINESS	0	1 (0.9%)
Digestive System	TOTAL	2 (1.7%)	2 (1.8%)
	DYSPEPSIA	1 (0.9%)	0
	GASTRITIS	1 (0.9%)	0
	NAUSEA	0	2 (1.8%)
Hemic and Lymphatic System	TOTAL	1 (0.9%)	0
	ANEMIA	1 (0.9%)	0
Skin and Appendages	TOTAL	1 (0.9%)	0
	CONTACT DERMATITIS	1 (0.9%)	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=46)	Placebo (N=66)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=46)	Placebo (N=66)
Body System	Preferred Term		
TOTAL	TOTAL	1 (2.2%)	0
Urogenital System	TOTAL	1 (2.2%)	0
	ABNORMAL EJACULATION	1 (2.2%)	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=46)	Placebo (N=66)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=71)	Placebo (N=45)
Body System	Preferred Term		
TOTAL	TOTAL	4 (5.6%)	2 (4.4%)
Urogenital System	TOTAL	4 (5.6%)	2 (4.4%)
	DYSMENORRHEA	3 (4.2%)	2 (4.4%)
	AMENORRHEA	1 (1.4%)	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=71)	Placebo (N=45)
TOTAL	TOTAL	3 (4.2%)	2 (4.4%)
Urogenital System	TOTAL	3 (4.2%)	2 (4.4%)
	DYSMENORRHEA	3 (4.2%)	2 (4.4%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=71)	Placebo (N=45)
TOTAL	TOTAL	1 (1.4%)	0
Urogenital System	TOTAL	1 (1.4%)	0
	DYSMENORRHEA	1 (1.4%)	0

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
TOTAL	TOTAL	135 (82.8%)	109 (69.9%)
Body as a Whole	TOTAL	89 (54.6%)	63 (40.4%)
	HEADACHE	50 (30.7%)	29 (18.6%)
	INFECTION	23 (14.1%)	13 (8.3%)
	ABDOMINAL PAIN	21 (12.9%)	12 (7.7%)
	ASTHENIA	15 (9.2%)	10 (6.4%)
	TRAUMA	9 (5.5%)	6 (3.8%)
	ALLERGIC REACTION	5 (3.1%)	3 (1.9%)
	FEVER	5 (3.1%)	2 (1.3%)
	BACK PAIN	2 (1.2%)	3 (1.9%)
	PAIN	2 (1.2%)	2 (1.3%)
	FLU SYNDROME	1 (0.6%)	0
	MONILIASIS	1 (0.6%)	0
	ABNORMAL LABORATORY VALUE	0	1 (0.6%)
	NEOPLASM	0	1 (0.6%)
Digestive System	TOTAL	52 (31.9%)	32 (20.5%)
	NAUSEA	15 (9.2%)	9 (5.8%)
	DECREASED APPETITE	11 (6.7%)	5 (3.2%)
	DYSPEPSIA	9 (5.5%)	3 (1.9%)
	VOMITING	9 (5.5%)	0
	DIARRHEA	5 (3.1%)	4 (2.6%)
	DRY MOUTH	4 (2.5%)	5 (3.2%)
	INCREASED APPETITE	4 (2.5%)	2 (1.3%)
	FECAL INCONTINENCE	2 (1.2%)	1 (0.6%)
	STOMATITIS	2 (1.2%)	1 (0.6%)
	ULCERATIVE STOMATITIS	1 (0.6%)	1 (0.6%)
	FLATULENCE	1 (0.6%)	0
	GASTROINTESTINAL DISORDER	1 (0.6%)	0
	GINGIVITIS	1 (0.6%)	0
	RECTAL DISORDER	1 (0.6%)	0
	GASTROENTERITIS	0	3 (1.9%)
	CONSTIPATION	0	1 (0.6%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (0.6%)
	TOOTH CARIES	0	1 (0.6%)
	TOOTH DISORDER	0	1 (0.6%)
Respiratory System	TOTAL	47 (28.8%)	48 (30.8%)
	RESPIRATORY DISORDER	18 (11.0%)	10 (6.4%)
	RHINITIS	15 (9.2%)	23 (14.7%)
	PHARYNGITIS	10 (6.1%)	10 (6.4%)
	SINUSITIS	8 (4.9%)	4 (2.6%)
	COUGH INCREASED	6 (3.7%)	8 (5.1%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
Respiratory System	YAWN	3 (1.8%)	1 (0.6%)
	EPISTAXIS	2 (1.2%)	1 (0.6%)
	BRONCHITIS	1 (0.6%)	2 (1.3%)
	ASTHMA	1 (0.6%)	1 (0.6%)
	PNEUMONIA	0	1 (0.6%)
Nervous System	TOTAL	45 (27.6%)	25 (16.0%)
	SOMNOLENCE	16 (9.8%)	8 (5.1%)
	INSOMNIA	13 (8.0%)	4 (2.6%)
	NERVOUSNESS	9 (5.5%)	6 (3.8%)
	DIZZINESS	7 (4.3%)	9 (5.8%)
	HYPERKINESIA	3 (1.8%)	0
	EMOTIONAL LABILITY	2 (1.2%)	2 (1.3%)
	HOSTILITY	2 (1.2%)	1 (0.6%)
	ABNORMAL DREAMS	2 (1.2%)	0
	CONCENTRATION IMPAIRED	1 (0.6%)	2 (1.3%)
	AGITATION	1 (0.6%)	0
	AMNESIA	1 (0.6%)	0
	DEPRESSION	1 (0.6%)	0
	LACK OF EMOTION	1 (0.6%)	0
	SPEECH DISORDER	1 (0.6%)	0
	TREMOR	1 (0.6%)	0
	ANXIETY	0	1 (0.6%)
	HYPERTONIA	0	1 (0.6%)
	INCOORDINATION	0	1 (0.6%)
	VERTIGO	0	1 (0.6%)
Skin and Appendages	TOTAL	15 (9.2%)	9 (5.8%)
	RASH	7 (4.3%)	4 (2.6%)
	SWEATING	3 (1.8%)	0
	CONTACT DERMATITIS	2 (1.2%)	0
	ACNE	1 (0.6%)	2 (1.3%)
	HERPES SIMPLEX	1 (0.6%)	1 (0.6%)
	NAIL DISORDER	1 (0.6%)	0
	PRURITUS	1 (0.6%)	0
	VESICULOBULLOUS RASH	1 (0.6%)	0
	ECZEMA	0	1 (0.6%)
	PHOTOSENSITIVITY	0	1 (0.6%)
Special Senses	TOTAL	12 (7.4%)	4 (2.6%)
	CONJUNCTIVITIS	4 (2.5%)	1 (0.6%)
	OTITIS MEDIA	4 (2.5%)	1 (0.6%)
	EAR PAIN	3 (1.8%)	0
	MYDRIASIS	1 (0.6%)	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
Special Senses	OTITIS EXTERNA	1 (0.6%)	0
	ABNORMAL VISION	0	1 (0.6%)
	PHOTOPHOBIA	0	1 (0.6%)
Musculoskeletal System	TOTAL	9 (5.5%)	6 (3.8%)
	MYALGIA	5 (3.1%)	4 (2.6%)
	ARTHRALGIA	4 (2.5%)	2 (1.3%)
Metabolic and Nutritional Disorders	TOTAL	8 (4.9%)	6 (3.8%)
	WEIGHT GAIN	4 (2.5%)	3 (1.9%)
	THIRST	1 (0.6%)	1 (0.6%)
	HYPERKALEMIA	1 (0.6%)	0
	KETOSIS	1 (0.6%)	0
	WEIGHT LOSS	1 (0.6%)	0
	BILIRUBINEMIA	0	1 (0.6%)
	HYPONATREMIA	0	1 (0.6%)
Cardiovascular System	TOTAL	5 (3.1%)	3 (1.9%)
	VASODILATATION	3 (1.8%)	1 (0.6%)
	MIGRAINE	1 (0.6%)	0
	QT INTERVAL PROLONGED	1 (0.6%)	0
	HYPOTENSION	0	1 (0.6%)
	TACHYCARDIA	0	1 (0.6%)
Urogenital System	TOTAL	4 (2.5%)	4 (2.6%)
	URINARY INCONTINENCE	3 (1.8%)	0
	ALBUMINURIA	2 (1.2%)	2 (1.3%)
	URINE ABNORMALITY	1 (0.6%)	0
	URINARY FREQUENCY	0	1 (0.6%)
	URINARY TRACT INFECTION	0	1 (0.6%)
Hemic and Lymphatic System	TOTAL	2 (1.2%)	2 (1.3%)
	LEUKOPENIA	1 (0.6%)	1 (0.6%)
	LEUKOCYTOSIS	1 (0.6%)	0
	PURPURA	1 (0.6%)	0
	EOSINOPHILIA	0	1 (0.6%)
	POLYCYTHEMIA	0	1 (0.6%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
TOTAL	TOTAL	81 (49.7%)	70 (44.9%)
Body as a Whole	TOTAL	43 (26.4%)	38 (24.4%)
	HEADACHE	16 (9.8%)	15 (9.6%)
	INFECTION	9 (5.5%)	12 (7.7%)
	ASTHENIA	9 (5.5%)	3 (1.9%)
	TRAUMA	4 (2.5%)	5 (3.2%)
	FLU SYNDROME	3 (1.8%)	2 (1.3%)
	ABDOMINAL PAIN	2 (1.2%)	2 (1.3%)
	ALLERGIC REACTION	2 (1.2%)	1 (0.6%)
	BACK PAIN	1 (0.6%)	3 (1.9%)
	FEVER	1 (0.6%)	1 (0.6%)
	CELLULITIS	1 (0.6%)	0
	MONILIASIS	1 (0.6%)	0
	RHEUMATOID ARTHRITIS	1 (0.6%)	0
	CHEST PAIN	0	1 (0.6%)
Nervous System	TOTAL	32 (19.6%)	16 (10.3%)
	INSOMNIA	11 (6.7%)	6 (3.8%)
	NERVOUSNESS	6 (3.7%)	3 (1.9%)
	SOMNOLENCE	5 (3.1%)	5 (3.2%)
	HOSTILITY	3 (1.8%)	1 (0.6%)
	AGITATION	2 (1.2%)	2 (1.3%)
	DEPRESSION	2 (1.2%)	0
	EMOTIONAL LABILITY	2 (1.2%)	0
	HYPERKINESIA	2 (1.2%)	0
	NEUROSIS	2 (1.2%)	0
	TREMOR	2 (1.2%)	0
	DIZZINESS	1 (0.6%)	1 (0.6%)
	CONCENTRATION IMPAIRED	1 (0.6%)	0
	DEPERSONALIZATION	1 (0.6%)	0
	LACK OF EMOTION	1 (0.6%)	0
	LIBIDO DECREASED	1 (0.6%)	0
	MYOCLONUS	1 (0.6%)	0
	EXTRAPYRAMIDAL SYNDROME	0	1 (0.6%)
	VERTIGO	0	1 (0.6%)
Respiratory System	TOTAL	18 (11.0%)	22 (14.1%)
	RESPIRATORY DISORDER	8 (4.9%)	11 (7.1%)
	PHARYNGITIS	4 (2.5%)	3 (1.9%)
	COUGH INCREASED	3 (1.8%)	3 (1.9%)
	RHINITIS	2 (1.2%)	2 (1.3%)
	BRONCHITIS	2 (1.2%)	1 (0.6%)
	ASTHMA	2 (1.2%)	0

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
Respiratory System	EPISTAXIS	1 (0.6%)	0
	SINUSITIS	0	5 (3.2%)
Digestive System	TOTAL	17 (10.4%)	13 (8.3%)
	NAUSEA	7 (4.3%)	3 (1.9%)
	DYSPEPSIA	3 (1.8%)	3 (1.9%)
	VOMITING	3 (1.8%)	3 (1.9%)
	DECREASED APPETITE	3 (1.8%)	0
	DIARRHEA	1 (0.6%)	3 (1.9%)
	TOOTH DISORDER	1 (0.6%)	2 (1.3%)
	CONSTIPATION	1 (0.6%)	0
	FLATULENCE	1 (0.6%)	0
	INCREASED APPETITE	1 (0.6%)	0
	GASTROENTERITIS	0	2 (1.3%)
	DRY MOUTH	0	1 (0.6%)
	GINGIVITIS	0	1 (0.6%)
Special Senses	TOTAL	5 (3.1%)	2 (1.3%)
	OTITIS MEDIA	2 (1.2%)	1 (0.6%)
	CONJUNCTIVITIS	2 (1.2%)	0
	EAR PAIN	1 (0.6%)	0
	OTITIS EXTERNA	0	1 (0.6%)
Hemic and Lymphatic System	TOTAL	4 (2.5%)	0
	PURPURA	4 (2.5%)	0
Urogenital System	TOTAL	4 (2.5%)	3 (1.9%)
	URINARY INCONTINENCE	3 (1.8%)	0
	URINARY FREQUENCY	1 (0.6%)	0
	CYSTITIS	0	1 (0.6%)
	URINARY RETENTION	0	1 (0.6%)
	URINARY TRACT INFECTION	0	1 (0.6%)
Cardiovascular System	TOTAL	3 (1.8%)	2 (1.3%)
	SYNCOPE	1 (0.6%)	2 (1.3%)
	HYPOTENSION	1 (0.6%)	1 (0.6%)
	MIGRAINE	1 (0.6%)	0
Skin and Appendages	TOTAL	3 (1.8%)	4 (2.6%)
	SWEATING	1 (0.6%)	1 (0.6%)
	CONTACT DERMATITIS	1 (0.6%)	0
	RASH	1 (0.6%)	0
	ACNE	0	1 (0.6%)
	ECZEMA	0	1 (0.6%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=163)	 Placebo (N=156)
Skin and Appendages	FUNGAL DERMATITIS	0	1 (0.6%)
Musculoskeletal System	TOTAL	1 (0.6%)	4 (2.6%)
	MYALGIA	1 (0.6%)	1 (0.6%)
	ARTHRALGIA	0	2 (1.3%)
	ARTHROSIS	0	1 (0.6%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (0.6%)
	WEIGHT LOSS	0	1 (0.6%)

Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=163)	 Placebo (N=156)
TOTAL	TOTAL	19 (11.7%)	9 (5.8%)
Body as a Whole	TOTAL	10 (6.1%)	6 (3.8%)
	INFECTION	4 (2.5%)	0
	HEADACHE	2 (1.2%)	2 (1.3%)
	ABDOMINAL PAIN	1 (0.6%)	1 (0.6%)
	FLU SYNDROME	1 (0.6%)	1 (0.6%)
	TRAUMA	1 (0.6%)	1 (0.6%)
	ASTHENIA	1 (0.6%)	0
	BACK PAIN	0	2 (1.3%)
	CHILLS	0	1 (0.6%)
Nervous System	TOTAL	5 (3.1%)	1 (0.6%)
	MANIC REACTION	3 (1.8%)	0
	ABNORMAL DREAMS	1 (0.6%)	0
	AGITATION	1 (0.6%)	0
	HYPERKINESIA	1 (0.6%)	0
	DIZZINESS	0	1 (0.6%)
Digestive System	TOTAL	2 (1.2%)	2 (1.3%)
	DYSPEPSIA	1 (0.6%)	0
	GASTRITIS	1 (0.6%)	0
	NAUSEA	0	2 (1.3%)
Hemic and Lymphatic System	TOTAL	1 (0.6%)	0
	ANEMIA	1 (0.6%)	0
Skin and Appendages	TOTAL	1 (0.6%)	0
	CONTACT DERMATITIS	1 (0.6%)	0
Respiratory System	TOTAL	0	1 (0.6%)
	PHARYNGITIS	0	1 (0.6%)
Special Senses	TOTAL	0	1 (0.6%)
	EAR PAIN	0	1 (0.6%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=71)	Placebo (N=89)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=71)	Placebo (N=89)
Body System	Preferred Term		
TOTAL	TOTAL	1 (1.4%)	0
Urogenital System	TOTAL	1 (1.4%)	0
	ABNORMAL EJACULATION	1 (1.4%)	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=71)	Placebo (N=89)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=92)	Placebo (N=67)
Body System	Preferred Term		
TOTAL	TOTAL	4 (4.3%)	2 (3.0%)
Urogenital System	TOTAL	4 (4.3%)	2 (3.0%)
	DYSMENORRHEA	3 (3.3%)	2 (3.0%)
	AMENORRHEA	1 (1.1%)	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=92)	Placebo (N=67)
Body System	Preferred Term		
TOTAL	TOTAL	3 (3.3%)	2 (3.0%)
Urogenital System	TOTAL	3 (3.3%)	2 (3.0%)
	DYSMENORRHEA	3 (3.3%)	2 (3.0%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=92)	Treatment Group: Placebo (N=67)
TOTAL	TOTAL	1 (1.1%)	0
Urogenital System	TOTAL	1 (1.1%)	0
	DYSMENORRHEA	1 (1.1%)	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=45)
TOTAL	40 (87.0%)	31 (68.9%)
HEADACHE	13 (28.3%)	9 (20.0%)
ABDOMINAL PAIN	9 (19.6%)	4 (8.9%)
RESPIRATORY DISORDER	5 (10.9%)	1 (2.2%)
INFECTION	4 (8.7%)	5 (11.1%)
TRAUMA	4 (8.7%)	4 (8.9%)
RASH	4 (8.7%)	2 (4.4%)
NERVOUSNESS	4 (8.7%)	1 (2.2%)
INSOMNIA	4 (8.7%)	0
COUGH INCREASED	3 (6.5%)	4 (8.9%)
SOMNOLENCE	3 (6.5%)	3 (6.7%)
DECREASED APPETITE	3 (6.5%)	2 (4.4%)
OTITIS MEDIA	3 (6.5%)	0
URINARY INCONTINENCE	3 (6.5%)	0
NAUSEA	2 (4.3%)	3 (6.7%)
SINUSITIS	2 (4.3%)	2 (4.4%)
DYSPEPSIA	2 (4.3%)	1 (2.2%)
FECAL INCONTINENCE	2 (4.3%)	1 (2.2%)
FEVER	2 (4.3%)	1 (2.2%)
ASTHENIA	2 (4.3%)	0
CONJUNCTIVITIS	2 (4.3%)	0
CONTACT DERMATITIS	2 (4.3%)	0
HYPERKINESIA	2 (4.3%)	0
VASODILATATION	2 (4.3%)	0
RHINITIS	1 (2.2%)	6 (13.3%)
PHARYNGITIS	1 (2.2%)	5 (11.1%)
DIARRHEA	1 (2.2%)	2 (4.4%)
ALLERGIC REACTION	1 (2.2%)	1 (2.2%)
BACK PAIN	1 (2.2%)	1 (2.2%)
EPISTAXIS	1 (2.2%)	1 (2.2%)
ALBUMINURIA	1 (2.2%)	0
ARTHRALGIA	1 (2.2%)	0
ASTHMA	1 (2.2%)	0
EAR PAIN	1 (2.2%)	0
FLATULENCE	1 (2.2%)	0
HOSTILITY	1 (2.2%)	0
INCREASED APPETITE	1 (2.2%)	0
MYALGIA	1 (2.2%)	0
PURPURA	1 (2.2%)	0
SWEATING	1 (2.2%)	0
VOMITING	1 (2.2%)	0
WEIGHT GAIN	1 (2.2%)	0
CONCENTRATION IMPAIRED	0	2 (4.4%)
ECZEMA	0	1 (2.2%)

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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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=46)	Treatment Group: Placebo (N=45)
GASTROENTERITIS	0	1 (2.2%)
PAIN	0	1 (2.2%)
TOOTH DISORDER	0	1 (2.2%)

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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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=45)
TOTAL	20 (43.5%)	18 (40.0%)
HEADACHE	3 (6.5%)	3 (6.7%)
NERVOUSNESS	3 (6.5%)	1 (2.2%)
URINARY INCONTINENCE	3 (6.5%)	0
INSOMNIA	2 (4.3%)	3 (6.7%)
RESPIRATORY DISORDER	2 (4.3%)	2 (4.4%)
VOMITING	2 (4.3%)	2 (4.4%)
ASTHENIA	2 (4.3%)	1 (2.2%)
OTITIS MEDIA	2 (4.3%)	1 (2.2%)
HOSTILITY	2 (4.3%)	0
INFECTION	1 (2.2%)	3 (6.7%)
DIARRHEA	1 (2.2%)	2 (4.4%)
NAUSEA	1 (2.2%)	2 (4.4%)
SOMNOLENCE	1 (2.2%)	2 (4.4%)
ALLERGIC REACTION	1 (2.2%)	1 (2.2%)
DIZZINESS	1 (2.2%)	1 (2.2%)
PHARYNGITIS	1 (2.2%)	1 (2.2%)
CONCENTRATION IMPAIRED	1 (2.2%)	0
CONJUNCTIVITIS	1 (2.2%)	0
FLATULENCE	1 (2.2%)	0
HYPERKINESIA	1 (2.2%)	0
LACK OF EMOTION	1 (2.2%)	0
NEUROSIS	1 (2.2%)	0
PURPURA	1 (2.2%)	0
RASH	1 (2.2%)	0
TRAUMA	1 (2.2%)	0
SINUSITIS	0	2 (4.4%)
ABDOMINAL PAIN	0	1 (2.2%)
AGITATION	0	1 (2.2%)
ARTHRALGIA	0	1 (2.2%)
BRONCHITIS	0	1 (2.2%)
COUGH INCREASED	0	1 (2.2%)
DYSPEPSIA	0	1 (2.2%)
GASTROENTERITIS	0	1 (2.2%)
RHINITIS	0	1 (2.2%)
TOOTH DISORDER	0	1 (2.2%)

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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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=45)
TOTAL	5 (10.9%)	2 (4.4%)
INFECTION	2 (4.3%)	0
ABDOMINAL PAIN	1 (2.2%)	0
HYPERKINESIA	1 (2.2%)	0
MANIC REACTION	1 (2.2%)	0
EAR PAIN	0	1 (2.2%)
PHARYNGITIS	0	1 (2.2%)

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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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=25)	 Placebo (N=23)
TOTAL	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=25)	 Placebo (N=23)
TOTAL	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=25)	 Placebo (N=23)
TOTAL	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Children, Intensity : Mild, Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=21)	 Placebo (N=22)
TOTAL	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Children, Intensity : Moderate, Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=21)	 Placebo (N=22)
TOTAL	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Children, Intensity : Severe, Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=21)	 Placebo (N=22)
TOTAL	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=117)	Treatment Group: Placebo (N=111)
TOTAL	93 (79.5%)	75 (67.6%)
HEADACHE	37 (31.6%)	20 (18.0%)
INFECTION	19 (16.2%)	8 (7.2%)
RHINITIS	14 (12.0%)	17 (15.3%)
ASTHENIA	13 (11.1%)	10 (9.0%)
RESPIRATORY DISORDER	13 (11.1%)	9 (8.1%)
NAUSEA	13 (11.1%)	6 (5.4%)
SOMNOLENCE	13 (11.1%)	5 (4.5%)
ABDOMINAL PAIN	12 (10.3%)	8 (7.2%)
PHARYNGITIS	9 (7.7%)	5 (4.5%)
INSOMNIA	9 (7.7%)	4 (3.6%)
DECREASED APPETITE	8 (6.8%)	3 (2.7%)
VOMITING	8 (6.8%)	0
DIZZINESS	7 (6.0%)	9 (8.1%)
DYSPEPSIA	7 (6.0%)	2 (1.8%)
SINUSITIS	6 (5.1%)	2 (1.8%)
NERVOUSNESS	5 (4.3%)	5 (4.5%)
TRAUMA	5 (4.3%)	2 (1.8%)
DRY MOUTH	4 (3.4%)	5 (4.5%)
MYALGIA	4 (3.4%)	4 (3.6%)
ALLERGIC REACTION	4 (3.4%)	2 (1.8%)
DIARRHEA	4 (3.4%)	2 (1.8%)
COUGH INCREASED	3 (2.6%)	4 (3.6%)
WEIGHT GAIN	3 (2.6%)	3 (2.7%)
ARTHRALGIA	3 (2.6%)	2 (1.8%)
INCREASED APPETITE	3 (2.6%)	2 (1.8%)
RASH	3 (2.6%)	2 (1.8%)
FEVER	3 (2.6%)	1 (0.9%)
YAWN	3 (2.6%)	1 (0.9%)
EMOTIONAL LABILITY	2 (1.7%)	2 (1.8%)
CONJUNCTIVITIS	2 (1.7%)	1 (0.9%)
PAIN	2 (1.7%)	1 (0.9%)
STOMATITIS	2 (1.7%)	1 (0.9%)
ABNORMAL DREAMS	2 (1.7%)	0
EAR PAIN	2 (1.7%)	0
SWEATING	2 (1.7%)	0
ACNE	1 (0.9%)	2 (1.8%)
ALBUMINURIA	1 (0.9%)	2 (1.8%)
BACK PAIN	1 (0.9%)	2 (1.8%)
BRONCHITIS	1 (0.9%)	2 (1.8%)
HOSTILITY	1 (0.9%)	1 (0.9%)
OTITIS MEDIA	1 (0.9%)	1 (0.9%)
VASODILATATION	1 (0.9%)	1 (0.9%)
AGITATION	1 (0.9%)	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=117)	Treatment Group: Placebo (N=111)
CONCENTRATION IMPAIRED	1 (0.9%)	0
DEPRESSION	1 (0.9%)	0
EPISTAXIS	1 (0.9%)	0
FLU SYNDROME	1 (0.9%)	0
HYPERKINESIA	1 (0.9%)	0
LACK OF EMOTION	1 (0.9%)	0
MONILIASIS	1 (0.9%)	0
TREMOR	1 (0.9%)	0
GASTROENTERITIS	0	2 (1.8%)
ASTHMA	0	1 (0.9%)
HYPOTENSION	0	1 (0.9%)
URINARY TRACT INFECTION	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=117)	 Placebo (N=111)
TOTAL	60 (51.3%)	50 (45.0%)
HEADACHE	13 (11.1%)	12 (10.8%)
INSOMNIA	9 (7.7%)	3 (2.7%)
INFECTION	8 (6.8%)	9 (8.1%)
ASTHENIA	7 (6.0%)	2 (1.8%)
RESPIRATORY DISORDER	6 (5.1%)	9 (8.1%)
NAUSEA	6 (5.1%)	1 (0.9%)
SOMNOLENCE	4 (3.4%)	3 (2.7%)
TRAUMA	3 (2.6%)	5 (4.5%)
COUGH INCREASED	3 (2.6%)	2 (1.8%)
DYSPEPSIA	3 (2.6%)	2 (1.8%)
FLU SYNDROME	3 (2.6%)	2 (1.8%)
NERVOUSNESS	3 (2.6%)	2 (1.8%)
PHARYNGITIS	3 (2.6%)	2 (1.8%)
DECREASED APPETITE	3 (2.6%)	0
PURPURA	3 (2.6%)	0
ABDOMINAL PAIN	2 (1.7%)	1 (0.9%)
AGITATION	2 (1.7%)	1 (0.9%)
RHINITIS	2 (1.7%)	1 (0.9%)
ASTHMA	2 (1.7%)	0
BRONCHITIS	2 (1.7%)	0
DEPRESSION	2 (1.7%)	0
EMOTIONAL LABILITY	2 (1.7%)	0
TREMOR	2 (1.7%)	0
BACK PAIN	1 (0.9%)	3 (2.7%)
SYNCOPE	1 (0.9%)	2 (1.8%)
FEVER	1 (0.9%)	1 (0.9%)
HOSTILITY	1 (0.9%)	1 (0.9%)
HYPOTENSION	1 (0.9%)	1 (0.9%)
MYALGIA	1 (0.9%)	1 (0.9%)
SWEATING	1 (0.9%)	1 (0.9%)
TOOTH DISORDER	1 (0.9%)	1 (0.9%)
VOMITING	1 (0.9%)	1 (0.9%)
ALLERGIC REACTION	1 (0.9%)	0
CONJUNCTIVITIS	1 (0.9%)	0
CONTACT DERMATITIS	1 (0.9%)	0
EAR PAIN	1 (0.9%)	0
EPISTAXIS	1 (0.9%)	0
HYPERKINESIA	1 (0.9%)	0
INCREASED APPETITE	1 (0.9%)	0
MONILIASIS	1 (0.9%)	0
NEUROSIS	1 (0.9%)	0
SINUSITIS	0	3 (2.7%)
ACNE	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=117)	 Placebo (N=111)
ARTHRALGIA	0	1 (0.9%)
DIARRHEA	0	1 (0.9%)
DRY MOUTH	0	1 (0.9%)
ECZEMA	0	1 (0.9%)
GASTROENTERITIS	0	1 (0.9%)
URINARY TRACT INFECTION	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=117)	 Placebo (N=111)
TOTAL	12 (10.3%)	7 (6.3%)
HEADACHE	2 (1.7%)	2 (1.8%)
INFECTION	2 (1.7%)	0
MANIC REACTION	2 (1.7%)	0
FLU SYNDROME	1 (0.9%)	1 (0.9%)
TRAUMA	1 (0.9%)	1 (0.9%)
ABNORMAL DREAMS	1 (0.9%)	0
AGITATION	1 (0.9%)	0
ASTHENIA	1 (0.9%)	0
CONTACT DERMATITIS	1 (0.9%)	0
DYSPEPSIA	1 (0.9%)	0
BACK PAIN	0	2 (1.8%)
NAUSEA	0	2 (1.8%)
ABDOMINAL PAIN	0	1 (0.9%)
DIZZINESS	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=46)	Treatment Group: Placebo (N=66)
TOTAL	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=66)
TOTAL	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=66)
TOTAL	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Mild, Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=71)	 Placebo (N=45)
TOTAL	3 (4.2%)	2 (4.4%)
DYSMENORRHEA	3 (4.2%)	2 (4.4%)

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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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Moderate, Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=71)	 Placebo (N=45)
TOTAL	3 (4.2%)	2 (4.4%)
DYSMENORRHEA	3 (4.2%)	2 (4.4%)

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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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Intensity : Severe, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=71)	Treatment Group: Placebo (N=45)
TOTAL	1 (1.4%)	0
DYSMENORRHEA	1 (1.4%)	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
TOTAL	133 (81.6%)	106 (67.9%)
HEADACHE	50 (30.7%)	29 (18.6%)
INFECTION	23 (14.1%)	13 (8.3%)
ABDOMINAL PAIN	21 (12.9%)	12 (7.7%)
RESPIRATORY DISORDER	18 (11.0%)	10 (6.4%)
SOMNOLENCE	16 (9.8%)	8 (5.1%)
RHINITIS	15 (9.2%)	23 (14.7%)
ASTHENIA	15 (9.2%)	10 (6.4%)
NAUSEA	15 (9.2%)	9 (5.8%)
INSOMNIA	13 (8.0%)	4 (2.6%)
DECREASED APPETITE	11 (6.7%)	5 (3.2%)
PHARYNGITIS	10 (6.1%)	10 (6.4%)
NERVOUSNESS	9 (5.5%)	6 (3.8%)
TRAUMA	9 (5.5%)	6 (3.8%)
DYSPEPSIA	9 (5.5%)	3 (1.9%)
VOMITING	9 (5.5%)	0
SINUSITIS	8 (4.9%)	4 (2.6%)
DIZZINESS	7 (4.3%)	9 (5.8%)
RASH	7 (4.3%)	4 (2.6%)
COUGH INCREASED	6 (3.7%)	8 (5.1%)
DIARRHEA	5 (3.1%)	4 (2.6%)
MYALGIA	5 (3.1%)	4 (2.6%)
ALLERGIC REACTION	5 (3.1%)	3 (1.9%)
FEVER	5 (3.1%)	2 (1.3%)
DRY MOUTH	4 (2.5%)	5 (3.2%)
WEIGHT GAIN	4 (2.5%)	3 (1.9%)
ARTHRALGIA	4 (2.5%)	2 (1.3%)
INCREASED APPETITE	4 (2.5%)	2 (1.3%)
CONJUNCTIVITIS	4 (2.5%)	1 (0.6%)
OTITIS MEDIA	4 (2.5%)	1 (0.6%)
VASODILATATION	3 (1.8%)	1 (0.6%)
YAWN	3 (1.8%)	1 (0.6%)
EAR PAIN	3 (1.8%)	0
HYPERKINESIA	3 (1.8%)	0
SWEATING	3 (1.8%)	0
URINARY INCONTINENCE	3 (1.8%)	0
BACK PAIN	2 (1.2%)	3 (1.9%)
ALBUMINURIA	2 (1.2%)	2 (1.3%)
EMOTIONAL LABILITY	2 (1.2%)	2 (1.3%)
PAIN	2 (1.2%)	2 (1.3%)
EPISTAXIS	2 (1.2%)	1 (0.6%)
FECAL INCONTINENCE	2 (1.2%)	1 (0.6%)
HOSTILITY	2 (1.2%)	1 (0.6%)
STOMATITIS	2 (1.2%)	1 (0.6%)

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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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=163)	 Placebo (N=156)
ABNORMAL DREAMS	2 (1.2%)	0
CONTACT DERMATITIS	2 (1.2%)	0
ACNE	1 (0.6%)	2 (1.3%)
BRONCHITIS	1 (0.6%)	2 (1.3%)
CONCENTRATION IMPAIRED	1 (0.6%)	2 (1.3%)
ASTHMA	1 (0.6%)	1 (0.6%)
AGITATION	1 (0.6%)	0
DEPRESSION	1 (0.6%)	0
FLATULENCE	1 (0.6%)	0
FLU SYNDROME	1 (0.6%)	0
LACK OF EMOTION	1 (0.6%)	0
MONILIASIS	1 (0.6%)	0
PURPURA	1 (0.6%)	0
TREMOR	1 (0.6%)	0
GASTROENTERITIS	0	3 (1.9%)
ECZEMA	0	1 (0.6%)
HYPOTENSION	0	1 (0.6%)
TOOTH DISORDER	0	1 (0.6%)
URINARY TRACT INFECTION	0	1 (0.6%)

Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=163)	 Placebo (N=156)
TOTAL	80 (49.1%)	68 (43.6%)
HEADACHE	16 (9.8%)	15 (9.6%)
INSOMNIA	11 (6.7%)	6 (3.8%)
INFECTION	9 (5.5%)	12 (7.7%)
ASTHENIA	9 (5.5%)	3 (1.9%)
RESPIRATORY DISORDER	8 (4.9%)	11 (7.1%)
NAUSEA	7 (4.3%)	3 (1.9%)
NERVOUSNESS	6 (3.7%)	3 (1.9%)
SOMNOLENCE	5 (3.1%)	5 (3.2%)
TRAUMA	4 (2.5%)	5 (3.2%)
PHARYNGITIS	4 (2.5%)	3 (1.9%)
PURPURA	4 (2.5%)	0
COUGH INCREASED	3 (1.8%)	3 (1.9%)
DYSPEPSIA	3 (1.8%)	3 (1.9%)
VOMITING	3 (1.8%)	3 (1.9%)
FLU SYNDROME	3 (1.8%)	2 (1.3%)
HOSTILITY	3 (1.8%)	1 (0.6%)
DECREASED APPETITE	3 (1.8%)	0
URINARY INCONTINENCE	3 (1.8%)	0
ABDOMINAL PAIN	2 (1.2%)	2 (1.3%)
AGITATION	2 (1.2%)	2 (1.3%)
RHINITIS	2 (1.2%)	2 (1.3%)
ALLERGIC REACTION	2 (1.2%)	1 (0.6%)
BRONCHITIS	2 (1.2%)	1 (0.6%)
OTITIS MEDIA	2 (1.2%)	1 (0.6%)
ASTHMA	2 (1.2%)	0
CONJUNCTIVITIS	2 (1.2%)	0
DEPRESSION	2 (1.2%)	0
EMOTIONAL LABILITY	2 (1.2%)	0
HYPERKINESIA	2 (1.2%)	0
NEUROSIS	2 (1.2%)	0
TREMOR	2 (1.2%)	0
BACK PAIN	1 (0.6%)	3 (1.9%)
DIARRHEA	1 (0.6%)	3 (1.9%)
SYNCOPE	1 (0.6%)	2 (1.3%)
TOOTH DISORDER	1 (0.6%)	2 (1.3%)
DIZZINESS	1 (0.6%)	1 (0.6%)
FEVER	1 (0.6%)	1 (0.6%)
HYPOTENSION	1 (0.6%)	1 (0.6%)
MYALGIA	1 (0.6%)	1 (0.6%)
SWEATING	1 (0.6%)	1 (0.6%)
CONCENTRATION IMPAIRED	1 (0.6%)	0
CONTACT DERMATITIS	1 (0.6%)	0
EAR PAIN	1 (0.6%)	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=163)	 Placebo (N=156)
EPISTAXIS	1 (0.6%)	0
FLATULENCE	1 (0.6%)	0
INCREASED APPETITE	1 (0.6%)	0
LACK OF EMOTION	1 (0.6%)	0
MONILIASIS	1 (0.6%)	0
RASH	1 (0.6%)	0
SINUSITIS	0	5 (3.2%)
ARTHRALGIA	0	2 (1.3%)
GASTROENTERITIS	0	2 (1.3%)
ACNE	0	1 (0.6%)
DRY MOUTH	0	1 (0.6%)
ECZEMA	0	1 (0.6%)
URINARY TRACT INFECTION	0	1 (0.6%)

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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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=163)	 Placebo (N=156)
TOTAL	17 (10.4%)	9 (5.8%)
INFECTION	4 (2.5%)	0
MANIC REACTION	3 (1.8%)	0
HEADACHE	2 (1.2%)	2 (1.3%)
ABDOMINAL PAIN	1 (0.6%)	1 (0.6%)
FLU SYNDROME	1 (0.6%)	1 (0.6%)
TRAUMA	1 (0.6%)	1 (0.6%)
ABNORMAL DREAMS	1 (0.6%)	0
AGITATION	1 (0.6%)	0
ASTHENIA	1 (0.6%)	0
CONTACT DERMATITIS	1 (0.6%)	0
DYSPEPSIA	1 (0.6%)	0
HYPERKINESIA	1 (0.6%)	0
BACK PAIN	0	2 (1.3%)
NAUSEA	0	2 (1.3%)
DIZZINESS	0	1 (0.6%)
EAR PAIN	0	1 (0.6%)
PHARYNGITIS	0	1 (0.6%)

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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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=71)	 Placebo (N=89)
TOTAL	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=71)	 Placebo (N=89)
TOTAL	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=71)	Treatment Group: Placebo (N=89)
TOTAL	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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Total, Intensity : Mild, Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=92)	 Placebo (N=67)
TOTAL	3 (3.3%)	2 (3.0%)
DYSMENORRHEA	3 (3.3%)	2 (3.0%)

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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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Total, Intensity : Moderate, Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=92)	 Placebo (N=67)
TOTAL	3 (3.3%)	2 (3.0%)
DYSMENORRHEA	3 (3.3%)	2 (3.0%)

