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SmithKline Beecham

Paroxetine

BRL-029060

A Randomized, Multicenter, 10-Week, Double-Blind, Placebo-Controlled, Flexible-Dose Study to Evaluate the Efficacy and Safety of Paroxetine in Children and Adolescents with Obsessive-Compulsive Disorder (OCD)

704

Final Clinical Report

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Signature Page

Report Title: A Randomized, Multicenter, 10-Week, Double-Blind, Placebo-Controlled, Flexible-Dose Study to Evaluate the Efficacy and Safety of Paroxetine in Children and Adolescents with Obsessive-Compulsive Disorder (OCD)

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 Randomized, Multicenter, 10-Week, Double-Blind, Placebo-Controlled, Flexible-Dose Study to Evaluate the Efficacy and Safety of Paroxetine in Children and Adolescents with Obsessive-Compulsive Disorder (OCD) (29060/704).

Investigators and Centers: The study was carried out in 37 centers in the United States and 2 centers in Canada. All investigators were appropriately experienced in the treatment of child and adolescent patients. The study was terminated prematurely at the study center (Center 055) of Dr. xx xxxxxxx, xxxxxxxxxxxxxxx due to significant compliance violations.

Publication: No publications as of 14 November 2001.

Study Dates: The first dose of randomized study medication was administered on 20 January 2000 and the last dose of study medication (including Taper) was administered on 3 July 2001.

Objectives: To assess the efficacy of paroxetine versus placebo in the treatment of children and adolescents with OCD as measured by the change from Baseline in Children's Yale-Brown Obsessive-Compulsive Scale (CY-BOCS) total score at Week 10 last observation carried forward (LOCF) endpoint.

To assess the safety and tolerability of paroxetine vs. placebo in children and adolescents with OCD.

Study Design: This was a 10-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group, flexible-dose trial in children (ages 7 through 11 years) and adolescents (ages 12 through 17 years). The randomization scheme was stratified by age subgroup.

Study Population: Male and female outpatients, 7 to 17 years of age, who met Diagnostic and Statistical Manual Version IV (DSM-IV) criteria for Obsessive-Compulsive Disorder (300.30), had a CY-BOCS total score ≥16, had a history of OCD symptoms for at least two months prior to the Screening visit, and met all other inclusion and exclusion criteria were eligible to enter the study. Each age subgroup was to account for at least 40% of the total number randomized.

Treatment and Administration: Both double-blind medications, i.e., paroxetine and placebo, were in the form of white, oval, film-coated tablets for oral

administration once daily. They were identical in size, shape and color. All active tablets contained 10 mg paroxetine. Batch numbers were U99074 and U00001 for paroxetine 10 mg and U96161 [X9-6B10PL] for placebo.

Following a 1-week Screening Phase, eligible patients were randomly assigned (1:1) to paroxetine or placebo. All randomized patients initiated therapy at Dose Level (DL) 1 (paroxetine 10 mg/day or matching placebo) for the first week of therapy. The dose could be titrated up in 10 mg weekly increments after the initial dose, up to a maximum of 50 mg per day (DL 5), according to the investigator's judgment based on efficacy and tolerability of the study medication. Dose reductions were allowed for an adverse event (AE); such a reduction was permitted only once. A Taper Phase with a gradual reduction of study medication was required for all patients on DL 2 or higher at the end of the study. Total study duration per patient, including Screening, Taper, and Follow-up Phases, was a maximum of 17 weeks.

Evaluation Criteria

Efficacy Parameters: The primary efficacy variable was the change from Baseline in the CY-BOCS total score.

Secondary efficacy variables were the proportion of responders in the CY-BOCS total score (where response was defined as a 25% [or greater] reduction from Baseline); the proportion of responders based on the Clinical Global Impressions (CGI) Global Improvement item (where response was defined as a score of 1 [very much improved] or 2 [much improved]); change from Baseline in the CGI Severity of Illness item score; change from Baseline in the Global Assessment of Functioning (GAF); and change from Baseline in the CY-BOCS Obsessions and Compulsions subscale scores.

Safety Parameters: Safety was assessed via AE monitoring, vital signs, laboratory evaluations, serum pregnancy tests, electrocardiograms (ECGs) and by physical examination.

Pharmacokinetic Parameters: Pharmacokinetic (PK) blood samples were drawn from consenting patients at Weeks 4 and 10 (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 676 (Social Anxiety 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 received at least one dose of randomized 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) and the observed cases (OC) 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. 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. 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.

Analysis of the primary efficacy variable was performed with and without data from patients at Center 055 in both the ITT and Per-Protocol (PP) populations. 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 265 patients were screened and 207 patients randomized, 100 (48.3%) to paroxetine and 107 (51.7%) to placebo. Of these, 203 patients were included in the ITT population. Four randomized patients were not included in the ITT population: One paroxetine patient and 2 placebo patients had no post-baseline assessments, and 1 paroxetine patient did not receive study medication. The all-randomized population comprised 57.0% children and 43.0% adolescents.

The percentage of randomized patients withdrawn prematurely from the study was slightly higher for the paroxetine group (35.0%, 35/100) than for the placebo group (25.2%, 27/107). The primary reasons for withdrawal in the ITT population were AE (10.2%, 10/98) in the paroxetine group and lack of efficacy (13.3%, 14/105) in the placebo group.

Patient Disposition

Study Stage/Population	Paroxetine	Placebo	Total
Screened	–	–	265
Randomized	100 (100.0%)	107 (100.0%)	207 (100.0%)
Withdrawn	35 (35.0%)	27 (25.2%)	62 (30.0%)
Completed Study	65 (65.0%)	80 (74.8%)	145 (70.0%)
Intention-to-Treat *	98 (98.0%)	105 (98.1%)	203 (98.1%)
Per Protocol **	73 (73.0%)	82 (76.6%)	155 (74.9%)
Entered Study 29060/716†	46 (46.0%)	62 (57.9%)	108 (52.2%)

* Randomized patients with at least one on-therapy safety or efficacy assessment. The Safety Population was the same as the ITT Population.
**Patients in the ITT population not identified as protocol violators during blind review.
†Information available at time of this Report.

There was no marked imbalance between the treatment groups in any of the patient characteristics, although there was a greater proportion of patients with comorbid psychiatric illnesses in the placebo group than in the paroxetine group. The percentage of males was also slightly higher in the placebo group than in the paroxetine group.

Demography and Baseline Characteristics (ITT Population)

	Paroxetine	Placebo	Total
Age Group: Total			
Females: Males	45:53	41:64	86:117
Mean age (SD): years	11.1 (3.03)	11.6 (2.97)	11.3 (3.00)
White: n (%)	85 (86.7)	94 (89.5)	179 (88.2)
Baseline CY-BOCS Total Score: Mean (SD)	24.4 (4.95)	25.3 (5.05)	24.8 (5.01)
Psychiatric Comorbidity: n (%)	30 (30.6)	42 (40.0)	72 (35.5)
Age Group: Children			
Females:Males	27:31	22:35	49:66
Mean age (SD): years	8.9 (1.47)	9.2 (1.51)	9.1 (1.49)
White: n (%)	49 (84.5)	51 (89.5)	100 (87.0)
Baseline CY-BOCS Total Score: Mean (SD)	23.8 (5.00)	25.3 (5.31)	24.4 (5.19)
Age Group: Adolescents			
Females: Males	18:22	19:29	37:51
Mean age (SD): years	14.2 (1.67)	14.3 (1.59)	14.3 (1.62)
White: n (%)	36 (90.0)	43 (89.6)	79 (89.8)
Baseline CY-BOCS Total Score: Mean (SD)	25.2 (4.82)	25.3 (4.79)	25.3 (4.77)

Efficacy Results

Datasets: Primary inferences from efficacy analyses were based on the ITT population at Week 10 LOCF. In addition, the primary efficacy variable was

analyzed using the PP population. The Week 10 OC and the 70% LOCF datasets were used to assess the robustness of the conclusions.

Primary Efficacy Variable: Analysis of the primary endpoint provided statistically significant evidence that paroxetine was more efficacious than placebo in the treatment of OCD in the pediatric population. The adjusted mean difference between the paroxetine and placebo groups in change from Baseline in CY-BOCS total score at Week 10 LOCF for the ITT population was -3.45 points in favor of paroxetine (95% confidence interval [-5.60, -1.29], p = 0.002). This result was supported by the Week 10 LOCF analysis in the PP population (-4.27 points in favor of paroxetine, 95% confidence interval [-6.50,-2.04], p<0.001) and by the Week 10 OC and 70% LOCF analyses in both populations. There was no evidence of any statistically significant treatment by covariate interactions.

Secondary Efficacy Variables: Analysis of 3 of the 6 secondary efficacy endpoints also provided statistically significant evidence that paroxetine was more efficacious than placebo in treating children and adolescents with OCD. The odds of being a CY-BOCS responder on paroxetine vs. placebo at Week 10 LOCF were 2.66 (95% confidence interval [1.45, 4.87], p=0.002). For the CY-BOCS Obsession and Compulsion Subscale scores, the adjusted mean differences between paroxetine and placebo at Week 10 LOCF were -1.80 points in favor of paroxetine (95% confidence interval [-2.94, -0.67], p=0.002) and -1.72 points in favor of paroxetine (95% confidence interval [-2.85, -0.60], p=0.003), respectively. The analysis of results for CGI Global Improvement, CGI Severity of Illness, and GAF did not detect a statistically significant difference between the effects of paroxetine and placebo. However, each of these secondary endpoints showed numerical superiority in favor of paroxetine.

Safety Results

Adverse Events: In the ITT population, 83 patients (84.7%) in the paroxetine group and 77 patients (73.3%) in the placebo group reported gender-non-specific, Treatment Phase-emergent AEs. The most common (>10%) gender-non-specific AEs on paroxetine were headache, abdominal pain, nausea, respiratory disorder, somnolence, hyperkinesia, and trauma; the most common (>10%) AEs on placebo were headache, abdominal pain, respiratory disorder, infection, nausea, and rhinitis. The only gender-specific AE reported was dysmenorrhea in 3 female patients on paroxetine and 1 female patient on placebo. Hyperkinesia, trauma, decreased appetite, hostility, diarrhea, asthenia, vomiting, agitation, and neurosis

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 (84.5% vs. 85.0%, respectively). However, among the most common AEs, nausea (25.0% vs. 10.3%), somnolence (17.5% vs. 8.6%), asthenia (12.5% vs. 5.2%), and dizziness (10.0% vs. 1.7%) were each reported more frequently in the adolescent subgroup. Abdominal pain (22.4% vs. 10.0%), hyperkinesia (17.2% vs. 5.0%), and insomnia and hostility (each 12.1% vs. 5.0%) were reported more frequently in children than in adolescent patients.

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, somnolence, hyperkinesia, abdominal pain, and nausea. 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, 20/98 patients in the paroxetine group (20.4%) and 8/105 patients in the placebo group (7.6%) had AEs that led to dose reductions.

Serious Adverse Events: There were no deaths during the study or within 30 days of the last dose of study medication.

No serious AEs (SAEs) were reported during the screening phase. Three patients in the paroxetine group and 1 patient in the placebo group had SAEs after the first dose of randomized medication, including the 30-day period following the last dose of study medication. Hostility (aggressive behavior) was experienced by 1 patient (2 occurrences) in the paroxetine group and 1 patient in the placebo group during the Treatment Phase and in 1 patient in the paroxetine group 1 day after stopping taper medication. Emotional lability (suicidal thoughts), which also led to withdrawal from the Treatment Phase, occurred in 1 patient in the paroxetine group. All of the SAEs were considered unrelated or probably unrelated to study medication, and all, except hostility in the placebo patient, were considered severe.

Withdrawals Due to Adverse Events: In total, 10.2% of patients (10/98 including 8 children) receiving paroxetine and 2.9% of patients (3/105 including 1 child) 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 hyperkinesia, experienced by 3 patients (all

children 7 to 8 years old) in the paroxetine group. Neurosis leading to withdrawal was experienced by 1 patient in each treatment group.

Vital Signs: Changes in vital signs values from Baseline to Week 10 and endpoint were small for both treatment groups and of no clinical concern. Only a small number of patients were identified as having a vital signs value meeting predefined potential clinical concern criteria (9 patients in the paroxetine group and 11 in the placebo group). The most common concern values were for diastolic blood pressure <50 mmHg and decrease from Baseline ≥ 20 mmHg.

Laboratory Data: In total, 14/98 patients (14.3%) in the paroxetine group and 11/105 patients (10.5%) in the placebo group had laboratory values that met predefined potential clinical concern criteria at any time during study treatment. The majority of these patients, 11 in the paroxetine group and 7 in the placebo group, had low hematocrit values of potential concern. No remarkable mean changes in laboratory parameters were observed in either treatment group.

Electrocardiograms: During the study, the only abnormal ECG (as assessed by the investigator) in either treatment group was noted in a patient in the placebo group at the end of the Treatment Phase; the patient's ECG was normal at the end of the Taper Phase.

Conclusions

Assessment of the primary efficacy variable, change from Baseline in the CY-BOCS total score at the Week 10 LOCF endpoint, provided statistically significant evidence that paroxetine was more efficacious than placebo in treating children and adolescents with OCD. This conclusion was supported by statistically significant results from analysis of 3 of the 6 secondary efficacy variables and numerical results indicating a benefit of paroxetine over placebo for the other secondary variables.

Data from this study demonstrated that paroxetine was safe and generally well tolerated when used in children and adolescents with OCD over a period of up to 10 weeks. 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(s)
ADECS	Adverse Drug Experience Coding System (based on COSTART system)
ADD	Attention Deficit Disorder
ADHD	Attention Deficit/Hyperactivity Disorder
AE	adverse event
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
BUN	blood urea nitrogen
CFR	Code of Federal Regulation
CGI	Clinical Global Impression
CI	confidence interval
CRF	case report form
CV	Curriculum Vitae
CY-BOCS	Children's Yale-Brown Obsessive Compulsive Scale
DL	dose level
DSM-III-R	Diagnostic and Statistical Manual of Mental Disorders, third edition revised
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, fourth edition
ECG	electrocardiogram
ECT	electroconvulsive therapy
EU CPMP	European Union Committee for Proprietary Medicinal Products
FDA	Food and Drug Administration
FU	Follow-up
GAD	Generalized Anxiety Disorder
GAF	Global Assessment of Functioning
GCP	Good Clinical Practice
GSK	GlaxoSmithKline
HCG	human chorionic gonadotropin
HDPE	high-density polyethylene
IRB	Institutional Review Board
ITT	Intention-to-Treat
IU	International Unit

K-SADS-PL	Kiddie-Sads [Schedule for Affective Disorders and Schizophrenia for School-Age Children - Children (6-18 years)] – Present and Lifetime Version
LOCF	last observation carried forward
LOE	lack of efficacy
MAOI	monoamine oxidase inhibitor
mcmol	micromole
mmol	millimole
mg	milligrams
mmHg	millimeters of mercury
mU	milliunit
N (n)	number in population (sample)
NOS	not otherwise specified
NSRI	noradrenergic serotonin reuptake inhibitor
OC	observed cases
OCD	Obsessive Compulsive Disorder
p	probability
PP	per protocol
PV	protocol violator
RBC	red blood cell
SAE	serious adverse event
SAS	Statistical Analysis System
SB	SmithKline Beecham, a GlaxoSmithKline company
SD	standard deviation
SE	standard error of the mean
SGOT	serum glutamic oxaloacetic transaminase (AST)
SGPT	serum glutamic pyruvic transaminase (ALT)
SOPs	Standard Operating Procedures
SSRI	selective serotonin reuptake inhibitor
TCA	tricyclic antidepressant
TSH	thyroid stimulating hormone
WBC	white blood cell
Wk	week
WHO	World Health Organization
WRC-GCP	Worldwide Regulatory Compliance-GCP
yr	year

1 Introduction

Paroxetine (Paxil®, Seroxat®, Deroxat®, Aropax®), a phenylpiperidine compound, is a selective serotonin reuptake inhibitor (SSRI) registered for use in adults in the treatment of Obsessive-Compulsive Disorder (OCD), Major Depressive Disorder (MDD), Panic Disorder, Social Anxiety Disorder (SAD) and Generalized Anxiety Disorder (GAD). Due to the success of paroxetine in the treatment of these psychiatric disorders in adults, this study was conducted in children and adolescents with OCD.

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

SSRIs such as paroxetine (Paxil®) are increasingly viewed as first-line treatment for OCD, and their efficacy has been established in a series of placebo-controlled trials.[1] Paroxetine has been shown in double-blind, placebo-controlled trials to be effective in the short-term management [2][3] and the long-term management [4][5] of adult outpatients with OCD. The minimally effective dose in this population is 40 mg per day, with daily doses of up to 60 mg showing additional benefit in some patients. Long-term paroxetine treatment has also been shown to prevent relapse of OCD in adult patients.[4]

Recent epidemiological studies have consistently found lifetime prevalence of OCD of 1-3% in adults and adolescents, suggesting that previous studies have clearly underestimated its prevalence in the general population.[6][7] Children and adolescents are frequently affected by OCD, and in fact the disorder usually emerges during childhood or adolescence, underscoring the importance of developing effective treatments for use in the pediatric population.[8] Recent data indicate that 80% of adults with OCD identify their onset of symptoms before age 18 [9], and although prevalence data in teenagers are non-existent [6], relatively recent reports of mean age of onset of pediatric OCD have ranged from 9 to 11 years.[8][10][11] Because OCD is a chronic and usually disabling condition, is of early onset, and is often comorbid with other psychiatric disorders [11], it is essential that intervention be exercised at the earliest stage possible in the disease. Although the presentation of OCD in children can differ from that in adults, and the type and intensity of obsessions and compulsions may change as the child

develops, in general the clinical features of OCD are strikingly similar across age groups, and OCD is generally felt to be the same disorder in children, adolescents, and adults.[12] Consequently, it is reasonable to assume that treatments shown to be effective in adults with OCD may also prove to be effective in children and adolescents with the disease.