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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 Treatment Phase
by Intensity by Descending Order
Intention-To-Treat Population
Age Group : Total, Intensity : Severe, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=92)	Treatment Group: Placebo (N=67)
TOTAL	1 (1.1%)	0
DYSMENORRHEA	1 (1.1%)	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Gender Non Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=29)
Body System	Preferred Term		
TOTAL	TOTAL	5 (20.0%)	5 (17.2%)
Body as a Whole	TOTAL	2 (8.0%)	1 (3.4%)
	ABDOMINAL PAIN	1 (4.0%)	0
	TRAUMA	1 (4.0%)	0
	HEADACHE	0	1 (3.4%)
Nervous System	TOTAL	2 (8.0%)	0
	DIZZINESS	1 (4.0%)	0
	INSOMNIA	1 (4.0%)	0
Digestive System	TOTAL	1 (4.0%)	0
	NAUSEA	1 (4.0%)	0
Respiratory System	TOTAL	1 (4.0%)	3 (10.3%)
	RHINITIS	1 (4.0%)	1 (3.4%)
	COUGH INCREASED	0	1 (3.4%)
	PHARYNGITIS	0	1 (3.4%)
	RESPIRATORY DISORDER	0	1 (3.4%)
Urogenital System	TOTAL	0	1 (3.4%)
	PYURIA	0	1 (3.4%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=25)	Placebo (N=29)
TOTAL	TOTAL	6 (24.0%)	1 (3.4%)
Body as a Whole	TOTAL	4 (16.0%)	0
	HEADACHE	3 (12.0%)	0
	FLU SYNDROME	1 (4.0%)	0
	TRAUMA	1 (4.0%)	0
Digestive System	TOTAL	1 (4.0%)	0
	DIARRHEA	1 (4.0%)	0
Nervous System	TOTAL	1 (4.0%)	1 (3.4%)
	NERVOUSNESS	1 (4.0%)	0
	ANXIETY	0	1 (3.4%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Gender Non Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=29)
Body System	Preferred Term		
TOTAL	TOTAL	1 (4.0%)	0
Respiratory System	TOTAL	1 (4.0%)	0
	SINUSITIS	1 (4.0%)	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=12)	Placebo (N=15)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=12)	Placebo (N=15)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=12)	Placebo (N=15)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=13)	Placebo (N=14)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=13)	Placebo (N=14)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=13)	Placebo (N=14)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=81)	Placebo (N=79)
TOTAL	TOTAL	15 (18.5%)	11 (13.9%)
Body as a Whole	TOTAL	6 (7.4%)	7 (8.9%)
	HEADACHE	3 (3.7%)	4 (5.1%)
	ABDOMINAL PAIN	2 (2.5%)	2 (2.5%)
	ALLERGIC REACTION	1 (1.2%)	0
	ASTHENIA	0	1 (1.3%)
	BACK PAIN	0	1 (1.3%)
Nervous System	TOTAL	5 (6.2%)	2 (2.5%)
	NERVOUSNESS	2 (2.5%)	1 (1.3%)
	DIZZINESS	2 (2.5%)	0
	SOMNOLENCE	2 (2.5%)	0
	EMOTIONAL LABILITY	1 (1.2%)	0
	ANXIETY	0	1 (1.3%)
Respiratory System	TOTAL	2 (2.5%)	4 (5.1%)
	PHARYNGITIS	1 (1.2%)	0
	SINUSITIS	1 (1.2%)	0
	LARYNX DISORDER	0	2 (2.5%)
	COUGH INCREASED	0	1 (1.3%)
	RESPIRATORY DISORDER	0	1 (1.3%)
Cardiovascular System	TOTAL	1 (1.2%)	0
	HYPOTENSION	1 (1.2%)	0
Digestive System	TOTAL	1 (1.2%)	0
	NAUSEA	1 (1.2%)	0
Special Senses	TOTAL	1 (1.2%)	0
	ABNORMAL VISION	1 (1.2%)	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Gender Non Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=81)	Placebo (N=79)
Body System	Preferred Term		
TOTAL	TOTAL	7 (8.6%)	5 (6.3%)
Body as a Whole	TOTAL	4 (4.9%)	4 (5.1%)
	HEADACHE	2 (2.5%)	2 (2.5%)
	INFECTION	1 (1.2%)	1 (1.3%)
	ABDOMINAL PAIN	1 (1.2%)	0
	ASTHENIA	1 (1.2%)	0
	TRAUMA	0	1 (1.3%)
Nervous System	TOTAL	4 (4.9%)	0
	DIZZINESS	1 (1.2%)	0
	MYOCLONUS	1 (1.2%)	0
	NERVOUSNESS	1 (1.2%)	0
	VERTIGO	1 (1.2%)	0
Digestive System	TOTAL	2 (2.5%)	0
	NAUSEA	2 (2.5%)	0
Respiratory System	TOTAL	1 (1.2%)	2 (2.5%)
	RESPIRATORY DISORDER	1 (1.2%)	2 (2.5%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Gender Non Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=81)	Placebo (N=79)
Body System	Preferred Term		
TOTAL	TOTAL	2 (2.5%)	1 (1.3%)
Body as a Whole	TOTAL	1 (1.2%)	1 (1.3%)
	TRAUMA	1 (1.2%)	0
	HEADACHE	0	1 (1.3%)
Nervous System	TOTAL	1 (1.2%)	0
	DIZZINESS	1 (1.2%)	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=30)	Placebo (N=48)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=30)	Placebo (N=48)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=30)	Placebo (N=48)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=51)	Placebo (N=31)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=51)	Placebo (N=31)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=51)	Placebo (N=31)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=106)	Placebo (N=108)
TOTAL	TOTAL	20 (18.9%)	16 (14.8%)
Body as a Whole	TOTAL	8 (7.5%)	8 (7.4%)
	HEADACHE	3 (2.8%)	5 (4.6%)
	ABDOMINAL PAIN	3 (2.8%)	2 (1.9%)
	ALLERGIC REACTION	1 (0.9%)	0
	TRAUMA	1 (0.9%)	0
	ASTHENIA	0	1 (0.9%)
	BACK PAIN	0	1 (0.9%)
Nervous System	TOTAL	7 (6.6%)	2 (1.9%)
	DIZZINESS	3 (2.8%)	0
	NERVOUSNESS	2 (1.9%)	1 (0.9%)
	SOMNOLENCE	2 (1.9%)	0
	EMOTIONAL LABILITY	1 (0.9%)	0
	INSOMNIA	1 (0.9%)	0
	ANXIETY	0	1 (0.9%)
Respiratory System	TOTAL	3 (2.8%)	7 (6.5%)
	PHARYNGITIS	1 (0.9%)	1 (0.9%)
	RHINITIS	1 (0.9%)	1 (0.9%)
	SINUSITIS	1 (0.9%)	0
	COUGH INCREASED	0	2 (1.9%)
	LARYNX DISORDER	0	2 (1.9%)
	RESPIRATORY DISORDER	0	2 (1.9%)
Digestive System	TOTAL	2 (1.9%)	0
	NAUSEA	2 (1.9%)	0
Cardiovascular System	TOTAL	1 (0.9%)	0
	HYPOTENSION	1 (0.9%)	0
Special Senses	TOTAL	1 (0.9%)	0
	ABNORMAL VISION	1 (0.9%)	0
Urogenital System	TOTAL	0	1 (0.9%)
	PYURIA	0	1 (0.9%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=106)	Placebo (N=108)
TOTAL	TOTAL	13 (12.3%)	6 (5.6%)
Body as a Whole	TOTAL	8 (7.5%)	4 (3.7%)
	HEADACHE	5 (4.7%)	2 (1.9%)
	INFECTION	1 (0.9%)	1 (0.9%)
	TRAUMA	1 (0.9%)	1 (0.9%)
	ABDOMINAL PAIN	1 (0.9%)	0
	ASTHENIA	1 (0.9%)	0
	FLU SYNDROME	1 (0.9%)	0
Nervous System	TOTAL	5 (4.7%)	1 (0.9%)
	NERVOUSNESS	2 (1.9%)	0
	DIZZINESS	1 (0.9%)	0
	MYOCLONUS	1 (0.9%)	0
	VERTIGO	1 (0.9%)	0
	ANXIETY	0	1 (0.9%)
Digestive System	TOTAL	3 (2.8%)	0
	NAUSEA	2 (1.9%)	0
	DIARRHEA	1 (0.9%)	0
Respiratory System	TOTAL	1 (0.9%)	2 (1.9%)
	RESPIRATORY DISORDER	1 (0.9%)	2 (1.9%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=106)	 Placebo (N=108)
TOTAL	TOTAL	3 (2.8%)	1 (0.9%)
Body as a Whole	TOTAL	1 (0.9%)	1 (0.9%)
	TRAUMA	1 (0.9%)	0
	HEADACHE	0	1 (0.9%)
Nervous System	TOTAL	1 (0.9%)	0
	DIZZINESS	1 (0.9%)	0
Respiratory System	TOTAL	1 (0.9%)	0
	SINUSITIS	1 (0.9%)	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=42)	Placebo (N=63)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=42)	Placebo (N=63)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=42)	Placebo (N=63)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=64)	Placebo (N=45)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=64)	Placebo (N=45)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=64)	Placebo (N=45)
Body System	Preferred Term		
TOTAL	TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=25)	Treatment Group: Placebo (N=29)
TOTAL	3 (12.0%)	3 (10.3%)
ABDOMINAL PAIN	1 (4.0%)	0
DIZZINESS	1 (4.0%)	0
NAUSEA	1 (4.0%)	0
TRAUMA	1 (4.0%)	0
COUGH INCREASED	0	1 (3.4%)
HEADACHE	0	1 (3.4%)
RESPIRATORY DISORDER	0	1 (3.4%)

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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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=25)	Treatment Group: Placebo (N=29)
TOTAL	5 (20.0%)	1 (3.4%)
HEADACHE	3 (12.0%)	0
NERVOUSNESS	1 (4.0%)	0
TRAUMA	1 (4.0%)	0
ANXIETY	0	1 (3.4%)

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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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=25)	Treatment Group: Placebo (N=29)
TOTAL	1 (4.0%)	0
SINUSITIS	1 (4.0%)	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=12)	Treatment Group: Placebo (N=15)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=12)	Treatment Group: Placebo (N=15)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=12)	Treatment Group: Placebo (N=15)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Mild, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=13)	Treatment Group: Placebo (N=14)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Moderate, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=13)	Treatment Group: Placebo (N=14)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Intensity : Severe, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=13)	Treatment Group: Placebo (N=14)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=81)	Treatment Group: Placebo (N=79)
TOTAL	12 (14.8%)	10 (12.7%)
HEADACHE	3 (3.7%)	4 (5.1%)
ABDOMINAL PAIN	2 (2.5%)	2 (2.5%)
NERVOUSNESS	2 (2.5%)	1 (1.3%)
DIZZINESS	2 (2.5%)	0
SOMNOLENCE	2 (2.5%)	0
NAUSEA	1 (1.2%)	0
SINUSITIS	1 (1.2%)	0
LARYNX DISORDER	0	2 (2.5%)
ANXIETY	0	1 (1.3%)
COUGH INCREASED	0	1 (1.3%)
RESPIRATORY DISORDER	0	1 (1.3%)

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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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=81)	Treatment Group: Placebo (N=79)
TOTAL	5 (6.2%)	4 (5.1%)
HEADACHE	2 (2.5%)	2 (2.5%)
NAUSEA	2 (2.5%)	0
RESPIRATORY DISORDER	1 (1.2%)	2 (2.5%)
ABDOMINAL PAIN	1 (1.2%)	0
DIZZINESS	1 (1.2%)	0
NERVOUSNESS	1 (1.2%)	0
TRAUMA	0	1 (1.3%)

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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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=81)	Treatment Group: Placebo (N=79)
TOTAL	2 (2.5%)	1 (1.3%)
DIZZINESS	1 (1.2%)	0
TRAUMA	1 (1.2%)	0
HEADACHE	0	1 (1.3%)

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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=30)	Treatment Group: Placebo (N=48)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=30)	Treatment Group: Placebo (N=48)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=30)	Treatment Group: Placebo (N=48)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Mild, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=51)	Treatment Group: Placebo (N=31)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Moderate, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=51)	Treatment Group: Placebo (N=31)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Intensity : Severe, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=51)	Treatment Group: Placebo (N=31)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=106)	Treatment Group: Placebo (N=108)
TOTAL	15 (14.2%)	13 (12.0%)
HEADACHE	3 (2.8%)	5 (4.6%)
ABDOMINAL PAIN	3 (2.8%)	2 (1.9%)
DIZZINESS	3 (2.8%)	0
NERVOUSNESS	2 (1.9%)	1 (0.9%)
NAUSEA	2 (1.9%)	0
SOMNOLENCE	2 (1.9%)	0
SINUSITIS	1 (0.9%)	0
TRAUMA	1 (0.9%)	0
COUGH INCREASED	0	2 (1.9%)
LARYNX DISORDER	0	2 (1.9%)
RESPIRATORY DISORDER	0	2 (1.9%)
ANXIETY	0	1 (0.9%)

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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=106)	Treatment Group: Placebo (N=108)
TOTAL	10 (9.4%)	5 (4.6%)
HEADACHE	5 (4.7%)	2 (1.9%)
NAUSEA	2 (1.9%)	0
NERVOUSNESS	2 (1.9%)	0
RESPIRATORY DISORDER	1 (0.9%)	2 (1.9%)
TRAUMA	1 (0.9%)	1 (0.9%)
ABDOMINAL PAIN	1 (0.9%)	0
DIZZINESS	1 (0.9%)	0
ANXIETY	0	1 (0.9%)

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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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=106)	Treatment Group: Placebo (N=108)
TOTAL	3 (2.8%)	1 (0.9%)
DIZZINESS	1 (0.9%)	0
SINUSITIS	1 (0.9%)	0
TRAUMA	1 (0.9%)	0
HEADACHE	0	1 (0.9%)

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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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=42)	Treatment Group: Placebo (N=63)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=42)	Treatment Group: Placebo (N=63)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=42)	Treatment Group: Placebo (N=63)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Mild, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=64)	Treatment Group: Placebo (N=45)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Moderate, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=64)	Treatment Group: Placebo (N=45)
TOTAL	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.
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Intensity : Severe, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=64)	Treatment Group: Placebo (N=45)
TOTAL	0	0

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase or Taper Phase by Intensity
By Body System.
Intention-To-Treat Population
Intensity : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
TOTAL	TOTAL	135 (82.8%)	109 (69.9%)
Body as a Whole	TOTAL	91 (55.8%)	66 (42.3%)
	HEADACHE	52 (31.9%)	33 (21.2%)
	ABDOMINAL PAIN	24 (14.7%)	13 (8.3%)
	INFECTION	23 (14.1%)	13 (8.3%)
	ASTHENIA	15 (9.2%)	10 (6.4%)
	TRAUMA	10 (6.1%)	6 (3.8%)
	ALLERGIC REACTION	6 (3.7%)	3 (1.9%)
	FEVER	5 (3.1%)	2 (1.3%)
	BACK PAIN	2 (1.2%)	4 (2.6%)
	PAIN	2 (1.2%)	2 (1.3%)
	FLU SYNDROME	1 (0.6%)	0
	MONILIASIS	1 (0.6%)	0
	ABNORMAL LABORATORY VALUE	0	1 (0.6%)
	NEOPLASM	0	1 (0.6%)
Digestive System	TOTAL	53 (32.5%)	32 (20.5%)
	NAUSEA	17 (10.4%)	9 (5.8%)
	DECREASED APPETITE	11 (6.7%)	5 (3.2%)
	DYSPEPSIA	9 (5.5%)	3 (1.9%)
	VOMITING	9 (5.5%)	0
	DIARRHEA	5 (3.1%)	4 (2.6%)
	DRY MOUTH	4 (2.5%)	5 (3.2%)
	INCREASED APPETITE	4 (2.5%)	2 (1.3%)
	FECAL INCONTINENCE	2 (1.2%)	1 (0.6%)
	STOMATITIS	2 (1.2%)	1 (0.6%)
	ULCERATIVE STOMATITIS	1 (0.6%)	1 (0.6%)
	FLATULENCE	1 (0.6%)	0
	GASTROINTESTINAL DISORDER	1 (0.6%)	0
	GINGIVITIS	1 (0.6%)	0
	RECTAL DISORDER	1 (0.6%)	0
	GASTROENTERITIS	0	3 (1.9%)
	CONSTIPATION	0	1 (0.6%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (0.6%)
	TOOTH CARIES	0	1 (0.6%)
	TOOTH DISORDER	0	1 (0.6%)
Nervous System	TOTAL	50 (30.7%)	26 (16.7%)
	SOMNOLENCE	18 (11.0%)	8 (5.1%)
	INSOMNIA	14 (8.6%)	4 (2.6%)
	NERVOUSNESS	11 (6.7%)	7 (4.5%)
	DIZZINESS	10 (6.1%)	9 (5.8%)
	EMOTIONAL LABILITY	3 (1.8%)	2 (1.3%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase or Taper Phase by Intensity
By Body System.
Intention-To-Treat Population
Intensity : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
Nervous System	HYPERKINESIA	3 (1.8%)	0
	HOSTILITY	2 (1.2%)	1 (0.6%)
	ABNORMAL DREAMS	2 (1.2%)	0
	CONCENTRATION IMPAIRED	1 (0.6%)	2 (1.3%)
	AGITATION	1 (0.6%)	0
	AMNESIA	1 (0.6%)	0
	DEPRESSION	1 (0.6%)	0
	LACK OF EMOTION	1 (0.6%)	0
	SPEECH DISORDER	1 (0.6%)	0
	TREMOR	1 (0.6%)	0
	ANXIETY	0	2 (1.3%)
	HYPERTONIA	0	1 (0.6%)
	INCOORDINATION	0	1 (0.6%)
	VERTIGO	0	1 (0.6%)
Respiratory System	TOTAL	50 (30.7%)	53 (34.0%)
	RESPIRATORY DISORDER	18 (11.0%)	12 (7.7%)
	RHINITIS	16 (9.8%)	24 (15.4%)
	PHARYNGITIS	11 (6.7%)	11 (7.1%)
	SINUSITIS	9 (5.5%)	4 (2.6%)
	COUGH INCREASED	6 (3.7%)	10 (6.4%)
	YAWN	3 (1.8%)	1 (0.6%)
	EPISTAXIS	2 (1.2%)	1 (0.6%)
	BRONCHITIS	1 (0.6%)	2 (1.3%)
	ASTHMA	1 (0.6%)	1 (0.6%)
	LARYNX DISORDER	0	2 (1.3%)
	PNEUMONIA	0	1 (0.6%)
Skin and Appendages	TOTAL	15 (9.2%)	9 (5.8%)
	RASH	7 (4.3%)	4 (2.6%)
	SWEATING	3 (1.8%)	0
	CONTACT DERMATITIS	2 (1.2%)	0
	ACNE	1 (0.6%)	2 (1.3%)
	HERPES SIMPLEX	1 (0.6%)	1 (0.6%)
	NAIL DISORDER	1 (0.6%)	0
	PRURITUS	1 (0.6%)	0
	VESICULOBULLOUS RASH	1 (0.6%)	0
	ECZEMA	0	1 (0.6%)
	PHOTOSENSITIVITY	0	1 (0.6%)
Special Senses	TOTAL	13 (8.0%)	4 (2.6%)
	CONJUNCTIVITIS	4 (2.5%)	1 (0.6%)
	OTITIS MEDIA	4 (2.5%)	1 (0.6%)
	EAR PAIN	3 (1.8%)	0

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase or Taper Phase by Intensity
By Body System.
Intention-To-Treat Population
Intensity : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
Special Senses	ABNORMAL VISION	1 (0.6%)	1 (0.6%)
	MYDRIASIS	1 (0.6%)	0
	OTITIS EXTERNA	1 (0.6%)	0
	PHOTOPHOBIA	0	1 (0.6%)
Musculoskeletal System	TOTAL	9 (5.5%)	6 (3.8%)
	MYALGIA	5 (3.1%)	4 (2.6%)
	ARTHRALGIA	4 (2.5%)	2 (1.3%)
Metabolic and Nutritional Disorders	TOTAL	8 (4.9%)	6 (3.8%)
	WEIGHT GAIN	4 (2.5%)	3 (1.9%)
	THIRST	1 (0.6%)	1 (0.6%)
	HYPERKALEMIA	1 (0.6%)	0
	KETOSIS	1 (0.6%)	0
	WEIGHT LOSS	1 (0.6%)	0
	BILIRUBINEMIA	0	1 (0.6%)
	HYPONATREMIA	0	1 (0.6%)
Cardiovascular System	TOTAL	6 (3.7%)	3 (1.9%)
	VASODILATATION	3 (1.8%)	1 (0.6%)
	HYPOTENSION	1 (0.6%)	1 (0.6%)
	MIGRAINE	1 (0.6%)	0
	QT INTERVAL PROLONGED	1 (0.6%)	0
	TACHYCARDIA	0	1 (0.6%)
Urogenital System	TOTAL	4 (2.5%)	5 (3.2%)
	URINARY INCONTINENCE	3 (1.8%)	0
	ALBUMINURIA	2 (1.2%)	2 (1.3%)
	URINE ABNORMALITY	1 (0.6%)	0
	PYURIA	0	1 (0.6%)
	URINARY FREQUENCY	0	1 (0.6%)
	URINARY TRACT INFECTION	0	1 (0.6%)
Hemic and Lymphatic System	TOTAL	2 (1.2%)	2 (1.3%)
	LEUKOPENIA	1 (0.6%)	1 (0.6%)
	LEUKOCYTOSIS	1 (0.6%)	0
	PURPURA	1 (0.6%)	0
	EOSINOPHILIA	0	1 (0.6%)
	POLYCYTHEMIA	0	1 (0.6%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase or Taper Phase by Intensity
By Body System.
Intention-To-Treat Population
Intensity : Moderate, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
TOTAL	TOTAL	85 (52.1%)	72 (46.2%)
Body as a Whole	TOTAL	50 (30.7%)	40 (25.6%)
	HEADACHE	21 (12.9%)	15 (9.6%)
	INFECTION	10 (6.1%)	13 (8.3%)
	ASTHENIA	10 (6.1%)	3 (1.9%)
	TRAUMA	5 (3.1%)	6 (3.8%)
	FLU SYNDROME	4 (2.5%)	2 (1.3%)
	ABDOMINAL PAIN	3 (1.8%)	2 (1.3%)
	ALLERGIC REACTION	2 (1.2%)	1 (0.6%)
	BACK PAIN	1 (0.6%)	3 (1.9%)
	FEVER	1 (0.6%)	1 (0.6%)
	CELLULITIS	1 (0.6%)	0
	MONILIASIS	1 (0.6%)	0
	RHEUMATOID ARTHRITIS	1 (0.6%)	0
	CHEST PAIN	0	1 (0.6%)
Nervous System	TOTAL	35 (21.5%)	17 (10.9%)
	INSOMNIA	11 (6.7%)	6 (3.8%)
	NERVOUSNESS	6 (3.7%)	3 (1.9%)
	SOMNOLENCE	5 (3.1%)	5 (3.2%)
	HOSTILITY	3 (1.8%)	1 (0.6%)
	AGITATION	2 (1.2%)	2 (1.3%)
	DIZZINESS	2 (1.2%)	1 (0.6%)
	DEPRESSION	2 (1.2%)	0
	EMOTIONAL LABILITY	2 (1.2%)	0
	HYPERKINESIA	2 (1.2%)	0
	MYOCLONUS	2 (1.2%)	0
	NEUROSIS	2 (1.2%)	0
	TREMOR	2 (1.2%)	0
	VERTIGO	1 (0.6%)	1 (0.6%)
	CONCENTRATION IMPAIRED	1 (0.6%)	0
	DEPERSONALIZATION	1 (0.6%)	0
	LACK OF EMOTION	1 (0.6%)	0
	LIBIDO DECREASED	1 (0.6%)	0
	ANXIETY	0	1 (0.6%)
	EXTRAPYRAMIDAL SYNDROME	0	1 (0.6%)
Digestive System	TOTAL	20 (12.3%)	13 (8.3%)
	NAUSEA	9 (5.5%)	3 (1.9%)
	DYSPEPSIA	3 (1.8%)	3 (1.9%)
	VOMITING	3 (1.8%)	3 (1.9%)
	DECREASED APPETITE	3 (1.8%)	0
	DIARRHEA	2 (1.2%)	3 (1.9%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase or Taper Phase by Intensity
By Body System.
Intention-To-Treat Population
Intensity : Moderate, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
Digestive System	TOOTH DISORDER	1 (0.6%)	2 (1.3%)
	CONSTIPATION	1 (0.6%)	0
	FLATULENCE	1 (0.6%)	0
	INCREASED APPETITE	1 (0.6%)	0
	GASTROENTERITIS	0	2 (1.3%)
	DRY MOUTH	0	1 (0.6%)
	GINGIVITIS	0	1 (0.6%)
Respiratory System	TOTAL	19 (11.7%)	24 (15.4%)
	RESPIRATORY DISORDER	9 (5.5%)	13 (8.3%)
	PHARYNGITIS	4 (2.5%)	3 (1.9%)
	COUGH INCREASED	3 (1.8%)	3 (1.9%)
	RHINITIS	2 (1.2%)	2 (1.3%)
	BRONCHITIS	2 (1.2%)	1 (0.6%)
	ASTHMA	2 (1.2%)	0
	EPISTAXIS	1 (0.6%)	0
	SINUSITIS	0	5 (3.2%)
Special Senses	TOTAL	5 (3.1%)	2 (1.3%)
	OTITIS MEDIA	2 (1.2%)	1 (0.6%)
	CONJUNCTIVITIS	2 (1.2%)	0
	EAR PAIN	1 (0.6%)	0
	OTITIS EXTERNA	0	1 (0.6%)
Hemic and Lymphatic System	TOTAL	4 (2.5%)	0
	PURPURA	4 (2.5%)	0
Urogenital System	TOTAL	4 (2.5%)	3 (1.9%)
	URINARY INCONTINENCE	3 (1.8%)	0
	URINARY FREQUENCY	1 (0.6%)	0
	CYSTITIS	0	1 (0.6%)
	URINARY RETENTION	0	1 (0.6%)
	URINARY TRACT INFECTION	0	1 (0.6%)
Cardiovascular System	TOTAL	3 (1.8%)	2 (1.3%)
	SYNCOPE	1 (0.6%)	2 (1.3%)
	HYPOTENSION	1 (0.6%)	1 (0.6%)
	MIGRAINE	1 (0.6%)	0
Skin and Appendages	TOTAL	3 (1.8%)	4 (2.6%)
	SWEATING	1 (0.6%)	1 (0.6%)
	CONTACT DERMATITIS	1 (0.6%)	0
	RASH	1 (0.6%)	0
	ACNE	0	1 (0.6%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase or Taper Phase by Intensity
By Body System.
Intention-To-Treat Population
Intensity : Moderate, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=163)	 Placebo (N=156)
Skin and Appendages	ECZEMA	0	1 (0.6%)
	FUNGAL DERMATITIS	0	1 (0.6%)
Musculoskeletal System	TOTAL	1 (0.6%)	4 (2.6%)
	MYALGIA	1 (0.6%)	1 (0.6%)
	ARTHRALGIA	0	2 (1.3%)
	ARTHROSIS	0	1 (0.6%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (0.6%)
	WEIGHT LOSS	0	1 (0.6%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase or Taper Phase by Intensity
By Body System.
Intention-To-Treat Population
Intensity : Severe, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
TOTAL	TOTAL	21 (12.9%)	10 (6.4%)
Body as a Whole	TOTAL	11 (6.7%)	7 (4.5%)
	INFECTION	4 (2.5%)	0
	HEADACHE	2 (1.2%)	3 (1.9%)
	TRAUMA	2 (1.2%)	1 (0.6%)
	ABDOMINAL PAIN	1 (0.6%)	1 (0.6%)
	FLU SYNDROME	1 (0.6%)	1 (0.6%)
	ASTHENIA	1 (0.6%)	0
	BACK PAIN	0	2 (1.3%)
	CHILLS	0	1 (0.6%)
Nervous System	TOTAL	6 (3.7%)	1 (0.6%)
	MANIC REACTION	3 (1.8%)	0
	DIZZINESS	1 (0.6%)	1 (0.6%)
	ABNORMAL DREAMS	1 (0.6%)	0
	AGITATION	1 (0.6%)	0
	HYPERKINESIA	1 (0.6%)	0
Digestive System	TOTAL	2 (1.2%)	2 (1.3%)
	DYSPEPSIA	1 (0.6%)	0
	GASTRITIS	1 (0.6%)	0
	NAUSEA	0	2 (1.3%)
Hemic and Lymphatic System	TOTAL	1 (0.6%)	0
	ANEMIA	1 (0.6%)	0
Respiratory System	TOTAL	1 (0.6%)	1 (0.6%)
	SINUSITIS	1 (0.6%)	0
	PHARYNGITIS	0	1 (0.6%)
Skin and Appendages	TOTAL	1 (0.6%)	0
	CONTACT DERMATITIS	1 (0.6%)	0
Special Senses	TOTAL	0	1 (0.6%)
	EAR PAIN	0	1 (0.6%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase or Taper Phase by Intensity
By Body System.
Intention-To-Treat Population
Intensity : Mild, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=71)	Placebo (N=89)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase or Taper Phase by Intensity
By Body System.
Intention-To-Treat Population
Intensity : Moderate, Male Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=71)	Treatment Group: Placebo (N=89)
TOTAL	TOTAL	1 (1.4%)	0
Urogenital System	TOTAL	1 (1.4%)	0
	ABNORMAL EJACULATION	1 (1.4%)	0

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase or Taper Phase by Intensity
By Body System.
Intention-To-Treat Population
Intensity : Severe, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=71)	Placebo (N=89)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase or Taper Phase by Intensity
By Body System.
Intention-To-Treat Population
Intensity : Mild, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=92)	Treatment Group: Placebo (N=67)
TOTAL	TOTAL	4 (4.3%)	2 (3.0%)
Urogenital System	TOTAL	4 (4.3%)	2 (3.0%)
	DYSMENORRHEA	3 (3.3%)	2 (3.0%)
	AMENORRHEA	1 (1.1%)	0

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase or Taper Phase by Intensity
By Body System.
Intention-To-Treat Population
Intensity : Moderate, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=92)	Treatment Group: Placebo (N=67)
TOTAL	TOTAL	3 (3.3%)	2 (3.0%)
Urogenital System	TOTAL	3 (3.3%)	2 (3.0%)
	DYSMENORRHEA	3 (3.3%)	2 (3.0%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase or Taper Phase by Intensity
By Body System.
Intention-To-Treat Population
Intensity : Severe, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=92)	Treatment Group: Placebo (N=67)
TOTAL	TOTAL	1 (1.1%)	0
Urogenital System	TOTAL	1 (1.1%)	0
	DYSMENORRHEA	1 (1.1%)	0

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Follow-Up Phase
Intensity : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=118)	 Placebo (N=100)
TOTAL	TOTAL	35 (29.7%)	17 (17.0%)
Body as a Whole	TOTAL	15 (12.7%)	7 (7.0%)
	HEADACHE	8 (6.8%)	5 (5.0%)
	ABDOMINAL PAIN	4 (3.4%)	1 (1.0%)
	ASTHENIA	2 (1.7%)	1 (1.0%)
	INFECTION	1 (0.8%)	1 (1.0%)
	FLU SYNDROME	1 (0.8%)	0
	TRAUMA	1 (0.8%)	0
Digestive System	TOTAL	15 (12.7%)	4 (4.0%)
	NAUSEA	9 (7.6%)	3 (3.0%)
	DYSPEPSIA	2 (1.7%)	0
	VOMITING	2 (1.7%)	0
	DECREASED APPETITE	1 (0.8%)	1 (1.0%)
	DIARRHEA	1 (0.8%)	0
	FLATULENCE	1 (0.8%)	0
	DRY MOUTH	0	1 (1.0%)
Nervous System	TOTAL	13 (11.0%)	2 (2.0%)
	DIZZINESS	9 (7.6%)	1 (1.0%)
	ANXIETY	2 (1.7%)	0
	EMOTIONAL LABILITY	2 (1.7%)	0
	SOMNOLENCE	1 (0.8%)	1 (1.0%)
	MYOCLONUS	1 (0.8%)	0
	NERVOUSNESS	1 (0.8%)	0
	TREMOR	0	1 (1.0%)
Respiratory System	TOTAL	5 (4.2%)	4 (4.0%)
	RESPIRATORY DISORDER	2 (1.7%)	2 (2.0%)
	PHARYNGITIS	1 (0.8%)	1 (1.0%)
	ASTHMA	1 (0.8%)	0
	SINUSITIS	1 (0.8%)	0
	RHINITIS	0	1 (1.0%)
Hemic and Lymphatic System	TOTAL	2 (1.7%)	0
	HYPOCHROMIC ANEMIA	1 (0.8%)	0
	LYMPHADENOPATHY	1 (0.8%)	0
Musculoskeletal System	TOTAL	1 (0.8%)	1 (1.0%)
	MYALGIA	1 (0.8%)	1 (1.0%)
Skin and Appendages	TOTAL	1 (0.8%)	1 (1.0%)
	SWEATING	1 (0.8%)	0

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Follow-Up Phase
Intensity : Mild, Gender Non Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=118)	Placebo (N=100)
Body System	Preferred Term		
Skin and Appendages	CONTACT DERMATITIS	0	1 (1.0%)
Urogenital System	TOTAL	0	1 (1.0%)
	URINARY TRACT INFECTION	0	1 (1.0%)

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=118)	Placebo (N=100)
TOTAL	TOTAL	23 (19.5%)	9 (9.0%)
Nervous System	TOTAL	12 (10.2%)	4 (4.0%)
	DIZZINESS	5 (4.2%)	1 (1.0%)
	ANXIETY	2 (1.7%)	1 (1.0%)
	DEPRESSION	2 (1.7%)	0
	NERVOUSNESS	2 (1.7%)	0
	INSOMNIA	1 (0.8%)	1 (1.0%)
	EMOTIONAL LABILITY	1 (0.8%)	0
	HYPERKINESIA	1 (0.8%)	0
	LACK OF EMOTION	1 (0.8%)	0
	TREMOR	1 (0.8%)	0
	WITHDRAWAL SYNDROME	1 (0.8%)	0
	AGITATION	0	1 (1.0%)
Body as a Whole	TOTAL	10 (8.5%)	3 (3.0%)
	HEADACHE	7 (5.9%)	2 (2.0%)
	ABDOMINAL PAIN	2 (1.7%)	0
	ASTHENIA	2 (1.7%)	0
	INFECTION	1 (0.8%)	1 (1.0%)
	FEVER	1 (0.8%)	0
Digestive System	TOTAL	4 (3.4%)	1 (1.0%)
	NAUSEA	3 (2.5%)	0
	VOMITING	1 (0.8%)	1 (1.0%)
Cardiovascular System	TOTAL	2 (1.7%)	0
	PALPITATION	1 (0.8%)	0
	SYNCOPE	1 (0.8%)	0
Respiratory System	TOTAL	2 (1.7%)	2 (2.0%)
	RESPIRATORY DISORDER	1 (0.8%)	1 (1.0%)
	RHINITIS	1 (0.8%)	1 (1.0%)
	PHARYNGITIS	0	1 (1.0%)
Special Senses	TOTAL	1 (0.8%)	0
	EAR PAIN	1 (0.8%)	0
Urogenital System	TOTAL	0	1 (1.0%)
	URINARY FREQUENCY	0	1 (1.0%)
	URINARY INCONTINENCE	0	1 (1.0%)

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Follow-Up Phase
Intensity : Severe, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=118)	 Placebo (N=100)
TOTAL	TOTAL	2 (1.7%)	3 (3.0%)
Body as a Whole	TOTAL	1 (0.8%)	2 (2.0%)
	HEADACHE	1 (0.8%)	0
	INFECTION	0	1 (1.0%)
	TRAUMA	0	1 (1.0%)
Nervous System	TOTAL	1 (0.8%)	0
	INSOMNIA	1 (0.8%)	0
Digestive System	TOTAL	0	1 (1.0%)
	GINGIVITIS	0	1 (1.0%)

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Follow-Up Phase
Intensity : Mild, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=57)
Body System	Preferred Term		
TOTAL	TOTAL	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
By Body System.
Intention-To Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=57)
Body System	Preferred Term		
TOTAL	TOTAL	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
By Body System.
Intention-To Treat Population Entering The Follow-Up Phase
Intensity : Severe, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=57)
Body System	Preferred Term		
TOTAL	TOTAL	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
By Body System.
Intention-To Treat Population Entering The Follow-Up Phase
Intensity : Mild, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=65)	Placebo (N=43)
Body System	Preferred Term		
TOTAL	TOTAL	0	1 (2.3%)
Urogenital System	TOTAL	0	1 (2.3%)
	DYSMENORRHEA	0	1 (2.3%)

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Intensity
By Body System.
Intention-To Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=65)	Placebo (N=43)
Body System	Preferred Term		
TOTAL	TOTAL	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
By Body System.
Intention-To Treat Population Entering The Follow-Up Phase
Intensity : Severe, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=65)	Placebo (N=43)
Body System	Preferred Term		
TOTAL	TOTAL	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.
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=118)	 Placebo (N=100)
TOTAL	32 (27.1%)	17 (17.0%)
NAUSEA	9 (7.6%)	3 (3.0%)
DIZZINESS	9 (7.6%)	1 (1.0%)
HEADACHE	8 (6.8%)	5 (5.0%)
ABDOMINAL PAIN	4 (3.4%)	1 (1.0%)
RESPIRATORY DISORDER	2 (1.7%)	2 (2.0%)
ASTHENIA	2 (1.7%)	1 (1.0%)
ANXIETY	2 (1.7%)	0
DYSPEPSIA	2 (1.7%)	0
EMOTIONAL LABILITY	2 (1.7%)	0
VOMITING	2 (1.7%)	0
DECREASED APPETITE	1 (0.8%)	1 (1.0%)
INFECTION	1 (0.8%)	1 (1.0%)
MYALGIA	1 (0.8%)	1 (1.0%)
PHARYNGITIS	1 (0.8%)	1 (1.0%)
SOMNOLENCE	1 (0.8%)	1 (1.0%)
NERVOUSNESS	1 (0.8%)	0
TRAUMA	1 (0.8%)	0
CONTACT DERMATITIS	0	1 (1.0%)
DRY MOUTH	0	1 (1.0%)
RHINITIS	0	1 (1.0%)
TREMOR	0	1 (1.0%)
URINARY TRACT INFECTION	0	1 (1.0%)

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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.
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=118)	Treatment Group: Placebo (N=100)
TOTAL	19 (16.1%)	9 (9.0%)
HEADACHE	7 (5.9%)	2 (2.0%)
DIZZINESS	5 (4.2%)	1 (1.0%)
NAUSEA	3 (2.5%)	0
ANXIETY	2 (1.7%)	1 (1.0%)
ABDOMINAL PAIN	2 (1.7%)	0
ASTHENIA	2 (1.7%)	0
DEPRESSION	2 (1.7%)	0
NERVOUSNESS	2 (1.7%)	0
INFECTION	1 (0.8%)	1 (1.0%)
INSOMNIA	1 (0.8%)	1 (1.0%)
RESPIRATORY DISORDER	1 (0.8%)	1 (1.0%)
RHINITIS	1 (0.8%)	1 (1.0%)
VOMITING	1 (0.8%)	1 (1.0%)
EMOTIONAL LABILITY	1 (0.8%)	0
TREMOR	1 (0.8%)	0
AGITATION	0	1 (1.0%)
PHARYNGITIS	0	1 (1.0%)
URINARY FREQUENCY	0	1 (1.0%)
URINARY INCONTINENCE	0	1 (1.0%)

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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.
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=118)	Treatment Group: Placebo (N=100)
TOTAL	2 (1.7%)	3 (3.0%)
HEADACHE	1 (0.8%)	0
INSOMNIA	1 (0.8%)	0
GINGIVITIS	0	1 (1.0%)
INFECTION	0	1 (1.0%)
TRAUMA	0	1 (1.0%)

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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.
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=53)	Treatment Group: Placebo (N=57)
TOTAL	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.
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=53)	Treatment Group: Placebo (N=57)
TOTAL	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.
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=53)	Treatment Group: Placebo (N=57)
TOTAL	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.
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Mild, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=65)	Treatment Group: Placebo (N=43)
TOTAL	0	1 (2.3%)
DYSMENORRHEA	0	1 (2.3%)

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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.
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Moderate, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=65)	Treatment Group: Placebo (N=43)
TOTAL	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.
Intention-To-Treat Population Entering The Follow-Up Phase
Intensity : Severe, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=65)	Treatment Group: Placebo (N=43)
TOTAL	0	0

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Table 15.1.4.1

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=46)	Treatment Group: Placebo (N=45)
TOTAL	TOTAL	31 (67.4%)	22 (48.9%)
Nervous System	TOTAL	22 (47.8%)	9 (20.0%)
	NERVOUSNESS	7 (15.2%)	2 (4.4%)
	INSOMNIA	5 (10.9%)	3 (6.7%)
	SOMNOLENCE	4 (8.7%)	3 (6.7%)
	HYPERKINESIA	4 (8.7%)	0
	HOSTILITY	2 (4.3%)	0
	CONCENTRATION IMPAIRED	1 (2.2%)	2 (4.4%)
	DIZZINESS	1 (2.2%)	1 (2.2%)
	MANIC REACTION	1 (2.2%)	0
	NEUROSIS	1 (2.2%)	0
	SPEECH DISORDER	1 (2.2%)	0
	AGITATION	0	1 (2.2%)
	INCOORDINATION	0	1 (2.2%)
Body as a Whole	TOTAL	16 (34.8%)	11 (24.4%)
	HEADACHE	10 (21.7%)	7 (15.6%)
	ABDOMINAL PAIN	6 (13.0%)	3 (6.7%)
	ASTHENIA	3 (6.5%)	1 (2.2%)
	ABNORMAL LABORATORY VALUE	0	1 (2.2%)
Digestive System	TOTAL	9 (19.6%)	7 (15.6%)
	DIARRHEA	2 (4.3%)	3 (6.7%)
	NAUSEA	2 (4.3%)	2 (4.4%)
	DECREASED APPETITE	2 (4.3%)	1 (2.2%)
	VOMITING	2 (4.3%)	1 (2.2%)
	FLATULENCE	2 (4.3%)	0
	CONSTIPATION	1 (2.2%)	1 (2.2%)
	DYSPEPSIA	1 (2.2%)	1 (2.2%)
	FECAL INCONTINENCE	1 (2.2%)	0
	INCREASED APPETITE	1 (2.2%)	0
Skin and Appendages	TOTAL	2 (4.3%)	0
	PRURITUS	1 (2.2%)	0
	SWEATING	1 (2.2%)	0
Urogenital System	TOTAL	2 (4.3%)	1 (2.2%)
	URINARY INCONTINENCE	2 (4.3%)	0
	URINARY RETENTION	0	1 (2.2%)
Metabolic and Nutritional Disorders	TOTAL	1 (2.2%)	1 (2.2%)
	WEIGHT GAIN	1 (2.2%)	0

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Table 15.1.4.1

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=46)	Treatment Group: Placebo (N=45)
Metabolic and Nutritional Disorders	HYPONATREMIA	0	1 (2.2%)
Cardiovascular System	TOTAL	0	1 (2.2%)
	TACHYCARDIA	0	1 (2.2%)
Respiratory System	TOTAL	0	1 (2.2%)
	PHARYNGITIS	0	1 (2.2%)

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Table 15.1.4.1

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Children, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=23)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.4.1

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Children, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=21)	Placebo (N=22)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.4.1

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=117)	Placebo (N=111)
TOTAL	TOTAL	72 (61.5%)	41 (36.9%)
Nervous System	TOTAL	42 (35.9%)	16 (14.4%)
	SOMNOLENCE	15 (12.8%)	7 (6.3%)
	INSOMNIA	15 (12.8%)	4 (3.6%)
	NERVOUSNESS	7 (6.0%)	3 (2.7%)
	DIZZINESS	5 (4.3%)	6 (5.4%)
	AGITATION	3 (2.6%)	0
	TREMOR	3 (2.6%)	0
	DEPRESSION	2 (1.7%)	0
	HYPERKINESIA	2 (1.7%)	0
	MANIC REACTION	2 (1.7%)	0
	EMOTIONAL LABILITY	1 (0.9%)	1 (0.9%)
	ABNORMAL DREAMS	1 (0.9%)	0
	AMNESIA	1 (0.9%)	0
	CONCENTRATION IMPAIRED	1 (0.9%)	0
	DEPERSONALIZATION	1 (0.9%)	0
	HOSTILITY	1 (0.9%)	0
	LACK OF EMOTION	1 (0.9%)	0
	LIBIDO DECREASED	1 (0.9%)	0
	MYOCLONUS	1 (0.9%)	0
	ANXIETY	0	1 (0.9%)
	EXTRAPYRAMIDAL SYNDROME	0	1 (0.9%)
Body as a Whole	TOTAL	41 (35.0%)	25 (22.5%)
	HEADACHE	25 (21.4%)	13 (11.7%)
	ASTHENIA	18 (15.4%)	10 (9.0%)
	ABDOMINAL PAIN	6 (5.1%)	4 (3.6%)
	FEVER	1 (0.9%)	0
	INFECTION	0	1 (0.9%)
Digestive System	TOTAL	30 (25.6%)	16 (14.4%)
	NAUSEA	10 (8.5%)	5 (4.5%)
	DECREASED APPETITE	10 (8.5%)	3 (2.7%)
	DRY MOUTH	4 (3.4%)	5 (4.5%)
	DYSPEPSIA	4 (3.4%)	1 (0.9%)
	INCREASED APPETITE	3 (2.6%)	2 (1.8%)
	DIARRHEA	3 (2.6%)	0
	VOMITING	3 (2.6%)	0
	GASTROINTESTINAL DISORDER	1 (0.9%)	0
Skin and Appendages	TOTAL	6 (5.1%)	2 (1.8%)
	SWEATING	3 (2.6%)	1 (0.9%)
	RASH	2 (1.7%)	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 Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=117)	Treatment Group: Placebo (N=111)
Skin and Appendages	ACNE	1 (0.9%)	0
Metabolic and Nutritional Disorders	TOTAL	5 (4.3%)	2 (1.8%)
	WEIGHT GAIN	3 (2.6%)	1 (0.9%)
	THIRST	1 (0.9%)	1 (0.9%)
	WEIGHT LOSS	1 (0.9%)	0
Respiratory System	TOTAL	4 (3.4%)	2 (1.8%)
	YAWN	3 (2.6%)	1 (0.9%)
	RESPIRATORY DISORDER	1 (0.9%)	0
	RHINITIS	0	1 (0.9%)
Special Senses	TOTAL	2 (1.7%)	1 (0.9%)
	CONJUNCTIVITIS	1 (0.9%)	0
	MYDRIASIS	1 (0.9%)	0
	ABNORMAL VISION	0	1 (0.9%)
Cardiovascular System	TOTAL	1 (0.9%)	2 (1.8%)
	QT INTERVAL PROLONGED	1 (0.9%)	0
	SYNCOPE	0	1 (0.9%)
	VASODILATATION	0	1 (0.9%)
Hemic and Lymphatic System	TOTAL	1 (0.9%)	0
	PURPURA	1 (0.9%)	0
Musculoskeletal System	TOTAL	1 (0.9%)	1 (0.9%)
	MYALGIA	1 (0.9%)	1 (0.9%)
Urogenital System	TOTAL	1 (0.9%)	0
	URINARY FREQUENCY	1 (0.9%)	0

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Table 15.1.4.1

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=46)	Placebo (N=66)
Body System	Preferred Term		
TOTAL	TOTAL	1 (2.2%)	0
Urogenital System	TOTAL	1 (2.2%)	0
	ABNORMAL EJACULATION	1 (2.2%)	0

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Table 15.1.4.1

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=71)	Treatment Group: Placebo (N=45)
TOTAL	TOTAL	0	1 (2.2%)
Urogenital System	TOTAL	0	1 (2.2%)
	DYSMENORRHEA	0	1 (2.2%)

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Table 15.1.4.1

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
TOTAL	TOTAL	103 (63.2%)	63 (40.4%)
Nervous System	TOTAL	64 (39.3%)	25 (16.0%)
	INSOMNIA	20 (12.3%)	7 (4.5%)
	SOMNOLENCE	19 (11.7%)	10 (6.4%)
	NERVOUSNESS	14 (8.6%)	5 (3.2%)
	DIZZINESS	6 (3.7%)	7 (4.5%)
	HYPERKINESIA	6 (3.7%)	0
	AGITATION	3 (1.8%)	1 (0.6%)
	HOSTILITY	3 (1.8%)	0
	MANIC REACTION	3 (1.8%)	0
	TREMOR	3 (1.8%)	0
	CONCENTRATION IMPAIRED	2 (1.2%)	2 (1.3%)
	DEPRESSION	2 (1.2%)	0
	EMOTIONAL LABILITY	1 (0.6%)	1 (0.6%)
	ABNORMAL DREAMS	1 (0.6%)	0
	AMNESIA	1 (0.6%)	0
	DEPERSONALIZATION	1 (0.6%)	0
	LACK OF EMOTION	1 (0.6%)	0
	LIBIDO DECREASED	1 (0.6%)	0
	MYOCLONUS	1 (0.6%)	0
	NEUROSIS	1 (0.6%)	0
	SPEECH DISORDER	1 (0.6%)	0
	ANXIETY	0	1 (0.6%)
	EXTRAPYRAMIDAL SYNDROME	0	1 (0.6%)
	INCOORDINATION	0	1 (0.6%)
Body as a Whole	TOTAL	57 (35.0%)	36 (23.1%)
	HEADACHE	35 (21.5%)	20 (12.8%)
	ASTHENIA	21 (12.9%)	11 (7.1%)
	ABDOMINAL PAIN	12 (7.4%)	7 (4.5%)
	FEVER	1 (0.6%)	0
	ABNORMAL LABORATORY VALUE	0	1 (0.6%)
	INFECTION	0	1 (0.6%)
Digestive System	TOTAL	39 (23.9%)	23 (14.7%)
	NAUSEA	12 (7.4%)	7 (4.5%)
	DECREASED APPETITE	12 (7.4%)	4 (2.6%)
	DIARRHEA	5 (3.1%)	3 (1.9%)
	DYSPEPSIA	5 (3.1%)	2 (1.3%)
	VOMITING	5 (3.1%)	1 (0.6%)
	DRY MOUTH	4 (2.5%)	5 (3.2%)
	INCREASED APPETITE	4 (2.5%)	2 (1.3%)
	FLATULENCE	2 (1.2%)	0

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Table 15.1.4.1

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
Digestive System	CONSTIPATION	1 (0.6%)	1 (0.6%)
	FECAL INCONTINENCE	1 (0.6%)	0
	GASTROINTESTINAL DISORDER	1 (0.6%)	0
Skin and Appendages	TOTAL	8 (4.9%)	2 (1.3%)
	SWEATING	4 (2.5%)	1 (0.6%)
	RASH	2 (1.2%)	1 (0.6%)
	ACNE	1 (0.6%)	0
	PRURITUS	1 (0.6%)	0
Metabolic and Nutritional Disorders	TOTAL	6 (3.7%)	3 (1.9%)
	WEIGHT GAIN	4 (2.5%)	1 (0.6%)
	THIRST	1 (0.6%)	1 (0.6%)
	WEIGHT LOSS	1 (0.6%)	0
	HYPONATREMIA	0	1 (0.6%)
Respiratory System	TOTAL	4 (2.5%)	3 (1.9%)
	YAWN	3 (1.8%)	1 (0.6%)
	RESPIRATORY DISORDER	1 (0.6%)	0
	PHARYNGITIS	0	1 (0.6%)
	RHINITIS	0	1 (0.6%)
Urogenital System	TOTAL	3 (1.8%)	1 (0.6%)
	URINARY INCONTINENCE	2 (1.2%)	0
	URINARY FREQUENCY	1 (0.6%)	0
	URINARY RETENTION	0	1 (0.6%)
Special Senses	TOTAL	2 (1.2%)	1 (0.6%)
	CONJUNCTIVITIS	1 (0.6%)	0
	MYDRIASIS	1 (0.6%)	0
	ABNORMAL VISION	0	1 (0.6%)
Cardiovascular System	TOTAL	1 (0.6%)	3 (1.9%)
	QT INTERVAL PROLONGED	1 (0.6%)	0
	SYNCOPE	0	1 (0.6%)
	TACHYCARDIA	0	1 (0.6%)
	VASODILATATION	0	1 (0.6%)
Hemic and Lymphatic System	TOTAL	1 (0.6%)	0
	PURPURA	1 (0.6%)	0
Musculoskeletal System	TOTAL	1 (0.6%)	1 (0.6%)
	MYALGIA	1 (0.6%)	1 (0.6%)

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Table 15.1.4.1

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Total, Male Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=71)	Treatment Group: Placebo (N=89)
TOTAL	TOTAL	1 (1.4%)	0
Urogenital System	TOTAL	1 (1.4%)	0
	ABNORMAL EJACULATION	1 (1.4%)	0

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Table 15.1.4.1

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Total, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=92)	Treatment Group: Placebo (N=67)
TOTAL	TOTAL	0	1 (1.5%)
Urogenital System	TOTAL	0	1 (1.5%)
	DYSMENORRHEA	0	1 (1.5%)

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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 Treatment Phase by Descending Order
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=45)
TOTAL	31 (67.4%)	19 (42.2%)
HEADACHE	10 (21.7%)	7 (15.6%)
NERVOUSNESS	7 (15.2%)	2 (4.4%)
ABDOMINAL PAIN	6 (13.0%)	3 (6.7%)
INSOMNIA	5 (10.9%)	3 (6.7%)
SOMNOLENCE	4 (8.7%)	3 (6.7%)
HYPERKINESIA	4 (8.7%)	0
ASTHENIA	3 (6.5%)	1 (2.2%)
DIARRHEA	2 (4.3%)	3 (6.7%)
NAUSEA	2 (4.3%)	2 (4.4%)
DECREASED APPETITE	2 (4.3%)	1 (2.2%)
VOMITING	2 (4.3%)	1 (2.2%)
FLATULENCE	2 (4.3%)	0
HOSTILITY	2 (4.3%)	0
URINARY INCONTINENCE	2 (4.3%)	0
CONCENTRATION IMPAIRED	1 (2.2%)	2 (4.4%)
DIZZINESS	1 (2.2%)	1 (2.2%)
DYSPEPSIA	1 (2.2%)	1 (2.2%)
INCREASED APPETITE	1 (2.2%)	0
MANIC REACTION	1 (2.2%)	0
SWEATING	1 (2.2%)	0
WEIGHT GAIN	1 (2.2%)	0
AGITATION	0	1 (2.2%)

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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 Treatment Phase by Descending Order
Intention-To-Treat Population
Age Group : Children, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=25)	 Placebo (N=23)
TOTAL	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 Treatment Phase by Descending Order
Intention-To-Treat Population
Age Group : Children, Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=21)	 Placebo (N=22)
TOTAL	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 Treatment Phase by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=117)	Treatment Group: Placebo (N=111)
TOTAL	70 (59.8%)	39 (35.1%)
HEADACHE	25 (21.4%)	13 (11.7%)
ASTHENIA	18 (15.4%)	10 (9.0%)
SOMNOLENCE	15 (12.8%)	7 (6.3%)
INSOMNIA	15 (12.8%)	4 (3.6%)
NAUSEA	10 (8.5%)	5 (4.5%)
DECREASED APPETITE	10 (8.5%)	3 (2.7%)
NERVOUSNESS	7 (6.0%)	3 (2.7%)
ABDOMINAL PAIN	6 (5.1%)	4 (3.6%)
DIZZINESS	5 (4.3%)	6 (5.4%)
DRY MOUTH	4 (3.4%)	5 (4.5%)
DYSPEPSIA	4 (3.4%)	1 (0.9%)
INCREASED APPETITE	3 (2.6%)	2 (1.8%)
SWEATING	3 (2.6%)	1 (0.9%)
WEIGHT GAIN	3 (2.6%)	1 (0.9%)
YAWN	3 (2.6%)	1 (0.9%)
AGITATION	3 (2.6%)	0
DIARRHEA	3 (2.6%)	0
TREMOR	3 (2.6%)	0
VOMITING	3 (2.6%)	0
RASH	2 (1.7%)	1 (0.9%)
DEPRESSION	2 (1.7%)	0
HYPERKINESIA	2 (1.7%)	0
MANIC REACTION	2 (1.7%)	0
CONCENTRATION IMPAIRED	1 (0.9%)	0
HOSTILITY	1 (0.9%)	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 Treatment Phase by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=46)	Treatment Group: Placebo (N=66)
TOTAL	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 Treatment Phase by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=71)	Treatment Group: Placebo (N=45)
TOTAL	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 Treatment Phase by Descending Order
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=163)	 Placebo (N=156)
TOTAL	101 (62.0%)	58 (37.2%)
HEADACHE	35 (21.5%)	20 (12.8%)
ASTHENIA	21 (12.9%)	11 (7.1%)
INSOMNIA	20 (12.3%)	7 (4.5%)
SOMNOLENCE	19 (11.7%)	10 (6.4%)
NERVOUSNESS	14 (8.6%)	5 (3.2%)
ABDOMINAL PAIN	12 (7.4%)	7 (4.5%)
NAUSEA	12 (7.4%)	7 (4.5%)
DECREASED APPETITE	12 (7.4%)	4 (2.6%)
DIZZINESS	6 (3.7%)	7 (4.5%)
HYPERKINESIA	6 (3.7%)	0
DIARRHEA	5 (3.1%)	3 (1.9%)
DYSPEPSIA	5 (3.1%)	2 (1.3%)
VOMITING	5 (3.1%)	1 (0.6%)
DRY MOUTH	4 (2.5%)	5 (3.2%)
INCREASED APPETITE	4 (2.5%)	2 (1.3%)
SWEATING	4 (2.5%)	1 (0.6%)
WEIGHT GAIN	4 (2.5%)	1 (0.6%)
AGITATION	3 (1.8%)	1 (0.6%)
YAWN	3 (1.8%)	1 (0.6%)
HOSTILITY	3 (1.8%)	0
MANIC REACTION	3 (1.8%)	0
TREMOR	3 (1.8%)	0
CONCENTRATION IMPAIRED	2 (1.2%)	2 (1.3%)
RASH	2 (1.2%)	1 (0.6%)
DEPRESSION	2 (1.2%)	0
FLATULENCE	2 (1.2%)	0
URINARY INCONTINENCE	2 (1.2%)	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 Treatment Phase by Descending Order
Intention-To-Treat Population
Age Group : Total, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=71)	Treatment Group: Placebo (N=89)
TOTAL	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 Treatment Phase by Descending Order
Intention-To-Treat Population
Age Group : Total, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=92)	Treatment Group: Placebo (N=67)
TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Gender Non Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=29)
Body System	Preferred Term		
TOTAL	TOTAL	3 (12.0%)	2 (6.9%)
Body as a Whole	TOTAL	2 (8.0%)	1 (3.4%)
	HEADACHE	2 (8.0%)	1 (3.4%)
	ABDOMINAL PAIN	1 (4.0%)	0
	FLU SYNDROME	1 (4.0%)	0
Digestive System	TOTAL	1 (4.0%)	0
	NAUSEA	1 (4.0%)	0
Nervous System	TOTAL	1 (4.0%)	1 (3.4%)
	DIZZINESS	1 (4.0%)	0
	ANXIETY	0	1 (3.4%)

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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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=12)	Placebo (N=15)
Body System	Preferred Term		
TOTAL	TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=13)	Placebo (N=14)
Body System	Preferred Term		
TOTAL	TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=81)	 Placebo (N=79)
TOTAL	TOTAL	11 (13.6%)	5 (6.3%)
Nervous System	TOTAL	8 (9.9%)	2 (2.5%)
	DIZZINESS	4 (4.9%)	0
	NERVOUSNESS	2 (2.5%)	1 (1.3%)
	SOMNOLENCE	2 (2.5%)	0
	EMOTIONAL LABILITY	1 (1.2%)	0
	MYOCLONUS	1 (1.2%)	0
	VERTIGO	1 (1.2%)	0
	ANXIETY	0	1 (1.3%)
Body as a Whole	TOTAL	5 (6.2%)	3 (3.8%)
	HEADACHE	2 (2.5%)	2 (2.5%)
	ABDOMINAL PAIN	2 (2.5%)	1 (1.3%)
	ASTHENIA	1 (1.2%)	1 (1.3%)
Digestive System	TOTAL	2 (2.5%)	0
	NAUSEA	2 (2.5%)	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=30)	Placebo (N=48)
Body System	Preferred Term		
TOTAL	TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=51)	Placebo (N=31)
Body System	Preferred Term		
TOTAL	TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=106)	 Placebo (N=108)
TOTAL	TOTAL	14 (13.2%)	7 (6.5%)
Nervous System	TOTAL	9 (8.5%)	3 (2.8%)
	DIZZINESS	5 (4.7%)	0
	NERVOUSNESS	2 (1.9%)	1 (0.9%)
	SOMNOLENCE	2 (1.9%)	0
	EMOTIONAL LABILITY	1 (0.9%)	0
	MYOCLONUS	1 (0.9%)	0
	VERTIGO	1 (0.9%)	0
	ANXIETY	0	2 (1.9%)
Body as a Whole	TOTAL	7 (6.6%)	4 (3.7%)
	HEADACHE	4 (3.8%)	3 (2.8%)
	ABDOMINAL PAIN	3 (2.8%)	1 (0.9%)
	ASTHENIA	1 (0.9%)	1 (0.9%)
	FLU SYNDROME	1 (0.9%)	0
Digestive System	TOTAL	3 (2.8%)	0
	NAUSEA	3 (2.8%)	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=42)	Placebo (N=63)
Body System	Preferred Term		
TOTAL	TOTAL	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
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=64)	Placebo (N=45)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.4.2.X

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences Occuring in 1% or More of the Population During the Taper Phase by Descending Order
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=25)	Treatment Group: Placebo (N=29)
TOTAL	3 (12.0%)	2 (6.9%)
HEADACHE	2 (8.0%)	1 (3.4%)
ABDOMINAL PAIN	1 (4.0%)	0
DIZZINESS	1 (4.0%)	0
NAUSEA	1 (4.0%)	0
ANXIETY	0	1 (3.4%)

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Table 15.1.4.2.X

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences Occuring in 1% or More of the Population During the Taper Phase by Descending Order
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=12)	Treatment Group: Placebo (N=15)
TOTAL	0	0

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Table 15.1.4.2.X

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences Occuring in 1% or More of the Population During the Taper Phase by Descending Order
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=13)	Treatment Group: Placebo (N=14)
TOTAL	0	0

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Table 15.1.4.2.X

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences Occuring in 1% or More of the Population During the Taper Phase by Descending Order
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=81)	Treatment Group: Placebo (N=79)
TOTAL	10 (12.3%)	4 (5.1%)
DIZZINESS	4 (4.9%)	0
HEADACHE	2 (2.5%)	2 (2.5%)
ABDOMINAL PAIN	2 (2.5%)	1 (1.3%)
NERVOUSNESS	2 (2.5%)	1 (1.3%)
NAUSEA	2 (2.5%)	0
SOMNOLENCE	2 (2.5%)	0
ANXIETY	0	1 (1.3%)

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Table 15.1.4.2.X

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences Occuring in 1% or More of the Population During the Taper Phase by Descending Order
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=30)	Treatment Group: Placebo (N=48)
TOTAL	0	0

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Table 15.1.4.2.X

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences Occuring in 1% or More of the Population During the Taper Phase by Descending Order
Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=51)	Treatment Group: Placebo (N=31)
TOTAL	0	0

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Table 15.1.4.2.X

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences Occuring in 1% or More of the Population During the Taper Phase by Descending Order
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=106)	Treatment Group: Placebo (N=108)
TOTAL	13 (12.3%)	6 (5.6%)
DIZZINESS	5 (4.7%)	0
HEADACHE	4 (3.8%)	3 (2.8%)
ABDOMINAL PAIN	3 (2.8%)	1 (0.9%)
NAUSEA	3 (2.8%)	0
NERVOUSNESS	2 (1.9%)	1 (0.9%)
SOMNOLENCE	2 (1.9%)	0
ANXIETY	0	2 (1.9%)

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Table 15.1.4.2.X

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences Occuring in 1% or More of the Population During the Taper Phase by Descending Order
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=42)	Treatment Group: Placebo (N=63)
TOTAL	0	0

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Table 15.1.4.2.X

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences Occuring in 1% or More of the Population During the Taper Phase by Descending Order
Intention-To-Treat Population Entering The Taper Phase
Age Group : Total, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=64)	Treatment Group: Placebo (N=45)
TOTAL	0	0

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Table 15.1.4.3

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase or Taper Phase
By Body System
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
TOTAL	TOTAL	107 (65.6%)	65 (41.7%)
Nervous System	TOTAL	70 (42.9%)	27 (17.3%)
	SOMNOLENCE	21 (12.9%)	10 (6.4%)
	INSOMNIA	20 (12.3%)	7 (4.5%)
	NERVOUSNESS	15 (9.2%)	6 (3.8%)
	DIZZINESS	11 (6.7%)	7 (4.5%)
	HYPERKINESIA	6 (3.7%)	0
	AGITATION	3 (1.8%)	1 (0.6%)
	HOSTILITY	3 (1.8%)	0
	MANIC REACTION	3 (1.8%)	0
	TREMOR	3 (1.8%)	0
	CONCENTRATION IMPAIRED	2 (1.2%)	2 (1.3%)
	EMOTIONAL LABILITY	2 (1.2%)	1 (0.6%)
	DEPRESSION	2 (1.2%)	0
	MYOCLONUS	2 (1.2%)	0
	ABNORMAL DREAMS	1 (0.6%)	0
	AMNESIA	1 (0.6%)	0
	DEPERSONALIZATION	1 (0.6%)	0
	LACK OF EMOTION	1 (0.6%)	0
	LIBIDO DECREASED	1 (0.6%)	0
	NEUROSIS	1 (0.6%)	0
	SPEECH DISORDER	1 (0.6%)	0
	VERTIGO	1 (0.6%)	0
	ANXIETY	0	3 (1.9%)
	EXTRAPYRAMIDAL SYNDROME	0	1 (0.6%)
	INCOORDINATION	0	1 (0.6%)
Body as a Whole	TOTAL	61 (37.4%)	37 (23.7%)
	HEADACHE	39 (23.9%)	21 (13.5%)
	ASTHENIA	22 (13.5%)	11 (7.1%)
	ABDOMINAL PAIN	15 (9.2%)	7 (4.5%)
	FEVER	1 (0.6%)	0
	FLU SYNDROME	1 (0.6%)	0
	ABNORMAL LABORATORY VALUE	0	1 (0.6%)
	INFECTION	0	1 (0.6%)
Digestive System	TOTAL	41 (25.2%)	23 (14.7%)
	NAUSEA	15 (9.2%)	7 (4.5%)
	DECREASED APPETITE	12 (7.4%)	4 (2.6%)
	DIARRHEA	5 (3.1%)	3 (1.9%)
	DYSPEPSIA	5 (3.1%)	2 (1.3%)
	VOMITING	5 (3.1%)	1 (0.6%)
	DRY MOUTH	4 (2.5%)	5 (3.2%)

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Table 15.1.4.3

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase or Taper Phase
By Body System
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
Digestive System	INCREASED APPETITE	4 (2.5%)	2 (1.3%)
	FLATULENCE	2 (1.2%)	0
	CONSTIPATION	1 (0.6%)	1 (0.6%)
	FECAL INCONTINENCE	1 (0.6%)	0
	GASTROINTESTINAL DISORDER	1 (0.6%)	0
Skin and Appendages	TOTAL	8 (4.9%)	2 (1.3%)
	SWEATING	4 (2.5%)	1 (0.6%)
	RASH	2 (1.2%)	1 (0.6%)
	ACNE	1 (0.6%)	0
	PRURITUS	1 (0.6%)	0
Metabolic and Nutritional Disorders	TOTAL	6 (3.7%)	3 (1.9%)
	WEIGHT GAIN	4 (2.5%)	1 (0.6%)
	THIRST	1 (0.6%)	1 (0.6%)
	WEIGHT LOSS	1 (0.6%)	0
	HYPONATREMIA	0	1 (0.6%)
Respiratory System	TOTAL	4 (2.5%)	3 (1.9%)
	YAWN	3 (1.8%)	1 (0.6%)
	RESPIRATORY DISORDER	1 (0.6%)	0
	PHARYNGITIS	0	1 (0.6%)
	RHINITIS	0	1 (0.6%)
Urogenital System	TOTAL	3 (1.8%)	1 (0.6%)
	URINARY INCONTINENCE	2 (1.2%)	0
	URINARY FREQUENCY	1 (0.6%)	0
	URINARY RETENTION	0	1 (0.6%)
Special Senses	TOTAL	2 (1.2%)	1 (0.6%)
	CONJUNCTIVITIS	1 (0.6%)	0
	MYDRIASIS	1 (0.6%)	0
	ABNORMAL VISION	0	1 (0.6%)
Cardiovascular System	TOTAL	1 (0.6%)	3 (1.9%)
	QT INTERVAL PROLONGED	1 (0.6%)	0
	SYNCOPE	0	1 (0.6%)
	TACHYCARDIA	0	1 (0.6%)
	VASODILATATION	0	1 (0.6%)
Hemic and Lymphatic System	TOTAL	1 (0.6%)	0
	PURPURA	1 (0.6%)	0

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Table 15.1.4.3

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase or Taper Phase
By Body System
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
Musculoskeletal System	TOTAL	1 (0.6%)	1 (0.6%)
	MYALGIA	1 (0.6%)	1 (0.6%)

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Table 15.1.4.3

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase or Taper Phase
By Body System
Intention-To-Treat Population
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=71)	Placebo (N=89)
Body System	Preferred Term		
TOTAL	TOTAL	1 (1.4%)	0
Urogenital System	TOTAL	1 (1.4%)	0
	ABNORMAL EJACULATION	1 (1.4%)	0

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Table 15.1.4.3

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase or Taper Phase
By Body System
Intention-To-Treat Population
Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=92)	Placebo (N=67)
Body System	Preferred Term		
TOTAL	TOTAL	0	1 (1.5%)
Urogenital System	TOTAL	0	1 (1.5%)
	DYSMENORRHEA	0	1 (1.5%)

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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
Intention-To-Treat Population Entering The Follow-Up Phase
Gender Non Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=118)	Placebo (N=100)
Body System	Preferred Term		
TOTAL	TOTAL	35 (29.7%)	6 (6.0%)
Body as a Whole	TOTAL	19 (16.1%)	2 (2.0%)
	HEADACHE	13 (11.0%)	2 (2.0%)
	ABDOMINAL PAIN	4 (3.4%)	0
	ASTHENIA	4 (3.4%)	0
	FLU SYNDROME	1 (0.8%)	0
	INFECTION	1 (0.8%)	0
Nervous System	TOTAL	19 (16.1%)	4 (4.0%)
	DIZZINESS	11 (9.3%)	0
	ANXIETY	3 (2.5%)	1 (1.0%)
	NERVOUSNESS	3 (2.5%)	0
	EMOTIONAL LABILITY	2 (1.7%)	0
	INSOMNIA	1 (0.8%)	1 (1.0%)
	SOMNOLENCE	1 (0.8%)	1 (1.0%)
	DEPRESSION	1 (0.8%)	0
	LACK OF EMOTION	1 (0.8%)	0
	MYOCLONUS	1 (0.8%)	0
	TREMOR	1 (0.8%)	0
	WITHDRAWAL SYNDROME	1 (0.8%)	0
	AGITATION	0	1 (1.0%)
Digestive System	TOTAL	12 (10.2%)	2 (2.0%)
	NAUSEA	10 (8.5%)	2 (2.0%)
	DECREASED APPETITE	1 (0.8%)	0
	DYSPEPSIA	1 (0.8%)	0
	VOMITING	1 (0.8%)	0
	DRY MOUTH	0	1 (1.0%)
Skin and Appendages	TOTAL	1 (0.8%)	0
	SWEATING	1 (0.8%)	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
Intention-To-Treat Population Entering The Follow-Up Phase
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=57)
Body System	Preferred Term		
TOTAL	TOTAL	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
Intention-To-Treat Population Entering The Follow-Up Phase
Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=65)	Placebo (N=43)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=45)
TOTAL	TOTAL	2 (4.3%)	2 (4.4%)
Nervous System	TOTAL	2 (4.3%)	1 (2.2%)
	HOSTILITY	1 (2.2%)	0
	HYPERKINESIA	1 (2.2%)	0
	AGITATION	0	1 (2.2%)
Skin and Appendages	TOTAL	1 (2.2%)	0
	PRURITUS	1 (2.2%)	0
Urogenital System	TOTAL	0	1 (2.2%)
	URINARY RETENTION	0	1 (2.2%)

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Children, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=23)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Children, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=21)	Placebo (N=22)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=117)	Treatment Group: Placebo (N=111)
TOTAL	TOTAL	8 (6.8%)	0
Nervous System	TOTAL	4 (3.4%)	0
	MANIC REACTION	2 (1.7%)	0
	ABNORMAL DREAMS	1 (0.9%)	0
	AGITATION	1 (0.9%)	0
	DEPRESSION	1 (0.9%)	0
	EMOTIONAL LABILITY	1 (0.9%)	0
Body as a Whole	TOTAL	2 (1.7%)	0
	ASTHENIA	1 (0.9%)	0
	HEADACHE	1 (0.9%)	0
Digestive System	TOTAL	1 (0.9%)	0
	VOMITING	1 (0.9%)	0
Hemic and Lymphatic System	TOTAL	1 (0.9%)	0
	ANEMIA	1 (0.9%)	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=46)	Placebo (N=66)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Adolescents, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=71)	Placebo (N=45)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=163)	 Placebo (N=156)
TOTAL	TOTAL	10 (6.1%)	2 (1.3%)
Nervous System	TOTAL	6 (3.7%)	1 (0.6%)
	MANIC REACTION	2 (1.2%)	0
	AGITATION	1 (0.6%)	1 (0.6%)
	ABNORMAL DREAMS	1 (0.6%)	0
	DEPRESSION	1 (0.6%)	0
	EMOTIONAL LABILITY	1 (0.6%)	0
	HOSTILITY	1 (0.6%)	0
	HYPERKINESIA	1 (0.6%)	0
Body as a Whole	TOTAL	2 (1.2%)	0
	ASTHENIA	1 (0.6%)	0
	HEADACHE	1 (0.6%)	0
Digestive System	TOTAL	1 (0.6%)	0
	VOMITING	1 (0.6%)	0
Hemic and Lymphatic System	TOTAL	1 (0.6%)	0
	ANEMIA	1 (0.6%)	0
Skin and Appendages	TOTAL	1 (0.6%)	0
	PRURITUS	1 (0.6%)	0
Urogenital System	TOTAL	0	1 (0.6%)
	URINARY RETENTION	0	1 (0.6%)

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Total, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=71)	Placebo (N=89)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Total, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=92)	Placebo (N=67)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase Occurring in 1% or More of the Population by Descending Order
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=46)	Treatment Group: Placebo (N=45)
TOTAL	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase Occurring in 1% or More of the Population by Descending Order
Intention-To-Treat Population
Age Group : Children, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=25)	 Placebo (N=23)
TOTAL	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase Occurring in 1% or More of the Population by Descending Order
Intention-To-Treat Population
Age Group : Children, Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=21)	 Placebo (N=22)
TOTAL	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase Occurring in 1% or More of the Population by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=117)	Treatment Group: Placebo (N=111)
TOTAL	2 (1.7%)	0
MANIC REACTION	2 (1.7%)	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase Occurring in 1% or More of the Population by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=46)	Placebo (N=66)
TOTAL	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase Occurring in 1% or More of the Population by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=71)	Treatment Group: Placebo (N=45)
TOTAL	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase Occurring in 1% or More of the Population by Descending Order
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=163)	 Placebo (N=156)
TOTAL	2 (1.2%)	0
MANIC REACTION	2 (1.2%)	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase Occurring in 1% or More of the Population by Descending Order
Intention-To-Treat Population
Age Group : Total, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=71)	 Placebo (N=89)
TOTAL	0	0

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Table 15.1.5.1.X

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase Occurring in 1% or More of the Population by Descending Order
Intention-To-Treat Population
Age Group : Total, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=92)	Treatment Group: Placebo (N=67)
TOTAL	0	0

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BRL-029060

Narratives for Patients Who Had Non-serious Adverse Events Leading to Withdrawal

Table 15.1.5.2

Protocol No. 676

xxxxx xxxxxxx, B.S.N.

Clinical Development and Medical Affairs

SB Document Number: BRL-029060/RSD-101SWF/1

Issue Date 29 May 2002

PID: 676.011.24282

Treatment Group: Paroxetine

Adverse Event: Manic Reaction (Manic Episode)

This 13-year-old Hispanic female was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

The patient entered the study with significant previous and current medical conditions of low back pain and morbid obesity. Psychiatric history (measured by the ADIS C/P semi-structured interview) includes an overall diagnostic label of Social Anxiety Disorder.

Prior and concomitant medication included Tylenol® (paracetamol) for low back pain.

The patient received the first dose of study medication on 17 March 2000. The patient began treatment at dose level 1 (10 mg/day). The dose was increased to dose level 2 (20 mg/day) on 31 March 2000, and was increased to dose level 3 (30 mg/day) on 07 April 2000, which continued throughout the remainder of the study. The last dose of study medication was taken on 18 April 2000 (Day 41).

On 18 March 2000 (Day 10), the patient reported mild nervousness (restlessness) that was considered to be possibly related to treatment with study medication. This condition continued beyond the end of the study; no corrective therapy was given.

On 10 April 2000 (Day 33) the patient reported mild headache, decreased appetite, dry mouth, dyspepsia (upset stomach), and insomnia (initial insomnia). All of these conditions continued without treatment through the end of the study, and all were considered to be possibly related to treatment with study medication.

On 18 April 2000 (Day 41), the patient experienced a severe manic reaction (manic episode), which was considered to be related to treatment with study medication. This event resulted in withdrawal from the study. No corrective treatment was given for this event, which continued beyond the end of the study.

No other adverse events were reported during the study.

PID: 676.014.24376

Treatment Group: Paroxetine

Adverse Event: Abnormal Dreams (Morbid Thoughts), Agitation (Panic Attack), Emotional Lability (Suicidal Thoughts)

This 13-year-old white female was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

The patient entered the study with significant previous medical conditions of bilateral ear infections, ear tubes, and frequent ear infections. No significant current medical conditions were reported. Psychiatric history (measured by the ADIS C/P semi-structured interview) included an overall diagnostic label of generalized anxiety disorder, panic disorder, and Social Anxiety Disorder.

No prior or concomitant medications were reported.

The patient received the first dose of study medication on 30 August 2000. The patient began treatment at dose level 1 (10 mg/day). The dose was increased to dose level 2 (20 mg/day) on 13 September 2000, to dose level 3 (30 mg/day) on 19 September 2000, and to dose level 4 (40 mg/day) on 25 September, 2000, which continued throughout the remainder of the study. The last dose of study medication was taken on 02 October 2000 (Day 34).

On 10 September 2000 (Day 12), the patient reported moderately severe myalgia (muscle discomfort), which was treated with ibuprofen and Tylenol® (paracetamol) and resolved in three days. The dose of study medication was increased in response to this condition. This event was considered to be unrelated to treatment with study medication.