To date, one study of paroxetine in pediatric patients with OCD has been conducted (study 453) by SmithKline Beecham (SB), a GlaxoSmithKline (GSK) company. In this study, patients aged 8 to 17 years with moderate to severe OCD (mean CY-BOCS Total Score at baseline was 26.3) received open-label paroxetine (10-60 mg/day, flexible-dose regimen) for 16 weeks. Those who achieved a therapeutic response (defined as ≥25% reduction in CY-BOCS Total Score and a CGI Global Improvement Item score of 1 [very much improved] or 2 [much improved] at week 16) were then randomly assigned (1:1) to continue on paroxetine or to be switched to placebo (in double-blind fashion) for an additional 16 weeks of treatment to assess maintenance of effect as well as longer term safety and tolerability. In this prior study, administration of paroxetine for up to 32 weeks in pediatric patients with OCD did not reveal any adverse findings that were unique to this population nor any that would preclude paroxetine use in this population. In the Open-Label Phase, the mean reduction from baseline in CY-BOCS Total Score was 13.0, and the majority of patients enrolled (69%) met the response criterion. The proportion of patients who met the criterion for relapse in the double-blind phase was lower in the paroxetine group (34.7%) than in the group of patients switched to placebo (43.9%), although this difference was not statistically significant. The results of this earlier study provide supportive evidence that paroxetine is beneficial in the treatment of children and adolescents with OCD.[13]

This present study was conducted to further evaluate the efficacy and safety of paroxetine in pediatric patients with OCD.

2 Objectives

2.1 Primary Objective

The primary objective of this study was to assess the efficacy of paroxetine versus placebo in the treatment of children and adolescents with OCD, as measured by the change from Baseline in Children's Yale-Brown Obsessive-Compulsive Scale (CY-BOCS) Total Score at the Week 10 LOCF endpoint.

2.2 Secondary Objective

The secondary objective was to assess the safety and tolerability of paroxetine versus placebo in children and adolescents with OCD.

3 Methodology

3.1 Study Design

This was a multicenter, randomized, double-blind, placebo-controlled, flexible-dose, parallel-group trial with a 10-week Treatment Phase. Children (ages 7 through 11) and adolescents (ages 12 through 17) who had a history of OCD for at least 2 months, who met DSM-IV diagnostic criteria for OCD (300.30), and who fulfilled the Screening 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 randomized (1:1 ratio) to receive either paroxetine or placebo. The randomization scheme was stratified by age subgroup (children and adolescents); each age subgroup was to account for at least 40% (and no more than 60%) of the total number of patients randomized.

The dose of active medication ranged from 10 to 50 mg daily. All patients in the Treatment Phase initiated therapy at Dose Level (DL) 1 (10 mg/day or matching placebo) for Week 1 of the Treatment Phase. The dosage could thereafter be increased at each visit by 10 mg/day (1 DL) increments at intervals 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 per day. Blinding was maintained by referring to daily paroxetine doses (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). Treatment occurred over a period of 10 weeks followed by a Taper Phase of up to 4 weeks.

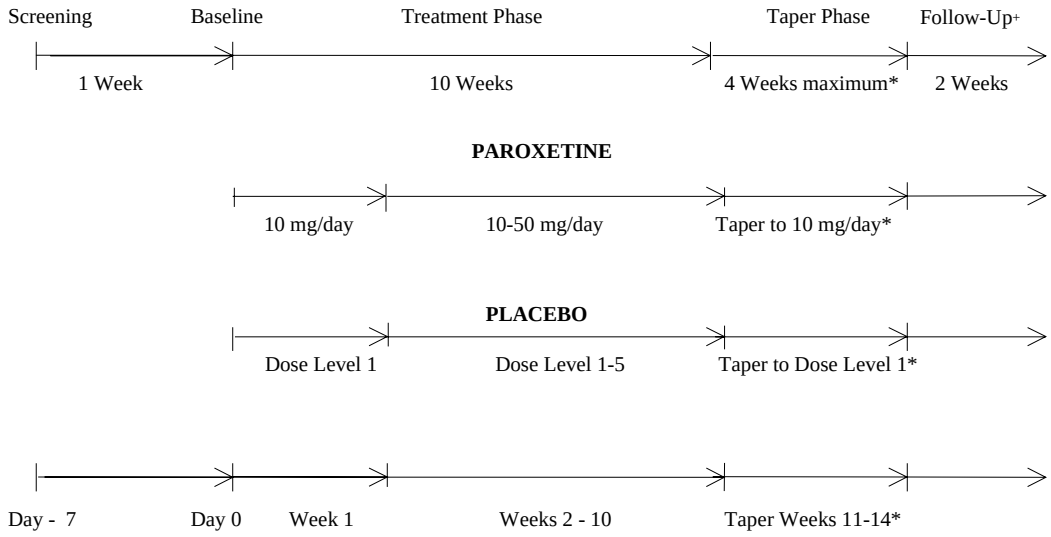
Dose reductions to the next lower level consequent to an adverse event were permitted after Week 2. The patient could then return to the previous dose level upon resolution of the adverse event. Patients who were unable to tolerate DL 1 (10 mg/day or placebo) were withdrawn from the study. Patients who required more than one dose reduction were also withdrawn from the study.

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 10-week Treatment Phase at DL 1 (10 mg/day or 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. A Follow-up Visit was required 14 days (± 3 days) after the last dose of study medication (including Taper Phase dosing), except for those patients who completed the 10-week Treatment Phase and elected to enter the separate, open-label extension study (Study 29060/716). [14]

The Study Design is depicted in Figure 1:

Figure 1 Study Design for 704



* The Taper Phase duration is dependent on ending Dosage Level at Week 10 or Early Withdrawal Visit.
\+ 14 days after last dose of study medication except for those patients entering the 716 extension study.

3.1.1 Protocol Amendments

Protocol 29060/704 was finalized on 17 November 1999, with one subsequent protocol amendment.[1] Amendment 1, dated 12 December 2000, clarified the language in the statistical evaluation section at the request of the United States Food and Drug Administration (FDA). It made clear that, in the situation where assumptions for the primary analysis did not hold, appropriate non-parametric methods would be used in order to assess the robustness of the conclusions. In addition, it clarified that investigation of interactions would be limited to the

[1] Appendix A contains the protocol and amendment.

primary variable at the primary timepoint and was to be used to assess the robustness of the conclusions from the primary analysis.

3.2 Investigators

It was planned that 204 patients in the United States and Canada would be randomized (102 per treatment arm). Each center aimed to enroll a minimum of 8 patients; therefore, approximately 25 centers in the United States and Canada were expected to participate. However, 37 investigative centers in the United States and 2 centers in Canada participated in this study, although center numbers 011, 023 and 058 in the United States screened but did not randomize patients.

The study center (number 055) of Dr. xxxxxx xxxxxxx of xxx xxxxxxx xx who screened 17 patients and entered 14 of those patients, was terminated by the Sponsor following an internal audit that detected significant compliance violations. The 14 patients who were entered had completed participation in the study by the time the site was terminated. As a conservative approach in analyzing the efficacy data, the primary outcome measure was analyzed with and without data generated from Dr. xxxxxxxxx patients for both the intention-to-treat (ITT) population as well as the per-protocol (PP) population. Removal of Dr. xxxxxxxxx patients from the database did not change the overall findings or the conclusions from the study. For purposes of this Report, the results are presented including Dr. xxxxxxxxx patients, except for Section 5.2.3, which presents the analyses of the primary outcome measure without these patients.

Table 1 presents a list of the Principal Investigators, their center numbers, their affiliated institution and their geographic location. These investigators were selected based on their experience with this 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 the curricula vitae (CVs) of all principal investigators, which provide details of the investigator's qualifications and experience.

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

Investigator	Center	Affiliated Institution	City	State
United States				
			Minneapolis	MN
		Medical School		
			Dallas	TX
		Center of Dallas		
.	005			
	006		Charlotte	NC
.				
			Salem	OR
		Investigations, Inc.		
			Piscataway	NJ
				TX
			Jackson	
	011			
			Madison	WI
			Baltimore	MD
			Cincinnati	OH
		Medicine		
.	020		Gainesville	FL
			Cleveland	OH
		LLC		
			Milwaukee	WI
		Research		
			Medina	OH
		Associates, Inc.		

* Patients were screened but not randomized.
Source: Table 13.0, Section 11
(continued)

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

Investigator	Center	Affiliated Institution	City	State
United States				
			Washington	DC
		Center		
	028	l	Richmond	VA
		Associates, LLC		
	029		Seattle	WA
		Health		
	040			
			Clearwater	FL
		Florida		
			Maitland	FL
		Center		
			Elkins Park	PA
	049		Hershey	PA
			Fort Walton Beach	FL
			Sioux Falls	SD
			New Orleans	LA
		New Orleans		
			San Antonio	TX
		Clinical Research		
	058		Vernon Hills	IL
M.D.*				
Canada				
				Scotia

* Patients were screened but not randomized.
Source: Table 13.0, Section 11

3.3 Ethics

The study was conducted in accordance with Good Clinical Practice[2], and the Declaration of Helsinki as amended in Somerset West, Republic of South Africa (1996). The protocol and statement of informed consent and/or assent were approved by an Institutional Review Board (or Ethics Committee) prior to each center's initiation.[3] Written informed consent and/or assent was obtained from each parent/guardian and/or patient prior to entry into the study. Case report forms (CRFs) were provided for each patient's data to be recorded. A sample CRF is provided in Appendix A.

The IRBs were informed by the investigators of the protocol amendment. The IRBs were also informed of serious or unexpected AEs 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 (7 to 17 years of age) with a history of OCD symptoms for at least two months prior to the Screening Visit and who met all of the other entrance criteria. The Kiddie-SADS [Schedule for Affective Disorders and Schizophrenia for School-Age Children (6-18 years)]-Present and Lifetime Version (K-SADS-PL) interview was used to confirm the OCD diagnosis and to determine the presence of any other comorbid psychiatric disorders.[15] All patients (or legal guardians) signed informed consent, and all patients signed consent and/or patient assent where required.

3.4.1 Inclusion Criteria

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

1. Male or female patients ages 7 years 0 months to 17 years 11 months inclusive.

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[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.

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

2. Diagnosis of OCD according to DSM-IV criteria (300.30) as the primary diagnosis and confirmed by the K-SADS-PL semi-structured interview.

3. History of OCD symptoms for a minimum of 2 months.

4. Patients with a total score of 16 or greater on the Children's Yale-Brown Obsessive-Compulsive Scale (CY-BOCS) at Screening and Baseline Visits.

5. Patients determined otherwise medically healthy by physical examination, medical history and laboratory screening.

6. Custodial parent's or legal guardian's written informed consent before performance of any study-specific procedures, and patient's assent and/or consent where required.

3.4.2 Exclusion Criteria

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

1. Patients who, in the investigator's judgment, presented with a clinically predominant Axis I disorder other than OCD.

2. Patients with a concurrent major depressive episode.

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

4. Patients diagnosed with substance abuse or dependence within 3 months prior to the Screening Visit.

5. Patients who tested positive for illicit drug use at Screening.

6. Patients who, in the investigator's judgment, posed a current suicidal or homicidal risk.

7. Patients who had taken other psychoactive drugs within the time frames specified below prior to the Screening Visit:

    - Fluoxetine, monoamine oxidase inhibitors (MAOIs) – 5 weeks or less

    - Depot antipsychotics – 12 weeks or less

- Antidepressants other than MAOIs or fluoxetine (e.g., TCAs, NSRIs, SSRIs), lithium and oral antipsychotics – 14 days or less
- Hypnotics, benzodiazepines, and all other sedatives – 5 half-lives or 14 days (whichever is longer) or less.
- Any CNS-active herbal/natural supplement or preparation – 14 days or less.

8. Patients with organic brain disease, epilepsy or mental retardation.
9. Patients who, in the opinion of the investigator, would be non-compliant with the visit schedule or other study procedures.
10. Patients with clinically significant abnormalities in hematology, blood chemistry, ECG or physical examination which were not resolved by the Baseline Visit.
11. Patients, in the opinion of the investigator, with a serious medical condition which would preclude the administration of paroxetine.
12. Patients with a known hypersensitivity to SSRIs.
13. Patients with electroconvulsive therapy (ECT) within 3 months of Screening.
14. Females who had a positive serum HCG pregnancy test or who were lactating.
15. Sexually active female patients who were not using a reliable method of contraception (e.g., oral contraception, condom in conjunction with spermicidal foam).
16. Patients who had received paroxetine in any previous investigational study or who received any investigational drug within 6 months prior to Screening.
17. Patient requiring concurrent psychotherapy.
18. Patients who, in the judgement of the investigator, had a clear history of non-response to SSRI treatment for their OCD, defined as non-response to at least two different SSRIs following adequate courses of treatment, (i.e., received recommended dosages for 4-6 weeks for each).

3.5 Study Medication and Administration

3.5.1 Study Medication

All double-blind medication, i.e., paroxetine and placebo, was in the form of white oval, film-coated tablets and was identical in size, shape and color. Active tablets each contained 10 mg paroxetine. The appearance, formulation, dose strength, and batch number of the study medication used are presented in Table 2.

Table 2 The Appearance, Formulation, Dose and Batch Numbers of Drug Used in 29060/704 Study

Study Medication	Appearance	Formulation	Dose Units	Batch/Lot Numbers
Paroxetine	white oval	tablet	10 mg	U99074
Paroxetine	white oval	tablet	10 mg	U00001
Placebo	white oval	tablet	--	U96161[X9-6B10PL]

Source: Certificates of Analyses, Appendix A.

Study medication was packaged in high-density polyethylene (HDPE) bottles and dispensed as double-blind medication tablets at the Baseline Visit and at the end of Weeks 1, 2, 3, 4, 6, and 8 in the Treatment Phase and at Week 10 or Early Withdrawal if the patient entered the Taper Phase. Each bottle dispensed during the Treatment Phase and Taper Phase was specific to the dose level and contained sufficient medication for one week (7 days +3 days extra medication). The total number of bottles dispensed at any given visit was dependent on the protocol-stipulated time interval before the next scheduled visit (i.e., one bottle was dispensed for each one-week dosing interval). Thus, one bottle was dispensed at Baseline and Weeks 1 to 3: two bottles at Weeks 4, 6, and 8; and one bottle per week of taper medication required at Week 10 or Early Withdrawal. Each bottle contained the appropriate number of tablets for the designated week, plus 3 days' extra supply for each week.

The sponsor initially provided each site with stratified study medication kits sufficient for 8 randomized patients (4 for each age subgroup). Each patient kit contained bottles with a pre-filled amount of double-blinded medication for all relative dose levels in both the Treatment and Taper Phases.

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 or 1, 2, 3, 4, or 5 tablets of placebo, respectively (Table 3).

Table 3 Double-Blind Study Medication by Dose Level (Treatment and Taper Phases)

Dose Level	Paroxetine* Daily Dose	Placebo Daily Dose
Level 1	10 mg/day	1 tablet placebo
Level 2	20 mg/day	2 tablets placebo
Level 3	30 mg/day	3 tablets placebo
Level 4	40 mg/day	4 tablets placebo
Level 5	50 mg/day	5 tablets placebo

*Paroxetine was taken as 1 to 5 10-mg tablets.

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 center, 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 SmithKline Beecham.

3.5.3 Dosage and Administration

Randomized patients, under parental supervision, were instructed to take from 1 to 5 tablets (dependent on Dose Level) each morning, with food, throughout the double-blind Treatment Phase of the study (Weeks 1-10) and the Taper Phase, if necessary (Weeks 11-14). Study medication was dispensed at each scheduled visit in the Treatment Phase in single bottles (except at Weeks 4, 6, and 8, when 2 bottles were dispensed) which contained sufficient medication to last until the next scheduled visit plus 3 days extra supply for each week. Patients were supplied all medication required for the Taper Phase, one bottle per week, at the Week 10 or Early Withdrawal Visit. Dosage instructions were provided on the label of each bottle, since the number of tablets to be taken per day varied as each patient's daily dosage was increased and/or decreased.

Patients were randomly allocated to receive either paroxetine or placebo (10 to 50 mg per day; DL 1 to 5, respectively) for a period of 10 weeks in the Treatment Phase. Patients who entered the Treatment Phase initiated therapy at DL 1 at either 10 mg/day of paroxetine or 1 tablet/day of placebo for Week 1. Beginning

with Week 2, the dose could be increased by dose level increments (10 mg/day paroxetine or 1 tablet/day of placebo) for both paroxetine and placebo patients, no more frequently than every 7 days and up to the maximum dose of 50 mg/day of paroxetine or 5 tablets/day of placebo according to clinical response and tolerability. Dose increases to the next higher level were permitted at the clinic visits only and could be authorized only by the Principal Investigator.

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 or placebo) were withdrawn from the study. Patients who required more than one dose reduction were withdrawn from the study.

During the Taper Phase, study medication was gradually reduced (1 dose level per week) for a period of up to 4 weeks for patients who completed the Treatment Phase or were prematurely withdrawn at DL 2 or greater. Patients completing or withdrawing at DL 1 did not enter the Taper Phase. Patients at DL 2 or greater commenced Taper Phase dosing at one level below the level of their final therapy and ended the Taper Phase as shown in Table 4.

Table 4 Double-Blind Study Medication Dosing Instructions (Taper Phase)

Dose level* at the end of treatment	Week 11**	Week 12**	Week 13**	Week 14**
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 10 or Early Withdrawal Visit. Each bottle of taper medication was for one week only (+ 3 days' extra medication supply) and contained sufficient tablets relative to the dose level for each week of down-titration. Patients were reminded that the weekly taper medication bottles were to be used in strict sequential order and study medication was to be taken for one week only before patients started dosing from the next bottle. Patients were

instructed to begin the next sequential bottle of study medication at the beginning of the next week of the Taper Phase, regardless of the number of doses taken the previous week. In certain instances, for patients who were entering the open-label extension (study 716) the investigator, in agreement with the Sponsor, permitted accelerated down-titration so that the patient could be returned to the optimal dose level more quickly.

3.5.4 Methods of Blinding

Blinding of study medication was maintained by referring to the daily medication dose as Dose Levels. Placebo tablets were identical in appearance to active study medication tablets. Labels on the packaging identified the randomization number.

A computer-generated randomization list was generated, stratified by age subgroups 7 to 11 years (children) and 12 to 17 years (adolescents), 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 CRF. Appendix A contains a copy of the randomization code.

Supplies for randomized patients were numbered for each age subgroup as follows: 01001 – 01252 (children) and 01253 - 01504 (adolescents). The master randomization list was held by the sponsor. Individual sealed code envelopes indicating the treatment assigned to each patient at a particular visit 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 SmithKline Beecham 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 dosing regimen as per protocol. All patients were instructed to return their medication bottles with any unused drug to the investigator when they returned for each visit. The amounts dispensed and returned were dependent on the number of days in each visit interval and the dose level. As drugs were dispensed, this information was

entered in the CRF along with the tear-off portion of the medication label. This CRF section was brought in-house at study completion.

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

3.7 Prior and Concomitant Medication

All non-psychoactive prior medications taken within one month prior to Screening and all non-psychoactive concomitant medications taken during the study were recorded in the CRF by drug name (trade name preferred), total daily dose, route of administration, medical illness/diagnosis, start date, and end date or notation that medication was continuing.

Psychoactive medications taken within three months prior to the Screening Visit and psychoactive medication ever taken for OCD were similarly recorded in the CRF with a pharmacotherapy class identification (SSRI, MAOI, TCA, benzodiazepine or other), drug name (trade name preferred), indication (if other than OCD), start date and end date. 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 3.4.2, Exclusion Criteria).

3.8 Study Procedures

3.8.1 Schedule of Assessments

A schedule of study assessments and procedures is presented in Table 5.

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 10 Visit (or Early Withdrawal Visit, if applicable). For those patients who entered the double-blind Taper Phase, this was the time period after the Week 10 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

10 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 except those entering the open-label extension study (29060/716). [14]

Table 5 Outline of Study Procedures for 29060/704

	Scrn Visit Day -7	Baseline Day 0	Wk 1	Wk 2	Wk 3	Wk 4	Wk 6	Wk 8	Wk 10	Early W/D	Taper End Visit	14-Day Study F/U[a]
Screen/Baseline												
Informed Consent/Assent	**X**											
Patient Demography	**X**											
Inclusion/Exclusion Criteria	**X**	**X**										
Psychiatric Interview	**X**											
Full K-SADS-PL Interview	**X**											
OCD criteria (DSM-IV)	**X**											
OCD History/Med History	**X**											
Medical/Surgical History	**X**											
Patient Randomization		**X**										
Efficacy Parameters												
CY-BOCS	**X**	**X**		**X**		**X**	**X**	**X**	**X**	**X**		

Kiddie-SADS-PL – Schedule for Affective Disorders and Schizophrenia for School-Aged Children – Present and Lifetime Version; CGI – Clinical Global Impression; GAF – Global Assessment of Functioning Scale; CY-BOCS – Children's Yale-Brown Obsessive-Compulsive Scale

a Follow-up visit completed 14 days after last dose of study medication for all patients except those continuing into the open-label extension study, 29060/716.

b Repeat ECG if results at previous visit were clinically significantly abnormal. Screen results were required to be interpreted prior to randomization.

c 3-minutes sitting systolic and diastolic blood pressure and heart rate

d For females of child-bearing potential

e Repeat Laboratory Evaluations were performed only if clinically significantly abnormal results and with the sponsor's/investigator's agreement. Results of repeat evaluation were required to be interpreted prior to randomization. Hematology (hemoglobin, hematocrit, WBC with differential, RBC, and platelet count); Blood Chemistry (creatinine, BUN, total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT[AST], electrolytes, TSH, free T3, free T4 [thyroid tests at Screening Visit only]); dipstick urinalysis (if positive for blood or protein, full microscopy was performed).

f Taper Medication dispensed for all patients ending Treatment Phase or withdrawing at DL 2-5.

g PK sampling was optional and patient consent was required.

(Continued)

Table 5 Outline of Study Procedures for 29060/704 (Continued)

	Scrn Visit Day -7	Baseline Day 0	Wk 1	Wk 2	Wk 3	Wk 4	Wk 6	Wk 8	Wk 10	Early W/D	Taper End Visit	14-Day Study F/U[a]
Efficacy Parameters (continued)												
CGI (Severity of Illness)		X	X	X	X	X	X	X	X	X		
CGI (Global Improvement)			X	X	X	X	X	X	X	X		
GAF		X		X		X	X	X	X	X		
Safety Evaluations												
12 Lead ECG	X	X[b]							X	X	X[b]	X[b]
Vital Signs[c]	X[c]	X[c]	X[c]	X[c]	X[c]	X[c]	X[c]	X[c]	X[c]	X[c]	X[c]	X[c]
Height and Weight	X								X	X		
AE Monitoring		X	X	X	X	X	X	X	X	X	X	X
Laboratory Evaluation	X	X[e]							X	X	X[e]	X[e]
Urine Drug Screen	X											
Physical Examination	X								X	X		

Kiddie-SADS-PL – Schedule for Affective Disorders and Schizophrenia for School-Aged Children – Present and Lifetime Version; CGI – Clinical Global Impression; GAF – Global Assessment of Functioning Scale; CY-BOCS – Children's Yale-Brown Obsessive-Compulsive Scale

a Follow-up visit completed 14 days after last dose of study medication for all patients except those continuing into the open-label extension study, 29060/716.

b Repeat ECG if results at previous visit were clinically significantly abnormal. Screen results were required to be interpreted prior to randomization.

c 3-minutes sitting systolic and diastolic blood pressure and heart rate

d For females of child-bearing potential

e Repeat Laboratory Evaluations were performed only if clinically significantly abnormal results and with the sponsor's/investigator's agreement. Results of repeat evaluation were required to be interpreted prior to randomization. Hematology (hemoglobin, hematocrit, WBC with differential, RBC, and platelet count); Blood Chemistry (creatinine, BUN, total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT[AST], electrolytes, TSH, free T3, free T4 [thyroid tests at Screening Visit only]); dipstick urinalysis (if positive for blood or protein, full microscopy was performed).

f Taper Medication dispensed for all patients ending Treatment Phase or withdrawing at DL 2-5.

g PK sampling was optional and patient consent was required.

(Continued)

Table 5 Outline of Study Procedures for 29060/704 (Continued)

	Scrn Visit Day -7	Baseline Day 0	Wk 1	Wk 2	Wk 3	Wk 4	Wk 6	Wk 8	Wk 10	Early W/D	Taper End Visit	14-Day Study F/U[a]
Safety Evaluations (continued)												
Serum Pregnancy Test[d]	X[d]								X[d]	X[d]		
Blood draw for PK[g]						X			X	X		
Miscellaneous Records												
Prior and Concomitant Meds	X	X	X	X	X	X	X	X	X	X	X	X
Dispense Study Medication		X	X	X	X	X	X	X	X[f]	X[f]		
Medical Procedures		X	X	X	X	X	X	X	X	X	X	X
Study Medication Record		X	X	X	X	X	X	X	X	X	X	
Study Conclusion Record									X	X		

K-SADS-PL – Schedule for Affective Disorders and Schizophrenia for School-Aged Children – Present and Lifetime Version; CGI – Clinical Global Impression; GAF – Global Assessment of Functioning Scale; CY-BOCS – Children's Yale-Brown Obsessive-Compulsive Scale

a Follow-up visit was completed 14 days after last dose of study medication for all patients except those continuing into the open-label extension study, 29060/716.

b Repeat ECG if results at previous visit were clinically significantly abnormal. Screen results were required to be interpreted prior to randomization.

c 3-minutes sitting systolic and diastolic blood pressure and heart rate

d For females of child-bearing potential

e Repeat Laboratory Evaluations were performed only if clinically significantly abnormal results and with the sponsor's/investigator's agreement. Results of repeat evaluation were required to be interpreted prior to randomization. Hematology (hemoglobin, hematocrit, WBC with differential, RBC, and platelet count); Blood Chemistry (creatinine, BUN, total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT[AST], electrolytes, TSH, free T3, free T4 [thyroid tests at Screening Visit only]); dipstick urinalysis (if positive for blood or protein, full microscopy was performed).

f Taper Medication dispensed for all patients ending Treatment Phase or withdrawing at DL 2-5.

g PK sampling was optional and patient consent was required.

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 study entry. At this visit, the following evaluations were performed or information recorded:

- Written informed consent by custodial parent (legal guardian) or by patient if emancipated minor and assent by minor patient (when required) to be obtained before any study procedures were conducted.
- Full K-SADS-PL semi-structured interview.
- Psychiatric interview and history of OCD and assessment versus DSM-IV Criteria for OCD (300.30) by Board Certified Psychiatrist.
- Assessment with respect to all other Inclusion/Exclusion criteria (see Sections 3.4.1 and 3.4.2).
- Patient demography.
- Children's Yale-Brown Obsessive Compulsive Scale (CY-BOCS).
- Vital signs – 3 minutes sitting heart rate and blood pressure. Blood pressure was measured in the same arm and, where possible, by the same person throughout the study.
- Height (cm) and weight (kg) measurements without shoes.
- 12-lead ECG. ECGs had to be interpreted and deemed clinically non-significant by the investigator prior to randomization.
- Medical/Surgical history and physical examination.
- Serum HCG pregnancy test for patients of child-bearing potential.
- Laboratory evaluations consisted of hematology (hemoglobin, hematocrit, red blood cell [RBC] count, white blood cell [WBC] count with differential, and platelet count); blood chemistry (blood urea nitrogen [BUN], creatinine, total bilirubin, alkaline phosphatase, SGPT [alanine aminotransferase (ALT)], SGOT [aspartate aminotransferase (AST)] and electrolytes [sodium and potassium]); thyroid function tests (TSH, Free T3 and Free T4); and dipstick urinalysis (if dipstick method was positive for blood or protein, full

microscopy was performed). Laboratory evaluations had to be interpreted and deemed clinically non-significant by the investigator prior to randomization.

- Urine drug Screening (amphetamines, benzodiazepines, cocaine, cannabinoids, methaqualone, methadone, opiates, propoxyphene, barbiturates, and phencyclidine)

- Prior and Concomitant medications (including psychoactive and OCD medication history separately)

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. At the end of this phase, baseline evaluations were conducted to determine eligibility to enter the Treatment Phase.

Patient tracking procedures for this study included the use of a Patient Log and a Patient Assignment Sheet, which were kept at each site. All patients interviewed as possible candidates for this study were entered on the Patient Log. This log captured patient initials, interview date, screening date, patient age, patient number, and reason for exclusion (if applicable). All patients who entered the Screening Phase received a patient number and were entered on the Patient Assignment Sheet. The Patient Assignment Sheet captured patient initials, patient number, drug code (for randomized patients), date drug dispensed, and patient status in the trial.

3.8.3 Baseline Visit (Day 0)

At the end of the Screening Phase, a Baseline Visit (Visit 2, Day 0) was conducted to determine eligibility to enter the Treatment Phase. At this visit, the following observations/assessments were performed prior to randomization and dispensation of double-blind medication:

- Reconfirmation that all entrance criteria were met (See Section 3.4, Eligibility Criteria).

- Vital signs (3-minute sitting blood pressure and heart rate).

- Laboratory evaluations (only if clinically significant abnormal at the Screening Visit). Results had to be interpreted and deemed clinically non-significant by the investigator prior to randomization.

- Baseline AEs (Baseline signs and symptoms)
- 12-Lead ECG (only if clinically significant abnormal values were noted at the Screening Visit as confirmed by the cardiologist). Results had to be interpreted and deemed clinically non-significant prior to randomization.
- Children's Yale-Brown Obsessive-Compulsive Scale (CY-BOCS).
- Global Assessment of Functioning (GAF) Scale.
- CGI – Severity of Illness Item.
- Concomitant medication.
- Medical Procedures Record.
- Study Medication Record.
- Patient randomization – study medication dispensed.

3.8.4 Double-Blind Treatment Phase (Weeks 1 - 10)

Study assessments during the Treatment Phase were scheduled at Weeks 1, 2, 3, 4, 6, 8 and Week 10 or upon Early Withdrawal, if applicable. Each study visit included the following evaluations unless otherwise specified:

- Vital signs (3-minute sitting blood pressure and heart rate)
- Height (cm) and weight (kg) measurements without shoes - Week 10 only (or Early Withdrawal Visit, if applicable).
- CGI – Global Improvement Item.
- CGI – Severity of Illness Item.
- CY-BOCS - at Weeks 2, 4, 6, 8, and 10 (or Early Withdrawal Visit, if applicable).
- GAF - at Weeks 2, 4, 6, 8, and 10 (or Early Withdrawal Visit, if applicable).
- Adverse events.
- Concomitant medications.

- Study medication dispensed. At Baseline and at Weeks 1, 2, and 3, a supply of study medication sufficient for a 1-week period was dispensed; at Weeks 4, 6, and 8, a supply of study medication sufficient for a 2-week period was dispensed; at Week 10 or Early Withdrawal Visit, Taper medication was dispensed to patients ending or withdrawing treatment at DL 2 or greater.

- Physical Examination - Week 10 (or Early Withdrawal Visit, if applicable).

- Serum HCG pregnancy for females of child-bearing potential - Week 10 (or Early Withdrawal Visit, if applicable).

- Laboratory evaluations consisting of hematology (hemoglobin, hematocrit, RBC, WBC with differential, and platelet count); blood chemistry (BUN, creatinine, total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT [AST], and electrolytes); and dipstick urinalysis (if dipstick method was positive for blood or protein, a full microscopy was performed) – at Week 10 (or Early Withdrawal, if applicable).

- Pharmacokinetic assessments (optional) - Weeks 4 and 10 (or Early Withdrawal, if applicable) for consenting patients only.

- 12-Lead ECG - Week 10 (or Early Withdrawal Visit, if applicable).

- Study Medication Record.

- Medical Procedures Record.

- Study Conclusion Record - Week 10 (or Early Withdrawal Visit, if applicable).

3.8.5 Taper Phase (Weeks 11 - 14)

Patients completing or withdrawing early from the Treatment Phase at DL 2 or greater had their study medication gradually reduced by 1 dose level (10 mg/day) increment at intervals of approximately 7 days.

3.8.6 Taper End Visit

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

- Vital signs.
- Adverse events.
- Concomitant medications.
- Repeat laboratory evaluation (hematology, blood chemistry and urinalysis) or ECG, if clinically significantly abnormal values were noted at previous visit.
- Taper medication record.
- Medical Procedures.

3.8.7 Follow-up Visit

All patients not entering the paroxetine open-label extension study (29060/716) [14] had to return for a safety Follow-up Visit 14 days after the last dose of study medication (including taper). The following evaluations were performed at this visit:

- Vital signs.
- Concomitant medications.
- Adverse events.
- Repeat laboratory evaluation or ECG if clinically significantly abnormal values were noted at previous visit.
- Medical Procedures Record.

3.9 Patient Completion and Early Withdrawal

3.9.1 Definition

A patient was considered to have completed the study if the Week 10 visit was completed.

A patient was considered to have prematurely withdrawn if he/she did not complete the Week 10 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 (AE section of the CRF had to be completed).
- Lack of efficacy.
- Protocol deviation (including non-compliance).
- Lost to follow-up (reason recorded if possible).
- Other (reason had to be specified).

The reason for withdrawal was recorded in the study conclusion section of the CRF. If a patient withdrew, every attempt was made to carry out the assessments at the patient's last visit that were scheduled for the Week 10 visit.

3.10 Efficacy Assessments

Complete descriptions of the efficacy assessments may be found in the protocol, Section 5.5.2, Efficacy Assessments. A copy of the efficacy instruments may be found in the protocol in Appendix F (CY-BOCS) for the primary efficacy parameter and Appendix H (CGI-Severity of Illness), Appendix I (CGI Global Improvement) and Appendix J (GAF) for the secondary parameters.

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.

3.10.1 Primary Efficacy Instrument

The primary measure of efficacy was Change from Baseline in the Children's Yale-Brown Obsessive-Compulsive Scale (CY-BOCS) Total Score at Week 10 LOCF Endpoint.

The CY-BOCS is a clinician-rated scale designed to rate the severity of obsessive and compulsive symptoms in children and adolescents.[16] It is identical in form and scoring to the widely used adult Yale-Brown Obsessive-Compulsive Scale, but the questions are slightly modified for age appropriateness.

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

CY-BOCS raters were required to attend the training sessions offered at the pre-study Investigator Meeting or to complete follow-up training requirements. Follow-up training for raters included reviewing the scoring conventions for the CY-BOCS and assessing an OCD patient on video through completion of the CY-BOCS score sheet. The raters' scores were then compared with an acceptable score range set for the OCD patient. This documentation was reviewed by the sponsor. Confirmation of an acceptable passing score was sent to the rater.

3.10.2 Secondary Efficacy Instruments

The Clinical Global Impression encompasses the Severity of Illness and Global Improvement Items. For the Severity of Illness Item, clinicians indicate their assessment of the patient's severity of illness 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; and 7 = Among the most extremely ill patients.

The CGI - Global Improvement Item (CGI-I) is also based on a 1 to 7 scale. In this item, clinicians indicate their assessment of the patient's total improvement or worsening compared to their condition at entry into the study (baseline), 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; and 7 = Very much worse. Patients were categorized as responders to the study medication

if at the end of treatment they were rated either as 1 (Very much improved) or 2 (Much improved), compared to Baseline.

The Global Assessment of Functioning Scale (GAF) is a clinician-rated scale for assessing a patient's overall level of functioning. The GAF has the ability to measure the impact of treatment through tracking the clinical progress of an individual in global terms using a single measure. The Scale Axis ranges from 0 = inadequate information or 1 = lowest level of functioning to 100 = superior functioning.

3.11 Safety Assessments

Safety was assessed primarily through AE monitoring and vital sign determinations at every visit; physical examinations (including weight and height) and a serum HCG pregnancy test (for females of child-bearing potential only) at Screening and at Week 10 (or Early Withdrawal, if applicable); and clinical laboratory evaluations and 12-Lead ECGs at Screening and Week 10 (or Early Withdrawal, if applicable). Any laboratory assessment or ECG that had abnormal values in the investigator's judgment, required a repeat of the assessment at the next visit.

3.11.1 Adverse Events

All (serious and non-serious) adverse events (AEs), whether observed by the investigator or reported by the patient (or parent or legal guardian, as appropriate), were evaluated by the investigator and recorded in the AE section of the patient's case report form (CRF). AEs were elicited by the investigator asking the patient (parent or legal guardian, as appropriate) a non-leading question such as ***"Do you feel different in any way since starting the new treatment or since the last visit?"*** If the patient (parent or legal guardian) responded "Yes," details of the AE and its severity, including any change in study drug administration, investigator attribution to study drug, any corrective therapy given and outcome status, were documented in the CRF. Attribution or relationship to study drug was judged by the investigator to be related, possibly related, probably unrelated, or unrelated.

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). In the separate database for reporting serious adverse events (SAEs), SAEs were coded by the WHO ART dictionary, but not mapped by ADECS. Corresponding terms are presented in Section 6.4.

A serious adverse event (SAE) was any event that was fatal, life threatening, or disabling/incapacitating, or resulted in hospitalization, prolonged a hospital stay or was associated with a 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 was associated with the use of the drug was documented as an SAE. Pregnancy was captured as an SAE for the purpose of tracking the status to term.

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

Complete 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, overdosages, and pregnancies; and for breaking the study blind are included in the protocol (Appendix A).