On 14 September, 2000 (Day 16), moderately severe agitation (panic attack) was reported. This cleared without treatment in one day and was considered to be probably unrelated to treatment with study medication. On 28 September 2000 (Day 30), the patient experienced severe agitation (panic attack worsening) lasting one day, which was considered by the investigator to be possibly related to treatment with study medication, and severely intense abnormal dreams (morbid thoughts) that were considered to be probably unrelated to treatment with study medication. In addition, moderately severe emotional lability (suicidal thoughts)

was also reported to have begun on this date. This condition was considered to be probably unrelated to treatment with study medication. All three conditions resulted in withdrawal from the study. No corrective therapy was given for any of these three conditions. Emotional lability and abnormal dreams continued beyond the end of the study.

On 10 October 2000, 8 days after withdrawal from the study and while the patient was on taper medication, severe insomnia (sleep disturbance) was reported. No treatment was given, and the insomnia was reported as ongoing. It was considered by the investigator to be probably unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID: 676.015.24406

Treatment Group: Paroxetine

Adverse Event: Vomiting (Nausea and Vomiting)

This 17-year-old Hispanic male was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

No significant previous or current medical conditions were reported. Psychiatric history (measured by the ADIS C/P semi-structured interview) included an overall diagnostic label of Social Anxiety Disorder.

No prior or concomitant medications were reported.

The patient received the first and last dose of study medication on 28 August 2000 (Day 1).

On 28 August 2000 (Day 1), the patient experienced mild vomiting (nausea and vomiting) that resolved in one day after treatment with Maalox® (aluminium hydroxide/ magnesium hydroxide). The patient was withdrawn from the study as a result of this event. The investigator considered this event to be possibly related to treatment with study medication.

No other adverse events were reported during the study.

PID: 676.015.24409

Treatment Group: Paroxetine

Adverse Event: Manic Reaction (Manic Episode)

This 9-year-old white male was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

No significant previous and current medical conditions were reported. Psychiatric history (measured by the ADIS C/P semi-structured interview) included an overall diagnostic label of separation anxiety disorder, specific phobia, and Social Anxiety Disorder.

Prior medication included ibuprofen for headache. No concomitant medications were reported.

The patient received the first dose of study medication on 06 December 2000. The patient began treatment at dose level 1 (10 mg/day) which was gradually increased to dose level 4 (40 mg/day) by 05 January 2001 (Day 31). The dose was gradually reduced from dose level 4 beginning 17 January 2001. The last dose of study medication (dose level 1, 10 mg/day) was taken on 29 January 2001 (Day 55).

On 04 December 2000 (Day –1), 10 December 2000 (Day 5), 17 December 2000 (Day 12), and 19 December 2000 (Day 14), the patient reported discrete episodes of mild headache, all of which resolved without treatment in one day. All events of headache that occurred after Day 0 were considered to be possibly related to treatment with study medication. On 04 December 2000 (Day –1), mild nausea was also reported. This resolved without treatment in one day.

On 08 January 2001 (Day 34) and on 16 January 2001 (Day 42), the patient reported mild abdominal pain (stomach ache), each of which resolved without treatment in one day. Both episodes of abdominal pain were considered by the investigator to be possibly related to study medication.

On 07 January 2001, severe hyperkinesia was reported. The dose of study medication was reduced in response to this event, which was reported to have resolved in 11 days. The investigator considered this event to be related to

treatment with study medication. However, on 18 January 2001 (Day 44), an AE of severe hyperkinesia (hyperactivity) was reported, which resolved without treatment in eight days. The investigator considered this event to be related to treatment with study medication and the patient was withdrawn from the study.

No other adverse events were reported during the study.

PID: 676.022.17841

Treatment Group: Paroxetine

Adverse Event: Manic Reaction (Behavioral Activation/Hypomania)

This 15-year-old white male was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

No significant previous and current medical conditions were reported. Psychiatric history (measured by the ADIS C/P semi-structured interview) included an overall diagnostic label of dysthymia, generalized anxiety disorder, specific phobia, and Social Anxiety Disorder.

No prior and concomitant non-psychoactive medications were reported. Previous psychoactive medication included Ritalin Slow Release® (methylphenidate HCl).

The patient received the first dose of study medication on 25 May 2000. The patient began treatment at dose level 1 (10 mg/day). The dose was gradually increased to dose level 3 (30 mg/day) on 17 June 2000, and was then titrated downward to dose level 2 on 23 June 2000. The last dose of study medication (10 mg/day) was taken on 28 June 2000 (Day 35).

On 6 June 2000 (Day 13) the patient experienced mild asthenia (fatigue) that was considered to be possibly related to treatment with study medication. No corrective therapy was given. The condition resolved in 2 days.

On 16 June 2000 (Day 23), the patient experienced a severe manic reaction (behavioral activation, hypomania), which was considered to be possibly related to treatment with study medication. This event resulted in withdrawal from the study. No corrective treatment was given for this event, which resolved in 11 days.

On 19 June 2000 (Day 26), the patient reported moderately severe insomnia (restless sleep/decrease sleep to 5 hours/night) that continued for 6 days. The dose of study medication was decreased in response to this event; no other corrective therapy was given. The investigator considered the insomnia to be possibly related to treatment with study medication.

On 21 June 2000 (Day 28) the patient reported moderately severe tremor (bilateral hand tremor) that was considered to be possibly related to treatment with study medication. The dose of study medication was decreased in response to this event, but no other corrective therapy was given. The condition continued through the end of the study.

On 26 June 2000 (Day 33), mild otitis media (probably right ear infection) was reported. This condition was reported as ongoing. The investigator considered this event to be unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID: 676.023.17877

Treatment Group: Paroxetine

Adverse Event: Hostility (Disinhibited), Pruritus (Itchy Back)

This 7-year-old white male was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

Significant previous medical conditions included chicken pox, obstructed tear duct (surgically repaired), and recurrent otitis. Current medical conditions included constipation. Psychiatric history (measured by the ADIS C/P semi-structured interview) included an overall diagnostic label of dysthymia, enuresis, externalizing disorders, and Social Anxiety Disorder.

Prior and concomitant non-psychoactive medications included Dulcolax® (bisacodyl) and paraffin liquid (mineral oil) for constipation. Previous psychoactive medication included oxybutynin.

The patient received the first dose of study medication at dose level 1 (10 mg/day) on 02 August 2000 and the last dose of study medication on 26 September 2000 (Day 56). The dose of study medication was increased from level 1 to level 2 on 09 August 2000, and then reduced to level 1 on 30 August 2000, where it remained until the study ended.

On 02 August 2000 (Day 1), mild abdominal pain (stomach ache), headache, and fecal/urinary incontinence (increase in bowel and bladder incontinence) were reported. All were considered by the investigator to be possibly related to treatment with study medication. No corrective therapy was given for any of these events. Fecal/urinary incontinence resolved within 3 days, abdominal pain resolved in 4 days, and headache resolved in 7 days.

On 08 August 2000 (Day 7), moderately severe hostility (disinhibition) was observed. This condition was considered to be related to treatment with study medication and the patient was withdrawn from the study 49 days later due to the event. The hostility continued through the end of the study; no corrective therapy was given. On 30 August 2000 (Day 29) mild pruritus was reported, which continued without treatment through the end of the study. The investigator

considered this event to be possibly related to treatment with study medication and the patient was withdrawn from the study for this event also.

On 11 August 2000 (Day 10), mild rash was reported. This was considered by the investigator to be unrelated to treatment with study medication, required no corrective therapy, and resolved in 5 days.

On 15 August 2000 (Day 14) severe manic reaction (hypomania) was reported. The investigator considered this event to be related to treatment with study medication and the dose of study medication was decreased in response. No other corrective treatment was given. The manic reaction continued through the end of the study.

On 19 August 2000 (Day 18), moderately severe oppositional behavior, coded to hostility, and neurosis (impulsive) were reported. The dose of study medication was decreased in response to these events, but no other corrective treatment was given. The manic reaction continued through the end of the study and the neurosis resolved in 15 days. Both events were considered by the investigator to be related to treatment with study medication.

Mild conjunctivitis was reported on 25 September 2000 (Day 55). This was considered to be unrelated to treatment with study medication, required no corrective therapy, and resolved in one day. Mild albuminuria was reported on 26 September 2000 (Day 56). This was considered to be unrelated to treatment with study medication, required no corrective treatment, and continued through the end of the study.

Listing 13.16.2.1 incorrectly indicates that this patient was taking ibuprofen and naproxen; they were actually taken by patient 676.023.17877.

No other adverse events were reported during the study.

PID: 676.024.25150

Treatment Group: Paroxetine

Adverse Event: Asthenia (Fatigue)

This 14-year-old white female was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

No significant previous and current medical conditions were reported. Psychiatric history (measured by the ADIS C/P semi-structured interview) included an overall diagnostic label of Social Anxiety Disorder.

No prior and concomitant medications were reported.

The patient received the first dose of study medication on 23 February 2001 at dose level 1 (10 mg/day), which was increased to dose level 2 (20 mg/day) on 01 March 2001. The dose was decreased to level 1 on 08 March 2001, where it remained throughout the rest of the study. The last dose of study medication was taken on 04 April 2001 (Day 41).

On 05 March 2001 (Day 11), moderately severe asthenia (fatigue) was reported. This continued, without treatment, for 51 days. The investigator considered this event 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: 676.100.24705

Treatment Group: Paroxetine

Adverse Event: Depression (Worsening Depression)

This 16-year-old white female was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

No previous medical conditions were reported. Significant current, active medical conditions included headaches and joint pain. Psychiatric history (measured by the ADIS C/P semi-structured interview) included an overall diagnostic label of dysthymia, generalized anxiety disorder, and Social Anxiety Disorder.

Prior and concomitant medications included Tylenol® (paracetamol) for headaches and joint pain.

The patient received the first dose of study medication on 17 October 2000 at dose level 1 (10 mg/day), which was increased to dose level 2 (20 mg/day) on 22 November 2000. The last dose of study medication was taken on 28 November 2000 (Day 43).

On 21 October 2000 (Day 5), mild lack of emotion was reported. This continued, without treatment, through the end of the study, and was considered by the investigator to be possibly related to treatment with study medication.

On 04 November 2000 (Day 19), mild dyspepsia (heartburn) was reported. This resolved in two days following treatment with Pepcid AC® (famotidine), and was considered by the investigator to be unrelated to treatment with study medication.

On 23 November 2000 (Day 38), mild emotional lability (self-inflicted scratch on right wrist) was reported. This condition abated in one day without corrective therapy, and was considered to be probably unrelated to treatment with study medication.

On 28 November 2000 (Day 43), moderately severe depression (worsening depression) was reported. The investigator considered this event to be possibly related to treatment with study medication and the patient was withdrawn from

the study. No taper medication was dispensed, but Paxil® (paroxetine) 20 mg per day was prescribed to treat the worsening depression.

On 11 December 2000, 13 days after the last dose of study medication, moderately severe headache was reported. This resolved in one day following treatment with Advil® (ibuprofen), and was considered to be unrelated to treatment with study medication.

No other adverse events were reported during the study.

PID: 676.200.24742

Treatment Group: Paroxetine

Adverse Event: Infection (Infected Foot)

This 13-year-old white male was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

No previous or current medical conditions were reported. Psychiatric history (measured by the ADIS C/P semi-structured interview) included an overall diagnostic label of generalized anxiety disorder, separation anxiety, and Social Anxiety Disorder.

No prior and concomitant medications were reported.

The patient received the first dose of study medication on 27 September 2000 at dose level 1 (10 mg/day), which was gradually increased to dose level 4 (40 mg/day) on 10 November 2000. The dose remained at dose level 4 until reduction during the taper phase of the study, which began on 26 January 2001 (Day 122). The last dose of study medication was taken on 27 January 2001 (Day 123).

On 27 September 2000 (Day 1), mild asthenia (fatigue/tiredness) was reported. This continued, without treatment, through the end of the study, and was considered by the investigator to be possibly related to treatment with study medication.

On 13 December 2000 (Day 19), mild headache was reported. This resolved in one day following treatment with paracetamol, and was considered by the investigator to be possibly related to treatment with study medication.

On 14 January 2001 (Day 110), moderately severe infection (infected foot) was reported. This resolved in 6 days following treatment with antibiotic NOS and Ponstan® (mefenamic acid). The investigator considered this event to be unrelated to treatment with study medication, but the patient was withdrawn from the study for this event.

No other adverse events were reported.

PID: 676.021.24562

Treatment Group: Placebo

Adverse Event: Agitation (Increased Agitation)

This 16-year-old white female was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

No significant previous and current medical conditions were reported. Psychiatric history (measured by the ADIS C/P semi-structured interview) included an overall diagnostic label of Social Anxiety Disorder.

No prior and concomitant non-psychoactive medications were reported. Previous psychoactive medication included Prozac® (fluoxetine).

The patient received the first dose of study medication on 08 February 2000 and the last dose of study medication on 09 February 2000 (Day 2). It is not known why the patient stopped taking study medication.

On 16 February 2000 (Day 9, 7 days after the last dose of study medication), the patient experienced moderately severe agitation (increased agitation) that resolved without treatment in 7 days. The investigator considered this event 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: 676.023.17878

Treatment Group: Placebo

Adverse Event: Agitation (Increased Agitation)

This 9-year-old white male was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

Previous significant medical and surgical conditions included ear tubes placed in ears, hay fever, recurrent ear infections, tonsillectomy, and adenoidectomy. Previous and current medical conditions included asthma. Current active medical conditions included allergy to grass. Psychiatric history (measured by the ADIS C/P semi-structured interview) included an overall diagnostic label of generalized anxiety disorder, separation anxiety disorder, specific phobia and Social Anxiety Disorder.

Prior and concomitant non-psychoactive medications included Claritin® (loratadine) for allergies, Albuterol® and Proventil® (salbutamol nebulizer) for asthma, and topical antibiotic NOS for conjunctivitis. Previous psychoactive medication included Zoloft® (sertraline HCl).

The patient received the first dose of study medication at dose level 1 (10 mg/day)on 13 September 2000 and the last dose of study medication on 22 October 2000 (Day 40). The dose of study medication was increased from level 1 to level 2 on 27 September 2000, where it remained until the study ended.

On 30 August 2000 (Day –13), moderately severe pain (foot pain) was reported, which continued through the course of the study without treatment. On 05 September 2000 (Day –7), the patient experienced mild flu syndrome (flu-like illness) that resolved without treatment in 2 days. On 09 September 2000 (Day -3), mild conjunctivitis was reported. This resolved in four days following treatment with topical antibiotics NOS.

On 16 September 2000 (Day 4), moderately severe increased cough was reported. No corrective treatment was given for this cough, which continued throughout the study. The cough was considered by the investigator to be unrelated to treatment with study medication.

On 23 September 2000 (Day 11), mildly decreased appetite was reported. This resolved without treatment in 8 days, and was considered by the investigator to be possibly related to treatment with study medication.

On 05 October 2000 (Day 23), moderately severe somnolence (drowsiness–fell asleep at school) was reported. This resolved without treatment in one day and was considered by the investigator to be possibly related to treatment with study medication.

On 10 October 2000 (Day 28), the patient experienced moderately severe agitation (agitation) that resolved without treatment in 15 days. The investigator considered this event to be related to treatment with study medication and the patient was withdrawn from the study.

No other adverse events were reported during the study.

PID: 676.205.24989

Treatment Group: Placebo

Adverse Event: Urinary Retention

This 9-year-old white male was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

No previous or current medical conditions were reported. Psychiatric history (measured by the ADIS C/P semi-structured interview) included an overall diagnostic label of major depression, specific phobia, and Social Anxiety Disorder.

No prior and concomitant medications were reported.

The patient received the first dose of study medication on 08 March 2001 and the last dose of study medication on 02 May 2001 (Day 56). The patient remained at dose level 1 (10 mg/day).

On 14 March 2001 (Day 7), mild infection (worm infection) was reported. This resolved in one day following treatment with Zentel® (albendazole), and was considered by the investigator to be unrelated to treatment with study medication.

On 19 March 2001 (Day 12), mild pharyngitis (sore throat) was reported. This resolved in 11 days following treatment with Grippon® (ascorbic acid/atropine sulfate/caffeine/phenylephrine), and was considered by the investigator to be unrelated to treatment with study medication.

Also on 19 March 2001 (Day 12), moderately severe urinary retention was reported. This resolved, without treatment, in 57 days. The investigator considered this event to be possibly related to treatment with study medication and the patient was withdrawn from the study on Day 56 for this event.

On 21 March 2001 (Day 14), mild increased cough was reported. This resolved in 9 days following treatment with Bronco-ped® (ambuphylline). It was considered by the investigator to be unrelated to treatment with study medication.

On 02 April 2001 (Day 26), the patient received intramuscular Agrippal S1® (influenza virus vaccine polyvalent) as prophylaxis for flu. On 04 April 2001 (Day 28), mild infection (flu symptoms) was reported. This resolved in one day following treatment with Panadol® (paracetamol) and Degoran® syrup (chlorpheniramine / dextromethorphan hydrobromide), and was considered by the investigator to be unrelated to treatment with study medication.

No other adverse events were reported.

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=46)	HEADACHE	9	19.6	1	2.2	1	2.2	2	4.3	0	0.0	1	2.2	0	0.0	0	0.0	1	2.2	0	0.0	15	32.6
	ABDOMINAL PAIN	4	8.7	1	2.2	1	2.2	2	4.3	0	0.0	0	0.0	1	2.2	0	0.0	1	2.2	0	0.0	10	21.7
	NERVOUSNESS	1	2.2	0	0.0	0	0.0	3	6.5	1	2.2	1	2.2	1	2.2	0	0.0	0	0.0	0	0.0	7	15.2
	RESPIRATORY DISORDER	3	6.5	0	0.0	1	2.2	0	0.0	1	2.2	0	0.0	1	2.2	0	0.0	1	2.2	0	0.0	7	15.2
	INFECTION	1	2.2	1	2.2	2	4.3	1	2.2	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	13.0
	INSOMNIA	3	6.5	0	0.0	0	0.0	3	6.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	13.0
	OTITIS MEDIA	1	2.2	0	0.0	0	0.0	1	2.2	0	0.0	1	2.2	1	2.2	0	0.0	1	2.2	0	0.0	5	10.9
	RASH	2	4.3	0	0.0	0	0.0	1	2.2	2	4.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	10.9
	TRAUMA	1	2.2	0	0.0	0	0.0	0	0.0	1	2.2	1	2.2	2	4.3	0	0.0	0	0.0	0	0.0	5	10.9
	URINARY INCONTINENCE	1	2.2	1	2.2	0	0.0	1	2.2	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	5	10.9
	HYPERKINESIA	0	0.0	0	0.0	1	2.2	2	4.3	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	4	8.7
	SOMNOLENCE	1	2.2	1	2.2	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	4	8.7
	ASTHENIA	2	4.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	3	6.5
	CONJUNCTIVITIS	0	0.0	2	4.3	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	3	6.5
	COUGH INCREASED	1	2.2	0	0.0	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.5
	DECREASED APPETITE	2	4.3	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.5
	HOSTILITY	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	2	4.3	0	0.0	0	0.0	0	0.0	0	0.0	3	6.5
	VOMITING	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	3	6.5

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=46)	ALLERGIC REACTION	1	2.2	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.3
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	2	4.3
	DIARRHEA	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.3
	DYSPEPSIA	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	2	4.3
	FECAL INCONTINENCE	1	2.2	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.3
	FEVER	2	4.3	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	4.3
	FLATULENCE	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.3
	NAUSEA	2	4.3	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	4.3
	PHARYNGITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	1	2.2	0	0.0	2	4.3
	SINUSITIS	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	2	4.3
	VASODILATATION	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.3
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	ARTHRALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	1	2.2
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	BACK 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	2.2	0	0.0	1	2.2
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	1	2.2
	CONSTIPATION	0	0.0	1	2.2	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	2.2
	DIZZINESS	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=46)	EAR PAIN	1	2.2	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	2.2
	EPISTAXIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	INCREASED APPETITE	0	0.0	1	2.2	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	2.2
	LACK OF EMOTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	1	2.2
	MANIC REACTION	0	0.0	1	2.2	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	2.2
	MYALGIA	0	0.0	1	2.2	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	2.2
	NAIL 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	2.2	0	0.0	1	2.2
	NEUROSIS	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	PRURITUS	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	PURPURA	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	RHINITIS	1	2.2	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	2.2
	SPEECH DISORDER	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	SWEATING	1	2.2	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	2.2
	ULCERATIVE STOMATITIS	0	0.0	1	2.2	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	2.2
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	1	2.2

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=45)	HEADACHE	4	8.9	0	0.0	1	2.2	0	0.0	3	6.7	2	4.4	1	2.2	0	0.0	0	0.0	0	0.0	11	24.4
	INFECTION	4	8.9	0	0.0	1	2.2	1	2.2	0	0.0	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	8	17.8
	PHARYNGITIS	1	2.2	3	6.7	0	0.0	0	0.0	1	2.2	0	0.0	1	2.2	0	0.0	1	2.2	0	0.0	7	15.6
	RHINITIS	3	6.7	1	2.2	1	2.2	0	0.0	1	2.2	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	7	15.6
	ABDOMINAL PAIN	2	4.4	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	5	11.1
	COUGH INCREASED	1	2.2	1	2.2	1	2.2	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	5	11.1
	SOMNOLENCE	3	6.7	0	0.0	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	11.1
	DIARRHEA	0	0.0	1	2.2	1	2.2	1	2.2	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	4	8.9
	NAUSEA	1	2.2	0	0.0	2	4.4	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	8.9
	TRAUMA	0	0.0	0	0.0	0	0.0	3	6.7	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	8.9
	INSOMNIA	0	0.0	0	0.0	1	2.2	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	3	6.7
	RESPIRATORY DISORDER	2	4.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	3	6.7
	SINUSITIS	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	3	6.7
	ALLERGIC REACTION	0	0.0	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4
	CONCENTRATION IMPAIRED	1	2.2	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4
	DECREASED APPETITE	0	0.0	1	2.2	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4
	DYSPEPSIA	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	2	4.4
	GASTROENTERITIS	0	0.0	0	0.0	0	0.0	1	2.2	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=45)	NERVOUSNESS	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4
	RASH	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4
	VOMITING	0	0.0	0	0.0	1	2.2	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.4
	ABNORMAL LABORATORY VALUE	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	AGITATION	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	ARTHRALGIA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	ASTHENIA	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	BACK 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	2.2	0	0.0	1	2.2
	BRONCHITIS	1	2.2	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	2.2
	CHEST PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	CONSTIPATION	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	DIZZINESS	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	EAR PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	1	2.2
	ECZEMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	EPISTAXIS	1	2.2	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	2.2
	FECAL INCONTINENCE	1	2.2	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	2.2
	FEVER	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	FUNGAL DERMATITIS	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
Treatment Group	Preferred Term	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=45)	HYPONATREMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	INCOORDINATION	1	2.2	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	2.2
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	PAIN	1	2.2	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	2.2
	PHOTOSENSITIVITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	1	2.2
	TACHYCARDIA	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2
	TOOTH DISORDER	1	2.2	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	2.2
	URINARY RETENTION	0	0.0	1	2.2	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	2.2

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Children, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																						
Paroxetine (N=25)	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

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Children, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
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

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Children, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																						
Paroxetine (N=21)	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

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Children, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
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

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=117)	HEADACHE	21	17.9	4	3.4	3	2.6	6	5.1	3	2.6	3	2.6	0	0.0	4	3.4	3	2.6	0	0.0	47	40.2
	INFECTION	2	1.7	4	3.4	3	2.6	4	3.4	5	4.3	0	0.0	3	2.6	3	2.6	3	2.6	0	0.0	27	23.1
	ASTHENIA	11	9.4	5	4.3	2	1.7	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	21	17.9
	RESPIRATORY DISORDER	2	1.7	1	0.9	3	2.6	0	0.0	3	2.6	3	2.6	0	0.0	2	1.7	4	3.4	0	0.0	18	15.4
	INSOMNIA	9	7.7	2	1.7	1	0.9	3	2.6	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	17	14.5
	SOMNOLENCE	10	8.5	1	0.9	1	0.9	3	2.6	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	17	14.5
	RHINITIS	3	2.6	2	1.7	2	1.7	2	1.7	3	2.6	1	0.9	0	0.0	0	0.0	3	2.6	0	0.0	16	13.7
	NAUSEA	7	6.0	0	0.0	0	0.0	0	0.0	3	2.6	0	0.0	3	2.6	1	0.9	1	0.9	0	0.0	15	12.8
	ABDOMINAL PAIN	3	2.6	2	1.7	1	0.9	3	2.6	0	0.0	0	0.0	1	0.9	0	0.0	4	3.4	0	0.0	14	12.0
	PHARYNGITIS	3	2.6	0	0.0	1	0.9	0	0.0	2	1.7	1	0.9	1	0.9	1	0.9	2	1.7	0	0.0	11	9.4
	DECREASED APPETITE	3	2.6	0	0.0	3	2.6	1	0.9	2	1.7	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	10	8.5
	DYSPEPSIA	0	0.0	0	0.0	4	3.4	2	1.7	2	1.7	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	10	8.5
	TRAUMA	0	0.0	0	0.0	0	0.0	2	1.7	2	1.7	3	2.6	0	0.0	2	1.7	0	0.0	0	0.0	9	7.7
	VOMITING	2	1.7	1	0.9	0	0.0	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	3	2.6	0	0.0	8	6.8
	DIZZINESS	3	2.6	1	0.9	0	0.0	1	0.9	1	0.9	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	7	6.0
	NERVOUSNESS	2	1.7	2	1.7	1	0.9	1	0.9	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	7	6.0
	COUGH INCREASED	1	0.9	0	0.0	0	0.0	1	0.9	1	0.9	1	0.9	0	0.0	1	0.9	1	0.9	0	0.0	6	5.1
	SINUSITIS	1	0.9	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	2	1.7	0	0.0	6	5.1

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=117)	ALLERGIC REACTION	0	0.0	1	0.9	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	2	1.7	0	0.0	5	4.3
	MYALGIA	0	0.0	2	1.7	0	0.0	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9	0	0.0	5	4.3
	DIARRHEA	0	0.0	1	0.9	0	0.0	2	1.7	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	4	3.4
	DRY MOUTH	1	0.9	1	0.9	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	3.4
	EMOTIONAL LABILITY	0	0.0	0	0.0	1	0.9	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	4	3.4
	FEVER	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	4	3.4
	FLU SYNDROME	1	0.9	1	0.9	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	3.4
	INCREASED APPETITE	0	0.0	1	0.9	1	0.9	0	0.0	2	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	3.4
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0	1	0.9	2	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.6
	AGITATION	1	0.9	1	0.9	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.6
	ARTHRALGIA	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9	0	0.0	3	2.6
	BRONCHITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	2	1.7	0	0.0	0	0.0	3	2.6
	CONJUNCTIVITIS	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	3	2.6
	DEPRESSION	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	3	2.6
	EAR PAIN	1	0.9	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	3	2.6
	PURPURA	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9	0	0.0	3	2.6
	RASH	1	0.9	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.6
	SWEATING	0	0.0	1	0.9	0	0.0	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	3	2.6

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=117)	TREMOR	1	0.9	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.6
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	2	1.7	0	0.0	3	2.6
	YAWN	3	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	3	2.6
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9	0	0.0	2	1.7
	BACK PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	2	1.7
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	2	1.7
	EPISTAXIS	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.7
	HOSTILITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9	0	0.0	0	0.0	2	1.7
	HYPERKINESIA	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	2	1.7
	MANIC REACTION	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.7
	MONILIASIS	1	0.9	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.7
	PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.7	0	0.0	0	0.0	0	0.0	2	1.7
	STOMATITIS	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	2	1.7
	ACNE	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	ALBUMINURIA	0	0.0	1	0.9	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	0.9
	AMNESIA	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	ANEMIA	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	CELLULITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=117)	DEPERSONALIZATION	0	0.0	1	0.9	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	0.9
	GASTRITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9
	GASTROINTESTINAL DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9
	GINGIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9
	HERPES SIMPLEX	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9
	HYPERKALEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9
	HYPOTENSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9
	KETOSIS	0	0.0	1	0.9	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	0.9
	LACK OF EMOTION	1	0.9	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	0.9
	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	1	0.9	0	0.0	1	0.9
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9
	LIBIDO DECREASED	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	MIGRAINE	1	0.9	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	0.9
	MYDRIASIS	1	0.9	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	0.9
	MYOCLONUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	NEUROSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	QT INTERVAL PROLONGED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=117)	RECTAL DISORDER	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	RHEUMATOID ARTHRITIS	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	SYNCOPE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9
	THIRST	0	0.0	1	0.9	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	0.9
	TOOTH DISORDER	0	0.0	1	0.9	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	0.9
	URINARY FREQUENCY	0	0.0	1	0.9	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	0.9
	URINE ABNORMALITY	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	VASODILATATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	VESICULOBULLOUS 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	1	0.9	0	0.0	1	0.9
	WEIGHT LOSS	1	0.9	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	0.9

Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=111)	HEADACHE	12	10.8	3	2.7	3	2.7	4	3.6	3	2.7	1	0.9	3	2.7	1	0.9	1	0.9	0	0.0	31	27.9
	RHINITIS	1	0.9	5	4.5	2	1.8	1	0.9	2	1.8	2	1.8	1	0.9	3	2.7	1	0.9	0	0.0	18	16.2
	INFECTION	7	6.3	2	1.8	1	0.9	2	1.8	2	1.8	1	0.9	2	1.8	0	0.0	0	0.0	0	0.0	17	15.3
	RESPIRATORY DISORDER	4	3.6	3	2.7	2	1.8	1	0.9	2	1.8	3	2.7	0	0.0	1	0.9	1	0.9	0	0.0	17	15.3
	ASTHENIA	7	6.3	2	1.8	0	0.0	2	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	11	9.9
	ABDOMINAL PAIN	4	3.6	2	1.8	1	0.9	2	1.8	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	10	9.0
	DIZZINESS	5	4.5	1	0.9	1	0.9	0	0.0	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	9	8.1
	NAUSEA	5	4.5	1	0.9	0	0.0	0	0.0	2	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	8	7.2
	SOMNOLENCE	3	2.7	1	0.9	1	0.9	1	0.9	2	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	8	7.2
	TRAUMA	0	0.0	2	1.8	1	0.9	2	1.8	0	0.0	0	0.0	0	0.0	0	0.0	3	2.7	0	0.0	8	7.2
	NERVOUSNESS	2	1.8	0	0.0	1	0.9	1	0.9	1	0.9	0	0.0	2	1.8	0	0.0	0	0.0	0	0.0	7	6.3
	PHARYNGITIS	1	0.9	3	2.7	0	0.0	2	1.8	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	7	6.3
	BACK PAIN	2	1.8	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9	2	1.8	0	0.0	0	0.0	6	5.4
	COUGH INCREASED	1	0.9	2	1.8	2	1.8	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	5.4
	INSOMNIA	0	0.0	2	1.8	0	0.0	2	1.8	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	6	5.4
	DRY MOUTH	1	0.9	1	0.9	0	0.0	3	2.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	4.5
	MYALGIA	2	1.8	0	0.0	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	5	4.5
	DYSPEPSIA	1	0.9	2	1.8	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	3.6
	SINUSITIS	0	0.0	0	0.0	2	1.8	2	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	3.6

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=111)	ACNE	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	1	0.9	0	0.0	3	2.7
	ARTHRALGIA	1	0.9	0	0.0	0	0.0	0	0.0	2	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.7
	DECREASED APPETITE	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	3	2.7
	DIARRHEA	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	3	2.7
	FLU SYNDROME	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	3	2.7
	WEIGHT GAIN	1	0.9	0	0.0	0	0.0	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.7
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	2	1.8
	ALLERGIC REACTION	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	2	1.8
	BRONCHITIS	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.8
	EMOTIONAL LABILITY	0	0.0	1	0.9	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.8
	FEVER	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	2	1.8
	GASTROENTERITIS	1	0.9	1	0.9	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	1.8
	HOSTILITY	1	0.9	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.8
	HYPOTENSION	2	1.8	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	1.8
	INCREASED APPETITE	1	0.9	1	0.9	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	1.8
	RASH	2	1.8	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	1.8
	SYNCOPE	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	2	1.8

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=111)	URINARY TRACT INFECTION	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	2	1.8
	ABNORMAL VISION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	AGITATION	0	0.0	1	0.9	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	0.9
	ANXIETY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9
	ARTHROSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9
	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	0.9	0	0.0	1	0.9
	BILIRUBINEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9
	CHILLS	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	CONJUNCTIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9
	CYSTITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	ECZEMA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	EOSINOPHILIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	GINGIVITIS	1	0.9	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	0.9
	HERPES SIMPLEX	0	0.0	1	0.9	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	0.9
	HYPERTONIA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9
	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	0	0.0	1	0.9	0	0.0	1	0.9

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=111)	NEOPLASM	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	OTITIS EXTERNA	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9
	PHOTOPHOBIA	1	0.9	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	0.9
	PNEUMONIA	0	0.0	1	0.9	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	0.9
	POLYCYTHEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	1	0.9
	STOMATITIS	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	SWEATING	1	0.9	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	0.9
	THIRST	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	TOOTH DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	1	0.9
	ULCERATIVE STOMATITIS	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	URINARY FREQUENCY	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	VASODILATATION	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9
	VERTIGO	0	0.0	1	0.9	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	0.9
	VOMITING	1	0.9	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	0.9
	WEIGHT LOSS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	1	0.9
	YAWN	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.9

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Adolescents, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																						
Paroxetine (N=46)	ABNORMAL EJACULATION	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.2

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Adolescents, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																						
Placebo (N=66)	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

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Adolescents, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																						
Paroxetine (N=71)	DYSMENORRHEA	1	1.4	0	0.0	2	2.8	1	1.4	0	0.0	0	0.0	1	1.4	0	0.0	0	0.0	0	0.0	5	7.0
	AMENORRHEA	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

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Adolescents, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																						
Placebo (N=45)	DYSMENORRHEA	1	2.2	0	0.0	0	0.0	1	2.2	1	2.2	0	0.0	0	0.0	1	2.2	0	0.0	0	0.0	4	8.9

Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=163)	HEADACHE	30	18.4	5	3.1	4	2.5	8	4.9	3	1.8	4	2.5	0	0.0	4	2.5	4	2.5	0	0.0	62	38.0
	INFECTION	3	1.8	5	3.1	5	3.1	5	3.1	6	3.7	0	0.0	3	1.8	3	1.8	3	1.8	0	0.0	33	20.2
	RESPIRATORY DISORDER	5	3.1	1	0.6	4	2.5	0	0.0	4	2.5	3	1.8	1	0.6	2	1.2	5	3.1	0	0.0	25	15.3
	ABDOMINAL PAIN	7	4.3	3	1.8	2	1.2	5	3.1	0	0.0	0	0.0	2	1.2	0	0.0	5	3.1	0	0.0	24	14.7
	ASTHENIA	13	8.0	5	3.1	2	1.2	1	0.6	1	0.6	0	0.0	0	0.0	0	0.0	2	1.2	0	0.0	24	14.7
	INSOMNIA	12	7.4	2	1.2	1	0.6	6	3.7	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	23	14.1
	SOMNOLENCE	11	6.7	2	1.2	2	1.2	3	1.8	1	0.6	0	0.0	1	0.6	1	0.6	0	0.0	0	0.0	21	12.9
	NAUSEA	9	5.5	0	0.0	0	0.0	0	0.0	3	1.8	0	0.0	3	1.8	1	0.6	1	0.6	0	0.0	17	10.4
	RHINITIS	4	2.5	2	1.2	2	1.2	2	1.2	3	1.8	1	0.6	0	0.0	0	0.0	3	1.8	0	0.0	17	10.4
	NERVOUSNESS	3	1.8	2	1.2	1	0.6	4	2.5	1	0.6	1	0.6	2	1.2	0	0.0	0	0.0	0	0.0	14	8.6
	TRAUMA	1	0.6	0	0.0	0	0.0	2	1.2	3	1.8	4	2.5	2	1.2	2	1.2	0	0.0	0	0.0	14	8.6
	DECREASED APPETITE	5	3.1	0	0.0	3	1.8	2	1.2	2	1.2	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	13	8.0
	PHARYNGITIS	3	1.8	0	0.0	1	0.6	0	0.0	2	1.2	1	0.6	2	1.2	1	0.6	3	1.8	0	0.0	13	8.0
	DYSPEPSIA	1	0.6	0	0.0	4	2.5	2	1.2	2	1.2	2	1.2	1	0.6	0	0.0	0	0.0	0	0.0	12	7.4
	VOMITING	3	1.8	1	0.6	1	0.6	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	4	2.5	0	0.0	11	6.7
	COUGH INCREASED	2	1.2	0	0.0	1	0.6	1	0.6	2	1.2	1	0.6	0	0.0	1	0.6	1	0.6	0	0.0	9	5.5
	DIZZINESS	3	1.8	1	0.6	1	0.6	1	0.6	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	8	4.9
	RASH	3	1.8	1	0.6	1	0.6	1	0.6	2	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	8	4.9
	SINUSITIS	1	0.6	1	0.6	2	1.2	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	3	1.8	0	0.0	8	4.9

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=163)	ALLERGIC REACTION	1	0.6	1	0.6	1	0.6	0	0.0	2	1.2	0	0.0	0	0.0	0	0.0	2	1.2	0	0.0	7	4.3
	CONJUNCTIVITIS	1	0.6	3	1.8	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	6	3.7
	DIARRHEA	1	0.6	1	0.6	1	0.6	2	1.2	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	6	3.7
	FEVER	2	1.2	0	0.0	1	0.6	0	0.0	1	0.6	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	6	3.7
	HYPERKINESIA	1	0.6	0	0.0	1	0.6	2	1.2	0	0.0	1	0.6	1	0.6	0	0.0	0	0.0	0	0.0	6	3.7
	MYALGIA	0	0.0	3	1.8	0	0.0	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	6	3.7
	OTITIS MEDIA	1	0.6	0	0.0	0	0.0	2	1.2	0	0.0	1	0.6	1	0.6	0	0.0	1	0.6	0	0.0	6	3.7
	HOSTILITY	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	2	1.2	1	0.6	1	0.6	0	0.0	0	0.0	5	3.1
	INCREASED APPETITE	0	0.0	2	1.2	1	0.6	0	0.0	2	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	3.1
	URINARY INCONTINENCE	1	0.6	1	0.6	0	0.0	1	0.6	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	5	3.1
	ARTHRALGIA	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	1	0.6	1	0.6	1	0.6	0	0.0	4	2.5
	CONTACT DERMATITIS	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6	0	0.0	2	1.2	0	0.0	0	0.0	4	2.5
	DRY MOUTH	1	0.6	1	0.6	1	0.6	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	2.5
	EAR PAIN	2	1.2	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	4	2.5
	EMOTIONAL LABILITY	0	0.0	0	0.0	1	0.6	1	0.6	1	0.6	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	4	2.5
	FLU SYNDROME	1	0.6	1	0.6	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	2.5
	PURPURA	0	0.0	0	0.0	1	0.6	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	4	2.5

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=163)	SWEATING	1	0.6	1	0.6	0	0.0	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	4	2.5
	WEIGHT GAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	3	1.8	0	0.0	4	2.5
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0	1	0.6	2	1.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1.8
	AGITATION	1	0.6	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1.8
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	3	1.8
	BACK PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6	0	0.0	1	0.6	0	0.0	3	1.8
	BRONCHITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	2	1.2	0	0.0	0	0.0	3	1.8
	DEPRESSION	0	0.0	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	3	1.8
	EPISTAXIS	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	3	1.8
	MANIC REACTION	0	0.0	1	0.6	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1.8
	TREMOR	1	0.6	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1.8
	VASODILATATION	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	3	1.8
	YAWN	3	1.8	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	1.8
	ALBUMINURIA	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	2	1.2
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	2	1.2
	FECAL INCONTINENCE	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.2
	FLATULENCE	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.2
	LACK OF EMOTION	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	2	1.2
	MONILIASIS	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.2