3.11.2 Other Safety Assessments

The other assessments related to safety were as follows:

- Complete physical examinations were required at the Screening Visit and at the Week 10 or Early Withdrawal Visit. Any adverse changes in the physical examination were to be recorded in the AE section of the CRF.

- 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 Week 10 or Early Withdrawal Visit. Likewise, any clinically significant adverse change in any of these parameters was to be recorded as an AE.

- An ECG was also performed at the Screening Visit and at the Week 10 or Early Withdrawal Visit. If the ECG assessments revealed a clinically significant finding, a repeat ECG was required.

- Laboratory monitoring was performed at the Screening Visit and at the Week 10 or Early Withdrawal Visit. If results were clinically significantly abnormal, laboratory assessments were repeated at the next visit. Analyses were performed by a central laboratory (Quest Diagnostics). The laboratory evaluation consisted of hematology (hemoglobin, hematocrit, RBC, WBC with differential, and platelet count), blood chemistry (BUN, creatinine, total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT [AST], and electrolytes), and dipstick urinalysis (if dipstick method was positive for blood or protein, a full microscopy was performed). Thyroid function tests (TSH, free T3 and free T4) were assessed at the Screening Visit only. Any abnormalities considered clinically significant were recorded in the AE pages of the CRF. In addition, laboratory values of clinical concern were identified and tabulated.

- Serum HCG pregnancy tests were performed at the Screening Visit and at Week 10 or Early Withdrawal for patients of child-bearing potential.

3.12 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 701 [19] and 676 [20]) and reported separately at a later time.

3.12.1 Sampling Times

Venous blood samples were drawn from consenting patients at Weeks 4 and 10 (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).

3.12.2 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 these procedures were provided by Quest Diagnostics before the start of the study.

3.12.3 Assay Methods and Pharmacokinetic Analysis

Plasma concentrations of paroxetine were determined by HPLC/MS/MS [17] under the direction of the Department of Drug Metabolism and Pharmacokinetics of SmithKline Beecham (a GlaxoSmithKline company).

3.13 Data Quality Assurance

To ensure that study procedures were correctly and consistently carried out across all investigator sites, the protocol, CRFs and safety reporting were reviewed with the investigator and his/her personnel responsible for the conduct of the study by the Company representative(s) at the investigator site. In addition, a multicenter Investigators' meeting was held on 8 – 9 December 1999, in St. Louis, Missouri, United States of America.

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

This study was subject to audit by SmithKline Beecham's department of Worldwide Regulatory Compliance-GCP (WRC-GCP). Worldwide Regulatory Compliance–GCP is an independent function within SmithKline Beecham with responsibility for assuring Company management that clinical trials are organized, performed and reported in compliance with Company protocols and working practices and the requirements of national and international GCP guidelines. This is achieved through a combination of study-specific audits of investigator sites and audits, at regular intervals, of SmithKline Beecham systems for data handling, reporting and archiving. Details of the selection of investigators for audit and the methods of performing and reporting the audits are documented in WRC SOPs.

A list of audited sites can be found in Appendix A.

3.14 Statistical Evaluation

The study center of Dr. cccccc ccccccc of xxx xxxxxxx xx who entered 14 patients (screened 17 patients), was terminated by the sponsor following an internal audit that detected significant compliance violations. These patients had completed participation in the study by the time the site was terminated. All 14 patients from this site were in the ITT population and 7 of these patients were in the PP population (see Section 15). As a conservative approach in analyzing the efficacy data, the primary outcome measure was analyzed with and without data generated from Dr. xxxxxxxs patients for both the ITT population as well as the PP population. Removal of Dr.xxxxxxxx patients from the database did not change the findings or the conclusions from the study. Therefore, results are presented in this Report including Dr. xxxxxxxpatients, except for Section 5.2.3, which presents the analyses of the primary outcome measure without these patients.

3.14.1 Target Sample Size

A total of 91 evaluable patients per treatment group was sufficient to detect a mean difference of 4 units between paroxetine and placebo in the change from baseline to LOCF endpoint in CY-BOCS total score. This was based on an estimated standard deviation of 8.25.[18] The mean difference was detectable with a power of 90%, given a significance level of 5% and using a two-sided significance test.

Assuming a 10% attrition rate between randomization and first post-dose assessment, it was necessary to randomize at least 204 patients (102 per treatment group) into the study.

3.14.2 Method of Randomization

A computer-generated randomization list, stratified by age subgroups 7 to 11 years (children)[4] and 12 to 17 years (adolescents), was used to balance assignment of patients to treatment groups in a 1:1 ratio of paroxetine to placebo. Each age subgroup was to account for at least 40% (and no more than 60%) of the total number randomized. Each center was initially allocated consecutively numbered treatment packs sufficient for 8 patients (4 in each age stratum). Treatment packs were allocated to patients in strict sequential order within the appropriate age stratum. Randomized patients were identified throughout the study by the randomization number allocated at the Baseline Visit.

The master randomization list was held by the sponsor. The randomization code is provided in Appendix A.

3.14.3 Planned Efficacy Evaluations

Primary inference was based on the last observation carried forward (LOCF) dataset at the Week 10 endpoint. Efficacy evaluations were collected for the following:

- Children's Yale-Brown Obsessive-Compulsive Scale (CY-BOCS) total score and Obsessions/Compulsions subscores at each visit except Weeks 1 and 3.
- Clinical Global Impression - Severity of Illness (CGI-S) at each visit except Screening.

[4] Six-year-olds were stratified in the subgroup of children.

- Clinical Global Impression - Global Improvement (CGI-I) at each visit except Screening and Baseline.

- Global Assessment of Functioning (GAF) at each visit except Screening, Week 1, and Week 3.

3.14.3.1 Primary Efficacy Variable

The primary measure of efficacy was the following:

- Change from Baseline in the Children's Yale-Brown Obsessive-Compulsive Scale (CY-BOCS) Total Score at Week 10 LOCF endpoint.

3.14.3.2 Secondary Efficacy Variables

The secondary measures of efficacy were the following:

- Proportion of Responders where Response was defined as a 25% (or greater) reduction on the Children's Yale-Brown Obsessive-Compulsive Scale (CY-BOCS) Total Score from Baseline to Week 10 LOCF endpoint.

- Proportion of Responders based on the Clinical Global Impressions (CGI) Global Improvement item. Response was defined as a score of 1 (very much improved) or 2 (much improved) at Week 10 LOCF endpoint.

- Change from Baseline in the Clinical Global Impressions (CGI) Severity of Illness item score at Week 10 LOCF endpoint.

- Change from Baseline on the Global Assessment of Functioning (GAF) Scale at Week 10 LOCF endpoint.

- Change from Baseline on the CY-BOCS Obsessions subscale score at Week 10 LOCF endpoint.

- Change from Baseline on the CY-BOCS compulsion subscale score at Week 10 LOCF endpoint.

3.14.4 Methods of Analysis

3.14.4.1 Comparisons of Interest

The primary comparison of interest was 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."

3.14.4.2 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% significance level.

The null hypothesis for this study was: There is no difference between paroxetine and placebo in the change from baseline of the CY-BOCS total score at the Week 10 LOCF endpoint in the ITT population.

The alternate hypothesis for this study was: There is a difference between paroxetine and placebo in the change from baseline of the CY-BOCS total score at the Week 10 LOCF endpoint in the ITT population.

3.14.4.3 Covariates for Adjustment in the Efficacy Analysis

The final model on which inference was based included terms for treatment group and each of the following candidate covariates:

- Age category of children (7-11 years) and adolescents (12-17 years.)
- Gender.
- Baseline efficacy score for each variable.
- Comorbidity category (Yes or No).

Individual centers were not considered in the analyses as it was anticipated that low numbers of patients would be recruited per center because of the nature of the population. Country grouping of centers was not considered because the study was conducted in the US and Canada only. Thus, a center/country term was not included in the model for any of the analyses.

3.14.4.4 Continuous Efficacy Variables

Continuous efficacy variables (e.g., change from Baseline on the CY-BOCS) were analyzed using parametric analysis of variance. The statistical model on which the primary inference was based included terms for each of the covariates specified above and treatment group.

Interactions between treatment and each of the covariates were investigated in turn, with all main effects in the model regardless of their statistical significance, in order to assess the robustness of the conclusions from the primary analysis. Any interaction terms found to be significant ($p \leq 0.10$) were to be explored and, where necessary, results were to be reported for each level of the covariate. Investigations of interactions were confined to the primary variable using the Week 10 LOCF dataset.

Results were presented as the mean, 95% confidence interval, and p-value for the difference between the treatment groups. The assumptions of normality and homogeneity of variance were assessed by inspection of normal probability plots, plots of standardized residuals versus predicted, and plots of standardized residuals versus continuous covariates. Observations with large residuals or that strongly influenced the fit of the model to the data were also 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 primary analysis.

3.14.4.5 Categorical Efficacy Variables

Categorical efficacy variables (e.g., proportion of patients scoring 1 or 2 on the CGI Global Improvement scale) were analyzed using logistic regression. As for the continuous efficacy variables, the statistical model on which inference was based included terms for each of the covariates specified above and treatment group.

For each treatment group, there is an odds of a patient being classed as a responder. Therefore, 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, and 95% confidence intervals and p-values for the odds ratios were provided.

Plots of standardized deviance residuals against continuous covariates were examined to check for linearity of the relationship on the logistic scale. 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 Severity of Illness 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 covariates, although the analysis was presented separately for each age group due to prior belief that this would be an important covariate (stratification factor).

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

3.14.5 Populations/Data Sets to be Evaluated

Two patient populations were evaluated; primary inferences were based on the intention-to-treat (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.

Any patients who were randomized but had no post-dose assessment or AE were listed under their randomized group but not tabulated (either as Screening only or ITT).

Intention-to-Treat (ITT) Population

The ITT population was 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 AE) was available. The primary inferences concerning the efficacy of paroxetine were made using the ITT population.

Per Protocol (PP) Population

The PP population consisted of all patients who were included in the ITT population who also met the following criteria:

- no major protocol violation existing with regard to inclusion or exclusion criteria.

- no major protocol violation during the course of the Treatment Phase.

- no break in study medication lasting for more than 3 consecutive days during the Treatment Phase (as recorded by the investigator).

- exposure to a minimum duration of 2 weeks of randomized study medication.

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

For both of the defined populations, primary inference was based on the LOCF dataset at the protocol-defined Week 10 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 were the LOCF dataset at the latest timepoint where at least 70% of the patients in each treatment group remained in the study (70% LOCF) and an Observed Cases (OC) dataset at the Week 10 endpoint. A decision on whether to analyze these datasets was 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 OC and LOCF datasets.

3.14.6 Safety Evaluations

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

3.14.6.1 Adverse Events

Adverse events were coded using the WHO coding system for each patient, which was mapped to the ADECS (COSTART-based) classification to produce a body system and preferred term.

The numbers (%) of patients in each treatment group with Treatment Phase-emergent AEs were compared both for overall incidence and by body system and preferred term. Tables of AEs are presented for the Pre-treatment, Treatment, Taper and Follow-up Phases.

Numbers and percentages are also presented for patients with AEs by severity and AEs by relationship to study medication during all post-randomization phases of the study, for patients with AEs leading to withdrawal during the Treatment Phase, and for patients with SAEs at any time up to 30 days after the last dose of study medication. Listings of AEs that occurred after the 14-day Follow-up Visit are presented.

AEs were summarized into four phases:

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

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

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

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

Definition of Emergent AEs:

Adverse events were categorized as emergent according to ICH E9 guidelines, which give the following definition of a Treatment Phase-emergent AE: "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 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).

3.14.6.2 Other Clinical Safety Evaluations

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

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 Section 6.8, Vital Signs.

Electrocardiograms were performed at Screening and at Week 10 (or Early Withdrawal), and assessments at both timepoints are presented. ECGs were repeated at Baseline, Taper End, and/or Follow-up if results at the previous visit were clinically significantly abnormal.

Laboratory data (hematology, blood chemistry and urinalysis) were evaluated by tabulating the number (%) of patients in each treatment group with values outside normal and potential clinical concern ranges. Sponsor-defined criteria for clinical concern values may be found in Section 6.9.1. 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.

3.14.7 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 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 91
Post-Week 10	—	Greater than 91 days

* Day 1 is included as Baseline (Visit 2) if data are recorded before study medication is taken; however, Day 1 is included as Week 1 (Visit 3) if data are recorded after study medication is taken.

Screening (Visit 1) data are all data that were collected on the Screening page of the CRF, providing they were 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 CRF, providing they were prior to the first dose of study medication.

Data recorded at specific visits only were slotted according to the intervals given above. All data were listed, but only data slotted into intervals corresponding to the protocol-defined assessment time were tabulated. For example, only GAF assessments that fell into baseline and Week 2, 4, 6, 8 and 10 intervals were tabulated. However, assessments slotted at unscheduled visits contributed to the LOCF analysis if they were the last on-treatment assessment.

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.

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 the last dose of randomized medication if the patient did not enter the Taper Phase, were excluded from the summary tables and analyses. However, all efficacy and safety data were provided in the patient data listings. Efficacy data slotted as post-Week 10 did not contribute to the LOCF analyses.

3.14.8 Phases of the Study

3.14.8.1 Pre-Treatment Phase

The pre-Treatment Phase was defined as the period of time prior to the first dose of study medication. This, 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.

3.14.8.2 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.

3.14.8.3 Taper Phase

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

3.14.8.4 Follow-up Phase

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

3.14.9 Interim Analysis

No interim analysis was planned or conducted for this study.

3.14.10 Data Irregularities

Three patients were stratified to the wrong age groups by investigators. According to the protocol definitions, children were patients aged 7 to 11 years inclusive and adolescents were patients aged 12 to 17 years inclusive at their last birthday. Two children in the placebo group (704.002.25443, an 11-year-old male, and 704.014.25352, an 8-year-old female) were stratified as adolescents. Patient 704.005.25407, a 14-year-old male in the paroxetine group, was stratified as a child. Data for these patients have been reported and analyzed in their appropriate age group rather than in the group to which they were stratified.

Patients 704.027.27089 and 704.055.28174 in the paroxetine group and 704.020.27030 in the placebo group completed the Week 10 visit CRF, but because the visit occurred less than 64 days after the first dose of study medication, the completions were slotted to Week 8. Patients 704.020.27030 and 704.027.27089 have no efficacy data included in the Week 10 OC dataset. A GAF assessment for Patient 704.055.28174 is included in the Week 10 OC dataset because it was completed within 7 days of the last dose of randomized medication, before the start of taper medication, and fell within the Week 10 visit window.

Patient 704.025.27059 in the placebo group completed the Week 10 visit CRF more than 91 days after the first dose of study medication and was slotted as completing post-Week 10.

4 Study Population

4.1 Study Dates

The first dose of double-blind study medication was taken on 20 January 2000 and the last dose of study medication (including Taper) was taken on 3 July 2001 (Listing 13.13.1, Appendix B). The last study visit for the last patient to complete participation occurred on 3 July 2001 (Listing 15.2.1, Appendix E).

4.2 Patient Disposition

4.2.1 Number and Distribution of Patients

A total of 265 patients completed the Screening Visit and 207 were randomized to double-blind treatment.[5] Among the 58 patients not randomized (25 adolescents [43.1%] and 33 children [56.9%]), the primary reason for pre-randomization withdrawal was failure to meet inclusion/exclusion criteria (Table 13.3.1a, Section 11). Reasons for all pre-randomization withdrawals are shown in Table 6, which provides data for both age groups combined.

Table 6 Number (%) of Patients Who Were Withdrawn Pre-randomization by the Reason for Withdrawal - Age Group: Total (Screening-only Population)

Total Withdrawn	**58 (100.0)**	
Reason for Pre-randomization Withdrawal	n	(%)
Baseline AE	1	(1.7)
Did not meet inclusion/exclusion criteria	36	(62.1)
Protocol deviation	0	
Lost to Follow-up	5	(8.6)
Other *	16	(27.6)

* 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 207 patients were randomized to treatment, 118 children (57%) and 89 adolescents (43%) (Table 13.1.1, Section 11). The numbers of patients in each treatment group and in each age subgroup are presented in Table 7.

[5] Appendix A contains the randomization code.

Four patients who were randomized are not included in the ITT population (Listing 13.1.1, Appendix B). One patient (704.020.27188) randomized to the paroxetine group and two patients (704.019.25385 and 704.041.27104) randomized to the placebo group had no post-baseline assessments. One patient (704.052.27197) randomized to paroxetine never received a dose of study medication.

The ITT population, therefore, consisted of a total of 203 patients (98 paroxetine patients and 105 placebo patients). 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 2 weeks of randomized study medication (see Section 4.3, Protocol Violations). The PP population consisted of 73 paroxetine patients and 82 placebo patients.

Overall, of all patients randomized, more patients in the placebo group (80/107, 74.8%) completed the study than in the paroxetine group (65/100, 65.0%). However, the results in this regard differed in the two age subgroups. Among children, more placebo patients completed the study (48/58, 82.8%, placebo; 36/60, 60.0%, paroxetine), whereas among adolescents, more paroxetine patients completed the study (29/40, 72.5%, paroxetine; 32/49, 65.3%, placebo).

Table 7 Number (%) of Patients by Population–Age Group: Total/Children/Adolescents (All Randomized)

Number of Patients, n (%)	Paroxetine	Placebo	Total
Age Group: Total	(N = 100)	(N = 107)	(N = 265)
Screened only	—	—	58
Randomized	100* (100.0)	107* (100.0)	207 (100.0)
Completed Study	65 (65.0)	80 (74.8)	145 (70.0)
Early Withdrawal	35 (35.0)	27 (25.2)	62 (30.0)
Intention-to-treat Population	98 (98.0)	105 (98.1)	203 (98.1)
Per Protocol Population	73 (73.0)	82 (76.6)	155 (74.9)
Entered Study 29060/716**	46 (46.0)	62 (57.9)	108 (52.2)
Age Group: Children	(N = 60)	(N = 58)	(N = 151)
Screened only	—	—	33
Randomized	60 (100.0)	58 (100.0)	118 (100.0)
Completed Study	36 (60.0)	48 (82.8)	84 (71.2)
Early Withdrawal	24 (40.0)	10 (17.2)	34 (28.8)
Intention-to-treat Population	58 (96.7)	57 (98.3)	115 (97.5)
Per Protocol Population	40 (66.7)	45 (77.6)	85 (72.0)
Entered Study 29060/716**	24 (40.0)	34 (58.6)	58 (49.2)
Age Group: Adolescents	(N = 40)	(N = 49)	(N = 114)
Screened only	—	—	25
Randomized	40 (100.0)	49 (100.0)	89 (100.0)
Completed Study	29 (72.5)	32 (65.3)	61 (68.5)
Early Withdrawal	11 (27.5)	17 (34.7)	28 (31.5)
Intention-to-treat Population	40 (100.0)	48 (98.0)	88 (98.9)
Per Protocol Population	33 (82.5)	37 (75.5)	70 (78.7)
Entered Study 29060/716**	22 (55.0)	28 (57.1)	50 (56.2)

*Paroxetine group includes 1 patient who was randomized but had no post-baseline assessments and 1 who did not receive study medication. Placebo group includes 2 patients who were randomized but withdrew before any post-baseline assessment was obtained. Denominator for percentages is the number of patients randomized.
**Information available at the time of this Report.
Source: Table 13.1.1, Section 11; Listings 13.1.1, 13.3.1a, 13.3.1b, Appendix B.

The study was conducted in 37 centers in the US (3 of which screened, but did not randomize any patients) and 2 centers in Canada. Table 8 presents the number of patients randomized and completed by center. Investigator name(s) at each center and affiliation may be found in Table 1, Section 3.2, Investigators.

The number of patients enrolled per center ranged from a single patient at 9 centers to 20 patients at Center 025. A total of 10 centers each randomized at least 8 patients.

Table 8 Number (%) of Patients Randomized and Completed by Center - Age Group: Total (ITT Population)

	Treatment Group								Total			
	Paroxetine (N=98)				Placebo (N=105)				(N=203)			
Center No.	Randomized		Completed*		Randomized		Completed*		Randomized		Completed*	
002	3	(3.1)	1	(1.0)	2	(1.9)	2	(1.9)	5	(2.5)	3	(1.5)
004	4	(4.1)	4	(4.1)	4	(3.8)	3	(2.9)	8	(3.9)	7	(3.4)
005	6	(6.1)	4	(4.1)	4	(3.8)	3	(2.9)	10	(4.9)	7	(3.4)
006	4	(4.1)	4	(4.1)	3	(2.9)	2	(1.9)	7	(3.4)	6	(3.0)
008	4	(4.1)	4	(4.1)	3	(2.9)	2	(1.9)	7	(3.4)	6	(3.0)
009	2	(2.0)	1	(1.0)	1	(1.0)	1	(1.0)	3	(1.5)	2	(1.0)
010	5	(5.1)	2	(2.0)	4	(3.8)	3	(2.9)	9	(4.4)	5	(2.5)
012	1	(1.0)	1	(1.0)	0		0		1	(0.5)	1	(0.5)
013	0		0		1	(1.0)	0		1	(0.5)	0	
014	3	(3.1)	2	(2.0)	3	(2.9)	3	(2.9)	6	(3.0)	5	(2.5)
015	5	(5.1)	3	(3.1)	5	(4.8)	3	(2.9)	10	(4.9)	6	(3.0)
016	8	(8.2)	5	(5.1)	9	(8.6)	8	(7.6)	17	(8.4)	13	(6.4)
017	1	(1.0)	1	(1.0)	0		0		1	(0.5)	1	(0.5)
019	4	(4.1)	2	(2.0)	4	(3.8)	3	(2.9)	8	(3.9)	5	(2.5)
020	7	(7.1)	5	(5.1)	8	(7.6)	6	(5.7)	15	(7.4)	11	(5.4)
021	0		0		1	(1.0)	0		1	(0.5)	0	
022	0		0		1	(1.0)	1	(1.0)	1	(0.5)	1	(0.5)
025	10	(10.2)	4	(4.1)	10	(9.5)	7	(6.7)	20	(9.9)	11	(5.4)
026	1	(1.0)	1	(1.0)	2	(1.9)	1	(1.0)	3	(1.5)	2	(1.0)
027	3	(3.1)	3	(3.1)	2	(1.9)	2	(1.9)	5	(2.5)	5	(2.5)
028	1	(1.0)	1	(1.0)	2	(1.9)	2	(1.9)	3	(1.5)	3	(1.5)
029	4	(4.1)	2	(2.0)	3	(2.9)	2	(1.9)	7	(3.4)	4	(2.0)
031	1	(1.0)	1	(1.0)	3	(2.9)	3	(2.9)	4	(2.0)	4	(2.0)
033	1	(1.0)	0		3	(2.9)	3	(2.9)	4	(2.0)	3	(1.5)
040	1	(1.0)	1	(1.0)	3	(2.9)	2	(1.9)	4	(2.0)	3	(1.5)
041	0		0		1	(1.0)	0		1	(0.5)	0	
043	1	(1.0)	1	(1.0)	0		0		1	(0.5)	1	(0.5)
044	0		0		2	(1.9)	2	(1.9)	2	(1.0)	2	(1.0)
047	1	(1.0)	1	(1.0)	2	(1.9)	2	(1.9)	3	(1.5)	3	(1.5)
048	5	(5.1)	4	(4.1)	4	(3.8)	4	(3.8)	9	(4.4)	8	(3.9)
049	2	(2.0)	2	(2.0)	3	(2.9)	3	(2.9)	5	(2.5)	5	(2.5)
051	2	(2.0)	0		0		0		2	(1.0)	0	

* A patient was considered to have completed the study if the Week 10 Visit was completed. Two paroxetine patients and 1 placebo patient were considered completers at the Week 8 visit and 1 placebo patient was considered a completer post-Week 10. See Section 3.14.10, Data Irregularities.

Source: Table 13.4.1, Section 11; Listing 13.3.1b, Appendix B

(*Continued)*

Table 8 Number (%) of Patients Randomized and Completed by Center - Age Group: Total (ITT Population) (Continued)

	Treatment Group								Total			
	Paroxetine (N=98)				Placebo (N=105)				(N=203)			
Center No.	Randomized		Completed*		Randomized		Completed*		Randomized		Completed*	
052	1	(1.0)	0		3	(2.9)	1	(1.0)	4	(2.0)	1	(0.5)
053	0		0		1	(1.0)	0		1	(0.5)	0	
055	7	(7.1)	5	(5.1)	7	(6.7)	5	(4.8)	14	(6.9)	10	(4.9)
056	0		0		1	(1.0)	1	(1.0)	1	(0.5)	1	(0.5)

* A patient was considered to have completed the study if the Week 10 Visit was completed. Two paroxetine patients and 1 placebo patient were considered completers at the Week 8 visit and 1 placebo patient was considered a completer post-Week 10. See Section 3.14.10 , Data Irregularities.
Source: Table 13.4.1, Section 11; Listing 13.3.1b, Appendix B

The number of patients enrolled per country may be found in Table 13.1.2, Section 11.

4.2.2 Number of Patients Present at Each Visit

Table 9 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 on the numbers of patients in the ITT population. A total of 145/203 patients (71.4%) completed the study (i.e., completed the Week 10 visit measurements: 141 patients at Week 10, 3 patients at Week 8, and 1 patient post Week 10). The percentage of patients who completed the study was lower for the paroxetine group (66.3%, 65/98 patients: 63 patients at Week 10 and 2 patients at Week 8) than for the placebo group (76.2%, 80/105 patients: 78 patients at Week 10, 1 patient at Week 8, and 1 patient post Week 10).

A slightly higher percentage of patients withdrew from the study at Week 6 (9.7% total, 13.3% paroxetine, 6.5% placebo) than at other weeks during the study (Table 13.3.2, Section 11; Listing 13.3.1b, Appendix B).

Table 9 Number (%) of Patients Remaining in the Study at Each Visit–Age Group: Total (ITT Population)

Visit	Paroxetine (N=98)		Placebo (N=105)		Total (N=203)	
	n	(%)	n	(%)	n	(%)
Baseline	98	(100.0)	105	(100.0)	203	(100.0)
Week 1	95	(96.9)	101	(96.2)	196	(96.6)
Week 2	92	(93.9)	98	(93.3)	190	(93.6)
Week 3	88	(89.8)	96	(91.4)	184	(90.6)
Week 4	83	(84.7)	92	(87.6)	175	(86.2)
Week 6	72	(73.5)	86	(81.9)	158	(77.8)
Week 8*	69	(70.4)	81	(77.1)	150	(73.9)
Week 10**	63	(64.3)	78	(74.3)	141	(69.5)

Note: Percentages for patients still in the study at each visit are based on the total number of patients at Baseline.
*Three patients (2 paroxetine, 1 placebo) completed the study at the Week 10 visit, but the completions were slotted to Week 8 because of visit windows (Section 3.14.7). These 3 patients are included in this table as remaining in the study at Week 8. See Section 3.14.10, Data Irregularities.
** These numbers represent patients who completed the study at the Week 10 visit window and do not include 2 paroxetine patients and 1 placebo patient who completed at the Week 8 visit window and 1 placebo patient who completed in the post-Week 10 window. See Section 3.14.10, Data Irregularities.
Source: Tables 13.3.2, Section 11; Listing 13.3.1b, Appendix B.

4.2.3 Withdrawal Reasons

Table 10 presents a summary of the number and percentage of patients not completing the study and the reason for withdrawal. A total of 28.6% (58/203) of patients were withdrawn during the Treatment Phase. Overall, the percentage of patients who were withdrawn prematurely was higher in the paroxetine group (33.7%, 33/98) than in the placebo group (23.8%, 25/105). The primary reason for withdrawal in the paroxetine group was AE (10.2%, 10/98 compared with 2.9%, 3/105 in the placebo group). In the placebo group, the primary reason for withdrawal was lack of efficacy (13.3%, 14/105, compared with 5.1%, 5/98, in the paroxetine group).

The overall withdrawal rates were similar for children (31/115, 27.0%) and adolescents (27/88, 30.7%). However, among children, more than twice as many paroxetine-treated patients were withdrawn (22/58, 37.9%) than placebo patients (9/57, 15.8%). The primary reason for withdrawal in the paroxetine group among children was AE (8/58, 13.8%, compared with 1/57, 1.8% in the placebo group). Contrary to the findings in the children subgroup, among adolescents, more

placebo patients were withdrawn (16/48, 33.3%) than paroxetine-treated patients (11/40, 27.5%). The primary reason for withdrawal in the placebo group among adolescents was lack of efficacy (10/48, 20.8%, compared with 2/40, 5.0%, in the paroxetine group). Among adolescents in the paroxetine group, protocol deviation (4/40, 10.0%, compared with 2/48, 4.2% in the placebo group) was the most frequent reason leading to withdrawal.

Table 10 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 = 98) n (%)	**Placebo** (N = 105) n (%)	**Total** (N = 203) n (%)	**Paroxetine** (N = 58) n (%)	**Placebo** (N = 57) n (%)	**Paroxetine** (N = 40) n (%)	**Placebo** (N = 48) n (%)
Adverse Event	10 (10.2)	3 (2.9)	13 (6.4)	8 (13.8)	1 (1.8)	2 (5.0)	2 (4.2)
Lack of efficacy	5 (5.1)	14 (13.3)	19 (9.4)	3 (5.2)	4 (7.0)	2 (5.0)	10 (20.8)
Protocol deviation (including non-compliance)	5 (5.1)	3 (2.9)	8 (3.9)	1 (1.7)	1 (1.8)	4 (10.0)	2 (4.2)
Lost to Follow-up	6 (6.1)	3 (2.9)	9 (4.4)	5 (8.6)	2 (3.5)	1 (2.5)	1 (2.1)
Other *	7 (7.1)	2 (1.9)	9 (4.4)	5 (8.6)	1 (1.8)	2 (5.0)	1 (2.1)
Total withdrawn	33 (33.7)	25 (23.8)	58 (28.6)	22 (37.9)	9 (15.8)	11 (27.5)	16 (33.3)
Completed study **	65 (66.3)	80 (76.2)	145 (71.4)	36 (62.1)	48 (84.2)	29 (72.5)	32 (66.7)

* Includes non-study-related personal reasons: family decided not to start medication, although it was dispensed (1 patient); patient required excluded medication (1 patient); withdrew consent (3 patients); patient sexually molested (1 patient); wrong medication dispensed (1 patient); patient did not wish to continue (1 patient); mother took patient off study, seeking other treatment (1 patient).

** Patients were considered to have completed the study if they completed the Week 10 visit. The total of 145 completers includes 3 patients who completed at Week 8 and 1 patient who completed post-Week 10.

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

Table 11 presents a cumulative summary of patients withdrawing from the study by visit and reason for withdrawal for both age groups combined, as well as for children and adolescents. The greatest percentage of withdrawals occurred at Week 6 overall; however, approximately half of the patients who withdrew did so before or at Week 4. The predominant reason for withdrawal at Week 6 was "Other" (protocol deviation [including non-compliance], lost to follow-up, and non-study related personal reasons) for the paroxetine group and "Lack of Efficacy" for the placebo group. The pattern of withdrawals was similar in all of the subpopulations.

In the paroxetine group, 7 of the 10 patients who were withdrawn due to AE were withdrawn before or at Week 4. This included 5 of the 8 children withdrawn due to AE. Two of the 3 patients in the placebo group who were withdrawn due to AE were withdrawn before or at Week 1.

Withdrawals by reason for withdrawal for children and adolescents in the PP population may be found in Table 13.3.1c, Section 11, and Listing 13.3.1b, Appendix B.

Table 11 Cumulative Number (%) of Patients Withdrawn During the Study by Reason for Withdrawal and by Visit–Age Group: Total/Children/Adolescents (ITT Population)

Visit	Treatment Group: Paroxetine AE n (%)	Paroxetine LOE n (%)	Paroxetine Other* n (%)	Paroxetine Total n (%)	Placebo AE n (%)	Placebo LOE n (%)	Placebo Other* n (%)	Placebo Total n (%)	Total n (%)
Total				(N = 98)				(N = 105)	(N = 203)
Week 1	1 (1.0)	0	2 (2.0)	3 (3.1)	2 (1.9)	0	2 (1.9)	4 (3.8)	7 (3.4)
Week 2	2 (2.0)	1 (1.0)	3 (3.1)	6 (6.1)	2 (1.9)	2 (1.9)	3 (2.9)	7 (6.7)	13 (6.4)
Week 3	4 (4.1)	1 (1.0)	5 (5.1)	10 (10.2)	2 (1.9)	4 (3.8)	3 (2.9)	9 (8.6)	19 (9.4)
Week 4	7 (7.1)	1 (1.0)	7 (7.1)	15 (15.3)	2(1.9)	5 (4.8)	6 (5.7)	13 (12.4)	28 (13.8)
Week 6	9 (9.2)	3 (3.1)	14 (14.3)	26 (26.5)	3 (2.9)	9 (8.6)	7 (6.7)	19 (18.1)	45 (22.2)
Week 8	9 (9.2)	4 (4.1)	16 (16.3)	29 (29.6)	3 (2.9)	13 (12.4)	8 (7.6)	24 (22.9)	53 (26.1)
Week 10	10 (10.2)	5 (5.1)	18 (18.4)	33 (33.7)	3 (2.9)	14 (13.3)	8 (7.6)	25 (23.8)	58 (28.6)
Children				(N = 58)				(N = 57)	(N = 115)
Week 1	1 (1.7)	0	2 (3.4)	3 (5.2)	1 (1.8)	0	1 (1.8)	2 (3.5)	5 (4.3)
Week 2	1 (1.7)	1 (1.7)	3 (5.2)	5 (8.6)	1 (1.8)	0	2 (3.5)	3 (5.3)	8 (7.0)
Week 3	3 (5.2)	1 (1.7)	3 (5.2)	7 (12.1)	1 (1.8)	0	2 (3.5)	3 (5.3)	10 (8.7)
Week 4	5 (8.6)	1 (1.7)	4 (6.9)	10 (17.2)	1 (1.8)	0	4 (7.0)	5 (8.8)	15 (13.0)
Week 6	7 (12.1)	2 (3.4)	8 (13.8)	17 (29.3)	1 (1.8)	2 (3.5)	4 (7.0)	7 (12.3)	24 (20.9)
Week 8	7 (12.1)	3 (5.2)	9 (15.5)	19 (32.8)	1 (1.8)	4 (7.0)	4 (7.0)	9 (15.8)	28 (24.3)
Week 10	8 (13.8)	3 (5.2)	11 (19.0)	22 (37.9)	1 (1.8)	4 (7.0)	4 (7.0)	9 (15.8)	31 (27.0)

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

(Continued)

Table 11 Cumulative Number (%) of Patients Withdrawn During the Study by Reason for Withdrawal and by Visit–Age Group: Total/Children/Adolescents (ITT Population) (Continued)

Visit	Treatment Group: Paroxetine AE n (%)	Paroxetine LOE n (%)	Paroxetine Other* n (%)	Paroxetine Total n (%)	Placebo AE n (%)	Placebo LOE n (%)	Placebo Other* n (%)	Placebo Total n (%)	Total n (%)
Adolescents				(N =40)				(N = 48)	(N = 88)
Week 1	0	0	0	0	1 (2.1)	0	1 (2.1)	2 (4.2)	2 (2.3)
Week 2	1 (2.5)	0	0	1 (2.5)	1 (2.1)	2 (4.2)	1 (2.1)	4 (8.3)	5 (5.7)
Week 3	1 (2.5)	0	2 (5.0)	3 (7.5)	1 (2.1)	4 (8.3)	1 (2.1)	6 (12.5)	9 (10.2
Week 4	2 (5.0)	0	3 (7.5)	5 (12.5)	1 (2.1)	5 (10.4)	2 (4.2)	8 (16.7)	13 (14.8)
Week 6	2 (5.0)	1 (2.5)	6 (15.0)	9 (22.5)	2 (4.2)	7 (14.6)	3 (6.3)	12 (25.0)	21 (23.9)
Week 8	2 (5.0)	1 (2.5)	7 (17.5)	10 (25.0)	2 (4.2)	9 (18.8)	4 (8.3)	15 (31.3)	25 (28.4)
Week 10	2 (5.0)	2 (5.0)	7 (17.5)	11 (27.5)	2 (4.2)	10 (20.8)	4 (8.3)	16 (33.3)	27 (30.7)

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 variation from the protocol-defined inclusion/exclusion criteria or conduct of the study that could potentially impact treatment efficacy. All randomized patients 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 12 summarizes the number (%) of patients excluded from the PP population 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 48/203 (23.6%). The percentage of major protocol violators was slightly higher in the paroxetine group (25/98, 25.5%) than in the placebo group (23/105, 21.9%). More children (30/115, 26.1%) were major protocol violators than adolescents (18/88, 20.5%). The most frequent violation in the overall population, in the total paroxetine group and in both paroxetine age subgroups, especially adolescents, was missing more than 3 consecutive days of study medication. In the placebo group overall and in both placebo age subgroups, the most frequent violations were taking or having taken psychoactive medications and missing more than 3 consecutive days of study medication.