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=163)	NEUROSIS	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	2	1.2
	PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.2	0	0.0	0	0.0	0	0.0	2	1.2
	STOMATITIS	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	2	1.2
	ACNE	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	AMNESIA	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	ANEMIA	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	CELLULITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	1	0.6
	CONSTIPATION	0	0.0	1	0.6	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	0.6
	DEPERSONALIZATION	0	0.0	1	0.6	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	0.6
	GASTRITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6
	GASTROINTESTINAL DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	1	0.6
	GINGIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	1	0.6
	HERPES SIMPLEX	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6
	HYPERKALEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6
	HYPOTENSION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	1	0.6
	KETOSIS	0	0.0	1	0.6	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	0.6
	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	1	0.6	0	0.0	1	0.6
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=163)	LIBIDO DECREASED	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	MIGRAINE	1	0.6	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	0.6
	MYDRIASIS	1	0.6	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	0.6
	MYOCLONUS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	NAIL 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	0.6	0	0.0	1	0.6
	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	PRURITUS	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	QT INTERVAL PROLONGED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6
	RECTAL DISORDER	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	RHEUMATOID ARTHRITIS	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	SPEECH DISORDER	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	SYNCOPE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6
	THIRST	0	0.0	1	0.6	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	0.6
	TOOTH DISORDER	0	0.0	1	0.6	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	0.6
	ULCERATIVE STOMATITIS	0	0.0	1	0.6	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	0.6
	URINARY FREQUENCY	0	0.0	1	0.6	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	0.6
	URINE ABNORMALITY	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6

(CONTINUED)

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																						
Paroxetine (N=163)	VESICULOBULLOUS RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	1	0.6
	WEIGHT LOSS	1	0.6	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	0.6

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=156)	HEADACHE	16	10.3	3	1.9	4	2.6	4	2.6	6	3.8	3	1.9	4	2.6	1	0.6	1	0.6	0	0.0	42	26.9
	INFECTION	11	7.1	2	1.3	2	1.3	3	1.9	2	1.3	2	1.3	2	1.3	1	0.6	0	0.0	0	0.0	25	16.0
	RHINITIS	4	2.6	6	3.8	3	1.9	1	0.6	3	1.9	3	1.9	1	0.6	3	1.9	1	0.6	0	0.0	25	16.0
	RESPIRATORY DISORDER	6	3.8	3	1.9	2	1.3	1	0.6	2	1.3	3	1.9	0	0.0	2	1.3	1	0.6	0	0.0	20	12.8
	ABDOMINAL PAIN	6	3.8	3	1.9	1	0.6	3	1.9	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	15	9.6
	PHARYNGITIS	2	1.3	6	3.8	0	0.0	2	1.3	1	0.6	0	0.0	1	0.6	1	0.6	1	0.6	0	0.0	14	9.0
	SOMNOLENCE	6	3.8	1	0.6	2	1.3	1	0.6	3	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	13	8.3
	ASTHENIA	7	4.5	2	1.3	1	0.6	2	1.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	12	7.7
	NAUSEA	6	3.8	1	0.6	2	1.3	1	0.6	2	1.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	12	7.7
	TRAUMA	0	0.0	2	1.3	1	0.6	5	3.2	1	0.6	0	0.0	0	0.0	0	0.0	3	1.9	0	0.0	12	7.7
	COUGH INCREASED	2	1.3	3	1.9	3	1.9	2	1.3	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	11	7.1
	DIZZINESS	5	3.2	1	0.6	1	0.6	1	0.6	1	0.6	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	10	6.4
	INSOMNIA	0	0.0	2	1.3	1	0.6	3	1.9	1	0.6	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	9	5.8
	NERVOUSNESS	2	1.3	0	0.0	1	0.6	1	0.6	3	1.9	0	0.0	2	1.3	0	0.0	0	0.0	0	0.0	9	5.8
	BACK PAIN	2	1.3	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	1	0.6	2	1.3	1	0.6	0	0.0	7	4.5
	DIARRHEA	0	0.0	2	1.3	1	0.6	1	0.6	0	0.0	1	0.6	0	0.0	2	1.3	0	0.0	0	0.0	7	4.5
	SINUSITIS	1	0.6	0	0.0	3	1.9	2	1.3	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	7	4.5
	DYSPEPSIA	1	0.6	2	1.3	2	1.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	6	3.8
	DECREASED APPETITE	1	0.6	2	1.3	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	5	3.2

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=156)	DRY MOUTH	1	0.6	1	0.6	0	0.0	3	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	3.2
	MYALGIA	2	1.3	0	0.0	1	0.6	1	0.6	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	5	3.2
	ALLERGIC REACTION	0	0.0	1	0.6	1	0.6	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	4	2.6
	ARTHRALGIA	1	0.6	0	0.0	0	0.0	0	0.0	3	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	2.6
	GASTROENTERITIS	1	0.6	1	0.6	0	0.0	1	0.6	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	2.6
	RASH	2	1.3	0	0.0	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	4	2.6
	ACNE	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	1	0.6	0	0.0	3	1.9
	BRONCHITIS	1	0.6	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1.9
	FEVER	1	0.6	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	3	1.9
	FLU SYNDROME	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	3	1.9
	VOMITING	1	0.6	0	0.0	1	0.6	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1.9
	WEIGHT GAIN	1	0.6	0	0.0	0	0.0	1	0.6	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	1.9
	AGITATION	0	0.0	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.3
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	2	1.3
	CONCENTRATION IMPAIRED	1	0.6	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.3
	ECZEMA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	2	1.3
	EMOTIONAL LABILITY	0	0.0	1	0.6	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.3
	HOSTILITY	1	0.6	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.3

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=156)	HYPOTENSION	2	1.3	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	1.3
	INCREASED APPETITE	1	0.6	1	0.6	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	1.3
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	2	1.3
	PAIN	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	2	1.3
	SYNCOPE	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	2	1.3
	TOOTH DISORDER	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	2	1.3
	URINARY TRACT INFECTION	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	2	1.3
	ABNORMAL LABORATORY VALUE	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	ABNORMAL VISION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	ANXIETY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	1	0.6
	ARTHROSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	1	0.6
	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	0.6	0	0.0	1	0.6
	BILIRUBINEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6
	CHEST PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	CHILLS	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	CONJUNCTIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	1	0.6
	CONSTIPATION	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	CYSTITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6

(CONTINUED)

Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=156)	EAR PAIN	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	1	0.6
	EOSINOPHILIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6
	EPISTAXIS	1	0.6	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	0.6
	EXTRAPYRAMIDAL SYNDROME	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	FECAL INCONTINENCE	1	0.6	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	0.6
	FUNGAL DERMATITIS	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	GINGIVITIS	1	0.6	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	0.6
	HERPES SIMPLEX	0	0.0	1	0.6	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	0.6
	HYPERTONIA	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	HYPONATREMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	INCOORDINATION	1	0.6	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	0.6
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6
	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	0	0.0	1	0.6	0	0.0	1	0.6
	NEOPLASM	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	OTITIS EXTERNA	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	PHOTOPHOBIA	1	0.6	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	0.6
	PHOTOSENSITIVITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																						
Placebo (N=156)	PNEUMONIA	0	0.0	1	0.6	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	0.6
	POLYCYTHEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	1	0.6
	STOMATITIS	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	SWEATING	1	0.6	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	0.6
	TACHYCARDIA	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	THIRST	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	ULCERATIVE STOMATITIS	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	URINARY FREQUENCY	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	URINARY RETENTION	0	0.0	1	0.6	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	0.6
	VASODILATATION	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6
	VERTIGO	0	0.0	1	0.6	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	0.6
	WEIGHT LOSS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	1	0.6
	YAWN	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.6

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																						
Paroxetine (N=71)	ABNORMAL EJACULATION	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

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																						
Placebo (N=89)	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

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																						
Paroxetine (N=92)	DYSMENORRHEA	1	1.1	0	0.0	2	2.2	1	1.1	0	0.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0	5	5.4
	AMENORRHEA	1	1.1	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	1	1.1

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total, Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Week 12		Week 16		Post Week 16		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																						
Placebo (N=67)	DYSMENORRHEA	1	1.5	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	4	6.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=163), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	131	80.4	81	49.7	19	11.7
Body as a Whole	TOTAL	85	52.1	43	26.4	10	6.1
	ABDOMINAL PAIN	21	12.9	2	1.2	1	0.6
	ALLERGIC REACTION	5	3.1	2	1.2	0	0.0
	ASTHENIA	14	8.6	9	5.5	1	0.6
	BACK PAIN	2	1.2	1	0.6	0	0.0
	CELLULITIS	0	0.0	1	0.6	0	0.0
	FEVER	5	3.1	1	0.6	0	0.0
	FLU SYNDROME	0	0.0	3	1.8	1	0.6
	HEADACHE	44	27.0	16	9.8	2	1.2
	INFECTION	21	12.9	8	4.9	4	2.5
	MONILIASIS	1	0.6	1	0.6	0	0.0
	PAIN	2	1.2	0	0.0	0	0.0
	RHEUMATOID ARTHRITIS	0	0.0	1	0.6	0	0.0
	TRAUMA	9	5.5	4	2.5	1	0.6
Cardiovascular System	TOTAL	4	2.5	3	1.8	0	0.0
	HYPOTENSION	0	0.0	1	0.6	0	0.0
	MIGRAINE	0	0.0	1	0.6	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=163), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Cardiovascular System	QT INTERVAL PROLONGED	1	0.6	0	0.0	0	0.0
	SYNCOPE	0	0.0	1	0.6	0	0.0
	VASODILATATION	3	1.8	0	0.0	0	0.0
Digestive System	TOTAL	48	29.4	17	10.4	2	1.2
	CONSTIPATION	0	0.0	1	0.6	0	0.0
	DECREASED APPETITE	10	6.1	3	1.8	0	0.0
	DIARRHEA	5	3.1	1	0.6	0	0.0
	DRY MOUTH	4	2.5	0	0.0	0	0.0
	DYSPEPSIA	8	4.9	3	1.8	1	0.6
	FECAL INCONTINENCE	2	1.2	0	0.0	0	0.0
	FLATULENCE	1	0.6	1	0.6	0	0.0
	GASTRITIS	0	0.0	0	0.0	1	0.6
	GASTROINTESTINAL DISORDER	1	0.6	0	0.0	0	0.0
	GINGIVITIS	1	0.6	0	0.0	0	0.0
	INCREASED APPETITE	4	2.5	1	0.6	0	0.0
	NAUSEA	10	6.1	7	4.3	0	0.0
	RECTAL DISORDER	1	0.6	0	0.0	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=163), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	STOMATITIS	2	1.2	0	0.0	0	0.0
	TOOTH DISORDER	0	0.0	1	0.6	0	0.0
	ULCERATIVE STOMATITIS	1	0.6	0	0.0	0	0.0
	VOMITING	8	4.9	3	1.8	0	0.0
Hemic and Lymphatic System	TOTAL	1	0.6	4	2.5	1	0.6
	ANEMIA	0	0.0	0	0.0	1	0.6
	LEUKOCYTOSIS	1	0.6	0	0.0	0	0.0
	LEUKOPENIA	1	0.6	0	0.0	0	0.0
	PURPURA	0	0.0	4	2.5	0	0.0
Metabolic and Nutritional Disorders	TOTAL	8	4.9	0	0.0	0	0.0
	HYPERKALEMIA	1	0.6	0	0.0	0	0.0
	KETOSIS	1	0.6	0	0.0	0	0.0
	THIRST	1	0.6	0	0.0	0	0.0
	WEIGHT GAIN	4	2.5	0	0.0	0	0.0
	WEIGHT LOSS	1	0.6	0	0.0	0	0.0
Musculoskeletal System	TOTAL	9	5.5	1	0.6	0	0.0
	ARTHRALGIA	4	2.5	0	0.0	0	0.0
	MYALGIA	5	3.1	1	0.6	0	0.0
Nervous System	TOTAL	44	27.0	32	19.6	5	3.1

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=163), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	ABNORMAL DREAMS	2	1.2	0	0.0	1	0.6
	AGITATION	1	0.6	1	0.6	1	0.6
	AMNESIA	1	0.6	0	0.0	0	0.0
	CONCENTRATION IMPAIRED	1	0.6	1	0.6	0	0.0
	DEPERSONALIZATION	0	0.0	1	0.6	0	0.0
	DEPRESSION	1	0.6	2	1.2	0	0.0
	DIZZINESS	7	4.3	1	0.6	0	0.0
	EMOTIONAL LABILITY	2	1.2	2	1.2	0	0.0
	HOSTILITY	2	1.2	3	1.8	0	0.0
	HYPERKINESIA	3	1.8	2	1.2	1	0.6
	INSOMNIA	12	7.4	11	6.7	0	0.0
	LACK OF EMOTION	1	0.6	1	0.6	0	0.0
	LIBIDO DECREASED	0	0.0	1	0.6	0	0.0
	MANIC REACTION	0	0.0	0	0.0	3	1.8
	MYOCLONUS	0	0.0	1	0.6	0	0.0
	NERVOUSNESS	8	4.9	6	3.7	0	0.0
	NEUROSIS	0	0.0	2	1.2	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=163), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	SOMNOLENCE	16	9.8	5	3.1	0	0.0
	SPEECH DISORDER	1	0.6	0	0.0	0	0.0
	TREMOR	1	0.6	2	1.2	0	0.0
Respiratory System	TOTAL	45	27.6	18	11.0	0	0.0
	ASTHMA	1	0.6	2	1.2	0	0.0
	BRONCHITIS	1	0.6	2	1.2	0	0.0
	COUGH INCREASED	6	3.7	3	1.8	0	0.0
	EPISTAXIS	2	1.2	1	0.6	0	0.0
	PHARYNGITIS	9	5.5	4	2.5	0	0.0
	RESPIRATORY DISORDER	17	10.4	8	4.9	0	0.0
	RHINITIS	15	9.2	2	1.2	0	0.0
	SINUSITIS	8	4.9	0	0.0	0	0.0
	YAWN	3	1.8	0	0.0	0	0.0
Skin and Appendages	TOTAL	15	9.2	3	1.8	1	0.6
	ACNE	1	0.6	0	0.0	0	0.0
	CONTACT DERMATITIS	2	1.2	1	0.6	1	0.6
	HERPES SIMPLEX	1	0.6	0	0.0	0	0.0
	NAIL DISORDER	1	0.6	0	0.0	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=163), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	PRURITUS	1	0.6	0	0.0	0	0.0
	RASH	7	4.3	1	0.6	0	0.0
	SWEATING	3	1.8	1	0.6	0	0.0
	VESICULOBULLOUS RASH	1	0.6	0	0.0	0	0.0
Special Senses	TOTAL	12	7.4	5	3.1	0	0.0
	CONJUNCTIVITIS	4	2.5	2	1.2	0	0.0
	EAR PAIN	3	1.8	1	0.6	0	0.0
	MYDRIASIS	1	0.6	0	0.0	0	0.0
	OTITIS EXTERNA	1	0.6	0	0.0	0	0.0
	OTITIS MEDIA	4	2.5	2	1.2	0	0.0
Urogenital System	TOTAL	3	1.8	4	2.5	0	0.0
	ALBUMINURIA	2	1.2	0	0.0	0	0.0
	URINARY FREQUENCY	0	0.0	1	0.6	0	0.0
	URINARY INCONTINENCE	2	1.2	3	1.8	0	0.0
	URINE ABNORMALITY	1	0.6	0	0.0	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=71), Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	1	1.4	0	0.0
Urogenital System	TOTAL	0	0.0	1	1.4	0	0.0
	ABNORMAL EJACULATION	0	0.0	1	1.4	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=92), Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	2	2.2	3	3.3	1	1.1
Urogenital System	TOTAL	2	2.2	3	3.3	1	1.1
	AMENORRHEA	1	1.1	0	0.0	0	0.0
	DYSMENORRHEA	1	1.1	3	3.3	1	1.1

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=156), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	108	69.2	70	44.9	9	5.8
Body as a Whole	TOTAL	60	38.5	38	24.4	6	3.8
	ABDOMINAL PAIN	12	7.7	2	1.3	1	0.6
	ABNORMAL LABORATORY VALUE	1	0.6	0	0.0	0	0.0
	ALLERGIC REACTION	3	1.9	1	0.6	0	0.0
	ASTHENIA	9	5.8	3	1.9	0	0.0
	BACK PAIN	2	1.3	3	1.9	2	1.3
	CHEST PAIN	0	0.0	1	0.6	0	0.0
	CHILLS	0	0.0	0	0.0	1	0.6
	FEVER	2	1.3	1	0.6	0	0.0
	FLU SYNDROME	0	0.0	2	1.3	1	0.6
	HEADACHE	25	16.0	15	9.6	2	1.3
	INFECTION	13	8.3	12	7.7	0	0.0
	NEOPLASM	1	0.6	0	0.0	0	0.0
	PAIN	2	1.3	0	0.0	0	0.0
	TRAUMA	6	3.8	5	3.2	1	0.6
Cardiovascular System	TOTAL	3	1.9	2	1.3	0	0.0
	HYPOTENSION	1	0.6	1	0.6	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=156), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Cardiovascular System	SYNCOPE	0	0.0	2	1.3	0	0.0
	TACHYCARDIA	1	0.6	0	0.0	0	0.0
	VASODILATATION	1	0.6	0	0.0	0	0.0
Digestive System	TOTAL	28	17.9	13	8.3	2	1.3
	CONSTIPATION	1	0.6	0	0.0	0	0.0
	DECREASED APPETITE	5	3.2	0	0.0	0	0.0
	DIARRHEA	4	2.6	3	1.9	0	0.0
	DRY MOUTH	4	2.6	1	0.6	0	0.0
	DYSPEPSIA	3	1.9	3	1.9	0	0.0
	FECAL INCONTINENCE	1	0.6	0	0.0	0	0.0
	GASTROENTERITIS	2	1.3	2	1.3	0	0.0
	GINGIVITIS	0	0.0	1	0.6	0	0.0
	INCREASED APPETITE	2	1.3	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	0.6	0	0.0	0	0.0
	NAUSEA	7	4.5	3	1.9	2	1.3
	STOMATITIS	1	0.6	0	0.0	0	0.0
	TOOTH CARIES	1	0.6	0	0.0	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=156), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	TOOTH DISORDER	0	0.0	2	1.3	0	0.0
	ULCERATIVE STOMATITIS	1	0.6	0	0.0	0	0.0
	VOMITING	0	0.0	3	1.9	0	0.0
Hemic and Lymphatic System	TOTAL	2	1.3	0	0.0	0	0.0
	EOSINOPHILIA	1	0.6	0	0.0	0	0.0
	LEUKOPENIA	1	0.6	0	0.0	0	0.0
	POLYCYTHEMIA	1	0.6	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	6	3.8	1	0.6	0	0.0
	BILIRUBINEMIA	1	0.6	0	0.0	0	0.0
	HYPONATREMIA	1	0.6	0	0.0	0	0.0
	THIRST	1	0.6	0	0.0	0	0.0
	WEIGHT GAIN	3	1.9	0	0.0	0	0.0
	WEIGHT LOSS	0	0.0	1	0.6	0	0.0
Musculoskeletal System	TOTAL	6	3.8	4	2.6	0	0.0
	ARTHRALGIA	2	1.3	2	1.3	0	0.0
	ARTHROSIS	0	0.0	1	0.6	0	0.0
	MYALGIA	4	2.6	1	0.6	0	0.0
Nervous System	TOTAL	22	14.1	16	10.3	1	0.6
	AGITATION	0	0.0	2	1.3	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=156), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	ANXIETY	1	0.6	0	0.0	0	0.0
	CONCENTRATION IMPAIRED	2	1.3	0	0.0	0	0.0
	DIZZINESS	8	5.1	1	0.6	1	0.6
	EMOTIONAL LABILITY	2	1.3	0	0.0	0	0.0
	EXTRAPYRAMIDAL SYNDROME	0	0.0	1	0.6	0	0.0
	HOSTILITY	1	0.6	1	0.6	0	0.0
	HYPERTONIA	1	0.6	0	0.0	0	0.0
	INCOORDINATION	1	0.6	0	0.0	0	0.0
	INSOMNIA	3	1.9	6	3.8	0	0.0
	NERVOUSNESS	6	3.8	3	1.9	0	0.0
	SOMNOLENCE	8	5.1	5	3.2	0	0.0
	VERTIGO	0	0.0	1	0.6	0	0.0
Respiratory System	TOTAL	46	29.5	22	14.1	1	0.6
	ASTHMA	1	0.6	0	0.0	0	0.0
	BRONCHITIS	2	1.3	1	0.6	0	0.0
	COUGH INCREASED	8	5.1	3	1.9	0	0.0
	EPISTAXIS	1	0.6	0	0.0	0	0.0
	PHARYNGITIS	10	6.4	3	1.9	1	0.6

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=156), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	PNEUMONIA	1	0.6	0	0.0	0	0.0
	RESPIRATORY DISORDER	9	5.8	11	7.1	0	0.0
	RHINITIS	23	14.7	2	1.3	0	0.0
	SINUSITIS	2	1.3	5	3.2	0	0.0
	YAWN	1	0.6	0	0.0	0	0.0
Skin and Appendages	TOTAL	9	5.8	4	2.6	0	0.0
	ACNE	2	1.3	1	0.6	0	0.0
	ECZEMA	1	0.6	1	0.6	0	0.0
	FUNGAL DERMATITIS	0	0.0	1	0.6	0	0.0
	HERPES SIMPLEX	1	0.6	0	0.0	0	0.0
	PHOTOSENSITIVITY	1	0.6	0	0.0	0	0.0
	RASH	4	2.6	0	0.0	0	0.0
	SWEATING	0	0.0	1	0.6	0	0.0
Special Senses	TOTAL	4	2.6	2	1.3	1	0.6
	ABNORMAL VISION	1	0.6	0	0.0	0	0.0
	CONJUNCTIVITIS	1	0.6	0	0.0	0	0.0
	EAR PAIN	0	0.0	0	0.0	1	0.6
	OTITIS EXTERNA	0	0.0	1	0.6	0	0.0

(CONTINUED)

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=156), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Special Senses	OTITIS MEDIA	1	0.6	1	0.6	0	0.0
	PHOTOPHOBIA	1	0.6	0	0.0	0	0.0
Urogenital System	TOTAL	4	2.6	3	1.9	0	0.0
	ALBUMINURIA	2	1.3	0	0.0	0	0.0
	CYSTITIS	0	0.0	1	0.6	0	0.0
	URINARY FREQUENCY	1	0.6	0	0.0	0	0.0
	URINARY RETENTION	0	0.0	1	0.6	0	0.0
	URINARY TRACT INFECTION	1	0.6	1	0.6	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=89), 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 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=67), Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	2	3.0	2	3.0	0	0.0
Urogenital System	TOTAL	2	3.0	2	3.0	0	0.0
	DYSMENORRHEA	2	3.0	2	3.0	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
By Body System.
Intention-To-Treat Population Entering The Taper Phase
Treatment Group : Paroxetine (N=106), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	20	18.9	13	12.3	3	2.8
Body as a Whole	TOTAL	8	7.5	8	7.5	1	0.9
	ABDOMINAL PAIN	3	2.8	1	0.9	0	0.0
	ALLERGIC REACTION	1	0.9	0	0.0	0	0.0
	ASTHENIA	0	0.0	1	0.9	0	0.0
	FLU SYNDROME	0	0.0	1	0.9	0	0.0
	HEADACHE	3	2.8	5	4.7	0	0.0
	INFECTION	0	0.0	1	0.9	0	0.0
	TRAUMA	1	0.9	1	0.9	1	0.9
Cardiovascular System	TOTAL	1	0.9	0	0.0	0	0.0
	HYPOTENSION	1	0.9	0	0.0	0	0.0
Digestive System	TOTAL	2	1.9	3	2.8	0	0.0
	DIARRHEA	0	0.0	1	0.9	0	0.0
	NAUSEA	2	1.9	2	1.9	0	0.0
Nervous System	TOTAL	7	6.6	5	4.7	1	0.9
	DIZZINESS	3	2.8	1	0.9	1	0.9
	EMOTIONAL LABILITY	1	0.9	0	0.0	0	0.0
	INSOMNIA	1	0.9	0	0.0	0	0.0

(CONTINUED)

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population Entering The Taper Phase
Treatment Group : Paroxetine (N=106), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	MYOCLONUS	0	0.0	1	0.9	0	0.0
	NERVOUSNESS	2	1.9	2	1.9	0	0.0
	SOMNOLENCE	2	1.9	0	0.0	0	0.0
	VERTIGO	0	0.0	1	0.9	0	0.0
Respiratory System	TOTAL	3	2.8	1	0.9	1	0.9
	PHARYNGITIS	1	0.9	0	0.0	0	0.0
	RESPIRATORY DISORDER	0	0.0	1	0.9	0	0.0
	RHINITIS	1	0.9	0	0.0	0	0.0
	SINUSITIS	1	0.9	0	0.0	1	0.9
Special Senses	TOTAL	1	0.9	0	0.0	0	0.0
	ABNORMAL VISION	1	0.9	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
By Body System.
Intention-To-Treat Population Entering The Taper Phase
Treatment Group : Paroxetine (N=42), 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
By Body System.
Intention-To-Treat Population Entering The Taper Phase
Treatment Group : Paroxetine (N=64), 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 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population Entering The Taper Phase
Treatment Group : Placebo (N=108), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	16	14.8	6	5.6	1	0.9
Body as a Whole	TOTAL	8	7.4	4	3.7	1	0.9
	ABDOMINAL PAIN	2	1.9	0	0.0	0	0.0
	ASTHENIA	1	0.9	0	0.0	0	0.0
	BACK PAIN	1	0.9	0	0.0	0	0.0
	HEADACHE	5	4.6	2	1.9	1	0.9
	INFECTION	0	0.0	1	0.9	0	0.0
	TRAUMA	0	0.0	1	0.9	0	0.0
Nervous System	TOTAL	2	1.9	1	0.9	0	0.0
	ANXIETY	1	0.9	1	0.9	0	0.0
	NERVOUSNESS	1	0.9	0	0.0	0	0.0
Respiratory System	TOTAL	7	6.5	2	1.9	0	0.0
	COUGH INCREASED	2	1.9	0	0.0	0	0.0
	LARYNX DISORDER	2	1.9	0	0.0	0	0.0
	PHARYNGITIS	1	0.9	0	0.0	0	0.0
	RESPIRATORY DISORDER	2	1.9	2	1.9	0	0.0
	RHINITIS	1	0.9	0	0.0	0	0.0
Urogenital System	TOTAL	1	0.9	0	0.0	0	0.0
	PYURIA	1	0.9	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
By Body System.
Intention-To-Treat Population Entering The Taper Phase
Treatment Group : Placebo (N=63), 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
By Body System.
Intention-To-Treat Population Entering The Taper Phase
Treatment Group : Placebo (N=45), 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

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=163), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	131	80.4	85	52.1	21	12.9
Body as a Whole	TOTAL	86	52.8	50	30.7	11	6.7
	ABDOMINAL PAIN	24	14.7	3	1.8	1	0.6
	ALLERGIC REACTION	6	3.7	2	1.2	0	0.0
	ASTHENIA	14	8.6	10	6.1	1	0.6
	BACK PAIN	2	1.2	1	0.6	0	0.0
	CELLULITIS	0	0.0	1	0.6	0	0.0
	FEVER	5	3.1	1	0.6	0	0.0
	FLU SYNDROME	0	0.0	4	2.5	1	0.6
	HEADACHE	44	27.0	21	12.9	2	1.2
	INFECTION	21	12.9	9	5.5	4	2.5
	MONILIASIS	1	0.6	1	0.6	0	0.0
	PAIN	2	1.2	0	0.0	0	0.0
	RHEUMATOID ARTHRITIS	0	0.0	1	0.6	0	0.0
	TRAUMA	10	6.1	5	3.1	2	1.2
Cardiovascular System	TOTAL	4	2.5	3	1.8	0	0.0
	HYPOTENSION	0	0.0	1	0.6	0	0.0
	MIGRAINE	0	0.0	1	0.6	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=163), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Cardiovascular System	QT INTERVAL PROLONGED	1	0.6	0	0.0	0	0.0
	SYNCOPE	0	0.0	1	0.6	0	0.0
	VASODILATATION	3	1.8	0	0.0	0	0.0
Digestive System	TOTAL	49	30.1	20	12.3	2	1.2
	CONSTIPATION	0	0.0	1	0.6	0	0.0
	DECREASED APPETITE	10	6.1	3	1.8	0	0.0
	DIARRHEA	4	2.5	2	1.2	0	0.0
	DRY MOUTH	4	2.5	0	0.0	0	0.0
	DYSPEPSIA	8	4.9	3	1.8	1	0.6
	FECAL INCONTINENCE	2	1.2	0	0.0	0	0.0
	FLATULENCE	1	0.6	1	0.6	0	0.0
	GASTRITIS	0	0.0	0	0.0	1	0.6
	GASTROINTESTINAL DISORDER	1	0.6	0	0.0	0	0.0
	GINGIVITIS	1	0.6	0	0.0	0	0.0
	INCREASED APPETITE	4	2.5	1	0.6	0	0.0
	NAUSEA	12	7.4	9	5.5	0	0.0
	RECTAL DISORDER	1	0.6	0	0.0	0	0.0

(CONTINUED)

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=163), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	STOMATITIS	2	1.2	0	0.0	0	0.0
	TOOTH DISORDER	0	0.0	1	0.6	0	0.0
	ULCERATIVE STOMATITIS	1	0.6	0	0.0	0	0.0
	VOMITING	8	4.9	3	1.8	0	0.0
Hemic and Lymphatic System	TOTAL	1	0.6	4	2.5	1	0.6
	ANEMIA	0	0.0	0	0.0	1	0.6
	LEUKOCYTOSIS	1	0.6	0	0.0	0	0.0
	LEUKOPENIA	1	0.6	0	0.0	0	0.0
	PURPURA	0	0.0	4	2.5	0	0.0
Metabolic and Nutritional Disorders	TOTAL	8	4.9	0	0.0	0	0.0
	HYPERKALEMIA	1	0.6	0	0.0	0	0.0
	KETOSIS	1	0.6	0	0.0	0	0.0
	THIRST	1	0.6	0	0.0	0	0.0
	WEIGHT GAIN	4	2.5	0	0.0	0	0.0
	WEIGHT LOSS	1	0.6	0	0.0	0	0.0
Musculoskeletal System	TOTAL	9	5.5	1	0.6	0	0.0
	ARTHRALGIA	4	2.5	0	0.0	0	0.0
	MYALGIA	5	3.1	1	0.6	0	0.0
Nervous System	TOTAL	48	29.4	35	21.5	6	3.7

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=163), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	ABNORMAL DREAMS	2	1.2	0	0.0	1	0.6
	AGITATION	1	0.6	1	0.6	1	0.6
	AMNESIA	1	0.6	0	0.0	0	0.0
	CONCENTRATION IMPAIRED	1	0.6	1	0.6	0	0.0
	DEPERSONALIZATION	0	0.0	1	0.6	0	0.0
	DEPRESSION	1	0.6	2	1.2	0	0.0
	DIZZINESS	10	6.1	2	1.2	1	0.6
	EMOTIONAL LABILITY	3	1.8	2	1.2	0	0.0
	HOSTILITY	2	1.2	3	1.8	0	0.0
	HYPERKINESIA	3	1.8	2	1.2	1	0.6
	INSOMNIA	13	8.0	11	6.7	0	0.0
	LACK OF EMOTION	1	0.6	1	0.6	0	0.0
	LIBIDO DECREASED	0	0.0	1	0.6	0	0.0
	MANIC REACTION	0	0.0	0	0.0	3	1.8
	MYOCLONUS	0	0.0	2	1.2	0	0.0
	NERVOUSNESS	9	5.5	6	3.7	0	0.0
	NEUROSIS	0	0.0	2	1.2	0	0.0

(CONTINUED)

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=163), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	SOMNOLENCE	18	11.0	5	3.1	0	0.0
	SPEECH DISORDER	1	0.6	0	0.0	0	0.0
	TREMOR	1	0.6	2	1.2	0	0.0
	VERTIGO	0	0.0	1	0.6	0	0.0
Respiratory System	TOTAL	48	29.4	19	11.7	1	0.6
	ASTHMA	1	0.6	2	1.2	0	0.0
	BRONCHITIS	1	0.6	2	1.2	0	0.0
	COUGH INCREASED	6	3.7	3	1.8	0	0.0
	EPISTAXIS	2	1.2	1	0.6	0	0.0
	PHARYNGITIS	10	6.1	4	2.5	0	0.0
	RESPIRATORY DISORDER	17	10.4	9	5.5	0	0.0
	RHINITIS	16	9.8	2	1.2	0	0.0
	SINUSITIS	9	5.5	0	0.0	1	0.6
	YAWN	3	1.8	0	0.0	0	0.0
Skin and Appendages	TOTAL	15	9.2	3	1.8	1	0.6
	ACNE	1	0.6	0	0.0	0	0.0
	CONTACT DERMATITIS	2	1.2	1	0.6	1	0.6
	HERPES SIMPLEX	1	0.6	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=163), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	NAIL DISORDER	1	0.6	0	0.0	0	0.0
	PRURITUS	1	0.6	0	0.0	0	0.0
	RASH	7	4.3	1	0.6	0	0.0
	SWEATING	3	1.8	1	0.6	0	0.0
	VESICULOBULLOUS RASH	1	0.6	0	0.0	0	0.0
Special Senses	TOTAL	13	8.0	5	3.1	0	0.0
	ABNORMAL VISION	1	0.6	0	0.0	0	0.0
	CONJUNCTIVITIS	4	2.5	2	1.2	0	0.0
	EAR PAIN	3	1.8	1	0.6	0	0.0
	MYDRIASIS	1	0.6	0	0.0	0	0.0
	OTITIS EXTERNA	1	0.6	0	0.0	0	0.0
	OTITIS MEDIA	4	2.5	2	1.2	0	0.0
Urogenital System	TOTAL	3	1.8	4	2.5	0	0.0
	ALBUMINURIA	2	1.2	0	0.0	0	0.0
	URINARY FREQUENCY	0	0.0	1	0.6	0	0.0
	URINARY INCONTINENCE	2	1.2	3	1.8	0	0.0
	URINE ABNORMALITY	1	0.6	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=71), Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	1	1.4	0	0.0
Urogenital System	TOTAL	0	0.0	1	1.4	0	0.0
	ABNORMAL EJACULATION	0	0.0	1	1.4	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity By Body System.
Intention-To-Treat Population
Treatment Group : Paroxetine (N=92), Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	2	2.2	3	3.3	1	1.1
Urogenital System	TOTAL	2	2.2	3	3.3	1	1.1
	AMENORRHEA	1	1.1	0	0.0	0	0.0
	DYSMENORRHEA	1	1.1	3	3.3	1	1.1

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=156), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	108	69.2	72	46.2	10	6.4
Body as a Whole	TOTAL	63	40.4	40	25.6	7	4.5
	ABDOMINAL PAIN	13	8.3	2	1.3	1	0.6
	ABNORMAL LABORATORY VALUE	1	0.6	0	0.0	0	0.0
	ALLERGIC REACTION	3	1.9	1	0.6	0	0.0
	ASTHENIA	9	5.8	3	1.9	0	0.0
	BACK PAIN	3	1.9	3	1.9	2	1.3
	CHEST PAIN	0	0.0	1	0.6	0	0.0
	CHILLS	0	0.0	0	0.0	1	0.6
	FEVER	2	1.3	1	0.6	0	0.0
	FLU SYNDROME	0	0.0	2	1.3	1	0.6
	HEADACHE	27	17.3	15	9.6	3	1.9
	INFECTION	13	8.3	13	8.3	0	0.0
	NEOPLASM	1	0.6	0	0.0	0	0.0
	PAIN	2	1.3	0	0.0	0	0.0
	TRAUMA	6	3.8	6	3.8	1	0.6
Cardiovascular System	TOTAL	3	1.9	2	1.3	0	0.0
	HYPOTENSION	1	0.6	1	0.6	0	0.0

(CONTINUED)

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=156), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Cardiovascular System	SYNCOPE	0	0.0	2	1.3	0	0.0
	TACHYCARDIA	1	0.6	0	0.0	0	0.0
	VASODILATATION	1	0.6	0	0.0	0	0.0
Digestive System	TOTAL	28	17.9	13	8.3	2	1.3
	CONSTIPATION	1	0.6	0	0.0	0	0.0
	DECREASED APPETITE	5	3.2	0	0.0	0	0.0
	DIARRHEA	4	2.6	3	1.9	0	0.0
	DRY MOUTH	4	2.6	1	0.6	0	0.0
	DYSPEPSIA	3	1.9	3	1.9	0	0.0
	FECAL INCONTINENCE	1	0.6	0	0.0	0	0.0
	GASTROENTERITIS	2	1.3	2	1.3	0	0.0
	GINGIVITIS	0	0.0	1	0.6	0	0.0
	INCREASED APPETITE	2	1.3	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	0.6	0	0.0	0	0.0
	NAUSEA	7	4.5	3	1.9	2	1.3
	STOMATITIS	1	0.6	0	0.0	0	0.0
	TOOTH CARIES	1	0.6	0	0.0	0	0.0

(CONTINUED)

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=156), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	TOOTH DISORDER	0	0.0	2	1.3	0	0.0
	ULCERATIVE STOMATITIS	1	0.6	0	0.0	0	0.0
	VOMITING	0	0.0	3	1.9	0	0.0
Hemic and Lymphatic System	TOTAL	2	1.3	0	0.0	0	0.0
	EOSINOPHILIA	1	0.6	0	0.0	0	0.0
	LEUKOPENIA	1	0.6	0	0.0	0	0.0
	POLYCYTHEMIA	1	0.6	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	6	3.8	1	0.6	0	0.0
	BILIRUBINEMIA	1	0.6	0	0.0	0	0.0
	HYPONATREMIA	1	0.6	0	0.0	0	0.0
	THIRST	1	0.6	0	0.0	0	0.0
	WEIGHT GAIN	3	1.9	0	0.0	0	0.0
	WEIGHT LOSS	0	0.0	1	0.6	0	0.0
Musculoskeletal System	TOTAL	6	3.8	4	2.6	0	0.0
	ARTHRALGIA	2	1.3	2	1.3	0	0.0
	ARTHROSIS	0	0.0	1	0.6	0	0.0
	MYALGIA	4	2.6	1	0.6	0	0.0
Nervous System	TOTAL	23	14.7	17	10.9	1	0.6
	AGITATION	0	0.0	2	1.3	0	0.0

(CONTINUED)

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=156), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	ANXIETY	2	1.3	1	0.6	0	0.0
	CONCENTRATION IMPAIRED	2	1.3	0	0.0	0	0.0
	DIZZINESS	8	5.1	1	0.6	1	0.6
	EMOTIONAL LABILITY	2	1.3	0	0.0	0	0.0
	EXTRAPYRAMIDAL SYNDROME	0	0.0	1	0.6	0	0.0
	HOSTILITY	1	0.6	1	0.6	0	0.0
	HYPERTONIA	1	0.6	0	0.0	0	0.0
	INCOORDINATION	1	0.6	0	0.0	0	0.0
	INSOMNIA	3	1.9	6	3.8	0	0.0
	NERVOUSNESS	7	4.5	3	1.9	0	0.0
	SOMNOLENCE	8	5.1	5	3.2	0	0.0
	VERTIGO	0	0.0	1	0.6	0	0.0
Respiratory System	TOTAL	51	32.7	24	15.4	1	0.6
	ASTHMA	1	0.6	0	0.0	0	0.0
	BRONCHITIS	2	1.3	1	0.6	0	0.0
	COUGH INCREASED	10	6.4	3	1.9	0	0.0
	EPISTAXIS	1	0.6	0	0.0	0	0.0
	LARYNX DISORDER	2	1.3	0	0.0	0	0.0

(CONTINUED)

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=156), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	PHARYNGITIS	10	6.4	3	1.9	1	0.6
	PNEUMONIA	1	0.6	0	0.0	0	0.0
	RESPIRATORY DISORDER	11	7.1	13	8.3	0	0.0
	RHINITIS	24	15.4	2	1.3	0	0.0
	SINUSITIS	2	1.3	5	3.2	0	0.0
	YAWN	1	0.6	0	0.0	0	0.0
Skin and Appendages	TOTAL	9	5.8	4	2.6	0	0.0
	ACNE	2	1.3	1	0.6	0	0.0
	ECZEMA	1	0.6	1	0.6	0	0.0
	FUNGAL DERMATITIS	0	0.0	1	0.6	0	0.0
	HERPES SIMPLEX	1	0.6	0	0.0	0	0.0
	PHOTOSENSITIVITY	1	0.6	0	0.0	0	0.0
	RASH	4	2.6	0	0.0	0	0.0
	SWEATING	0	0.0	1	0.6	0	0.0
Special Senses	TOTAL	4	2.6	2	1.3	1	0.6
	ABNORMAL VISION	1	0.6	0	0.0	0	0.0
	CONJUNCTIVITIS	1	0.6	0	0.0	0	0.0
	EAR PAIN	0	0.0	0	0.0	1	0.6

(CONTINUED)

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=156), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Special Senses	OTITIS EXTERNA	0	0.0	1	0.6	0	0.0
	OTITIS MEDIA	1	0.6	1	0.6	0	0.0
	PHOTOPHOBIA	1	0.6	0	0.0	0	0.0
Urogenital System	TOTAL	5	3.2	3	1.9	0	0.0
	ALBUMINURIA	2	1.3	0	0.0	0	0.0
	CYSTITIS	0	0.0	1	0.6	0	0.0
	PYURIA	1	0.6	0	0.0	0	0.0
	URINARY FREQUENCY	1	0.6	0	0.0	0	0.0
	URINARY RETENTION	0	0.0	1	0.6	0	0.0
	URINARY TRACT INFECTION	1	0.6	1	0.6	0	0.0

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=89), 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 Treatment or Taper Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population
Treatment Group : Placebo (N=67), Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	2	3.0	2	3.0	0	0.0
Urogenital System	TOTAL	2	3.0	2	3.0	0	0.0
	DYSMENORRHEA	2	3.0	2	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 By Body System.
Intention-To-Treat Population Entering The Follow-Up Phase
Treatment Group : Paroxetine (N=118), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	35	29.7	23	19.5	2	1.7
Body as a Whole	TOTAL	15	12.7	10	8.5	1	0.8
	ABDOMINAL PAIN	4	3.4	2	1.7	0	0.0
	ASTHENIA	2	1.7	2	1.7	0	0.0
	FEVER	0	0.0	1	0.8	0	0.0
	FLU SYNDROME	1	0.8	0	0.0	0	0.0
	HEADACHE	8	6.8	7	5.9	1	0.8
	INFECTION	1	0.8	1	0.8	0	0.0
	TRAUMA	1	0.8	0	0.0	0	0.0
Cardiovascular System	TOTAL	0	0.0	2	1.7	0	0.0
	PALPITATION	0	0.0	1	0.8	0	0.0
	SYNCOPE	0	0.0	1	0.8	0	0.0
Digestive System	TOTAL	15	12.7	4	3.4	0	0.0
	DECREASED APPETITE	1	0.8	0	0.0	0	0.0
	DIARRHEA	1	0.8	0	0.0	0	0.0
	DYSPEPSIA	2	1.7	0	0.0	0	0.0
	FLATULENCE	1	0.8	0	0.0	0	0.0
	NAUSEA	9	7.6	3	2.5	0	0.0
	VOMITING	2	1.7	1	0.8	0	0.0

(CONTINUED)

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Maximum Intensity By Body System.
Intention-To-Treat Population Entering The Follow-Up Phase
Treatment Group : Paroxetine (N=118), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Hemic and Lymphatic System	TOTAL	2	1.7	0	0.0	0	0.0
	HYPOCHROMIC ANEMIA	1	0.8	0	0.0	0	0.0
	LYMPHADENOPATHY	1	0.8	0	0.0	0	0.0
Musculoskeletal System	TOTAL	1	0.8	0	0.0	0	0.0
	MYALGIA	1	0.8	0	0.0	0	0.0
Nervous System	TOTAL	12	10.2	12	10.2	1	0.8
	ANXIETY	2	1.7	2	1.7	0	0.0
	DEPRESSION	0	0.0	2	1.7	0	0.0
	DIZZINESS	8	6.8	5	4.2	0	0.0
	EMOTIONAL LABILITY	2	1.7	1	0.8	0	0.0
	HYPERKINESIA	0	0.0	1	0.8	0	0.0
	INSOMNIA	0	0.0	1	0.8	1	0.8
	LACK OF EMOTION	0	0.0	1	0.8	0	0.0
	MYOCLONUS	1	0.8	0	0.0	0	0.0
	NERVOUSNESS	1	0.8	2	1.7	0	0.0
	SOMNOLENCE	1	0.8	0	0.0	0	0.0
	TREMOR	0	0.0	1	0.8	0	0.0
	WITHDRAWAL SYNDROME	0	0.0	1	0.8	0	0.0

(CONTINUED)

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population Entering The Follow-Up Phase
Treatment Group : Paroxetine (N=118), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	TOTAL	5	4.2	2	1.7	0	0.0
	ASTHMA	1	0.8	0	0.0	0	0.0
	PHARYNGITIS	1	0.8	0	0.0	0	0.0
	RESPIRATORY DISORDER	2	1.7	1	0.8	0	0.0
	RHINITIS	0	0.0	1	0.8	0	0.0
	SINUSITIS	1	0.8	0	0.0	0	0.0
Skin and Appendages	TOTAL	1	0.8	0	0.0	0	0.0
	SWEATING	1	0.8	0	0.0	0	0.0
Special Senses	TOTAL	0	0.0	1	0.8	0	0.0
	EAR PAIN	0	0.0	1	0.8	0	0.0

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population Entering The Follow-Up Phase
Treatment Group : Paroxetine (N=53), 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
By Body System.
Intention-To-Treat Population Entering The Follow-Up Phase
Treatment Group : Paroxetine (N=65), 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
By Body System.
Intention-To-Treat Population Entering The Follow-Up Phase
Treatment Group : Placebo (N=100), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	17	17.0	9	9.0	3	3.0
Body as a Whole	TOTAL	7	7.0	3	3.0	2	2.0
	ABDOMINAL PAIN	1	1.0	0	0.0	0	0.0
	ASTHENIA	1	1.0	0	0.0	0	0.0
	HEADACHE	5	5.0	2	2.0	0	0.0
	INFECTION	1	1.0	1	1.0	1	1.0
	TRAUMA	0	0.0	0	0.0	1	1.0
Digestive System	TOTAL	4	4.0	1	1.0	1	1.0
	DECREASED APPETITE	1	1.0	0	0.0	0	0.0
	DRY MOUTH	1	1.0	0	0.0	0	0.0
	GINGIVITIS	0	0.0	0	0.0	1	1.0
	NAUSEA	3	3.0	0	0.0	0	0.0
	VOMITING	0	0.0	1	1.0	0	0.0
Musculoskeletal System	TOTAL	1	1.0	0	0.0	0	0.0
	MYALGIA	1	1.0	0	0.0	0	0.0
Nervous System	TOTAL	2	2.0	4	4.0	0	0.0
	AGITATION	0	0.0	1	1.0	0	0.0
	ANXIETY	0	0.0	1	1.0	0	0.0
	DIZZINESS	1	1.0	1	1.0	0	0.0

(CONTINUED)

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Maximum Intensity
By Body System.
Intention-To-Treat Population Entering The Follow-Up Phase
Treatment Group : Placebo (N=100), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	INSOMNIA	0	0.0	1	1.0	0	0.0
	SOMNOLENCE	1	1.0	0	0.0	0	0.0
	TREMOR	1	1.0	0	0.0	0	0.0
Respiratory System	TOTAL	4	4.0	2	2.0	0	0.0
	PHARYNGITIS	1	1.0	1	1.0	0	0.0
	RESPIRATORY DISORDER	2	2.0	1	1.0	0	0.0
	RHINITIS	1	1.0	1	1.0	0	0.0
Skin and Appendages	TOTAL	1	1.0	0	0.0	0	0.0
	CONTACT DERMATITIS	1	1.0	0	0.0	0	0.0
Urogenital System	TOTAL	1	1.0	1	1.0	0	0.0
	URINARY FREQUENCY	0	0.0	1	1.0	0	0.0
	URINARY INCONTINENCE	0	0.0	1	1.0	0	0.0
	URINARY TRACT INFECTION	1	1.0	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
By Body System.
Intention-To-Treat Population Entering The Follow-Up Phase
Treatment Group : Placebo (N=57), 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
By Body System.
Intention-To-Treat Population Entering The Follow-Up Phase
Treatment Group : Placebo (N=43), Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	1	2.3	0	0.0	0	0.0
Urogenital System	TOTAL	1	2.3	0	0.0	0	0.0
	DYSMENORRHEA	1	2.3	0	0.0	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 Treatment Phase
By Body System.
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=46)	Treatment Group: Placebo (N=45)
TOTAL	TOTAL	12 (26.1%)	2 (4.4%)
Nervous System	TOTAL	12 (26.1%)	2 (4.4%)
	NERVOUSNESS	4 (8.7%)	2 (4.4%)
	HYPERKINESIA	4 (8.7%)	0
	HOSTILITY	3 (6.5%)	0
	DIZZINESS	1 (2.2%)	0
	MANIC REACTION	1 (2.2%)	0
	NEUROSIS	1 (2.2%)	0
	SPEECH DISORDER	1 (2.2%)	0
Body as a Whole	TOTAL	2 (4.3%)	0
	ASTHENIA	1 (2.2%)	0
	HEADACHE	1 (2.2%)	0
Digestive System	TOTAL	1 (2.2%)	0
	DIARRHEA	1 (2.2%)	0
	VOMITING	1 (2.2%)	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 Treatment Phase
By Body System.
Intention-To-Treat Population
Age Group : Children, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=23)
Body System	Preferred Term		
TOTAL	TOTAL	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 Treatment Phase
By Body System.
Intention-To-Treat Population
Age Group : Children, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=21)	Placebo (N=22)
Body System	Preferred Term		
TOTAL	TOTAL	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 Treatment Phase
By Body System.
Intention-To-Treat Population
Age Group : Adolescents, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=117)	 Placebo (N=111)
TOTAL	TOTAL	16 (13.7%)	4 (3.6%)
Nervous System	TOTAL	10 (8.5%)	3 (2.7%)
	INSOMNIA	4 (3.4%)	0
	NERVOUSNESS	2 (1.7%)	2 (1.8%)
	AGITATION	1 (0.9%)	0
	AMNESIA	1 (0.9%)	0
	CONCENTRATION IMPAIRED	1 (0.9%)	0
	DEPERSONALIZATION	1 (0.9%)	0
	HOSTILITY	1 (0.9%)	0
	HYPERKINESIA	1 (0.9%)	0
	TREMOR	1 (0.9%)	0
	EXTRAPYRAMIDAL SYNDROME	0	1 (0.9%)
Body as a Whole	TOTAL	3 (2.6%)	0
	ASTHENIA	2 (1.7%)	0
	HEADACHE	1 (0.9%)	0
Digestive System	TOTAL	2 (1.7%)	1 (0.9%)
	NAUSEA	1 (0.9%)	1 (0.9%)
	DECREASED APPETITE	1 (0.9%)	0
Cardiovascular System	TOTAL	1 (0.9%)	0
	QT INTERVAL PROLONGED	1 (0.9%)	0
Metabolic and Nutritional Disorders	TOTAL	1 (0.9%)	0
	WEIGHT GAIN	1 (0.9%)	0
Musculoskeletal System	TOTAL	1 (0.9%)	0
	MYALGIA	1 (0.9%)	0
Urogenital System	TOTAL	1 (0.9%)	0
	URINARY FREQUENCY	1 (0.9%)	0
Respiratory System	TOTAL	0	1 (0.9%)
	YAWN	0	1 (0.9%)
Special Senses	TOTAL	0	1 (0.9%)
	ABNORMAL VISION	0	1 (0.9%)

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Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences During the Treatment Phase
By Body System.
Intention-To-Treat Population
Age Group : Adolescents, Male Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=46)	Placebo (N=66)
TOTAL	TOTAL	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 Treatment Phase
By Body System.
Intention-To-Treat Population
Age Group : Adolescents, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=71)	Placebo (N=45)
Body System	Preferred Term		
TOTAL	TOTAL	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 Treatment Phase
By Body System.
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=163)	Treatment Group: Placebo (N=156)
TOTAL	TOTAL	28 (17.2%)	6 (3.8%)
Nervous System	TOTAL	22 (13.5%)	5 (3.2%)
	NERVOUSNESS	6 (3.7%)	4 (2.6%)
	HYPERKINESIA	5 (3.1%)	0
	HOSTILITY	4 (2.5%)	0
	INSOMNIA	4 (2.5%)	0
	AGITATION	1 (0.6%)	0
	AMNESIA	1 (0.6%)	0
	CONCENTRATION IMPAIRED	1 (0.6%)	0
	DEPERSONALIZATION	1 (0.6%)	0
	DIZZINESS	1 (0.6%)	0
	MANIC REACTION	1 (0.6%)	0
	NEUROSIS	1 (0.6%)	0
	SPEECH DISORDER	1 (0.6%)	0
	TREMOR	1 (0.6%)	0
	EXTRAPYRAMIDAL SYNDROME	0	1 (0.6%)
Body as a Whole	TOTAL	5 (3.1%)	0
	ASTHENIA	3 (1.8%)	0
	HEADACHE	2 (1.2%)	0
Digestive System	TOTAL	3 (1.8%)	1 (0.6%)
	NAUSEA	1 (0.6%)	1 (0.6%)
	DECREASED APPETITE	1 (0.6%)	0
	DIARRHEA	1 (0.6%)	0
	VOMITING	1 (0.6%)	0
Cardiovascular System	TOTAL	1 (0.6%)	0
	QT INTERVAL PROLONGED	1 (0.6%)	0
Metabolic and Nutritional Disorders	TOTAL	1 (0.6%)	0
	WEIGHT GAIN	1 (0.6%)	0
Musculoskeletal System	TOTAL	1 (0.6%)	0
	MYALGIA	1 (0.6%)	0
Urogenital System	TOTAL	1 (0.6%)	0
	URINARY FREQUENCY	1 (0.6%)	0
Respiratory System	TOTAL	0	1 (0.6%)
	YAWN	0	1 (0.6%)

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Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences During the Treatment Phase
By Body System.
Intention-To-Treat Population
Age Group : Total, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=163)	Treatment Group Placebo (N=156)
Special Senses	TOTAL	0	1 (0.6%)
	ABNORMAL VISION	0	1 (0.6%)

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Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences During the Treatment Phase
By Body System.
Intention-To-Treat Population
Age Group : Total, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=71)	Placebo (N=89)
Body System	Preferred Term		
TOTAL	TOTAL	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 Treatment Phase
By Body System.
Intention-To-Treat Population
Age Group : Total, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=92)	Placebo (N=67)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.2.1.1

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
(Pre-Treatment Phase and Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Baseline	163	107.4	109.0	13.01	80	153	155	108.8	110.0	13.23	80	150
Change from baseline to:												
Week 1	158	1.3	0.0	10.95	-31	32	147	-0.4	0.0	8.58	-22	27
Week 2	154	2.5	2.5	10.64	-33	37	141	0.3	0.0	11.18	-24	31
Week 3	143	0.8	0.0	11.23	-40	25	137	-1.1	0.0	11.18	-30	30
Week 4	154	0.4	0.0	11.43	-28	26	144	-0.0	0.0	11.30	-24	36
Week 6	143	0.3	0.0	11.53	-33	23	137	-0.0	0.0	10.07	-24	30
Week 8	139	-0.7	0.0	11.16	-36	43	125	1.4	0.0	9.61	-24	28
Week 10	126	-0.3	0.0	12.42	-34	32	111	-0.1	0.0	10.95	-25	25
Week 12	131	-1.5	0.0	11.28	-33	25	110	0.7	0.0	11.00	-28	39
Week 16	112	1.3	0.0	11.64	-29	25	89	3.3	2.0	12.16	-34	45
Post Week 16	1	-3.0	-3.0		-3	-3	1	21.0	21.0		21	21

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline

Table 15.2.1.1

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
(Pre-Treatment Phase and Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Baseline	163	67.7	68.0	8.80	50	90	155	68.1	70.0	8.96	50	93
Change from baseline to:												
Week 1	158	0.5	0.0	8.14	-22	22	147	0.1	0.0	8.73	-35	20
Week 2	154	-0.1	0.0	7.63	-24	20	141	0.0	0.0	8.68	-29	20
Week 3	143	-0.9	0.0	9.06	-24	20	137	-1.1	0.0	9.60	-37	24
Week 4	154	-0.4	0.0	9.49	-20	24	144	0.5	0.0	8.94	-33	24
Week 6	143	-0.8	0.0	9.48	-30	29	137	-0.1	0.0	9.48	-31	20
Week 8	139	-1.0	0.0	9.64	-22	25	125	0.8	0.0	9.42	-33	24
Week 10	126	-0.1	0.0	9.90	-30	23	111	-1.1	0.0	10.17	-24	24
Week 12	131	-1.0	0.0	9.25	-30	23	110	-1.5	0.0	9.77	-33	30
Week 16	112	0.1	0.0	8.12	-20	20	89	1.3	0.0	8.91	-20	20
Post Week 16	1	-15.0	-15.0		-15	-15	1	10.0	10.0		10	10

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline

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Table 15.2.1.1

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
(Pre-Treatment Phase and Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Baseline	163	76.1	76.0	11.23	52	112	155	75.4	76.0	11.32	51	120
Change from baseline to:												
Week 1	158	0.8	0.0	10.50	-38	36	147	1.1	0.0	10.55	-24	41
Week 2	154	0.2	0.0	11.22	-39	24	142	1.1	0.0	11.87	-28	38
Week 3	143	2.2	2.0	10.84	-30	35	137	1.4	0.0	10.95	-26	33
Week 4	154	2.5	4.0	11.33	-34	29	145	0.7	0.0	11.23	-36	27
Week 6	143	2.7	2.0	10.96	-24	32	137	1.2	0.0	11.26	-32	34
Week 8	139	2.5	4.0	11.40	-30	36	125	0.9	0.0	11.16	-24	31
Week 10	127	3.2	2.0	11.41	-22	30	111	1.1	0.0	10.28	-24	25
Week 12	131	3.1	2.0	14.91	-28	108	110	-0.7	0.0	12.27	-48	37
Week 16	111	3.8	4.0	11.77	-32	40	88	2.0	0.0	15.06	-41	56
Post Week 16	1	-22.0	-22.0		-22	-22	1	7.0	7.0		7	7

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline

Table 15.2.1.1

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
(Pre-Treatment Phase and Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Height / cm

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Baseline	163	156.71	160.02	16.807	70.0	183.0	153	159.97	162.56	14.896	114.3	193.0
Change from baseline to:												
Week 16	111	0.35	0.50	11.184	-101.1	24.1	87	1.23	1.00	4.248	-25.9	15.2
Post Week 16	1	2.29	2.29		2.3	2.3	0					

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline

Table 15.2.1.1

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
(Pre-Treatment Phase and Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Weight / kg

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Baseline	163	55.12	52.20	20.141	20.5	115.5	154	58.84	56.88	20.298	24.1	140.7
Change from baseline to:												
Week 16	110	1.69	1.50	3.045	-11.3	11.0	88	1.19	1.00	2.947	-6.6	8.5
Post Week 16	1	0.60	0.60		0.6	0.6	0					

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline

Table 15.2.1.1

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
(Pre-Treatment Phase and Treatment Phase)
Intention-To-Treat Population
Vital Signs Variable : Body Mass Index / kg/m2

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Baseline	163	22.10	20.40	6.568	14.1	57.1	153	22.62	21.30	6.523	13.7	59.6
Change from baseline to:												
Week 16	110	1.17	0.40	9.289	-9.3	95.3	87	0.15	0.00	1.581	-3.8	9.0
Post Week 16	1	-0.70	-0.70		-0.7	-0.7	0					

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline

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Table 15.2.1.2

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
(Pre-Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Baseline	163	107.4	109.0	13.01	80	153	155	108.8	110.0	13.23	80	150
Change from baseline to:												
Week 1	0						1	0.0	0.0		0	0
Week 2	1	6.0	6.0		6	6	0					
Week 3	4	7.5	9.5	8.89	-4	15	2	0.0	0.0	7.07	-5	5
Week 4	4	-2.0	-2.0	3.65	-6	2	1	0.0	0.0		0	0
Week 6	1	2.0	2.0		2	2	5	1.4	2.0	10.38	-14	15
Week 8	3	2.7	2.0	1.15	2	4	2	-1.0	-1.0	7.07	-6	4
Week 10	4	5.8	1.5	20.53	-14	34	4	-1.3	0.0	6.50	-10	5
Week 12	4	-7.0	-5.5	10.23	-20	3	6	4.8	5.0	8.06	-4	14
Week 16	82	1.0	0.0	11.65	-29	30	68	0.9	0.0	13.07	-25	43
Post Week 16	53	-1.8	0.0	12.14	-26	28	60	3.8	2.0	11.72	-24	33

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline
Subjects who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 16')
have both assessments in the summary statistics, but N represents the number of subjects at that week.

Table 15.2.1.2

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
(Pre-Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Baseline	163	67.7	68.0	8.80	50	90	155	68.1	70.0	8.96	50	93
Change from baseline to:												
Week 1	0						1	2.0	2.0		2	2
Week 2	1	-2.0	-2.0		-2	-2	0					
Week 3	4	8.0	7.5	4.24	4	13	2	8.5	8.5	2.12	7	10
Week 4	4	3.5	5.0	10.25	-10	14	1	-4.0	-4.0		-4	-4
Week 6	1	4.0	4.0		4	4	5	-2.6	2.0	16.61	-22	15
Week 8	3	-2.7	-4.0	6.11	-8	4	2	-17.0	-17.0	15.56	-28	-6
Week 10	4	6.5	6.0	16.42	-13	27	4	-5.0	-7.0	10.13	-14	8
Week 12	4	-3.5	0.5	9.75	-18	3	6	1.8	0.5	4.58	-2	10
Week 16	82	-0.1	0.0	10.08	-30	26	68	-1.3	0.0	10.01	-35	25
Post Week 16	53	-1.7	0.0	8.78	-20	16	60	0.9	0.0	9.04	-24	20

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline
Subjects who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 16')
have both assessments in the summary statistics, but N represents the number of subjects at that week.

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Table 15.2.1.2

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
(Pre-Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Baseline	163	76.1	76.0	11.23	52	112	155	75.4	76.0	11.32	51	120
Change from baseline to:												
Week 1	0						1	0.0	0.0		0	0
Week 2	1	-4.0	-4.0		-4	-4	0					
Week 3	4	-11.0	-14.0	7.57	-16	0	2	4.5	4.5	6.36	0	9
Week 4	4	12.0	12.0	3.65	8	16	1	13.0	13.0		13	13
Week 6	1	10.0	10.0		10	10	5	12.4	16.0	12.68	-2	24
Week 8	3	6.7	4.0	10.26	-2	18	2	6.0	6.0	8.49	0	12
Week 10	4	6.5	8.0	4.43	0	10	4	5.3	8.5	12.37	-12	16
Week 12	4	-1.5	-2.0	13.99	-18	16	6	-2.0	-2.0	9.78	-14	12
Week 16	83	1.9	0.0	10.71	-30	30	69	-0.2	0.0	11.79	-46	31
Post Week 16	53	1.8	1.0	10.83	-26	34	60	2.4	1.0	12.77	-32	32

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline
Subjects who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 16')
have both assessments in the summary statistics, but N represents the number of subjects at that week.

Table 15.2.1.2

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
(Pre-Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Height / cm

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Baseline	163	156.71	160.02	16.807	70.0	183.0	153	159.97	162.56	14.896	114.3	193.0
Change from baseline to:												
Week 16	14	0.99	1.35	1.783	-2.5	4.2	15	1.59	1.27	1.885	-0.5	7.0

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline
Subjects who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 16')
have both assessments in the summary statistics, but N represents the number of subjects at that week.

Table 15.2.1.2

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
(Pre-Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Weight / kg

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Baseline	163	55.12	52.20	20.141	20.5	115.5	154	58.84	56.88	20.298	24.1	140.7
Change from baseline to:												
Week 16	14	2.97	3.01	3.960	-3.0	11.0	15	3.07	2.80	3.057	-1.0	8.6

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline
Subjects who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 16')
have both assessments in the summary statistics, but N represents the number of subjects at that week.

Table 15.2.1.2

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
(Pre-Treatment Phase, Taper Phase and Follow-Up Phase)
Intention-To-Treat Population
Vital Signs Variable : Body Mass Index / kg/m2

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Min	Max	N	Mean	Median	Std Dev	Min	Max
Baseline	163	22.10	20.40	6.568	14.1	57.1	153	22.62	21.30	6.523	13.7	59.6
Change from baseline to:												
Week 16	14	1.11	0.85	1.786	-1.8	4.3	15	0.74	0.50	0.990	-1.0	2.5

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline
Subjects who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 16')
have both assessments in the summary statistics, but N represents the number of subjects at that week.

Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern during the Treatment Phase (including Taper)

Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	162	N/A	153	N/A
Number with Baseline and Post-Baseline Assessment	162	100.0	153	100.0
Low	65	40.1	57	37.3
Significant Decrease	8	4.9	2	1.3
Low & Significant Decrease	5	3.1	1	0.7
Low & Significant Increase	0	0.0	1	0.7
High	4	2.5	5	3.3
Significant Increase	1	0.6	2	1.3
High & Significant Increase	1	0.6	0	0.0
High & Significant Decrease	1	0.6	0	0.0

Number of patients with assessment = number of patients who had a measurement for this vital sign at any time.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-17 years), see Clinical Report for Weight Limits used
Significant Increase from Baseline: SBP>=40mmHg, DBP>=30mmHg, Pulse>=30, Weight>=7%
Significant Decrease from 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 Treatment Phase (including Taper)

Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	162	N/A	153	N/A
Number with Baseline and Post-Baseline Assessment	162	100.0	153	100.0
Low	9	5.6	9	5.9
Significant Decrease	22	13.6	16	10.5
Low & Significant Decrease	3	1.9	3	2.0
Low & Significant Increase	0	0.0	0	0.0
High	18	11.1	23	15.0
Significant Increase	0	0.0	1	0.7
High & Significant Increase	0	0.0	1	0.7
High & Significant Decrease	4	2.5	5	3.3

Number of patients with assessment = number of patients who had a measurement for this vital sign at any time.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-17 years), see Clinical Report for Weight Limits used
Significant Increase from Baseline: SBP>=40mmHg, DBP>=30mmHg, Pulse>=30, Weight>=7%
Significant Decrease from 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 Treatment Phase (including Taper)

Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	162	N/A	153	N/A
Number with Baseline and Post-Baseline Assessment	162	100.0	153	100.0
Low	25	15.4	26	17.0
Significant Decrease	4	2.5	3	2.0
Low & Significant Decrease	1	0.6	2	1.3
Low & Significant Increase	4	2.5	2	1.3
High	3	1.9	2	1.3
Significant Increase	9	5.6	11	7.2
High & Significant Increase	1	0.6	2	1.3
High & Significant Decrease	1	0.6	0	0.0

Number of patients with assessment = number of patients who had a measurement for this vital sign at any time.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-17 years), see Clinical Report for Weight Limits used
Significant Increase from Baseline: SBP>=40mmHg, DBP>=30mmHg, Pulse>=30, Weight>=7%
Significant Decrease from 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 Treatment Phase (including Taper)

Intention-To-Treat Population
Vital Signs Variable : Weight / kg

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	135	N/A	130	N/A
Number with Baseline and Post-Baseline Assessment	135	100.0	129	100.0
Low	1	0.7	1	0.8
Significant Decrease	4	3.0	2	1.6
Low & Significant Decrease	0	0.0	0	0.0
Low & Significant Increase	0	0.0	0	0.0
High	31	23.0	37	28.7
Significant Increase	33	24.4	21	16.3
High & Significant Increase	12	8.9	9	7.0
High & Significant Decrease	0	0.0	0	0.0

Number of patients with assessment = number of patients who had a measurement for this vital sign at any time.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-17 years), see Clinical Report for Weight Limits used
Significant Increase from Baseline: SBP>=40mmHg, DBP>=30mmHg, Pulse>=30, Weight>=7%
Significant Decrease from 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 Treatment Phase, Taper Phase or Follow-up Phase

Intention-To-Treat Population
Vital Signs Variable : Systolic Blood Pressure / mmHg

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	163	N/A	154	N/A
Number with Baseline and Post-Baseline Assessment	163	100.0	154	100.0
Low	68	41.7	59	38.3
Significant Decrease	8	4.9	2	1.3
Low & Significant Decrease	5	3.1	1	0.6
Low & Significant Increase	0	0.0	1	0.6
High	4	2.5	6	3.9
Significant Increase	1	0.6	2	1.3
High & Significant Increase	1	0.6	0	0.0
High & Significant Decrease	1	0.6	0	0.0

Number of patients with assessment = number of patients who had a measurement for this vital sign at any time.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-17 years), see Clinical Report for Weight Limits used
Significant Increase from Baseline: SBP>=40mmHg, DBP>=30mmHg, Pulse>=30, Weight>=7%
Significant Decrease from 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 Treatment Phase, Taper Phase or Follow-up Phase

Intention-To-Treat Population
Vital Signs Variable : Diastolic Blood Pressure / mmHg

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	163	N/A	154	N/A
Number with Baseline and Post-Baseline Assessment	163	100.0	154	100.0
Low	10	6.1	9	5.8
Significant Decrease	23	14.1	19	12.3
Low & Significant Decrease	4	2.5	3	1.9
Low & Significant Increase	0	0.0	0	0.0
High	21	12.9	23	14.9
Significant Increase	0	0.0	1	0.6
High & Significant Increase	0	0.0	1	0.6
High & Significant Decrease	5	3.1	5	3.2

Number of patients with assessment = number of patients who had a measurement for this vital sign at any time.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-17 years), see Clinical Report for Weight Limits used
Significant Increase from Baseline: SBP>=40mmHg, DBP>=30mmHg, Pulse>=30, Weight>=7%
Significant Decrease from 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 Treatment Phase, Taper Phase or Follow-up Phase

Intention-To-Treat Population
Vital Signs Variable : Heart Rate / BPM

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	163	N/A	154	N/A
Number with Baseline and Post-Baseline Assessment	163	100.0	154	100.0
Low	25	15.3	28	18.2
Significant Decrease	4	2.5	4	2.6
Low & Significant Decrease	1	0.6	2	1.3
Low & Significant Increase	4	2.5	2	1.3
High	3	1.8	3	1.9
Significant Increase	11	6.7	12	7.8
High & Significant Increase	1	0.6	3	1.9
High & Significant Decrease	1	0.6	0	0.0

Number of patients with assessment = number of patients who had a measurement for this vital sign at any time.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-17 years), see Clinical Report for Weight Limits used
Significant Increase from Baseline: SBP>=40mmHg, DBP>=30mmHg, Pulse>=30, Weight>=7%
Significant Decrease from 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 Treatment Phase, Taper Phase or Follow-up Phase

Intention-To-Treat Population
Vital Signs Variable : Weight / kg

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	154	N/A	136	N/A
Number with Baseline and Post-Baseline Assessment	154	100.0	135	100.0
Low	1	0.6	1	0.7
Significant Decrease	5	3.2	2	1.5
Low & Significant Decrease	0	0.0	0	0.0
Low & Significant Increase	0	0.0	0	0.0
High	35	22.7	37	27.4
Significant Increase	36	23.4	23	17.0
High & Significant Increase	13	8.4	9	6.7
High & Significant Decrease	0	0.0	0	0.0

Number of patients with assessment = number of patients who had a measurement for this vital sign at any time.
Normal Ranges: Systolic Blood Pressure 95-145 mmHg, Diastolic Blood Pressure 50-85 mmHg, Pulse 65-115 bpm (7-12 years), 55-110 bpm (13-17 years), see Clinical Report for Weight Limits used
Significant Increase from Baseline: SBP>=40mmHg, DBP>=30mmHg, Pulse>=30, Weight>=7%
Significant Decrease from Baseline: SBP>=30mmHg, DBP>=20mmHg, Pulse>=30, Weight>=7%

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Paroxetine

BRL-029060

Narratives for Patients with Vital Signs of Potential Clinical Concern

Table 15.2.2.3

Protocol No. 676

xxxxx xxxxxx, B.S.N.

Clinical Development and Medical Affairs

SB Document Number: BRL-029060/RSD-101SWG/1

Issue Date 29 May 2002

PID: 676.013.24344

Treatment Group: Paroxetine

Vital Sign Value of Potential Clinical Concern: Increased Body Weight

Adverse Event Remarks: Weight Gain (Weight Gain)

This 10-year-old white female was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

The patient entered the study with no previous medical history reported and a current, active medical history of allergy (penicillin), elevated Free T3, intermittent headaches, motion sickness, seasonal allergies, and sore throat. Psychiatric history (measured by ADIS C/P semi-structured interview) includes an overall diagnostic label of Social Anxiety Disorder.

Previous medications included Ceclor® (cefaclor) for sore throat. Previous and concomitant medications included Nasonex® (mometasone furoate) for seasonal allergies.

The patient received the first dose of study medication at level 1 (10 mg/day) on 16 May 2000. The dose was gradually increased to level 3 (30 mg/day) on 29 June 2000 (Day 45) at which it remained until the start of the taper phase on 08 September 2000 (Day 116). The last dose of study medication was taken on 15 September 2000 (Day 123).

At screening, the patient weighed 50.8 kg (111.8 lbs). Normal range for 10-year-old females is 21.8 to 49.5 kg (48 to 109 lbs). At Week 16, the patient's weight had increased by 3.7 kg (8.1 lbs) to 54.5 kg (119.9 lbs). This increase in body weight 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 follow-up body weight was provided. Mild weight gain was reported as an adverse experience with an onset date of 07 September 2000 (Day 115). The AE was reported as ongoing. The investigator considered this event to be possibly related to treatment with study medication.

Systolic blood pressure values ranged from 92 mmHg to 118 mmHg throughout the study (normal range: 95 to 145 mmHg). Systolic blood pressure values fell

slightly below normal range (92 mmHg) on one occasion at Week 6. Diastolic blood pressure values ranged from 42 to 84 mmHg throughout the study (normal range: 50-85 mmHg), with one slightly decreased value of 42 mmHg on Week 8.

Pulse rate values ranged from 64-88 beats per minute (bpm) throughout the study (normal range: 65 to 115 bpm), with three slightly decreased values of 64 bpm at screening, baseline and Week 2.

Laboratory values at screening and throughout the study were within normal limits except for Free T3 at screening, which was 7.36 pmol/L (normal range: 3.44-6.47 pmol/L). Retest at Baseline 7 days later showed Free T3 of 6.07 pmol/L, within normal range. Thyroid stimulating hormone and total free thyroxine were within normal range at both timepoints.

Other non-serious adverse experiences were reported in addition to the weight gain. On 7 June 2000 (Day 23), the onset of mild somnolence (drowsiness) was reported. This continued, without treatment, throughout the study, and was considered by the investigator to be possibly related to treatment with study medication.

On 12 June 2000 (Day 28), and again on 18 September 2000 (Day 126), the patient reported mild abdominal pain (stomach ache). The first episode resolved without treatment in one day; the second resolved without treatment in three days. The investigator considered the first event to be possibly related to treatment with study medication and the second to be related to treatment with study medication.

On 10 September 2000 (Day 118), while the patient was on taper medication, the onset of mild rhinitis was reported. The event was reported as ongoing and no corrective therapy was given. The investigator considered this event to be unrelated to treatment with study medication.

No other adverse events were reported. The patient completed the study as planned.

PID: 676.013.24352

Treatment Group: Paroxetine

Vital Sign Value of Potential Clinical Concern: Increased Body Weight

Adverse Event Remarks: Weight Gain (Weight Gain)

This 15-year-old white female was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

The patient entered the study with previous and current medical conditions of amenorrhea and obesity. Psychiatric history (measured by ADIS C/P semi-structured interview) includes an overall diagnostic label of Social Anxiety Disorder.

Previous and current medications included Prometrium® (progesterone) for amenorrhea.

The patient received the first dose of study medication at level 1 (10 mg/day) on 30 March 2001. The dose was gradually increased to level 5 (50 mg/day) on 28 April 2001 (Day 30) at which it remained until the start of the taper phase on 21 July 2001 (Day 114). The last dose of study medication was taken on 17 August 2001 (Day 141).

At screening, the patient weighed 87.6 kg (192.7 lbs). Normal range for 15-year-old females is 38.6 to 80.0 kg (85 to 176 lbs). At Week 16, the patient's weight had increased by 6.8 kg (15 lbs) to 94.4 kg (207.7 lbs). This increase in body weight 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 follow-up body weight was provided. Mild weight gain was reported as an adverse experience with an onset date of 20 July 2001 (Day 113). The AE was reported as ongoing. The investigator considered this event to be possibly related to treatment with study medication.

All other vital signs values were within normal limits at screening and throughout the study.

Laboratory values at screening and throughout the study were within normal limits with the exception of a single slightly decreased value in absolute monocytes of 0.18 10^9/L (normal range: 0.20 to 1.10 10^9/L) at Week 16.

Other non-serious adverse experiences were reported in addition to the weight gain. On 31 March 2001 (Day 2), mild somnolence (drowsiness) was reported. This continued throughout the study, without treatment. The investigator considered this event to be possibly related to treatment with study medication.

Mild headaches were reported on 24 April (Day 26) and 27 April 2001 (Day 29). Both resolved without treatment within one day and were considered to be possibly related to treatment with study medication by the investigator.

On 06 June 2001 (Day 69), mild nausea was reported. This condition was treated with Pepto-Bismol ® (bismuth subsalicylate) and cleared in one day. It was considered by the investigator to be probably unrelated to treatment with study medication.

On 24 July 2001 (Day 117), moderately severe asthenia was reported. This resolved without treatment in 4 days, and was considered to be possibly related to treatment with study medication.

No other adverse events were reported. The patient completed the study as planned.

PID: 676.102.24589

Treatment Group: Paroxetine

Vital Sign Value of Potential Clinical Concern: Increased Body Weight

Adverse Event Remarks: Weight Gain (9.5% Weight Gain)

This 12-year-old white female was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

The patient entered the study with previous medical history of tetralogy of Fallot and a previous and current medical history of asthma, deviated septum, heart murmur present during systolic and diastolic phase, right bundle branch block, conduction delay pattern, and seasonal allergies. Psychiatric history (measured by ADIS C/P semi-structured interview), includes an overall diagnosis label of enuresis, specific phobia, and Social Anxiety Disorder.

Previous and concomitant medications include Ventolin® (salbutamol) for asthma, and Flonase® and Flovent® (fluticasone propionate) for seasonal allergies and asthma.

The patient received the first dose of study medication at level 1 (10 mg/day) on 06 June 2000. The dose was gradually increased to level 5 (50 mg/day) on 19 July 2000 (Day 44) at which it remained throughout the study. The last dose of study medication was taken on 16 October 2000 (Day 133).