Two additional patients in the placebo group (704.055.28171 and 704.055.28190) should have been excluded from the per-protocol population because of significant compliance violations found by CRF review and audit of Center 055 (see Section 15). It was concluded that inclusion of these 2 patients in the per-protocol population did not affect the overall conclusion of the primary efficacy analysis since an additional analysis showed that removal of all Center 055 patients from the per-protocol population had no effect on the overall conclusion (see Section 5.2.3).

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

- **Patient was taking or took a psychoactive medication.** Seventeen patients, 6 in the paroxetine group and 11 in the placebo group, were so identified before unblinding (Listing 13.2.1, Appendix B). Two additional patients who were taking or took a psychoactive medication were not considered protocol violators: Patient 704.004.25403 was screened on Day 14 of washout from

psychoactive medication, and Patient 704.049.28148 was screened on Day 18 of washout from psychoactive medication (Listing PV 1, Appendix B). These washout periods were considered adequate.

- **Patient had a positive urine drug screen.** Three placebo patients were so identified before unblinding. One of these patients, 704.005.27055, had a questionable initial drug screen; a repeat test was negative and the patient was not considered a protocol violator (Listings PV 1 and 9, Appendix B and Listing 15.3.1, Appendix F).

- **Patient required more than 1 dose reduction.** Two patients in the paroxetine group were so identified before unblinding (Listing PV 14, Appendix B). For 1 additional patient, 704.006.25421 in the placebo group, the dose was reduced 2 levels at 1 visit as the result of an AE, and this patient was also considered a protocol violator (Listings 13.2.1 and 13.13.1, Appendix B and Listing 15.1.1, Appendix D).

- **Patient missed more than 3 consecutive days of study medication as recorded by the investigator.** Twenty-five patients were so identified before unblinding, 15 in the paroxetine group and 10 in the placebo group. None 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 13.13.1, Appendix B; Listing PV15, Appendix B).

- **Patient took less than 2 weeks of study medication.** Four patients in each treatment group were so identified before unblinding (Listing PV16, Appendix B).

- **Patient did not have current or past and current history of Obsessive-Compulsive Disorder recorded on the K-SADS-PL.** Two patients in the placebo group were so identified before unblinding (Listing PV3, Appendix B). These patients were not considered protocol violators because documentation was provided by the investigators to reflect that both patients had past and current history of OCD.

- **Patient had an OCD duration of less than 2 months.** One patient in the placebo group was so identified before unblinding (Listing PV4, Appendix B). The sponsor did not consider the patient (704.028.27080) a protocol violator and allowed the patient to enter the study with a duration of OCD of 1.6 months. However, the patient was excluded from the PP population due to taking psychoactive medication.

- **Patient had a psychotic, bipolar, schizophrenic or other psychiatric disorder.** One patient in the paroxetine group was so identified before unblinding (Listing PV7, Appendix B). The patient had cannabis-induced hallucinations. This substance abuse psychosis was not considered the same as a psychotic episode, therefore, the patient was not considered a protocol violator.

No randomized patient had any other violation resulting in exclusion from the PP analysis (Listings PV2, PV5, PV6, PV8, PV10, PV11, PV12, and PV13, Appendix B).

Table 12 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 = 98)	**Placebo** (N = 105)	**Paroxetine** (N = 58)	**Placebo** (N = 57)	**Paroxetine** (N = 40)	**Placebo** (N = 48)
Total number of patients excluded*	25 (25.5)	23 (21.9)	18 (31.0)	12 (21.1)	7 (17.5)	11 (22.9)
Patient taking or took psychoactive medications	6 (6.1)	11 (10.5)	5 (8.6)	6 (10.5)	1 (2.5)	5 (10.4)
Illicit drug use – urine drug screening	0	2 (1.9)	0	1 (1.8)	0	1 (2.1)
Patient required >1 dosage reduction	2 (2.0)	1 (1.0)	2 (3.4)	0	0	1 (2.1)
Patient missed more > 3 consecutive days study medication	15 (15.3)	10 (9.5)	8 (13.8)	5 (8.8)	7 (17.5)	5 (10.4)
Patient took < 2 weeks study medication	4 (4.1)	4 (3.8)	4 (6.9)	2 (3.5)	0	2 (4.2)
Total number of patients with no protocol violations	73 (74.5)	82 (78.1)	40 (69.0)	45 (78.9)	33 (82.5)	37 (77.1)

* A patient could have more than one protocol violation leading to exclusion.
Source: Table 13.2.1, Section 11; Listing 13.2.1, Appendix B

4.3.2 Protocol Deviations Included in the Per Protocol Analysis

Table 13.2.2, Section 11, presents a summary of the number and percentage of patients with protocol deviations only, included in the per protocol analysis. Deviations are failures of criteria that are not considered to adversely affect the efficacy evaluation. Only one patient (704.005.27055, a 14-year-old male in the placebo group) was considered to have a protocol deviation, specifically that he was not considered medically healthy by the investigator.

4.4 Demographic and Baseline Characteristics

4.4.1 Demographic Characteristics

The demographic characteristics of the overall ITT population are summarized in Table 13. Table 14 summarizes the demographic data by age subgroup. More than 57% of the patients in the overall population and in each age subgroup were males. There was no marked imbalance between the treatment groups in any demographic characteristics, although the percentage of males in the placebo group (61.0%, 64/105) was slightly higher than in the paroxetine group (54.1%, 53/98). The same pattern was observed in the child and adolescent subgroups. Also, the percentage of patients with comorbid psychiatric illnesses was greater in the placebo group (40.0%, 42/105) than in the paroxetine group (30.6%, 30/98).

Mean ages of children in both treatment subgroups were similar (8.9 years and 9.2 years in the paroxetine and placebo groups, respectively), as were mean ages of adolescents (14.2 years and 14.3 years in the paroxetine and placebo groups, respectively), with an overall mean pediatric age of 11.3 years (SD 3.00). Overall, 88.2% of the patients (179/203) were white. "Other" race included 7 Hispanic patients and 1 mixed Hispanic and white; 1 mixed black and white; 1 biracial; 2 American Indian; 1 Indian; and 1 mixed Iranian and Cherokee. Mean height, weight, and body mass index (BMI) of children were similar in both treatment groups, as were mean height, weight, and BMI of adolescents.

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

Table 13 Demographic Characteristics–Age Group: Total (ITT Population)

Demographic Characteristics	Paroxetine (N = 98)	Placebo (N = 105)	Total (N = 203)
Gender n (%)			
Male	53 (54.1)	64 (61.0)	117 (57.6)
Female	45 (45.9)	41 (39.0)	86 (42.4)
Age (yrs)			
Mean (SD)	11.1 (3.03)	11.6 (2.97)	11.3 (3.00)
Range*	6-17	6-17	6-17
Race n (%)			
White	85 (86.7)	94 (89.5)	179 (88.2)
Black	8 (8.2)	5 (4.8)	13 (6.4)
Oriental	0	0	0
Other **	5 (5.1)	6 (5.7)	11 (5.4)
Height (cm)†			
Mean (SD)	148.0 (18.74)	150.5 (17.47)	149.3 (18.10)
Range	106.6-188.0	106.6-192.0	106.6-192.0
Weight (kg)†,††			
Mean (SD)	46.3 (20.52)	48.9 (19.51)	47.7 (20.00)
Range	18.6-110.9	19.0-104.0	18.6-110.9
BMI (kg/m^2)†			
Mean (SD)	20.2 (5.29)	20.9 (5.32)	20.5 (5.31)
Range	13.0-41.9	13.7-40.1	13.0-41.9
Psychiatric Comorbidity			
yes:no; % yes	30:68; 30.6%	42:63; 40.0%	72:131; 35.5%

*Two patients under 7 years old, 704.016.27018 (paroxetine) and 704.025.27036 (placebo), were enrolled; both were more than 6 years and 6 months old at study entry.
**Other race includes 7 Hispanic patients and 1 mixed Hispanic and white; 1 mixed black and white; 1 biracial; 2 American Indian; 1 Indian; and 1 mixed Iranian and Cherokee.
†Values for height, weight and body mass index (BMI) are missing for 1 patient.
††Weight measured in pounds was converted to kilograms using the conversion 1 lb. = 0.454 kg.
Source: Tables 13.5.1b, 13.5.2b, Section 11; Listing 13.5.1, Appendix B; Listing 15.2.1, Appendix E; Statistical Appendix, Appendix H

Table 14 Demographic Characteristics–Age Group: Children/Adolescents (ITT Population)

	Age Group: Children			Age Group: Adolescents		
Demographic Characteristics	**Paroxetine (N = 58)**	**Placebo (N = 57)**	**Total (N = 115)**	**Paroxetine (N = 40)**	**Placebo (N = 48)**	**Total (N = 88)**
Gender n (%)						
Male	31 (53.4)	35 (61.4)	66 (57.4)	22 (55.0)	29 (60.4)	51 (58.0)
Female	27 (46.6)	22 (38.6)	49 (42.6)	18 (45.0)	19 (39.6)	37 (42.0)
Age (yrs)						
Mean (SD)	8.9 (1.47)	9.2 (1.51)	9.1 (1.49)	14.2 (1.67)	14.3 (1.59)	14.3 (1.62)
Range	6-11	6-11	6-11	12-17	12-17	12-17
Race n (%)						
White	49 (84.5)	51 (89.5)	100 (87.0)	36 (90.0)	43 (89.6)	79 (89.8)
Black	6 (10.3)	4 (7.0)	10 (8.7)	2 (5.0)	1 (2.1)	3 (3.4)
Oriental	0	0	0	0	0	0
Other *	3 (5.2)	2 (3.5)	5 (4.3)	2 (5.0)	4 (8.3)	6 (6.8)
Height (cm)**						
Mean (SD)	136.4 (12.53)	138.1 (10.80)	137.2 (11.68)	164.7 (12.59)	165.7 (10.70)	165.2 (11.55)
Range	106.6-161.3	106.6-161.0	106.6-161.3	135.9-188.0	127.0-192.0	127.0-192.0

* Other race includes 6 Hispanic patients; 1 mixed Hispanic and white; 1 mixed black and white; 1 biracial; 2 American Indian; 1 Indian; and 1 mixed Iranian and Cherokee.

** Values for height, weight and body mass index (BMI) are missing for 1 adolescent.

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

Source: Tables 13.5.1b, 13.5.2b, Section 11; Listing 13.5.1, Appendix B; Listing 15.2.1, Appendix E.

(Continued)

Table 14 Demographic Characteristics–Age Group: Children/Adolescents (ITT Population) (Continued)

	Age Group: Children			Age Group: Adolescents		
Demographic Characteristics	**Paroxetine (N = 58)**	**Placebo (N = 57)**	**Total (N = 115)**	**Paroxetine (N = 40)**	**Placebo (N = 48)**	**Total (N = 88)**
Weight (kg)†**						
Mean (SD)	35.0 (13.68)	36.3 (12.67)	35.7 (13.15)	62.7 (17.56)	64.3 (14.73)	63.6 (16.01)
Range	18.6-79.5	19.0-104.0	18.6-104.0	32.5-110.9	37.7-100.9	32.5-110.9
BMI (kg/m^2)**						
Mean (SD)	18.2 (4.27)	18.7 (4.33)	18.5 (4.29)	22.9 (5.44)	23.5 (5.27)	23.2 (5.33)
Range	13.0-32.8	13.7-40.1	13.0-40.1	16.2-41.9	16.1-37.7	16.1-41.9

* Other race includes 6 Hispanic patients; 1 mixed Hispanic and white; 1 mixed black and white; 1 biracial; 2 American Indian; 1 Indian; and 1 mixed Iranian and Cherokee.
** Values for height, weight and body mass index (BMI) are missing for 1 adolescent.
†Weight measured in pounds was converted to kilograms using the conversion 1 lb. = 0.454 kg.
Source: Tables 13.5.1b, 13.5.2b, Section 11; Listing 13.5.1, Appendix B; Listing 15.2.1, Appendix E.

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 OCD severity.

Table 15 summarizes the mean baseline scores by treatment group and by age subgroup for the efficacy scales CY-BOCS and GAF. The mean total CY-BOCS score was 24.8 (SD 5.01) and the mean total GAF score was 52.5 (SD 6.94) at Baseline for the two treatment groups combined.

Summary statistics for total CY-BOCS scores at Baseline for the PP population were similar to those in the ITT population. Total CY-BOCS scores for the PP population may be found in Table 14.1.1c, Section 12.

Table 15 Mean Baseline Efficacy Parameter Scores by Treatment–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group								
	Paroxetine (N = 98)			Placebo (N = 105)			Total (N = 203)		
Instrument	**n**	**Mean**	**SD**	**n**	**Mean**	**SD**	**n**	**Mean**	**SD**
CY-BOCS Total Score									
Age Group: Total	98	24.5	(4.95)	105	25.3	(5.05)	203	24.8	(5.01)
Age Group: Children	58	23.8	(5.00)	57	25.3	(5.31)	115	24.4	(5.19)
Age Group: Adolescents	40	25.2	(4.82)	48	25.3	(4.79)	88	25.3	(4.77)
GAF									
Age Group: Total	98	53.4	(6.59)	105	51.6	(7.18)	203	52.5	(6.94)
Age Group: Children	58	53.2	(6.89)	57	52.3	(7.57)	115	52.7	(7.22)
Age Group: Adolescents	40	53.8	(6.19)	48	50.8	(6.67)	88	52.1	(6.59)

CY-BOCS – Children's Yale-Brown Obsessive-Compulsive Scale; GAF – Global Assessment of Functioning
Source: Tables 13.9.1, 13.11.1, Section 11; Listings 14.1.1, 14.5.1, Appendix C

Table 16 summarizes the proportion of patients in each category of CGI Severity of Illness item at Baseline by treatment group. Overall, there was a slightly greater percentage of moderately ill patients in the paroxetine treatment group (57/98, 58.2%) than in the placebo group (49/105, 46.7%) and a slightly higher percentage of severely ill patients in the placebo group (16/105, 15.2%) than in the paroxetine group (6/98, 6.1%). The same pattern appeared among children; however, among adolescents, the percentage of moderately ill patients was nearly the same in both treatment groups, although there was still a higher percentage of severely ill patients in the placebo group. Overall and among children, the greatest percentage of the patients in each treatment group were classified as moderately ill.

Table 16 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		
	Paroxetine	**Placebo**	**Total**
CGI Severity of Illness	n (%)	n (%)	n (%)
Age Group: Total	(N =98)	(N = 105)	(N = 203)
Not Assessed	0	0	0
Normal, Not Ill	0	0	0
Borderline Ill	0	0	0
Mildly Ill	0	4 (3.8)	4 (2.0)
Moderately Ill	57 (58.2)	49 (46.7)	106 (52.2)
Markedly Ill	33 (33.7)	36 (34.3)	69 (34.0)
Severely Ill	6 (6.1)	16 (15.2)	22 (10.8)
Most Extremely Ill	2 (2.0)	0	2 (1.0)
Age Group: Children	(N = 58)	(N = 57)	(N = 115)
Not Assessed	0	0	0
Normal, Not Ill	0	0	0
Borderline Ill	0	0	0
Mildly Ill	0	3 (5.3)	3 (2.6)
Moderately Ill	39 (67.2)	28 (49.1)	67 (58.3)
Markedly Ill	15 (25.9)	16 (28.1)	31 (27.0)
Severely Ill	3 (5.2)	10 (17.5)	13 (11.3)
Most Extremely Ill	1 (1.7)	0	1 (0.9)
Age Group: Adolescents	(N = 40)	(N = 48)	(N = 88)
Not Assessed	0	0	0
Normal, Not Ill	0	0	0
Borderline Ill	0	0	0
Mildly Ill	0	1 (2.1)	1 (1.1)
Moderately Ill	18 (45.0)	21 (43.8)	39 (44.3)
Markedly Ill	18 (45.0)	20 (41.7)	38 (43.2)
Severely Ill	3 (7.5)	6 (12.5)	9 (10.2)
Most Extremely Ill	1 (2.5)	0	1 (1.1)

CGI – Clinical Global Impression
Source: Table 13.10.1, Section 11; Listing 14.4.1, Appendix C

4.5 Medical History

Medical history at Baseline was summarized using the ICD-9 classification.

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 numbers of patients reporting a positive prior medical or surgical history (excluding psychiatric disorders) were similar in both treatment groups: 54/98 patients (55.1%) in the paroxetine group and 64/105 patients (61.0%) in the placebo group (Table 13.6.1.1, Section 11). Most of the reported prior medical conditions were benign. The most frequently reported prior medical condition in the paroxetine group was asthma (8.2% of patients [8/98] in the paroxetine group and 5.7% of patients [6/105] in the placebo group), while the most frequent prior condition in the placebo group was otitis media (9.5% of patients [10/105] in the placebo group and 7.1% of patients [7/98] in the paroxetine group). The most frequently reported prior surgical procedure in the paroxetine group was ear operation (7.1% of patients [7/98] in the paroxetine group and 8.6% of patients [9/105] in the placebo group), while the most frequent prior operation in the placebo group was nose/mouth operation (9.5% of patients [10/105] in the placebo group and 4.1% of patients [4/98] in the paroxetine group). Consistent with these numbers, the body systems with the highest proportions of patients having a medical history were the Respiratory System (23.5% of paroxetine-treated patients [23/98] and 28.6% of placebo patients [30/105]) and Nervous/Sense Organs (21.4% of paroxetine-treated patients [21/98] and 21.9% of placebo patients [23/105]) . 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, and Listing 13.6.1, Appendix B.

The number of patients reporting active medical conditions at Screening (excluding psychiatric disorders) was slightly higher in the placebo group (68/105, 64.8%) than in the paroxetine group (54/98, 55.1%) (Table 17). The only active medical conditions reported for 10% or more of patients in either treatment group were allergic rhinitis (18.4% of patients [18/98] in the paroxetine group and 21.0% of patients [22/105] in the placebo group) and asthma (10.2% of patients [10/98] in the paroxetine group and 7.6% of patients [8/105] in the placebo group). Consistent with these numbers, the body system with the highest proportion of patients having an active medical condition was the Respiratory System (26.5% of paroxetine-treated patients [26/98] and 31.4% of placebo patients [33/105]). 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.