At screening, the patient weighed 58.4 kg (128.5 lbs). Normal range for 12-year-old females is 28.2 to 63.2 kg (62 to 139 lbs). At Week 16, the patient's weight had increased by 5.6 kg (12.3 lbs) to 64.0 kg (140.8 lbs). This increase in body weight 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 follow-up body weight was provided. Mild weight gain (9.5% weight gain) was reported as an adverse experience with an onset date of 16 October 2000 (Day 133). The AE was reported as ongoing. The investigator considered this event to be possibly related to treatment with study medication.

Diastolic blood pressure and pulse rates were within normal limits at screening and throughout the study. Systolic blood pressure values ranged from 92 mmHg

to 124 mmHg throughout the study (normal range: 95 to 145 mmHg). Systolic blood pressure values fell slightly below normal range (92 mmHg) at Week 3 and at Week 12 (94 mmHg), but were within normal limits otherwise.

Laboratory values at screening and baseline were within normal limits; no further laboratory values are provided.

Other non-serious adverse experiences were reported in addition to the weight gain. On 19 June 2000 (Day 14), the onset of mild allergic reaction (hay fever) was reported. This event resolved in one day following treatment with Claritin® (loratadine). It was considered by the investigator to be probably unrelated to treatment with study medication.

On 27 July 2000 (Day 52), the patient reported moderately severe asthma (asthma attack) and mild pharyngitis (throat infection). Corrective treatment was given for both: Ventolin and Flovent were both increased from 2 puffs prn to 2 puffs bid, and Zithromax was administered. The asthma resolved within one day and the pharyngitis continued through the end of the study. The investigator considered both events to be unrelated to treatment with study medication.

No other adverse events were reported. The patient withdrew from the study at Week 16 for “other” reason (patient’s mother withdrew consent at Week 16).

PID: 676.013.24346

Treatment Group: Placebo

Vital Sign Value of Potential Clinical Concern: Increased Body Weight

Adverse Event Remarks: Weight Gain (Weight Gain)

This 14-year-old white male was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

The patient entered the study with previous medical history of ingrown toenail with removal. Previous and current medical history includes acne, intermittent headaches, and seasonal allergies. Psychiatric history (measured by ADIS C/P semi-structured interview) includes an overall diagnosis label of Social Anxiety Disorder.

Previous and concomitant medications include Differin® (topical adapalene) and Cleocin® (topical clindamycin), both for acne.

The patient received the first dose of study medication on 24 June 2000 and the last dose of study medication on 28 August 2000 (Day 66).

At screening, the patient weighed 79.5 kg (174.9 lbs). Normal range for 14-year-old males is 35.9 to 74.5 kg (79 to 164 lbs). At Week 16, the patient's weight had increased by 7.2 kg (15.8 lbs) to 86.7 kg (190.7 lbs). This increase in body weight 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 follow-up body weight was provided. Mild weight gain was reported as an adverse experience with an onset date of 04 August 2000 (Day 42). The AE was reported as ongoing. The investigator considered this event to be possibly related to treatment with study medication.

All other vital signs values were within normal limits at screening and throughout the study.

At screening, the hemoglobin value was slightly elevated at 164 G/L (normal range: 120 to 160 g/L), red blood cell count was slightly elevated at 5.60×10^{12}/L (normal range: 4.10 to 5.30 $\times 10^{12}$/L), and the absolute monocyte

count was slightly elevated at 1.19 x 10^9/L (normal range: 0.20 to 1.10 x 10^9/L). All other screening and baseline laboratory values were within normal limits. At Week 8, all laboratory values were within normal limits, with the exception of an absolute monocyte count of 0.14 x 10^9/L, which was slightly decreased. Except for generic dipstick urinalysis obtained at Week 12, no other laboratory values were obtained during the study.

Other non-serious adverse experiences were reported in addition to the weight gain. On 10 September 2000 (Day 79), moderately severe pharyngitis (sore throat) and rhinitis (sinus infection) were reported. Both cleared within 2 days; Extra Strength Tylenol® (paracetamol) was given for the pharyngitis, and no treatment was given for the rhinitis. The investigator considered both events to be unrelated to treatment with study medication.

No other adverse events were reported. The patient withdrew from the study at Week 8 due to lack of efficacy.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Hemoglobin, Unit:G/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Low (Extended)	0 .	2 (4.4%)	0 .
Number of Patients with Assessment	17 (100.0%)	45 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Hematocrit, Unit:%

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Low (Extended)	0 .	4 (8.9%)	1 (2.4%)
Number of Patients with Assessment	17 (100.0%)	45 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Red Blood Cell Count, Unit:10^12/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	17 (100.0%)	45 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:White Blood Cell Count, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	0 .	0 .	1 (2.3%)
Number of Patients with Assessment	17 (100.0%)	45 (100.0%)	43 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Platelets, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	17 (100.0%)	45 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Basophils Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	17 (100.0%)	45 (100.0%)	43 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Eosinophils Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	2 (11.8%)	1 (2.2%)	2 (4.7%)
Number of Patients with Assessment	17 (100.0%)	45 (100.0%)	43 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Lymphocytes Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	2 (11.8%)	1 (2.2%)	1 (2.3%)
Number of Patients with Assessment	17 (100.0%)	45 (100.0%)	43 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Monocytes Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	17 (100.0%)	45 (100.0%)	43 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Neutrophils Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed		Treatment Group: Paroxetine		Treatment Group: Placebo	
High (Extended)	0	.	0	.	1	(2.3%)
Low (Extended)	0	.	0	.	1	(2.3%)
Number of Patients with Assessment	17	(100.0%)	45	(100.0%)	43	(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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Sodium, Unit:MMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	17 (100.0%)	47 (100.0%)	45 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Potassium, Unit:MMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	1 (5.9%)	0 .	1 (2.2%)
Number of Patients with Assessment	17 (100.0%)	47 (100.0%)	45 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Blood Urea Nitrogen, Unit:MMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	17 (100.0%)	47 (100.0%)	45 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Creatinine, Unit:UMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	17 (100.0%)	47 (100.0%)	45 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Aspartate Aminotransferase, Unit:IU/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	17 (100.0%)	47 (100.0%)	45 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Alanine Aminotransferase, Unit:IU/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	17 (100.0%)	47 (100.0%)	45 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Total Bilirubin, Unit:UMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	17 (100.0%)	47 (100.0%)	45 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Thyroid Stimulating Hormone, Unit:MU/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	15 (100.0%)	47 (100.0%)	43 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Hemoglobin, Unit:G/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Low (Extended)	1 (3.4%)	0 .	0 .
Number of Patients with Assessment	29 (100.0%)	108 (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

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Hematocrit, Unit:%

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Low (Extended)	3 (10.3%)	5 (4.6%)	4 (3.7%)
Number of Patients with Assessment	29 (100.0%)	108 (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

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Red Blood Cell Count, Unit:10^12/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	29 (100.0%)	108 (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

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:White Blood Cell Count, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Low (Extended)	0 .	0 .	1 (0.9%)
Number of Patients with Assessment	29 (100.0%)	115 (100.0%)	111 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Platelets, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	29 (100.0%)	108 (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

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Basophils Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	29 (100.0%)	113 (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

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Eosinophils Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	0 .	0 .	1 (0.9%)
Number of Patients with Assessment	29 (100.0%)	115 (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

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Lymphocytes Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	29 (100.0%)	115 (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

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Monocytes Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	0 .	1 (0.9%)	0 .
Number of Patients with Assessment	29 (100.0%)	115 (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

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Neutrophils Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Low (Extended)	0 .	2 (1.7%)	2 (1.8%)
Number of Patients with Assessment	29 (100.0%)	115 (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

Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Sodium, Unit:MMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	31 (100.0%)	117 (100.0%)	112 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Potassium, Unit:MMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	30 (100.0%)	117 (100.0%)	112 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Blood Urea Nitrogen, Unit:MMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	31 (100.0%)	117 (100.0%)	111 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Creatinine, Unit:UMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	31 (100.0%)	117 (100.0%)	111 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Aspartate Aminotransferase, Unit:IU/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	1 (3.3%)	0 .	0 .
Number of Patients with Assessment	30 (100.0%)	117 (100.0%)	112 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Alanine Aminotransferase, Unit:IU/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	30 (100.0%)	117 (100.0%)	112 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Total Bilirubin, Unit:UMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	0 .	3 (2.6%)	2 (1.8%)
Number of Patients with Assessment	31 (100.0%)	117 (100.0%)	111 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Thyroid Stimulating Hormone, Unit:MU/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	0 .	0 .	1 (0.9%)
Number of Patients with Assessment	31 (100.0%)	118 (100.0%)	111 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Hemoglobin, Unit:G/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Low (Extended)	1 (2.2%)	2 (1.3%)	0 .
Number of Patients with Assessment	46 (100.0%)	153 (100.0%)	151 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Hematocrit, Unit:%

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Low (Extended)	3 (6.5%)	9 (5.9%)	5 (3.3%)
Number of Patients with Assessment	46 (100.0%)	153 (100.0%)	151 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Red Blood Cell Count, Unit:10^12/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	46 (100.0%)	153 (100.0%)	151 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:White Blood Cell Count, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed		Paroxetine		Placebo	
High (Extended)	0	.	0	.	1	(0.6%)
Low (Extended)	0	.	0	.	1	(0.6%)
Number of Patients with Assessment	46	(100.0%)	160	(100.0%)	154	(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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Platelets, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	46 (100.0%)	153 (100.0%)	151 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Basophils Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	46 (100.0%)	158 (100.0%)	152 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Eosinophils Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	2 (4.3%)	1 (0.6%)	3 (2.0%)
Number of Patients with Assessment	46 (100.0%)	160 (100.0%)	153 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Lymphocytes Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	2 (4.3%)	1 (0.6%)	1 (0.7%)
Number of Patients with Assessment	46 (100.0%)	160 (100.0%)	153 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Monocytes Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	0 .	1 (0.6%)	0 .
Number of Patients with Assessment	46 (100.0%)	160 (100.0%)	153 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Neutrophils Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed		Paroxetine		Placebo	
High (Extended)	0	.	0	.	1	(0.7%)
Low (Extended)	0	.	2	(1.3%)	3	(2.0%)
Number of Patients with Assessment	46	(100.0%)	160	(100.0%)	153	(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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Sodium, Unit:MMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	48 (100.0%)	164 (100.0%)	157 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Potassium, Unit:MMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	1 (2.1%)	0 .	1 (0.6%)
Number of Patients with Assessment	47 (100.0%)	164 (100.0%)	157 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Blood Urea Nitrogen, Unit:MMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	48 (100.0%)	164 (100.0%)	156 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Creatinine, Unit:UMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	48 (100.0%)	164 (100.0%)	156 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Aspartate Aminotransferase, Unit:IU/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	1 (2.1%)	0 .	0 .
Number of Patients with Assessment	47 (100.0%)	164 (100.0%)	157 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Alanine Aminotransferase, Unit:IU/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	47 (100.0%)	164 (100.0%)	157 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Total Bilirubin, Unit:UMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	0 .	3 (1.8%)	2 (1.3%)
Number of Patients with Assessment	48 (100.0%)	164 (100.0%)	156 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Thyroid Stimulating Hormone, Unit:MU/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	0 .	0 .	1 (0.6%)
Number of Patients with Assessment	46 (100.0%)	165 (100.0%)	154 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Hemoglobin, Unit : G/L

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	1 (3.2%)	0 .
Number of Patients with Assessment	31 (100.0%)	31 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Hematocrit, Unit : %

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	3 (9.7%)	0 .
Number of Patients with Assessment	31 (100.0%)	31 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Red Blood Cell Count, Unit : 10^12/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	31 (100.0%)	31 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : White Blood Cell Count, Unit : 10^9/L

Flag	Treatment Group: Paroxetine		Treatment Group: Placebo	
High (Extended)	0	.	1	(3.2%)
Number of Patients with Assessment	30	(100.0%)	31	(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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Platelets, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	31 (100.0%)	31 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Basophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	30 (100.0%)	31 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Eosinophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
High (Extended)	1 (3.3%)	2 (6.5%)
Number of Patients with Assessment	30 (100.0%)	31 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
High (Extended)	1 (3.3%)	0 .
Number of Patients with Assessment	30 (100.0%)	31 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Monocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine		Treatment Group: Placebo	
High (Extended)	0	.	1	(3.2%)
Number of Patients with Assessment	30	(100.0%)	31	(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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine		Treatment Group: Placebo	
High (Extended)	0	.	3	(9.7%)
Low (Extended)	0	.	1	(3.2%)
Number of Patients with Assessment	30	(100.0%)	31	(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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Sodium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	29 (100.0%)	32 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Potassium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	29 (100.0%)	32 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	29 (100.0%)	32 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Creatinine, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	29 (100.0%)	32 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Aspartate Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	29 (100.0%)	32 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	29 (100.0%)	32 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Total Bilirubin, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	29 (100.0%)	32 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Thyroid Stimulating Hormone, Unit : MU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	4 (100.0%)	1 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Hemoglobin, Unit : G/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	86 (100.0%)	79 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Hematocrit, Unit : %

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Low (Extended)	8 (9.3%)	5 (6.3%)
Number of Patients with Assessment	86 (100.0%)	79 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Red Blood Cell Count, Unit : 10^12/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	86 (100.0%)	79 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : White Blood Cell Count, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	1 (1.1%)	0 .
Number of Patients with Assessment	91 (100.0%)	80 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Platelets, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	86 (100.0%)	79 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Basophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	90 (100.0%)	79 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Eosinophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
High (Extended)	1 (1.1%)	2 (2.5%)
Number of Patients with Assessment	90 (100.0%)	79 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	90 (100.0%)	79 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Monocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	90 (100.0%)	79 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
High (Extended)	3 (3.3%)	0 .
Low (Extended)	3 (3.3%)	2 (2.5%)
Number of Patients with Assessment	90 (100.0%)	79 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Sodium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	92 (100.0%)	75 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Potassium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
High (Extended)	1 (1.1%)	0 .
Number of Patients with Assessment	92 (100.0%)	75 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

Flag	Treatment Group: Paroxetine		Treatment Group: Placebo	
Number of Patients with Assessment	89	(100.0%)	75	(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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Creatinine, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	90 (100.0%)	75 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Aspartate Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	91 (100.0%)	75 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	91 (100.0%)	75 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Total Bilirubin, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Placebo
High (Extended)	1 (1.1%)	0 .
Number of Patients with Assessment	91 (100.0%)	75 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Thyroid Stimulating Hormone, Unit : MU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	8 (100.0%)	2 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Hemoglobin, Unit : G/L

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	1 (0.9%)	0 .
Number of Patients with Assessment	117 (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

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Hematocrit, Unit : %

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	11 (9.4%)	5 (4.5%)
Number of Patients with Assessment	117 (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

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Red Blood Cell Count, Unit : 10^12/L

Flag	Treatment Group: Paroxetine		Treatment Group: Placebo	
Number of Patients with Assessment	117	(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

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : White Blood Cell Count, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
High (Extended)	0 .	1 (0.9%)
Low (Extended)	1 (0.8%)	0 .
Number of Patients with Assessment	121 (100.0%)	111 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Platelets, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	117 (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

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Basophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	120 (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

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Eosinophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
High (Extended)	2 (1.7%)	4 (3.6%)
Number of Patients with Assessment	120 (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

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
High (Extended)	1 (0.8%)	0 .
Number of Patients with Assessment	120 (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

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Monocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine		Treatment Group: Placebo	
High (Extended)	0	.	1	(0.9%)
Number of Patients with Assessment	120	(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

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
High (Extended)	3 (2.5%)	3 (2.7%)
Low (Extended)	3 (2.5%)	3 (2.7%)
Number of Patients with Assessment	120 (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

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Sodium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine		Treatment Group: Placebo	
Number of Patients with Assessment	121	(100.0%)	107	(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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Potassium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
High (Extended)	1 (0.8%)	0 .
Number of Patients with Assessment	121 (100.0%)	107 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

Flag	Treatment Group: Paroxetine		Treatment Group: Placebo	
Number of Patients with Assessment	118	(100.0%)	107	(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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Creatinine, Unit : UMOL/L

Flag	Treatment Group: Paroxetine		Treatment Group: Placebo	
Number of Patients with Assessment	119	(100.0%)	107	(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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Aspartate Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine		Treatment Group: Placebo	
Number of Patients with Assessment	120	(100.0%)	107	(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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine		Treatment Group: Placebo	
Number of Patients with Assessment	120	(100.0%)	107	(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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Total Bilirubin, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Placebo
High (Extended)	1 (0.8%)	0 .
Number of Patients with Assessment	120 (100.0%)	107 (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 Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Thyroid Stimulating Hormone, Unit : MU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	12 (100.0%)	3 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Hemoglobin, Unit : G/L

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	1 (9.1%)	0 .
Number of Patients with Assessment	11 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Hematocrit, Unit : %

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	2 (18.2%)	0 .
Number of Patients with Assessment	11 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Red Blood Cell Count, Unit : 10^12/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	11 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : White Blood Cell Count, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	11 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Platelets, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	11 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Basophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	11 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Eosinophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	11 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	11 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Monocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	11 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	11 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Sodium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	12 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Potassium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	12 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	12 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Creatinine, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	12 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Aspartate Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	12 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	12 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Children
Parameter : Total Bilirubin, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	12 (100.0%)	2 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Hemoglobin, Unit : G/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	4 (100.0%)	7 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Hematocrit, Unit : %

Flag	Treatment Group: Paroxetine		Treatment Group: Placebo	
Low (Extended)	0	.	1	(14.3%)
Number of Patients with Assessment	4	(100.0%)	7	(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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Red Blood Cell Count, Unit : 10^12/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	4 (100.0%)	7 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : White Blood Cell Count, Unit : 10^9/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	4 (100.0%)	8 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Platelets, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	4 (100.0%)	7 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Basophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	4 (100.0%)	8 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Eosinophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	4 (100.0%)	8 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	4 (100.0%)	8 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Monocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	4 (100.0%)	8 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	1 (25.0%)	0 .
Number of Patients with Assessment	4 (100.0%)	8 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Sodium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	8 (100.0%)	8 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Potassium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	8 (100.0%)	8 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	8 (100.0%)	8 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Creatinine, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	8 (100.0%)	8 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Aspartate Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	8 (100.0%)	8 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	8 (100.0%)	8 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Total Bilirubin, Unit : UMOL/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	8 (100.0%)	8 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Adolescents
Parameter : Thyroid Stimulating Hormone, Unit : MU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	2 (100.0%)	1 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Hemoglobin, Unit : G/L

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	1 (6.7%)	0 .
Number of Patients with Assessment	15 (100.0%)	9 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Hematocrit, Unit : %

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	2 (13.3%)	1 (11.1%)
Number of Patients with Assessment	15 (100.0%)	9 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Red Blood Cell Count, Unit : 10^12/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	15 (100.0%)	9 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : White Blood Cell Count, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	15 (100.0%)	10 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Platelets, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	15 (100.0%)	9 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Basophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	15 (100.0%)	10 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Eosinophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	15 (100.0%)	10 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	15 (100.0%)	10 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Monocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	15 (100.0%)	10 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Low (Extended)	1 (6.7%)	0 .
Number of Patients with Assessment	15 (100.0%)	10 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Sodium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	20 (100.0%)	10 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Potassium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	20 (100.0%)	10 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	20 (100.0%)	10 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Creatinine, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	20 (100.0%)	10 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Aspartate Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	20 (100.0%)	10 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	20 (100.0%)	10 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Total Bilirubin, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	20 (100.0%)	10 (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 Potential Clinical Concern, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Age Group : Total
Parameter : Thyroid Stimulating Hormone, Unit : MU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	2 (100.0%)	1 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Hemoglobin, Unit : G/L

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	2 (5.0%)	0 .
Number of Patients with Assessment	40 (100.0%)	32 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Hematocrit, Unit : %

Flag	Treatment Group: Paroxetine		Placebo	
Low (Extended)	5	(12.5%)	0	.
Number of Patients with Assessment	40	(100.0%)	32	(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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Red Blood Cell Count, Unit : 10^12/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	40 (100.0%)	32 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : White Blood Cell Count, Unit : 10^9/L

	Treatment Group			
	Paroxetine		Placebo	
Flag				
High (Extended)	0	.	1	(3.1%)
Number of Patients with Assessment	39	(100.0%)	32	(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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Platelets, Unit : 10^9/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	40 (100.0%)	32 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Basophils Absolute, Unit : 10^9/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	39 (100.0%)	32 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Eosinophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
High (Extended)	1 (2.6%)	2 (6.3%)
Number of Patients with Assessment	39 (100.0%)	32 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
High (Extended)	1 (2.6%)	0 .
Number of Patients with Assessment	39 (100.0%)	32 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Monocytes Absolute, Unit : 10^9/L

	Treatment Group			
	Paroxetine		Placebo	
Flag				
High (Extended)	0	.	1	(3.1%)
Number of Patients with Assessment	39	(100.0%)	32	(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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine		Placebo	
High (Extended)	0	.	3	(9.4%)
Low (Extended)	0	.	1	(3.1%)
Number of Patients with Assessment	39	(100.0%)	32	(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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Sodium, Unit : MMOL/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	39 (100.0%)	33 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Potassium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	39 (100.0%)	33 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	39 (100.0%)	33 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Creatinine, Unit : UMOL/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	39 (100.0%)	33 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Aspartate Aminotransferase, Unit : IU/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	39 (100.0%)	33 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Alanine Aminotransferase, Unit : IU/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	39 (100.0%)	33 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Total Bilirubin, Unit : UMOL/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	39 (100.0%)	33 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Thyroid Stimulating Hormone, Unit : MU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	4 (100.0%)	1 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Hemoglobin, Unit : G/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	90 (100.0%)	85 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Hematocrit, Unit : %

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Low (Extended)	8 (8.9%)	6 (7.1%)
Number of Patients with Assessment	90 (100.0%)	85 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Red Blood Cell Count, Unit : 10^12/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	90 (100.0%)	85 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : White Blood Cell Count, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	1 (1.1%)	0 .
Number of Patients with Assessment	95 (100.0%)	87 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Platelets, Unit : 10^9/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	90 (100.0%)	85 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Basophils Absolute, Unit : 10^9/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	94 (100.0%)	86 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Eosinophils Absolute, Unit : 10^9/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
High (Extended)	1 (1.1%)	2 (2.3%)
Number of Patients with Assessment	94 (100.0%)	86 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Lymphocytes Absolute, Unit : 10^9/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	94 (100.0%)	86 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Monocytes Absolute, Unit : 10^9/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	94 (100.0%)	86 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
High (Extended)	3 (3.2%)	0 .
Low (Extended)	4 (4.3%)	2 (2.3%)
Number of Patients with Assessment	94 (100.0%)	86 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Sodium, Unit : MMOL/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	98 (100.0%)	83 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Potassium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
High (Extended)	1 (1.0%)	0 .
Number of Patients with Assessment	98 (100.0%)	83 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	95 (100.0%)	83 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Creatinine, Unit : UMOL/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	96 (100.0%)	83 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Aspartate Aminotransferase, Unit : IU/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	97 (100.0%)	83 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Alanine Aminotransferase, Unit : IU/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	97 (100.0%)	83 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Total Bilirubin, Unit : UMOL/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
High (Extended)	1 (1.0%)	0 .
Number of Patients with Assessment	97 (100.0%)	83 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Thyroid Stimulating Hormone, Unit : MU/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	10 (100.0%)	3 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Hemoglobin, Unit : G/L

Flag	Treatment Group: Paroxetine		Placebo	
Low (Extended)	2	(1.5%)	0	.
Number of Patients with Assessment	130	(100.0%)	117	(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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Hematocrit, Unit : %

	Treatment Group	
	Paroxetine	Placebo
Flag		
Low (Extended)	13 (10.0%)	6 (5.1%)
Number of Patients with Assessment	130 (100.0%)	117 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Red Blood Cell Count, Unit : 10^12/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	130 (100.0%)	117 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : White Blood Cell Count, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
High (Extended)	0 .	1 (0.8%)
Low (Extended)	1 (0.7%)	0 .
Number of Patients with Assessment	134 (100.0%)	119 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Platelets, Unit : 10^9/L

	Treatment Group			
	Paroxetine		Placebo	
Flag				
Number of Patients with Assessment	130	(100.0%)	117	(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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Basophils Absolute, Unit : 10^9/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	133 (100.0%)	118 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Eosinophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
High (Extended)	2 (1.5%)	4 (3.4%)
Number of Patients with Assessment	133 (100.0%)	118 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine		Placebo	
High (Extended)	1	(0.8%)	0	.
Number of Patients with Assessment	133	(100.0%)	118	(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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Monocytes Absolute, Unit : 10^9/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
High (Extended)	0 .	1 (0.8%)
Number of Patients with Assessment	133 (100.0%)	118 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
High (Extended)	3 (2.3%)	3 (2.5%)
Low (Extended)	4 (3.0%)	3 (2.5%)
Number of Patients with Assessment	133 (100.0%)	118 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Sodium, Unit : MMOL/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	137 (100.0%)	116 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Potassium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
High (Extended)	1 (0.7%)	0 .
Number of Patients with Assessment	137 (100.0%)	116 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	134 (100.0%)	116 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Creatinine, Unit : UMOL/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	135 (100.0%)	116 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Aspartate Aminotransferase, Unit : IU/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	136 (100.0%)	116 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Alanine Aminotransferase, Unit : IU/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	136 (100.0%)	116 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Total Bilirubin, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Placebo
High (Extended)	1 (0.7%)	0 .
Number of Patients with Assessment	136 (100.0%)	116 (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 Potential Clinical Concern
Treatment Phase, Taper Phase or Follow-Up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Thyroid Stimulating Hormone, Unit : MU/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	14 (100.0%)	4 (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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The GlaxoSmithKline group of companies

Paroxetine

BRL-029060

Narratives for Patients with Laboratory Values of Potential Clinical Concern

Table 15.3.1.5

Protocol No. 676

xxxxx xxxxx, B.S.N.

Clinical Development and Medical Affairs

SB Document Number: BRL-029060/RSD-101SWH/1

Issue Date 29 May 2002

PID: 676.020.24536

Treatment Group: Paroxetine

Laboratory Value of Potential Clinical Concern: Increased Absolute Neutrophils

Adverse Event Remarks: Leukocytosis (Neutrophils Absolute 8.90 and Segs 78.1 [above range]), Leukopenia (lymphocytes 14.5 [below range])

This 16-year-old white male was a participant in the trial of BRL-29060/676. Protocol 676 is a 16-week double-blind, placebo-controlled study to assess the efficacy and tolerability of paroxetine in children and adolescents with Social Anxiety Disorder/Social Phobia.

The patient entered the study with a previous and current medical history of acne and bradycardia, and a current, active medical history of bad memory, gas (gastrointestinal), increased bilirubin and seasonal allergies. Psychiatric history (measured by ADIS C/P semi-structured interview) includes an overall diagnostic label of Social Anxiety Disorder.

Previous and concomitant medications included Zyrtec® (cetirizine HCl) for allergies, and Pepcid AC® (famotidine) for gas.

The patient received the first dose of study medication at level 1 (10 mg/day) on 12 September 2000. The dose was gradually increased to level 3 (30 mg/day) on 07 October 2000 (Day 26) and the patient was maintained at that dose level until the start of the taper phase on 10 January 2001 (Day 108). The last dose of study medication was taken on 26 January 2001 (Day 124).

All laboratory values at screening and at baseline were within normal limits with the exception of a slightly elevated total bilirubin value of 25.65 (normal: 22.23 g/L) at screening. At screening, absolute lymphocyte count was 1.93 10^9/L (normal range: 0.85 to 4.10 10^9/L) and absolute neutrophil count was 3.23 10^9/L (normal range: 1.80 to 8.00 10^9/L). At week 16 (Day 120), the patient had an increased absolute neutrophil count of 8.90 10^9/L; this value was at the level of potential clinical concern. Absolute lymphocyte count was 1.65 10^9/L, which was within normal range. A repeat laboratory test on Day 137 showed an absolute neutrophil count of 4.64 10^9/L, which was within normal range. Except for a dipstick urinalysis done on Day 144, no further laboratory results are provided.

On 09 January 2001 (Day 120), mild adverse events of leukocytosis (Verbatim: neutrophils absolute 8.90 and segs 78.1 [above range]) and mild leukopenia (Verbatim: lymphocytes 14.5 [below range]) were reported.

No corrective treatment was given, and both events were reported as ongoing. The investigator considered these events to be probably unrelated to treatment with study medication.

Several other non-serious adverse events were reported during the study. On 30 October 2000 (Day 49), moderately severe back pain was reported. This resolved without treatment in 68 days, and was considered by the investigator to be unrelated to treatment with study medication. On 07 January 2001 (Day 118), mild respiratory disorder (cold) was reported. This event was treated with Tylenol® (paracetamol) and resolved in 3 days. It was considered by the investigator to be unrelated to treatment with study medication. On 09 January 2001 (Day 120), mild rhinitis was reported. This event continued beyond the end of the study. No corrective therapy was given. The investigator considered this event to be unrelated to treatment with study medication. On 18 January 2001 (Day 129), mild headache was reported. It was treated with ibuprofen and resolved in one day, and was considered by the investigator to be probably unrelated to treatment with study medication. On 31 January 2001 (Day 142), mild flatulence (gas) was reported. The event was treated with Pepcid AC® (famotidine) and resolved in one day. It was considered to be probably unrelated to treatment with study medication.

No other adverse events were reported. The patient completed the study as planned.

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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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Hemoglobin (Grams per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	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	105	3	1	110	0	1	11	0	0	12
L	N	0	0	1	1	0	2	0	0	0	0	0	0
-	N	0	0	0	0	0	0	0	0	0	0	1	1
+	%	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	95	3	1	100	0	8	92	0	0	100
L	%	0	0	50	50	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	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-treatment assessment is taken to be Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Hemoglobin (Grams per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	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	0	1	0	0	1
I	N	0	0	98	2	0	100	0	0	8	0	0	8
L	N	0	0	3	1	0	4	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	0	100	0	0	100
I	%	0	0	98	2	0	100	0	0	100	0	0	100
L	%	0	0	75	25	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-treatment assessment is taken to be Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Hematocrit (Percentage)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	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	98	0	8	106	0	0	11	0	1	12
L	N	0	0	0	0	0	0	0	0	0	0	0	0
-	N	0	0	3	0	3	6	0	0	0	0	1	1
+	%	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	92	0	8	100	0	0	92	0	8	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	50	0	50	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-treatment assessment is taken to be Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Hematocrit (Percentage)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	0	0	0	0	0	0	0	0	0	0	0
H	N	0	1	2	0	0	3	0	0	0	0	0	0
I	N	0	0	98	0	2	100	0	0	8	0	1	9
L	N	0	0	1	0	0	1	0	0	0	0	0	0
-	N	0	0	3	0	2	5	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	33	67	0	0	100	0	0	0	0	0	0
I	%	0	0	98	0	2	100	0	0	89	0	11	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	60	0	40	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Red Blood Cell Count (10^12 per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	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	102	3	0	106	0	0	12	1	0	13
L	N	0	0	1	4	0	5	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	96	3	0	100	0	0	92	8	0	100
L	%	0	0	20	80	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-treatment assessment is taken to be Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Red Blood Cell Count (10^12 per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	0	0	0	0	0	0	0	0	0	0	0
H	N	0	2	6	0	0	8	0	0	0	0	0	0
I	N	0	2	92	3	0	97	0	1	7	1	0	9
L	N	0	0	2	2	0	4	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	25	75	0	0	100	0	0	0	0	0	0
I	%	0	2	95	3	0	100	0	11	78	11	0	100
L	%	0	0	50	50	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-treatment assessment is taken to be Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:White Blood Cell Count (10^9 per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	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	104	7	0	111	0	0	13	0	0	13
L	N	0	0	5	1	0	6	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	94	6	0	100	0	0	100	0	0	100
L	%	0	0	83	17	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-treatment assessment is taken to be Baseline

BRL 29060 - 676

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:White Blood Cell Count (10^9 per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	1	0	0	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	99	3	0	102	0	0	10	0	0	10
L	N	0	0	5	1	0	6	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	%	0	0	97	3	0	100	0	0	100	0	0	100
L	%	0	0	83	17	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-treatment assessment is taken to be Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Segmented Neutrophils (10^9 per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	0	0	0	0	0	0	0	0	0	0	0
H	N	0	1	6	0	0	7	0	3	1	0	0	4
I	N	0	9	92	2	0	103	0	1	8	0	0	9
L	N	0	0	0	1	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	14	86	0	0	100	0	75	25	0	0	100
I	%	0	9	89	2	0	100	0	11	89	0	0	100
L	%	0	0	0	100	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-treatment assessment is taken to be Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Segmented Neutrophils (10^9 per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	0	0	0	0	0	0	0	0	0	0	0
H	N	0	1	7	0	0	8	0	0	0	0	0	0
I	N	0	9	87	0	0	96	0	0	9	0	0	9
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	13	88	0	0	100	0	0	0	0	0	0
I	%	0	9	91	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-treatment assessment is taken to be Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Lymphocytes (10^9 per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	0	0	0	0	0	0	0	0	0	0	0
H	N	0	1	2	0	0	3	0	0	0	0	0	0
I	N	0	2	99	5	0	106	0	2	9	1	0	12
L	N	0	0	2	0	0	2	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	33	67	0	0	100	0	0	0	0	0	0
I	%	0	2	93	5	0	100	0	17	75	8	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Lymphocytes (10^9 per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	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	0	0	0	0	0
I	N	0	4	87	5	0	96	0	1	8	0	0	9
L	N	0	0	4	1	0	5	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	0	0	0	0	0
I	%	0	4	91	5	0	100	0	11	89	0	0	100
L	%	0	0	80	20	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Monocytes (10^9 per Litre)

		Endpoint (incl. Taper)					Follow Up				
BASELINE	+	H	I	L	-	T	+	H	I	L	-	T
+	N	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	5	104	0	0	109	0	0	12	0	0	12
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	5	95	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Monocytes (10^9 per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	0	0	0	0	0	0	0	0	0	0	0
H	N	0	1	2	0	0	3	0	0	0	0	0	0
I	N	0	2	101	0	0	103	0	0	9	0	0	9
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	33	67	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Eosinophils (10^9 per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	0	0	0	0	0	0	0	0	0	0	0
H	N	0	14	6	0	0	20	0	1	3	0	0	4
I	N	0	6	85	0	0	91	0	1	8	0	0	9
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	70	30	0	0	100	0	25	75	0	0	100
I	%	0	7	93	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-treatment assessment is taken to be Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Eosinophils (10^9 per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	0	0	0	0	0	0	0	0	0	0	0
H	N	0	16	10	0	0	26	0	2	0	0	0	2
I	N	0	8	72	0	0	80	0	1	6	0	0	7
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	62	38	0	0	100	0	100	0	0	0	100
I	%	0	10	90	0	0	100	0	14	86	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-treatment assessment is taken to be Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Basophils (10^9 per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	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	110	0	0	110	0	0	13	0	0	13
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	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-treatment assessment is taken to be Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Basophils (10^9 per Litre)

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	106	0	0	106	0	0	9	0	0	9
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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Platelets (10^9 per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	0	0	0	0	0	0	0	0	0	0	0
H	N	0	2	3	0	0	5	0	0	0	0	0	0
I	N	0	3	103	0	0	106	0	0	12	1	0	13
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	40	60	0	0	100	0	0	0	0	0	0
I	%	0	3	97	0	0	100	0	0	92	8	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-treatment assessment is taken to be Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Platelets (10^9 per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	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	0	0	0	0
I	N	0	0	104	0	0	104	0	0	9	0	0	9
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	75	25	0	0	100	0	0	0	0	0	0
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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Basophils Absolute (10^9 per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	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	117	0	0	117	0	0	13	0	0	13
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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Basophils Absolute (10^9 per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	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	108	0	0	108	0	0	10	0	0	10
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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Eosinophils Absolute (10^9 per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	0	1	0	0	1	0	0	0	0	0	0
H	N	0	1	3	0	0	4	0	0	0	0	0	0
I	N	2	6	93	3	0	104	0	1	12	0	0	13
L	N	0	0	4	4	0	8	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	25	75	0	0	100	0	0	0	0	0	0
I	%	2	6	89	3	0	100	0	8	92	0	0	100
L	%	0	0	50	50	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Eosinophils Absolute (10^9 per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	1	1	0	0	2	0	0	0	0	0	0
H	N	1	2	3	0	0	6	0	0	0	0	0	0
I	N	2	3	82	9	0	96	0	0	10	0	0	10
L	N	0	1	3	0	0	4	0	0	0	0	0	0
-	N	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	50	50	0	0	100	0	0	0	0	0	0
H	%	17	33	50	0	0	100	0	0	0	0	0	0
I	%	2	3	85	9	0	100	0	0	100	0	0	100
L	%	0	25	75	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Lymphocytes Absolute (10^9 per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	0	1	0	0	1	0	0	0	0	0	0
H	N	0	1	1	0	0	2	0	0	0	0	0	0
I	N	1	0	113	0	0	114	0	0	13	0	0	13
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	100	0	0	100	0	0	0	0	0	0
H	%	0	50	50	0	0	100	0	0	0	0	0	0
I	%	1	0	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Lymphocytes Absolute (10^9 per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	0	1	0	0	1	0	0	0	0	0	0
H	N	0	0	2	0	0	2	0	0	0	0	0	0
I	N	0	0	105	0	0	105	0	0	10	0	0	10
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	100	0	0	100	0	0	0	0	0	0
H	%	0	0	100	0	0	100	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Monocytes Absolute (10^9 per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	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	1	91	13	0	105	0	0	11	1	0	12
L	N	0	0	9	2	0	11	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	1	87	12	0	100	0	0	92	8	0	100
L	%	0	0	82	18	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Monocytes Absolute (10^9 per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	0	0	0	0	0	0	0	0	0	0	0
H	N	1	0	0	1	0	2	0	0	0	0	0	0
I	N	0	0	89	7	0	96	0	0	6	1	0	7
L	N	0	0	8	2	0	10	0	0	3	0	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	%	50	0	0	50	0	100	0	0	0	0	0	0
I	%	0	0	93	7	0	100	0	0	86	14	0	100
L	%	0	0	80	20	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Neutrophils Absolute (10^9 per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	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	2	0	108	2	2	114	0	0	12	0	1	13
L	N	0	0	0	0	0	0	0	0	0	0	0	0
-	N	0	0	1	0	1	2	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	%	2	0	95	2	2	100	0	0	92	0	8	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	50	0	50	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Neutrophils Absolute (10^9 per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	1	0	0	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	2	1	95	2	3	103	0	0	8	2	0	10
L	N	0	0	1	0	0	1	0	0	0	0	0	0
-	N	0	0	3	0	0	3	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	92	2	3	100	0	0	80	20	0	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Sodium (Millimoles per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	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	2	117	0	0	119	0	0	20	0	0	20
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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Sodium (Millimoles per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	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	105	1	0	106	0	0	10	0	0	10
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-treatment assessment is taken to be Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Potassium (Millimoles per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	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	1	0	119	0	0	120	0	0	20	0	0	20
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	%	1	0	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Potassium (Millimoles per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	0	1	0	0	1	0	0	0	0	0	0
H	N	0	0	2	0	0	2	0	0	0	0	0	0
I	N	0	1	103	0	0	104	0	0	10	0	0	10
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	100	0	0	100	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-treatment assessment is taken to be Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Blood Urea Nitrogen (Millimoles per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	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	3	0	112	0	1	18	1	0	20
L	N	0	0	4	1	0	5	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	97	3	0	100	0	5	90	5	0	100
L	%	0	0	80	20	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Blood Urea Nitrogen (Millimoles per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	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	94	5	0	100	0	0	10	0	0	10
L	N	0	0	5	0	0	5	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	94	5	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Creatinine (Micromoles per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	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	1	0	0	1
I	N	0	0	110	4	0	114	0	0	17	2	0	19
L	N	0	0	2	2	0	4	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	100	0	0	100
I	%	0	0	96	4	0	100	0	0	89	11	0	100
L	%	0	0	50	50	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Creatinine (Micromoles per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	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	1	0	100	0	0	8	0	0	8
L	N	0	0	4	1	0	5	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	0	100	0	0	100	0	0	100	0	0	100
I	%	0	0	99	1	0	100	0	0	100	0	0	100
L	%	0	0	80	20	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Alkaline Phosphatase (International Units per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	0	0	0	0	0	0	0	0	0	0	0
H	N	0	3	2	0	0	5	0	2	0	0	0	2
I	N	0	1	108	2	0	111	0	0	18	0	0	18
L	N	0	0	0	3	0	3	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	60	40	0	0	100	0	100	0	0	0	100
I	%	0	1	97	2	0	100	0	0	100	0	0	100
L	%	0	0	0	100	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Alkaline Phosphatase (International Units per Litre)