Table 17 Number (%) of Patients with Active Medical Conditions (Occurring in ≥5% of Patients in Either Treatment Group) (ITT Population)

	Treatment Group		
Active Condition	**Paroxetine (N=98) n (%)**	**Placebo (N=105) n (%)**	**Total (N = 203) n (%)**
Total number of patients with at least one active condition	54 (55.1)	68 (64.8)	122 (60.1)
Rhinitis, Allergic	18 (18.4)	22 (21.0)	40 (19.7)
Asthma	10 (10.2)	8 (7.6)	18 (8.9)
Headache	9 (9.2)	10 (9.5)	19 (9.4)
Skin/Subcutaneous Disorder, Other	6 (6.1)	5 (4.8)	11 (5.4)
Adverse Effect/Antibiotic	4 (4.1)	8 (7.6)	12 (5.9)

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

4.5.2 Psychiatric History

The diagnosis of OCD was based on DSM-IV (300.3). The K-SADS–PL semi-structured diagnostic interview was used to confirm the diagnosis of OCD and to assess current and past episodes of other psychopathology according to DSM-III–R (Diagnostic and Statistical Manual of Mental Disorders, third edition revised) and DSM-IV criteria. Two adolescents in the placebo group did not have a diagnosis of OCD recorded from the K-SADS-PL interview (Listing 13.8.1, Appendix B); however, documentation provided by the investigators confirmed that the patients had OCD (Section 15.).

The diagnosis of any psychiatric disorder, including OCD, was to be made solely by the psychiatrist. Any randomized patient diagnosed with a clinically predominant Axis I disorder other than OCD was a protocol violator and was to be removed from the PP population. In the present study, no patients were so identified (see Section 4.3, Protocol Violations).

4.5.2.1 History of OCD

The mean age at onset of OCD in both age groups combined was 7.4 years (SD 3.08) in the paroxetine group and 7.5 years (SD 3.12) in the placebo group. The mean age at onset of OCD was also similar between treatment groups in both age subgroups: among children, 6.1 years for paroxetine-treated patients and

6.0 years for placebo patients, and among adolescents, 9.3 years for patients in both treatment groups (Table 13.7.1, Section 11).

The mean duration of OCD (calculated from first onset) in both age groups combined was 1496.0 days (SD 1089.64) in the paroxetine group and 1599.7 days (SD 1022.35) in the placebo group. The mean duration of OCD was also similar between treatment groups in both age subgroups: among children, 1178.4 days for paroxetine-treated patients and 1300.8 days for placebo patients, and among adolescents, 1948.7 days for paroxetine-treated patients and 1954.6 days for placebo patients (Table 13.7.1, Section 11).

Based on the K-SADS–PL and the psychiatric interview, 57.1% (56/98) of patients in the paroxetine group and 60.0% (63/105) of patients in the placebo group had a prior episode of OCD (Table 13.8.1, Section 11). As shown in Table 18, family history of OCD, number of times hospitalized for OCD, tic disorder or family history of tic disorder, and prior treatment given for the current episode (psychotherapy and/or pharmacotherapy) were also similar between treatment groups except for prior treatment for the current episode of OCD. A greater percentage of patients in the placebo group (17.1%, 18/105) had already been treated with pharmacotherapy than in the paroxetine group (7.1%, 7/98), although a greater percentage of patients in the paroxetine group had already been treated with psychotherapy (paroxetine, 13.3%, 13/98; placebo, 6.7%, 7/105). Prior intake of psychoactive medication is discussed in more detail in Section 4.7.1.1. The history of OCD in the two age subgroups was also similar except for family history and prior treatment for the current episode. Among children, a greater percentage of patients in the placebo group (47.4%, 27/57) had no family history of OCD than in the paroxetine group (34.5%, 20/58). Among adolescents, a greater percentage of patients in the paroxetine group (72.5%, 29/40) had received no treatment for their current episode of OCD compared with patients in the placebo group (60.4%, 29/48).

Table 18 Family and Personal History of OCD - Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group	
	Paroxetine n (%)	**Placebo** n (%)
Age Group: Total	(N = 98)	(N = 105)
Family OCD History		
None	40 (40.8)	47 (44.8)
Mother	28 (28.6)	25 (23.8)
Father	16 (16.3)	22 (21.0)
Sibling	17 (17.3)	12 (11.4)
Grandparent	17 (17.3)	22 (21.0)
Other	11 (11.2)	8 (7.6)
Times Hospitalized for OCD		
Never	98 (100.0)	103 (98.1)
1 time	0	1 (1.0)
2 times	0	1 (1.0)
>2 times	0	0
Personal or Family History of Tic Disorder		
Yes	10 (10.2)	16 (15.2)
No	88 (89.8)	89 (84.8)
Treatment for Current Episode		
No Therapy	70 (71.4)	71 (67.6)
Psychotherapy	13 (13.3)	7 (6.7)
Pharmacotherapy	7 (7.1)	18 (17.1)
Both Psychotherapy and Pharmacotherapy	8 (8.2)	9 (8.6)
Age Group: Children	(N = 58)	(N = 57)
Family OCD History		
None	20 (34.5)	27 (47.4)
Mother	17 (29.3)	15 (26.3)
Father	7 (12.1)	9 (15.8)
Sibling	11 (19.0)	7 (12.3)
Grandparent	9 (15.5)	13 (22.8)
Other	9 (15.5)	2 (3.5)
Times Hospitalized for OCD		
Never	58 (100.0)	57 (100.0)
Personal or Family History of Tic Disorder		
Yes	5 (8.6)	7 (12.3)
No	53 (91.4)	50 (87.7)

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

(Continued)

Table 18 Family and Personal History of OCD - Age Group: Total/Children/Adolescents (ITT Population) (Continued)

	Treatment Group	
	Paroxetine	**Placebo**
	n (%)	n (%)
Age Group: Children	(N = 58)	(N = 57)
Treatment for Current Episode		
No Therapy	41 (70.7)	42 (73.7)
Psychotherapy	8 (13.8)	3 (5.3)
Pharmacotherapy	6 (10.3)	10 (17.5)
Both Psychotherapy and Pharmacotherapy	3 (5.2)	2 (3.5)
Age Group: Adolescents	(N = 40)	(N = 48)
Family OCD History		
None	20 (50.0)	20 (41.7)
Mother	11 (27.5)	10 (20.8)
Father	9 (22.5)	13 (27.1)
Sibling	6 (15.0)	5 (10.4)
Grandparent	8 (20.0)	9 (18.8)
Other	2 (5.0)	6 (12.5)
Times Hospitalized for OCD		
Never	40 (100.0)	46 (95.8)
1 time	0	1 (2.1)
2 times	0	1 (2.1)
>2 times	0	0
Personal or Family History of Tic Disorder		
Yes	5 (12.5)	9 (18.8)
No	35 (87.5)	39 (81.3)
Treatment for Current Episode		
No Therapy	29 (72.5)	29 (60.4)
Psychotherapy	5 (12.5)	4 (8.3)
Pharmacotherapy	1 (2.5)	8 (16.7)
Both Psychotherapy and Pharmacotherapy	5 (12.5)	7 (14.6)

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

Per-patient details for OCD psychiatric history may be found in Listing 13.7.1, Appendix B. Per-patient information obtained using the K-SADS–PL and during the psychiatric interview is provided in Listing 13.8.1, Appendix B.

4.5.2.2 History of Other Psychiatric Illness

Table 19, Table 20, and Table 21 summarize the psychiatric history (from the K-SADS-PL) for both age groups combined, for children, and for adolescents, respectively, by treatment group. The proportions of patients with a past and/or current history of psychiatric illness other than OCD were similar in both treatment groups except that more patients in the placebo group (8/105, 7.6%) had a past and/or current history of Oppositional Defiant Disorder than in the paroxetine group (2/98, 2.0%). There were also 5 patients (4.8%) in the placebo group who had a past and/or current history of Chronic Motor or Vocal Tic Disorder and none in the paroxetine group. The most common conditions in the psychiatric histories (past and/or current) of patients overall were Attention Deficit Disorder (27/203, 13.3%) and enuresis (23/203, 11.3%) (Table 19). The most common comorbid condition in both treatment groups was Attention Deficit Disorder (9/98, 9.2% in the paroxetine group and 10/105, 9.5% in the placebo group). There was a slightly higher percentage of patients with any comorbid psychiatric illnesses in the placebo group (40.0%, 42/105) than in the paroxetine group (30.6%, 30/98) (Appendix H, Statistical Appendix). In the overall population, the majority of patients with a past and/or current history of Attention Deficit Disorder (20 of 27) or Enuresis (16 of 23) were children, while the majority of patients with a past history of Major Depressive Disorder (9 of 11) were adolescents.

Table 19 Summary of Psychiatric History from K-SADS–PL at Baseline–Age Group: Total (ITT Population)

	Treatment Group								
	Paroxetine (N = 98)			Placebo (N = 105)			Total (N = 203)		
Psychiatric Condition*	Past n (%)	Current n (%)	Both n (%)	Past n (%)	Current n (%)	Both n (%)	Past n (%)	Current n (%)	Both n (%)
Obsessive-Compulsive Disorder**	0	42 (42.9)	56 (57.1)	0	40 (38.1)	63 (60.0)	0	82 (40.4)	119 (58.6)
Attention Deficit Disorder	3 (3.1)	5 (5.1)	4 (4.1)	5 (4.8)	5 (4.8)	5 (4.8)	8 (3.9)	10 (4.9)	9 (4.4)
Generalized Anxiety Disorder	0	4 (4.1)	3 (3.1)	1 (1.0)	4 (3.8)	3 (2.9)	1 (0.5)	8 (3.9)	6 (3.0)
Simple Phobia	1 (1.0)	4 (4.1)	0	1 (1.0)	4 (3.8)	2 (1.9)	2 (1.0)	8 (3.9)	2 (1.0)
Overanxious Disorder	0	2 (2.0)	3 (3.1)	0	4 (3.8)	3 (2.9)	0	6 (3.0)	6 (3.0)
Separation Anxiety Disorder	3 (3.1)	2 (2.0)	1 (1.0)	3 (2.9)	2 (1.9)	3 (2.9)	6 (3.0)	4 (2.0)	4 (2.0)
Transient Tic Disorder	0	2 (2.0)	0	1 (1.0)	1 (1.0)	3 (2.9)	1 (0.5)	3 (1.5)	3 (1.5)
Enuresis	3 (3.1)	1 (1.0)	5 (5.1)	6 (5.7)	0	8 (7.6)	9 (4.4)	1 (0.5)	13 (6.4)
Oppositional Defiant Disorder	0	1 (1.0)	1 (1.0)	0	3 (2.9)	5 (4.8)	0	4 (2.0)	6 (3.0)
Social Phobia	1 (1.0)	1 (1.0)	0	1 (1.0)	1 (1.0)	3 (2.9)	2 (1.0)	2 (1.0)	3 (1.5)
Adjustment Disorder with Depressed Mood	1 (1.0)	0	0	0	1 (1.0)	1 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)
Agoraphobia	0	0	0	2 (1.9)	1 (1.0)	0	2 (1.0)	1 (0.5)	0
Chronic Motor or Vocal Tic Disorder	0	0	0	3 (2.9)	2 (1.9)	0	3 (1.5)	2 (1.0)	0

* Sorted by descending order of current conditions among patients in the paroxetine treatment group. A patient may have had more than one psychiatric condition.

** Obsessive-Compulsive Disorder was not indicated for 2 patients in the placebo group (see Section 15, Errata).

Source: Table 13.8.1, Section 11; Listing 13.8.1, Appendix B.

(Continued)

Table 19 Summary of Psychiatric History from K-SADS–PL at Baseline–Age Group: Total (ITT Population) (Continued)

Psychiatric Condition*	Treatment Group: Paroxetine (N = 98) Past n (%)	Paroxetine (N = 98) Current n (%)	Paroxetine (N = 98) Both n (%)	Placebo (N = 105) Past n (%)	Placebo (N = 105) Current n (%)	Placebo (N = 105) Both n (%)	Total (N = 203) Past n (%)	Total (N = 203) Current n (%)	Total (N = 203) Both n (%)
Conduct Disorder	0	0	1 (1.0)	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (0.5)	1 (0.5)
Panic Disorder	0	0	1 (1.0)	0	1 (1.0)	1 (1.0)	0	1 (0.5)	2 (1.0)
Tourette's Syndrome	0	0	1 (1.0)	0	2 (1.9)	1 (1.0)	0	2 (1.0)	2 (1.0)
Avoidant Disorder of Childhood	0	0	1 (1.0)	2 (1.9)	0	1 (1.0)	2 (1.0)	0	2 (1.0)
Depressive Disorder NOS	1 (1.0)	0	0	0	0	0	1 (0.5)	0	0
Dysthymia	0	0	0	0	0	1 (1.0)	0	0	1 (1.0)
Encopresis	2 (2.0)	0	1 (1.0)	0	0	1 (1.0)	2 (1.0)	0	2 (1.0)
Major Depressive Disorder	7 (7.1)	0	0	4 (3.8)	0	0	11 (5.4)	0	0
No Psychiatric Disorder	1 (1.0)	0	0	1 (1.0)	0	0	2 (1.0)	0	0
Other Psychiatric Disorder	1 (1.0)	0	0	0	0	0	1 (0.5)	0	0
Post-Traumatic Stress Disorder	1 (1.0)	0	0	2 (1.9)	0	1 (1.0)	3 (1.5)	0	1 (0.5)

* Sorted by descending order of current conditions among patients in the paroxetine treatment group. A patient may have had more than one psychiatric condition.

** Obsessive-Compulsive Disorder was not indicated for 2 patients in the placebo group (see Section 15, Errata).

Source: Table 13.8.1, Section 11; Listing 13.8.1, Appendix B.

Table 20 Summary of Psychiatric History from K-SADS–PL at Baseline–Age Group: Children (ITT Population)

	Treatment Group								
	Paroxetine (N = 58)			Placebo (N = 57)			Total (N = 115)		
Psychiatric Condition*	Past n (%)	Current n (%)	Both n (%)	Past n (%)	Current n (%)	Both n (%)	Past n (%)	Current n (%)	Both n (%)
Obsessive-Compulsive Disorder	0	28 (48.3)	30 (51.7)	0	19 (33.3)	38 (66.7)	0	47 (40.9)	68 (59.1)
Attention Deficit Disorder	2 (3.4)	4 (6.9)	4 (6.9)	0	5 (8.8)	5 (8.8)	2 (1.7)	9 (7.8)	9 (7.8)
Simple Phobia	1 (1.7)	3 (5.2)	0	1 (1.8)	0	1 (1.8)	2 (1.7)	3 (2.6)	1 (0.9)
Generalized Anxiety Disorder	0	2 (3.4)	1 (1.7)	1 (1.8)	2 (3.5)	2 (3.5)	1 (0.9)	4 (3.5)	3 (2.6)
Separation Anxiety Disorder	2 (3.4)	2 (3.4)	1 (1.7)	1 (1.8)	1 (1.8)	3 (5.3)	3 (2.6)	3 (2.6)	4 (3.5)
Transient Tic Disorder	0	2 (3.4)	0	0	1 (1.8)	2 (3.5)	0	3 (2.6)	2 (1.7)
Enuresis	2 (3.4)	1 (1.7)	4 (6.9)	3 (5.3)	0	6 (10.5)	5 (4.3)	1 (0.9)	10 (8.7)
Oppositional Defiant Disorder	0	1 (1.7)	1 (1.7)	0	0	2 (3.5)	0	1 (0.9)	3 (2.6)
Chronic Motor or Vocal Tic Disorder	0	0	0	1 (1.8)	1 (1.8)	0	1 (0.9)	1 (0.9)	0
Conduct Disorder	0	0	1 (1.7)	1 (1.8)	1 (1.8)	0	1 (0.9)	1 (0.9)	1 (0.9)
Overanxious Disorder	0	0	1 (1.7)	0	3 (5.3)	2 (3.5)	0	3 (2.6)	3 (2.6)
Panic Disorder	0	0	1 (1.7)	0	1 (1.8)	1 (1.8)	0	1 (0.9)	2 (1.7)
Adjustment Disorder with Depressed Mood	1 (1.7)	0	0	0	0	1 (1.8)	1 (0.9)	0	1 (0.9)
Agoraphobia	0	0	0	1 (1.8)	0	0	1 (0.9)	0	0
Avoidant Disorder of Childhood	0	0	1 (1.7)	2 (3.5)	0	0	2 (1.7)	0	1 (0.9)

* Sorted by descending order of current conditions among patients in the paroxetine treatment group. A patient may have had more than one psychiatric condition.

Source: Table 13.8.1, Section 11; Listing 13.8.1, Appendix B.

(Continued)

Table 20 Summary of Psychiatric History from K-SADS–PL at Baseline–Age Group: Children (ITT Population) (Continued)

	Treatment Group								
	Paroxetine (N = 58)			Placebo (N = 57)			Total (N = 115)		
Psychiatric Condition*	Past n (%)	Current n (%)	Both n (%)	Past n (%)	Current n (%)	Both n (%)	Past n (%)	Current n (%)	Both n (%)
Depressive Disorder NOS	1 (1.7)	0	0	0	0	0	1 (0.9)	0	0
Dysthymia	0	0	0	0	0	1 (1.8)	0	0	1 (0.9)
Encopresis	0	0	1 (1.7)	0	0	1 (1.8)	0	0	2 (1.7)
Major Depressive Disorder	1 (1.7)	0	0	1 (1.8)	0	0	2 (1.7)	0	0
No Psychiatric Disorder	0	0	0	1 (1.8)	0	0	1 (0.9)	0	0
Post-Traumatic Stress Disorder	1 (1.7)	0	0	0	0	1 (1.8)	1 (0.9)	0	1 (0.9)
Social Phobia	1 (1.7)	0	0	1 (1.8)	0	1 (1.8)	2 (1.7)	0	1 (0.9)
Tourette's Syndrome	0	0	1 (1.7)	0	0	0	0	0	1 (0.9)

* Sorted by descending order of current conditions among patients in the paroxetine treatment group. A patient may have had more than one psychiatric condition.

Source: Table 13.8.1, Section 11; Listing 13.8.1, Appendix B.