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	5	1	0	0	6	0	0	0	0	0	0
I	N	0	4	95	0	0	99	0	0	10	0	0	10
L	N	0	0	0	1	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	83	17	0	0	100	0	0	0	0	0	0
I	%	0	4	96	0	0	100	0	0	100	0	0	100
L	%	0	0	0	100	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Aspartate Aminotransferase (International Units per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	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	1	0	0	1
I	N	0	2	117	0	0	119	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	0	0	0	0	0	0	100	0	0	100
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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Aspartate Aminotransferase (International Units per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	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	107	0	0	107	0	0	10	0	0	10
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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Alanine Aminotransferase (International Units per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	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	0	0	0	0
I	N	0	3	115	0	0	118	0	0	20	0	0	20
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	0	0	0	0	0
I	%	0	3	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Alanine Aminotransferase (International Units per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	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	104	0	0	105	0	0	10	0	0	10
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	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-treatment assessment is taken to be Baseline

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Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Total Bilirubin (Micromoles per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	1	1	0	0	2	0	0	0	0	0	0
H	N	0	1	3	0	0	4	0	0	0	0	0	0
I	N	0	0	113	0	0	113	0	1	19	0	0	20
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	50	50	0	0	100	0	0	0	0	0	0
H	%	0	25	75	0	0	100	0	0	0	0	0	0
I	%	0	0	100	0	0	100	0	5	95	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Total Bilirubin (Micromoles per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	N	0	2	0	0	0	2	0	0	0	0	0	0
H	N	0	1	1	0	0	2	0	0	0	0	0	0
I	N	0	1	101	0	0	102	0	0	10	0	0	10
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	100	0	0	0	100	0	0	0	0	0	0
H	%	0	50	50	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Thyroid Stimulating Hormone (MU/L)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	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	12	0	0	12	0	0	2	0	0	2
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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Thyroid Stimulating Hormone (MU/L)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	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	2	0	0	2	0	0	1	0	0	1
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	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Free T3 (Picomoles per Litre)

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	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	11	0	0	11	0	0	2	0	0	2
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	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Free T3 (Picomoles per Litre)

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	3	0	0	3	0	1	0	0	0	1
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	100	0	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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Paroxetine
Parameter:Total Free Thyroxine (Picomoles per Litre)

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	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	12	0	0	12	0	0	2	0	0	2
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-treatment assessment is taken to be Baseline

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter

Intention-To-Treat Population
Treatment Group:Placebo
Parameter:Total Free Thyroxine (Picomoles per Litre)

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	3	0	0	3	0	0	1	0	0	1
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-treatment assessment is taken to be Baseline

Table 15.3.5.1

Number (%) of Patients with Abnormal Urinalysis Findings, Pre-Treatment Phase

Intention-To-Treat Population
Parameter : Urine Glucose - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Positive	1 (2.4%)	0
Trace	1 (2.4%)	0
Number of Patients with Assessment	41 (100.0%)	37 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.1

Number (%) of Patients with Abnormal Urinalysis Findings, Pre-Treatment Phase

Intention-To-Treat Population
Parameter : Urine Blood - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Positive	5 (12.2%)	4 (10.8%)
Trace	2 (4.9%)	0
Number of Patients with Assessment	41 (100.0%)	37 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

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Table 15.3.5.1

Number (%) of Patients with Abnormal Urinalysis Findings, Pre-Treatment Phase

Intention-To-Treat Population
Parameter : Urine Red Blood Cells/HPF

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	1 (2.3%)	0
Many	4 (9.3%)	4 (11.1%)
Number of Patients with Assessment	43 (100.0%)	36 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.1

Number (%) of Patients with Abnormal Urinalysis Findings, Pre-Treatment Phase

Intention-To-Treat Population
Parameter : Urine White Blood Cells/HPF

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	8 (18.6%)	5 (13.9%)
Many	1 (2.3%)	0
Moderate	3 (7.0%)	0
Number of Patients with Assessment	43 (100.0%)	36 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.1

Number (%) of Patients with Abnormal Urinalysis Findings, Pre-Treatment Phase

Intention-To-Treat Population
Parameter : Urine Bacteria

Result	Treatment Group: Paroxetine	Placebo
Few	12 (75.0%)	6 (75.0%)
Many	1 (6.3%)	0
Moderate	4 (25.0%)	2 (25.0%)
Number of Patients with Assessment	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.1

Number (%) of Patients with Abnormal Urinalysis Findings, Pre-Treatment Phase

Intention-To-Treat Population
Parameter : Urine Protein - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Positive	5 (12.2%)	5 (13.5%)
Trace	5 (12.2%)	2 (5.4%)
Number of Patients with Assessment	41 (100.0%)	37 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

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Table 15.3.5.1

Number (%) of Patients with Abnormal Urinalysis Findings, Pre-Treatment Phase

Intention-To-Treat Population
Parameter : Calcium Oxalate Crystals

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	5 (100.0%)	1 (100.0%)
Number of Patients with Assessment	5 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.1

Number (%) of Patients with Abnormal Urinalysis Findings, Pre-Treatment Phase

Intention-To-Treat Population
Parameter : Urinalysis Triple Phosphorus Crystals

Result	Treatment Group: Placebo
Few	1 (100.0%)
Number of Patients with Assessment	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.1

Number (%) of Patients with Abnormal Urinalysis Findings, Pre-Treatment Phase

Intention-To-Treat Population
Parameter : Urine Amorphous Sediment

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	16 (88.9%)	14 (77.8%)
Many	1 (5.6%)	4 (22.2%)
Moderate	1 (5.6%)	0
Number of Patients with Assessment	18 (100.0%)	18 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.1

Number (%) of Patients with Abnormal Urinalysis Findings, Pre-Treatment Phase

Intention-To-Treat Population
Parameter : Urine Generic - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Positive	32 (19.9%)	27 (17.4%)
Number of Patients with Assessment	161 (100.0%)	155 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.1

Number (%) of Patients with Abnormal Urinalysis Findings, Pre-Treatment Phase

Intention-To-Treat Population
Parameter : Urine Mucous Threads

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	10 (50.0%)	20 (95.2%)
Many	2 (10.0%)	0
Moderate	9 (45.0%)	1 (4.8%)
Number of Patients with Assessment	20 (100.0%)	21 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.1

Number (%) of Patients with Abnormal Urinalysis Findings, Pre-Treatment Phase

Intention-To-Treat Population
Parameter : Urine Squamous Epithelial Cells

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	17 (77.3%)	16 (88.9%)
Many	1 (4.5%)	1 (5.6%)
Moderate	4 (18.2%)	2 (11.1%)
Number of Patients with Assessment	22 (100.0%)	18 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.1

Number (%) of Patients with Abnormal Urinalysis Findings, Pre-Treatment Phase

Intention-To-Treat Population
Parameter : Urine Yeast

Result	Treatment Group Paroxetine
Few	1 (50.0%)
Moderate	1 (50.0%)
Number of Patients with Assessment	2 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)

Intention-To-Treat Population
Parameter : Urine Glucose - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Positive	1 (4.0%)	0
Number of Patients with Assessment	25 (100.0%)	21 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)

Intention-To-Treat Population
Parameter : Urine Blood - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Positive	2 (8.0%)	2 (9.5%)
Trace	0	2 (9.5%)
Number of Patients with Assessment	25 (100.0%)	21 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)

Intention-To-Treat Population
Parameter : Urine Red Blood Cells/HPF

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Many	1 (4.0%)	3 (14.3%)
Number of Patients with Assessment	25 (100.0%)	21 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)

Intention-To-Treat Population
Parameter : Urine White Blood Cells/HPF

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	4 (16.0%)	2 (9.5%)
Many	1 (4.0%)	1 (4.8%)
Number of Patients with Assessment	25 (100.0%)	21 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)

Intention-To-Treat Population
Parameter : Urine Bacteria

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	3 (75.0%)	3 (60.0%)
Many	1 (25.0%)	2 (40.0%)
Number of Patients with Assessment	4 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)

Intention-To-Treat Population
Parameter : Urine Protein - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Positive	2 (8.0%)	5 (23.8%)
Trace	9 (36.0%)	4 (19.0%)
Number of Patients with Assessment	25 (100.0%)	21 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)

Intention-To-Treat Population
Parameter : Calcium Oxalate Crystals

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	5 (71.4%)	2 (66.7%)
Moderate	3 (42.9%)	1 (33.3%)
Number of Patients with Assessment	7 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)

Intention-To-Treat Population
Parameter : Uric Acid Crystals

Result	Treatment Group Placebo
Few	1 (100.0%)
Number of Patients with Assessment	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)

Intention-To-Treat Population
Parameter : Urine Amorphous Sediment

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	1 (10.0%)	5 (41.7%)
Many	8 (80.0%)	4 (33.3%)
Moderate	1 (10.0%)	3 (25.0%)
Number of Patients with Assessment	10 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)

Intention-To-Treat Population
Parameter : Urine Generic - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Positive	20 (15.6%)	13 (10.7%)
Number of Patients with Assessment	128 (100.0%)	122 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)

Intention-To-Treat Population
Parameter : Urine Mucous Threads

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	9 (75.0%)	9 (75.0%)
Many	2 (16.7%)	1 (8.3%)
Moderate	1 (8.3%)	2 (16.7%)
Number of Patients with Assessment	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)

Intention-To-Treat Population
Parameter : Urine Squamous Epithelial Cells

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	5 (55.6%)	7 (77.8%)
Many	1 (11.1%)	0
Moderate	3 (33.3%)	2 (22.2%)
Number of Patients with Assessment	9 (100.0%)	9 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

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Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis Findings, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Parameter : Urine Glucose - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	4 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis Findings, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Parameter : Urine Blood - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	4 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

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Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis Findings, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Parameter : Urine Red Blood Cells/HPF

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	4 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis Findings, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Parameter : Urine White Blood Cells/HPF

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	1 (25.0%)	1 (100.0%)
Many	1 (25.0%)	0
Number of Patients with Assessment	4 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

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Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis Findings, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Parameter : Urine Protein - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	4 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis Findings, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Parameter : Urine Amorphous Sediment

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	1 (50.0%)	1 (100.0%)
Many	1 (50.0%)	0
Number of Patients with Assessment	2 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis Findings, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Parameter : Urine Generic - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Positive	2 (9.5%)	0
Number of Patients with Assessment	21 (100.0%)	6 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

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Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis Findings, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Parameter : Urine Mucous Threads

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	2 (100.0%)	1 (100.0%)
Number of Patients with Assessment	2 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis Findings, Follow-Up Phase

Intention-To-Treat Population entering the Follow-Up Phase
Parameter : Urine Squamous Epithelial Cells

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	3 (100.0%)	0
Moderate	0	1 (100.0%)
Number of Patients with Assessment	3 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time
Where no Negative, Positive, Trace, Few, Moderate or Many rows are shown for a parameter,
no patients fell into these respective categories.

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Table 15.3.6

Summary Statistics for Baseline and Change from Baseline to Endpoint for Laboratory Parameters By Treatment Group and Visit

Intention-To-Treat Population

Treatment Group : Paroxetine

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Alanine Aminotransferase	IU/L	Baseline	162	15.15432	8.378893	13.00000	5.0000	63.0000
		Week 16	105	16.29524	8.216919	14.00000	7.0000	52.0000
		Change to Week 16	105	1.77143	6.755706	0.00000	-19.0000	36.0000
		Endpoint	120	16.73333	11.347627	14.00000	4.0000	104.0000
		Change to Endpoint	119	1.73950	7.553720	0.00000	-19.0000	41.0000
Alkaline Phosphatase	IU/L	Baseline	162	182.95062	99.546724	166.50000	46.0000	526.0000
		Week 16	105	166.29524	85.868854	145.00000	49.0000	365.0000
		Change to Week 16	105	-12.99048	33.674487	-10.00000	-161.0000	83.0000
		Endpoint	120	167.95833	84.803321	149.00000	49.0000	365.0000
		Change to Endpoint	119	-12.95798	33.404403	-9.00000	-161.0000	83.0000
Aspartate Aminotransferase	IU/L	Baseline	162	21.49383	6.555304	20.50000	12.0000	68.0000
		Week 16	105	21.92381	5.841982	21.00000	9.0000	51.0000
		Change to Week 16	105	1.34286	4.432894	1.00000	-14.0000	23.0000
		Endpoint	120	22.49167	8.219669	21.00000	9.0000	84.0000
		Change to Endpoint	119	1.59664	5.797895	1.00000	-12.0000	44.0000
Basophils Absolute	10^9/L	Baseline	156	0.02423	0.020448	0.02000	0.0000	0.1800
		Week 16	105	0.02210	0.014980	0.02000	0.0000	0.1000
		Change to Week 16	104	-0.00317	0.022823	0.00000	-0.1400	0.0900
		Endpoint	120	0.02325	0.017207	0.02000	0.0000	0.1100
		Change to Endpoint	117	-0.00214	0.024664	0.00000	-0.1400	0.0900
Blood Urea Nitrogen	MMOL/L	Baseline	162	4.20645	1.146508	4.01350	1.7850	8.5680
		Week 16	103	4.29045	1.078943	4.28400	2.1420	6.7830
		Change to Week 16	103	0.22617	1.185585	0.35700	-2.8560	3.2000
		Endpoint	118	4.34754	1.107176	4.28400	2.1420	6.7830
		Change to Endpoint	117	0.22597	1.254029	0.35700	-3.2130	3.2000
Creatinine	UMOL/L	Baseline	162	55.21679	16.394845	53.04000	26.5200	176.8000
		Week 16	104	55.83240	11.834373	53.04000	35.3600	97.2400
		Change to Week 16	104	1.63817	9.000833	0.00000	-17.6800	44.2000
		Endpoint	119	56.18412	11.835374	53.04000	35.3600	97.2400
		Change to Endpoint	118	1.67008	9.210302	0.00000	-26.5200	44.2000
Eosinophils Absolute	10^9/L	Baseline	158	0.20962	0.163001	0.16500	0.0000	0.8500
		Week 16	105	0.22429	0.174101	0.18000	0.0100	0.9100
		Change to Week 16	104	0.01202	0.161764	0.01500	-0.7100	0.8000
		Endpoint	120	0.21975	0.167685	0.18000	0.0100	0.9100
		Change to Endpoint	117	0.01359	0.151711	0.01000	-0.7100	0.8000

Note: For laboratory assessments, the last pre-treatment assessment is taken to be Baseline
Week 16 includes only assessments that are on-treatment (including taper)
Endpoint is the last on treatment assessment (including Taper Phase)

Table 15.3.6

Summary Statistics for Baseline and Change from Baseline to Endpoint for Laboratory Parameters By Treatment Group and Visit

Intention-To-Treat Population

Treatment Group : Paroxetine

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Free T3	PMOL/L	Baseline	163	5.19598	0.831519	5.26680	2.8000	9.3786
		Week 16	7	4.20026	0.885056	4.40000	2.3000	4.8000
		Change to Week 16	7	-0.90463	1.012399	-0.60000	-3.0000	0.0000
		Endpoint	12	4.31150	0.802776	4.40000	2.3000	5.4362
		Change to Endpoint	12	-0.62065	0.964174	-0.46940	-3.0000	0.8000
Hematocrit	%	Baseline	151	39.97483	2.764639	40.00000	32.7000	46.5000
		Week 16	102	39.59804	3.279791	39.05000	33.1000	48.7000
		Change to Week 16	99	-0.88283	2.015402	-0.90000	-5.3000	3.7000
		Endpoint	117	39.45299	3.169890	39.00000	33.1000	48.7000
		Change to Endpoint	112	-0.90000	1.925317	-0.90000	-5.3000	3.6000
Hemoglobin	G/L	Baseline	151	134.91186	9.460326	135.00000	108.7628	159.0000
		Week 16	102	133.18174	11.163112	132.52945	106.0000	163.0000
		Change to Week 16	99	-3.41692	6.620850	-3.00000	-18.0000	12.0848
		Endpoint	117	132.70653	10.795102	132.12660	106.0000	163.0000
		Change to Endpoint	112	-3.50586	6.251553	-3.00000	-18.0000	10.4734
Lymphocytes Absolute	10^9/L	Baseline	158	2.44361	0.646637	2.35500	1.1900	4.5000
		Week 16	105	2.35152	0.686364	2.22000	1.1200	4.7500
		Change to Week 16	104	-0.04442	0.529304	-0.02000	-1.6800	1.6800
		Endpoint	120	2.33683	0.684690	2.23000	1.1200	4.7500
		Change to Endpoint	117	-0.06974	0.526677	-0.02000	-1.6800	1.6800
Monocytes Absolute	10^9/L	Baseline	158	0.40791	0.233446	0.37000	0.0100	2.3400
		Week 16	105	0.39419	0.185725	0.37000	0.0000	1.1200
		Change to Week 16	104	-0.01750	0.258309	0.01500	-1.9200	0.3600
		Endpoint	120	0.38167	0.176413	0.36500	0.0000	1.1200
		Change to Endpoint	117	-0.02462	0.256419	0.01000	-1.9200	0.3600
Neutrophils Absolute	10^9/L	Baseline	158	3.90443	1.428192	3.57500	1.2800	8.3300
		Week 16	105	3.98752	1.562780	3.74000	0.6700	10.1900
		Change to Week 16	104	0.06692	1.629379	0.07000	-5.0300	6.6200
		Endpoint	120	3.93350	1.486344	3.74500	0.6700	10.1900
		Change to Endpoint	117	0.05026	1.512579	0.08000	-5.0300	6.6200
Platelets	10^9/L	Baseline	151	284.23179	60.170031	276.00000	121.0000	479.0000
		Week 16	102	283.29412	57.337733	274.50000	149.0000	453.0000
		Change to Week 16	99	-3.49495	41.862841	0.00000	-156.0000	69.0000
		Endpoint	117	283.41880	57.993793	275.00000	149.0000	453.0000
		Change to Endpoint	112	-5.32143	41.115792	-2.50000	-156.0000	69.0000

Note: For laboratory assessments, the last pre-treatment assessment is taken to be Baseline
Week 16 includes only assessments that are on-treatment (including taper)
Endpoint is the last on treatment assessment (including Taper Phase)

Table 15.3.6

Summary Statistics for Baseline and Change from Baseline to Endpoint for Laboratory Parameters By Treatment Group and Visit

Intention-To-Treat Population

Treatment Group : Paroxetine

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Potassium	MMOL/L	Baseline	162	4.28025	0.310847	4.30000	3.5000	5.2000
		Week 16	106	4.26321	0.462771	4.20000	3.5000	7.1000
		Change to Week 16	106	-0.03208	0.477603	-0.05000	-1.3000	2.5000
		Endpoint	121	4.26777	0.454279	4.20000	3.5000	7.1000
		Change to Endpoint	120	-0.01583	0.465805	0.00000	-1.3000	2.5000
Red Blood Cell Count	10^12/L	Baseline	151	4.61424	0.336734	4.60000	3.6000	5.4000
		Week 16	102	4.52422	0.380381	4.55000	3.6000	5.7400
		Change to Week 16	99	-0.11980	0.227322	-0.10000	-0.6000	0.4000
		Endpoint	117	4.52795	0.371415	4.60000	3.6000	5.7400
		Change to Endpoint	112	-0.12107	0.218786	-0.10000	-0.6000	0.4000
Sodium	MMOL/L	Baseline	162	140.65432	2.279591	141.00000	134.0000	149.0000
		Week 16	106	141.06604	2.534594	141.00000	134.0000	150.0000
		Change to Week 16	106	0.53774	3.207653	1.00000	-6.0000	12.0000
		Endpoint	121	140.99174	2.447774	141.00000	134.0000	150.0000
		Change to Endpoint	120	0.36667	3.164757	0.00000	-6.0000	12.0000
Thyroid Stimulating Hormone	MU/L	Baseline	163	1.89712	0.902702	1.70000	0.3000	6.0000
		Week 16	7	1.41857	0.797484	1.30000	0.6700	2.9000
		Change to Week 16	7	-0.80286	0.759357	-0.70000	-1.9800	0.0300
		Endpoint	12	1.37250	0.714832	1.15000	0.6000	2.9000
		Change to Endpoint	12	-0.64000	0.685711	-0.54000	-1.9800	0.2000
Total Bilirubin	UMOL/L	Baseline	162	9.11290	6.203564	8.00000	0.0000	44.0000
		Week 16	105	8.46086	4.872572	6.84000	1.7100	30.7800
		Change to Week 16	105	-0.88543	4.512266	0.00000	-23.0000	9.0000
		Endpoint	120	8.46550	4.698525	6.84000	1.7100	30.7800
		Change to Endpoint	119	-0.93252	4.373129	0.00000	-23.0000	9.0000
Total Free Thyroxine	PMOL/L	Baseline	163	14.07043	1.901817	14.19000	9.0300	20.9000
		Week 16	7	12.41286	1.949758	12.30000	9.3000	15.4800
		Change to Week 16	7	-1.89571	2.302925	-2.70000	-4.7000	0.9000
		Endpoint	12	12.52333	1.672561	12.45000	9.3000	15.4800
		Change to Endpoint	12	-2.19667	1.977989	-2.30000	-5.2000	0.9000
White Blood Cell Count	10^9/L	Baseline	158	6.99361	1.791340	6.83500	3.5000	12.2000
		Week 16	106	6.96943	1.944871	6.55000	1.9000	13.0000
		Change to Week 16	105	-0.00057	1.886583	0.20000	-5.1000	6.5000
		Endpoint	121	6.89678	1.850489	6.50000	3.1000	13.0000
		Change to Endpoint	118	-0.03441	1.747615	0.20000	-5.1000	6.5000

Note: For laboratory assessments, the last pre-treatment assessment is taken to be Baseline
Week 16 includes only assessments that are on-treatment (including taper)
Endpoint is the last on treatment assessment (including Taper Phase)

Table 15.3.6

Summary Statistics for Baseline and Change from Baseline to Endpoint for Laboratory Parameters By Treatment Group and Visit

Intention-To-Treat Population

Treatment Group : Placebo

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Alanine Aminotransferase	IU/L	Baseline	156	15.33974	7.978598	13.00000	5.0000	52.0000
		Week 16	88	15.43182	8.669931	13.00000	6.0000	68.0000
		Change to Week 16	88	0.10227	6.739896	0.00000	-30.0000	20.0000
		Endpoint	107	15.35514	8.362373	13.00000	6.0000	68.0000
		Change to Endpoint	107	0.09346	6.266913	0.00000	-30.0000	20.0000
Alkaline Phosphatase	IU/L	Baseline	155	205.23871	102.630410	200.00000	50.0000	638.0000
		Week 16	88	187.07955	96.213271	175.00000	51.0000	445.0000
		Change to Week 16	87	-8.51724	58.207900	-9.00000	-464.0000	135.0000
		Endpoint	107	192.71028	96.123153	185.00000	51.0000	445.0000
		Change to Endpoint	106	-8.45283	54.825808	-9.50000	-464.0000	135.0000
Aspartate Aminotransferase	IU/L	Baseline	156	21.14744	5.542568	21.00000	11.0000	42.0000
		Week 16	88	20.69318	5.692015	20.00000	11.0000	42.0000
		Change to Week 16	88	0.36364	4.887662	0.00000	-11.0000	23.0000
		Endpoint	107	20.75701	5.696475	20.00000	11.0000	42.0000
		Change to Endpoint	107	0.10280	4.553528	-1.00000	-11.0000	23.0000
Basophils Absolute	10^9/L	Baseline	151	0.02192	0.015306	0.02000	0.0000	0.0900
		Week 16	90	0.01878	0.012163	0.02000	0.0000	0.0600
		Change to Week 16	88	-0.00216	0.016220	0.00000	-0.0800	0.0300
		Endpoint	110	0.01927	0.013993	0.02000	0.0000	0.0900
		Change to Endpoint	108	-0.00250	0.018652	0.00000	-0.0800	0.0900
Blood Urea Nitrogen	MMOL/L	Baseline	155	4.19501	1.193656	3.92700	1.7850	8.2110
		Week 16	88	4.35976	1.216821	4.28400	2.1420	9.2820
		Change to Week 16	87	0.17189	1.092414	0.35700	-2.5000	3.5700
		Endpoint	107	4.42846	1.273436	4.30000	2.1420	9.2820
		Change to Endpoint	106	0.24105	1.090824	0.35700	-2.5000	3.5700
Creatinine	UMOL/L	Baseline	155	57.18303	15.671916	53.04000	28.0000	123.7600
		Week 16	88	58.00523	14.897393	59.23500	26.5200	106.0800
		Change to Week 16	87	1.69080	8.939713	0.00000	-26.5200	26.5200
		Endpoint	107	57.41664	14.693284	56.00000	26.5200	106.0800
		Change to Endpoint	106	0.72057	12.036147	0.00000	-79.5600	26.5200
Eosinophils Absolute	10^9/L	Baseline	152	0.25007	0.189703	0.20000	0.0100	1.0500
		Week 16	90	0.25811	0.287374	0.19500	0.0100	2.1900
		Change to Week 16	88	0.00102	0.250760	-0.02000	-0.5800	1.5300
		Endpoint	110	0.24591	0.271352	0.17500	0.0100	2.1900
		Change to Endpoint	108	-0.00926	0.230439	-0.03000	-0.5800	1.5300

Note: For laboratory assessments, the last pre-treatment assessment is taken to be Baseline
Week 16 includes only assessments that are on-treatment (including taper)
Endpoint is the last on treatment assessment (including Taper Phase)

Table 15.3.6

Summary Statistics for Baseline and Change from Baseline to Endpoint for Laboratory Parameters By Treatment Group and Visit

Intention-To-Treat Population

Treatment Group : Placebo

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Free T3	PMOL/L	Baseline	151	5.29232	0.800436	5.26680	3.1000	9.2000
		Week 16	3	4.83333	0.873689	4.60000	4.1000	5.8000
		Change to Week 16	3	-0.70000	0.953939	-0.60000	-1.7000	0.2000
		Endpoint	3	4.83333	0.873689	4.60000	4.1000	5.8000
		Change to Endpoint	3	-0.70000	0.953939	-0.60000	-1.7000	0.2000
Hematocrit	%	Baseline	150	40.92000	3.292803	40.35000	34.3000	51.0000
		Week 16	89	40.76742	3.345444	40.20000	34.4000	52.3000
		Change to Week 16	88	-0.39205	2.069106	-0.20000	-4.6000	4.5000
		Endpoint	110	40.77182	3.369021	40.40000	34.0000	52.3000
		Change to Endpoint	109	-0.40642	2.118187	-0.30000	-4.6000	4.6000
Hemoglobin	G/L	Baseline	150	137.90020	11.014258	137.00000	114.0000	170.7978
		Week 16	89	137.61156	11.785004	136.00000	118.0000	178.8543
		Change to Week 16	88	-0.85583	6.193418	-1.00000	-20.2961	12.0848
		Endpoint	110	137.44605	11.748732	135.67460	113.0000	178.8543
		Change to Endpoint	109	-1.13711	6.150814	-1.00000	-20.2961	12.0848
Lymphocytes Absolute	10^9/L	Baseline	152	2.36579	0.670770	2.27500	0.8800	5.0500
		Week 16	90	2.30567	0.614205	2.29000	1.0600	4.2900
		Change to Week 16	88	-0.07568	0.540999	-0.01500	-1.6800	1.2200
		Endpoint	110	2.35609	0.649505	2.30000	1.0600	4.2900
		Change to Endpoint	108	-0.05389	0.515907	0.00000	-1.6800	1.2200
Monocytes Absolute	10^9/L	Baseline	152	0.38368	0.179579	0.37000	0.0000	1.2700
		Week 16	90	0.38867	0.205165	0.35500	0.0200	1.6000
		Change to Week 16	88	0.00307	0.175082	-0.01000	-0.5100	0.4900
		Endpoint	110	0.38173	0.193746	0.36000	0.0200	1.6000
		Change to Endpoint	108	-0.00639	0.199679	-0.01000	-1.0500	0.4900
Neutrophils Absolute	10^9/L	Baseline	152	3.67888	1.525077	3.46000	1.0100	14.8400
		Week 16	90	3.95444	2.205028	3.43000	1.3300	18.8000
		Change to Week 16	88	0.21580	1.763839	0.19500	-4.8300	6.5300
		Endpoint	110	3.96409	2.137126	3.41000	1.3300	18.8000
		Change to Endpoint	108	0.21907	1.779117	0.12000	-4.8300	7.3400
Platelets	10^9/L	Baseline	150	272.78667	61.117511	265.00000	93.0000	469.0000
		Week 16	89	273.62921	50.991617	269.00000	178.0000	404.0000
		Change to Week 16	88	3.07955	53.808776	1.50000	-108.0000	203.0000
		Endpoint	110	272.96364	54.604487	268.00000	170.0000	472.0000
		Change to Endpoint	109	1.05505	50.015708	0.00000	-108.0000	203.0000

Note: For laboratory assessments, the last pre-treatment assessment is taken to be Baseline
Week 16 includes only assessments that are on-treatment (including taper)
Endpoint is the last on treatment assessment (including Taper Phase)

Table 15.3.6

Summary Statistics for Baseline and Change from Baseline to Endpoint for Laboratory Parameters By Treatment Group and Visit

Intention-To-Treat Population

Treatment Group : Placebo

Parameter	Unit	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Potassium	MMOL/L	Baseline	156	4.34231	0.590247	4.20000	3.6000	10.0000
		Week 16	88	4.29318	0.367907	4.20000	3.7000	5.8000
		Change to Week 16	88	-0.07159	0.807002	0.00000	-5.8000	1.9000
		Endpoint	107	4.28411	0.340685	4.20000	3.7000	5.8000
		Change to Endpoint	107	-0.05981	0.747178	0.00000	-5.8000	1.9000
Red Blood Cell Count	10^12/L	Baseline	150	4.72673	0.402280	4.70000	3.8000	6.1000
		Week 16	89	4.68708	0.454908	4.70000	3.4000	6.3000
		Change to Week 16	88	-0.02818	0.237286	0.00000	-0.6000	0.4100
		Endpoint	110	4.70418	0.443835	4.70000	3.4000	6.3000
		Change to Endpoint	109	-0.03459	0.241793	0.00000	-0.6000	0.5000
Sodium	MMOL/L	Baseline	156	140.80769	2.353077	141.00000	136.0000	147.0000
		Week 16	88	141.44318	1.747629	141.00000	137.0000	145.0000
		Change to Week 16	88	0.79545	2.779891	1.00000	-6.0000	9.0000
		Endpoint	107	141.31776	2.007524	141.00000	131.0000	145.0000
		Change to Endpoint	107	0.54206	2.930904	1.00000	-10.0000	9.0000
Thyroid Stimulating Hormone	MU/L	Baseline	153	2.12229	1.625554	1.90000	0.0000	16.8000
		Week 16	3	1.85667	0.496622	1.95000	1.3200	2.3000
		Change to Week 16	3	-1.47667	1.729345	-0.98000	-3.4000	-0.0500
		Endpoint	3	1.85667	0.496622	1.95000	1.3200	2.3000
		Change to Endpoint	3	-1.47667	1.729345	-0.98000	-3.4000	-0.0500
Total Bilirubin	UMOL/L	Baseline	155	9.69032	5.322604	8.55000	3.0000	40.0000
		Week 16	88	10.48648	5.661504	8.77500	3.4200	33.0000
		Change to Week 16	87	0.00046	4.295737	0.00000	-9.0000	18.8100
		Endpoint	107	10.13981	5.450079	8.55000	3.4200	33.0000
		Change to Endpoint	106	0.14585	4.048055	0.00000	-9.0000	18.8100
Total Free Thyroxine	PMOL/L	Baseline	152	13.94007	2.105361	14.19000	9.0300	24.4000
		Week 16	3	14.36667	0.321455	14.50000	14.0000	14.6000
		Change to Week 16	3	-1.90000	1.873499	-1.30000	-4.0000	-0.4000
		Endpoint	3	14.36667	0.321455	14.50000	14.0000	14.6000
		Change to Endpoint	3	-1.90000	1.873499	-1.30000	-4.0000	-0.4000
White Blood Cell Count	10^9/L	Baseline	153	6.65725	1.940990	6.50000	2.4000	21.5000
		Week 16	91	6.92440	2.604890	6.30000	3.5000	24.5000
		Change to Week 16	89	0.20079	2.005972	-0.10000	-4.9000	6.3200
		Endpoint	111	6.96595	2.508046	6.40000	3.5000	24.5000
		Change to Endpoint	109	0.19514	1.993932	-0.10000	-4.9000	7.5000

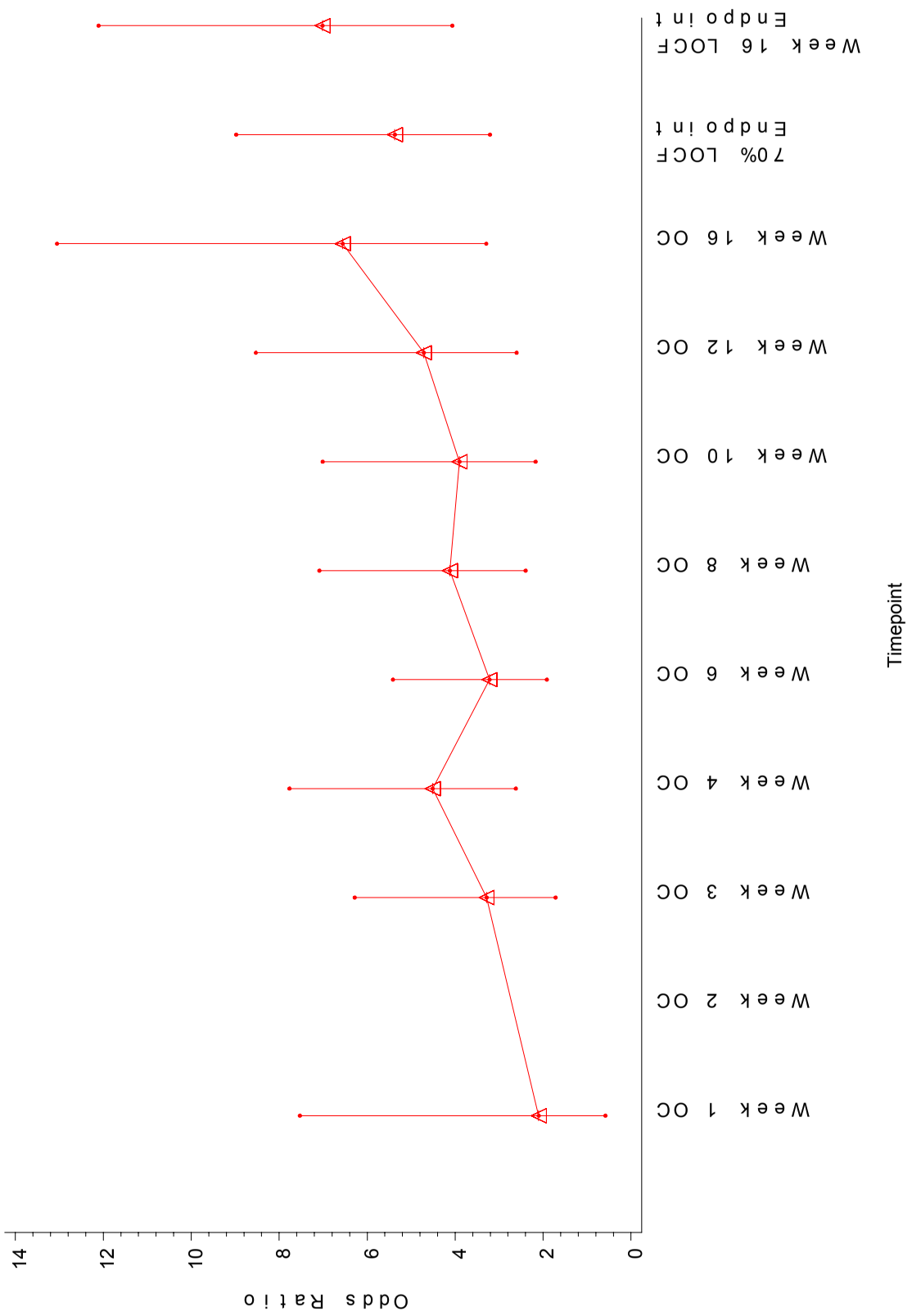
Note: For laboratory assessments, the last pre-treatment assessment is taken to be Baseline
Week 16 includes only assessments that are on-treatment (including taper)
Endpoint is the last on treatment assessment (including Taper Phase)

14 Source Figures

/bioenv/dart10/sbbrl29060_paed/676_rst/list/f4401b.cgm f4401b.sas 26MAR2002:13:25 xxxxxxx
BRL 29060 - 676

Figure 14.1b

Proportion of CGI Responders at each visit
Intention-To-Treat Population



15 Errata

Table/Listing	Error
All tables and listings for the ITT population	One placebo patient (676.015.24401) was randomized and dispensed medication but was unable to swallow the study medication capsules. Therefore, this patient is included erroneously in the ITT population, both total and adolescents, and is included in the total Ns (including the denominator for efficacy and safety assessments) for the ITT population at all visits except baseline. Post-baseline efficacy assessments were completed, but are not presented.
Listing 13.2.1, Listing 13.2.2, Appendix B; Table 13.2.1, Section 11	Patient 676.013.24344, a child in the paroxetine group, had active thyroid disease at screening that was not treated with medication; it was considered a serious illness that contraindicated the use of paroxetine. The condition should have been considered a protocol violation since the condition could adversely affect the efficacy evaluation. However, it was categorized as a protocol deviation in error and the patient is included in the PP population.
Table 13.7.2, Section 11; Listing 13.7.1, Appendix B	The denominator used for the percentages of patients with "Other" psychiatric conditions was the number of patients who had an additional condition listed; for named conditions, it was the total number of patients.
Table 15.1.5.1 and 15.1.5.1.X, Section 13; Listing 15.1.4, Appendix D.	Patient 676.101.24629 had a headache on Day 3 that was coded medication stopped. However, the patient took study medication for 119 days and completed the study.
Listing 15.4.1, Appendix D	Patient 676.015.24403 is listed as having a medical procedure of nosebleeds, consequent to an AE of nosebleed. This event was not to have been considered a medical procedure.
Tables 13.17.2, 13.17.3, 13.17.4, 13.17.5.1, 13.17.5.2, 13.17.6, 13.17.7, Section 11	Data for PID 676.021.24565, an adolescent in the paroxetine group, are not included in these dosing tables due to irreconcilable dosing data. The data are included in Listing 13.7.1, Appendix B.