Table 21 Summary of Psychiatric History from K-SADS–PL at Baseline–Age Group: Adolescents (ITT Population)

	Treatment Group								
	Paroxetine (N = 40)			Placebo (N = 48)			Total (N = 88)		
Psychiatric Condition*	Past n (%)	Current n (%)	Both n (%)	Past n (%)	Current n (%)	Both n (%)	Past n (%)	Current n (%)	Both n (%)
Obsessive-Compulsive Disorder**	0	14 (35.0)	26 (65.0)	0	21 (43.8)	25 (52.1)	0	35 (39.8)	51 (58.0)
Generalized Anxiety Disorder	0	2 (5.0)	2 (5.0)	0	2 (4.2)	1 (2.1)	0	4 (4.5)	3 (3.4)
Overanxious Disorder	0	2 (5.0)	2 (5.0)	0	1 (2.1)	1 (2.1)	0	3 (3.4)	3 (3.4)
Attention Deficit Disorder	1 (2.5)	1 (2.5)	0	5 (10.4)	0	0	6 (6.8)	1 (1.1)	0
Simple Phobia	0	1 (2.5)	0	0	4 (8.3)	1 (2.1)	0	5 (5.7)	1 (1.1)
Social Phobia	0	1 (2.5)	0	0	1 (2.1)	2 (4.2)	0	2 (2.3)	2 (2.3)
Adjustment Disorder with Depressed Mood	0	0	0	0	1 (2.1)	0	0	1 (1.1)	0
Agoraphobia	0	0	0	1 (2.1)	1 (2.1)	0	1 (1.1)	1 (1.1)	0
Chronic Motor or Vocal Tic Disorder	0	0	0	2 (4.2)	1 (2.1)	0	2 (2.3)	1 (1.1)	0
Oppositional Defiant Disorder	0	0	0	0	3 (6.3)	3 (6.3)	0	3 (3.4)	3 (3.4)
Separation Anxiety Disorder	1 (2.5)	0	0	2 (4.2)	1 (2.1)	0	3 (3.4)	1 (1.1)	0
Tourette's Syndrome	0	0	0	0	2 (4.2)	1 (2.1)	0	2 (2.3)	1 (1.1)

* Sorted by descending order of current conditions among patients in the paroxetine treatment group. A patient may have had more than one psychiatric condition.

**Obsessive-Compulsive Disorder was not indicated for 2 patients in the placebo group (see Section 15, Errata).

Source: Table 13.8.1, Section 11; Listing 13.8.1, Appendix B.

(*Continued*)

Table 21 Summary of Psychiatric History from K-SADS–PL at Baseline–Age Group: Adolescents (ITT Population) (Continued)

	Treatment Group								
	Paroxetine (N = 40)			Placebo (N = 48)			Total (N = 88)		
Psychiatric Condition*	**Past n (%)**	**Current n (%)**	**Both n (%)**	**Past n (%)**	**Current n (%)**	**Both n (%)**	**Past n (%)**	**Current n (%)**	**Both n (%)**
Avoidant Disorder of Childhood	0	0	0	0	0	1 (2.1)	0	0	1 (1.1)
Encopresis	2 (5.0)	0	0	0	0	0	2 (2.3)	0	0
Enuresis	1 (2.5)	0	1 (2.5)	3 (6.3)	0	2 (4.2)	4 (4.5)	0	3 (3.4)
Major Depressive Disorder	6 (15.0)	0	0	3 (6.3)	0	0	9 (10.2)	0	0
No Psychiatric Disorder	1 (2.5)	0	0	0	0	0	1 (1.1)	0	0
Other Psychiatric Disorder	1 (2.5)	0	0	0	0	0	1 (1.1)	0	0
Post-Traumatic Stress Disorder	0	0	0	2 (4.2)	0	0	2 (2.3)	0	0
Transient Tic Disorder	0	0	0	1 (2.1)	0	1 (2.1)	1 (1.1)	0	1 (1.1)

*Sorted by descending order of current conditions among patients in the paroxetine treatment group. A patient may have had more than one psychiatric condition.

**Obsessive-Compulsive Disorder was not indicated for 2 patients in the placebo group (see Section 15, Errata).

Source: Table 13.8.1, Section 11; Listing 13.8.1, Appendix B.

4.6 Baseline Signs and Symptoms

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 provides details of the onset, severity and duration of the events.

A total of 24/98 patients (24.5%) randomized to paroxetine and 20/105 patients (19.0%) in the placebo group reported one or more gender-non-specific baseline signs/symptoms. No patients reported gender-specific baseline signs/symptoms. The nature and incidence of baseline signs and symptoms were comparable between the treatment groups. The most frequent baseline sign/symptom was headache, which occurred in 10/98 paroxetine patients (10.2%) and 6/105 placebo patients (5.7%). The only other baseline sign/symptom that occurred in more than 5% of patients in either treatment group was rhinitis in 5.1% of paroxetine patients (5/98) and 1.9% of placebo patients (2/105).

4.7 Prior and Concomitant Medications

4.7.1 Prior Medications

4.7.1.1 Prior Psychoactive Medications

Table 22 summarizes psychoactive medications taken at any time in the past for OCD. The prior use of psychoactive medications for OCD was somewhat more prevalent among placebo patients (26.7%, 28/105) compared with paroxetine-treated patients (16.3%, 16/98). Previous use of SSRIs occurred in 14/98 (14.3%) paroxetine patients and 22/105 (21.0%) placebo patients. The previous use of psychoactive medication characterized as "other," which included psychoactive herbal medication (i.e., hypericum extract), was reported for 3/98 (3.1%) paroxetine patients and 8/105 (7.6%) placebo patients.

The most frequently used prior medications taken for OCD were fluvoxamine maleate taken by 5/98 paroxetine patients (5.1%) and 13/105 placebo patients (12.4%) and fluoxetine taken by 6/98 (6.1%) paroxetine patients and 6/105 (5.7%) placebo patients. Paroxetine had previously been used by 5/98 paroxetine patients (5.1%) and 4/105 placebo patients (3.8%).

Previous psychoactive medication taken for OCD at any time is summarized in Table 13.12.1.1, Section 11 by class identification and generic term and in Table 13.12.1.2, Section 11 by generic term ordered by decreasing frequency. Individual patient information is provided in Listing 13.12.1, Appendix B.

Table 22 Obsessive-Compulsive Medication History by Psychoactive Class–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group					
	Paroxetine		Placebo		Total	
Previous OCD Medication *	**n**	**%**	**n**	**%**	**n**	**%**
Therapeutic Class and Medication						
Age Group: Total	(N = 98)		(N = 105)		(N = 203)	
Total Patients Taking Prior OCD Therapy	16	(16.3)	28	(26.7)	44	(21.7)
SSRI	14	(14.3)	22	(21.0)	36	(17.7)
TCA	2	(2.0)	6	(5.7)	8	(3.9)
Benzodiazepines	0		2	(1.9)	2	(1.0)
Other psychoactive medications **	3	(3.1)	8	(7.6)	11	(5.4)
No Prior OCD Therapy	82	(83.7)	77	(73.3)	159	(78.3)
Age Group: Children	(N = 58)		(N = 57)		(N = 115)	
Total Children Taking Prior OCD Therapy	9	(15.5)	14	(24.6)	23	(20.0)
SSRI	7	(12.1)	8	(14.0)	15	(13.0)
TCA	1	(1.7)	2	(3.5)	3	(2.6)
Benzodiazepines	0		1	(1.8)	1	(0.9)
Other psychoactive medications **	2	(3.4)	5	(8.8)	7	(6.1)
No Prior OCD Therapy	49	(84.5)	43	(75.4)	92	(80.0)
Age Group: Adolescents	(N = 40)		(N = 48)		(N = 88)	
Total Adolescents Taking Prior OCD Therapy	7	(17.5)	14	(29.2)	21	(23.9)
SSRI	7	(17.5)	14	(29.2)	21	(23.9)
TCA	1	(2.5)	4	(8.3)	5	(5.7)
Benzodiazepines	0		1	(2.1)	1	(1.1)
Other psychoactive medications **	1	(2.5)	3	(6.3)	4	(4.5)
No Prior OCD Therapy	33	(82.5)	34	(70.8)	67	(76.1)

SSRI – selective serotonin reuptake inhibitor, TCA – tricyclic antidepressant

* Taken by the patient at any time prior to Screening. Patients could have taken more than one prior medication for OCD.

** Other includes amfebutamone, amphetamine aspartate, amphetamine sulfate, buspirone, clonidine, dextroamphetamine saccharate, dextroamphetamine sulfate, hypericum extract, nefazodone, quetiapine, risperidone and venlafaxine.

Source: Table 13.12.1.1, Section 11; Listing 13.12.1, Appendix B.

Table 23 presents prior psychoactive medication taken during the 3 months prior to Screening for indications other than OCD by psychoactive class. Psychoactive medication history for indications other than OCD may be found in Tables 13.12.2.1, presented by psychoactive class and generic term, and 13.12.2.2 presented by generic term, in order of decreasing frequency, both in Section 11, and in Listing 13.12.2, Appendix B.

The most frequent prior psychoactive medication taken for indications other than OCD was dextroamphetamine sulfate taken by 4/98 (4.1%) paroxetine patients and 6/105 (5.7%) placebo patients. This medication was taken for Attention Deficit/Hyperactive Disorder (ADHD) and Attention Deficit Disorder (ADD) and as a stimulant. No patients had taken MAOIs.

Table 23 Psychoactive Medication History for Indications Other than Obsessive-Compulsive Disorder–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group		
Previous Psychoactive Medication for Indications Other Than OCD*	**Paroxetine**	**Placebo**	**Total**
Therapeutic Class and Medication	**n (%)**	**n (%)**	**n (%)**
Age Group: Total	(N = 98)	(N = 105)	(N = 203)
Total Patients Taking Prior Psychoactive Medication**	17 (17.3)	18 (17.1)	35 (17.2)
SSRI	2 (2.0)	2 (1.9)	4 (2.0)
TCA	0	1 (1.0)	1 (0.5)
Benzodiazepines	0	1 (1.0)	1 (0.5)
Other psychoactive medications †	16 (16.3)	14 (13.3)	30 (14.8)
No prior other psychoactive medication	81 (82.7)	87 (82.9)	168 (82.8)
Age Group: Children	(N = 58)	(N = 57)	(N = 115)
Total Patients Taking Prior Psychoactive Medication**	10 (17.2)	12 (21.1)	22 (19.1)
SSRI	1 (1.7)	0	1 (0.9)
TCA	0	1 (1.8)	1 (0.9)
Benzodiazepines	0	0	0
Other psychoactive medications †	9 (15.5)	11 (19.3)	20 (17.4)
No prior other psychoactive medication	48 (82.8)	45 (78.9)	93 (80.9)
Age Group: Adolescents	(N = 40)	(N = 48)	(N = 88)
Total Patients Taking Prior Psychoactive Medication**	7 (17.5)	6 (12.5)	13 (14.8)
SSRI	1 (2.5)	2 (4.2)	3 (3.4)
TCA	0	0	0
Benzodiazepines	0	1 (2.1)	1 (1.1)
Other psychoactive medications †	7 (17.5)	3 (6.3)	10 (11.4)
No prior other psychoactive medication	33 (82.5)	42 (87.5)	75 (85.2)

TCA – tricyclic antidepressant, SSRI – selective serotonin reuptake inhibitor
* Taken during the 3 months prior to Screening.
**Patients could have taken more than one other prior psychoactive medication.
† Other includes amfebutamone, amphetamine aspartate, amphetamine sulfate, buspirone, carbamazepine, clonidine, cyproheptadine, dextroamphetamine saccharate, dextroamphetamine sulfate, diphenhydramine, hydroxyzine embonate, guanfacine, hypericum extract, methylphenidate, olanzapine, risperidone, trazodone, valproate, and venlafaxine.
Source: Table 13.12.2.1, Section 11; Listing 13.12.2, 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 13.12.3.1, 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 level and the respiratory level. Non-psychoactive medications taken within the month prior to entry into the trial are summarized by generic name in order of decreasing frequency in Table 13.12.3.2, Section 11. In this tabulation, components are counted only once. Listing 13.12.3, Appendix B, presents details of these medications for each patient, including dosage, indication, and starting and ending days relative to start and end of randomized study medication.

Table 24 presents the most frequently used (≥5% of patients in either treatment group) non-psychoactive medication taken within the month prior to Screening.

A total of 38/98 (38.8%) paroxetine patients and 49/105 (46.7%) placebo patients had used non-psychoactive medication within the month prior to Screening. The most frequent single medications used were over-the-counter (OTC) analgesics, paracetamol in the paroxetine group (10/98, 10.2%, compared with 4/105, 3.8%, in the placebo group) and ibuprofen in the placebo group (11/105, 10.5%, compared with 8/98, 8.2%, in the paroxetine group). There were no substantial differences between the treatment groups relative to medication use prior to study entry.

Table 24 Frequently Reported (≥5% of Patients in Either Treatment Group) Prior Non-psychoactive Medication by Therapeutic Class and Drug–Age Group: Total (ITT Population)

	Treatment Group			
	Paroxetine (N = 98)		Placebo (N = 105)	
Therapeutic Class and Medication	**n**	**%**	**n**	**%**
Total Patients with a Prior Medication*	38	(38.8)	49	(46.7)
Alimentary tract/metabolic	10	(10.2)	12	(11.4)
Vitamins NOS	5	(5.1)	4	(3.8)
Central nervous system	21	(21.4)	19	(18.1)
Paracetamol	10	(10.2)	4	(3.8)
Ibuprofen	8	(8.2)	11	(10.5)
Musculoskeletal	10	(10.2)	11	(10.5)
Ibuprofen	8	(8.2)	11	(10.5)
Respiratory	20	(20.4)	22	(21.0)
Loratadine	5	(5.1)	6	(5.7)

Note: Medications sorted by descending frequency in the paroxetine group within each therapeutic class.
NOS – not otherwise specified
* Taken during the month prior to Screening. Patients taking multiple prior medications are counted only once.
Source: Table 13.12.3.1, Section 11; Listing 13.12.3, Appendix B

4.7.2 Concomitant Medications

Table 25 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 66.0% of the ITT population (134/203) were reported to have taken at least one concomitant medication, 61/98 patients (62.2%) in the paroxetine group and 73/105 patients (69.5%) in the placebo group. The proportion of patients taking each medication by therapeutic class was generally similar between treatment groups.

The most frequently reported concomitant medications by therapeutic class were central nervous system agents, primarily paracetamol and ibuprofen for pain (paroxetine group: 38.8%, 38/98 patients; placebo group: 40.0%, 42/105 patients), and respiratory agents, primarily pseudoephedrine and loratadine for cold and flu symptoms and allergies (paroxetine group: 35.7%, 35/98 patients; placebo group: 41.9%, 44/105). The most frequent single medication used was paracetamol,

taken by 28/98 patients (28.6%) in the paroxetine group and 25/105 patients (23.8%) in the placebo group (Table 13.12.3.4, Section 11). There were no important differences between treatment groups in specific medication intake.

If a patient took any psychoactive medication for a psychiatric indication during the Treatment Phase, the patient was excluded from the PP population. If a patient took a psychoactive medication for any indication other than a psychiatric indication for more than 7 days during the Treatment Phase, the patient was excluded from the PP population (see Section 4.3, Protocol Violations).

A complete summary by WHO ATC generic names and the Level I drug classification system may be found in Table 13.12.3.3, 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 13.12.3.4, 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 Listing 13.12.3, Appendix B.

Table 25 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			
Total Number of Patients	**Paroxetine (N = 98)**		**Placebo (N = 105)**	
Total Patients with a Concomitant Medication*	61 (62.2%)		73 (69.5%)	
Therapeutic Class and Medication	**n (%)**		**n (%)**	
Alimentary tract/metabolic	19	(19.4)	16	(15.2)
Vitamins NOS	6	(6.1)	4	(3.8)
Central nervous system	38	(38.8)	42	(40.0)
Paracetamol	26	(26.5)	25	(23.8)
Ibuprofen	14	(14.3)	21	(20.0)
Acetylsalicylic acid	5	(5.1)	1	(1.0)
Dermatologicals	15	(15.3)	19	(18.1)
Diphenhydramine HCl	6	(6.1)	4	(3.8)
Musculoskeletal	16	(16.3)	21	(20.0)
Ibuprofen	14	(14.3)	21	(20.0)
Respiratory	35	(35.7)	44	(41.9)
Pseudoephedrine HCl	9	(9.2)	8	(7.6)
Loratadine	8	(8.2)	8	(7.6)
Paracetamol	7	(7.1)	4	(3.8)
Diphenhydramine HCl	6	(6.1)	5	(4.8)
Phenylpropanolamine HCl	6	(6.1)	10	(9.5)
Dextromethorphan hydrobromide	5	(5.1)	6	(5.7)
Fexofenadine HCl	5	(5.1)	3	(2.9)
Guaifenesin	5	(5.1)	5	(4.8)
Brompheniramine maleate	3	(3.1)	6	(5.7)

Note: Medications sorted by descending frequency in the paroxetine group within each therapeutic class.
*Patients taking multiple concomitant medications are counted only once.
Source: Table 13.12.3.3, Section 11; Listing 13.12.3, Appendix B

During the Taper and Follow-up Phases, concomitant medication usage was reported for 52.5% (42/80) and 53.9% (48/89) of the paroxetine and placebo patients, respectively, who entered either of those phases (Tables 13.12.3.5 [by Level I classification] and 13.12.3.6 [by generic name in order of decreasing frequency], Section 11, and Listing 13.12.3, Appendix B). (Note: Tables 13.12.3.5 and 13.12.3.6 may include concomitant medication usage for some

patients who did not enter the Follow-up Phase (see Errata, Section 15). The medications most frequently used by patients in the paroxetine group during the Taper and Follow-up Phases were paracetamol and ibuprofen (8/80 patients each [10.0%] compared with 6/89 [6.7%] and 5/89 [5.6%], respectively, in the placebo group). Loratadine was the medication most frequently used in the placebo group (7/89 patients [7.9%] compared with 5/80 patients [6.3%] in the paroxetine group).

Three patients in the paroxetine group and four patients in the placebo group took paroxetine during the Follow-up Phase, or during the Taper Phase in addition to scheduled Taper Medication. The reason for taking paroxetine was to continue the treatment of OCD, except for 1 patient in the placebo group, who was given paroxetine by the investigator after the Treatment Phase to treat depression/OCD (Listing 13.12.3, Appendix B). None of these patients entered the extension study, Study 716.

4.8 Treatment Compliance and Titration

4.8.1 Treatment Compliance

Table 26 presents a summary of the patients who missed more than 3 consecutive days study medication, at any time during the study and by each visit interval. Patients with unknown compliance and a duration of study medication of >3 days at a visit were considered to have missed more than 3 consecutive days study medication for that visit. The percentage of patients who missed more than 3 consecutive days study medication at any time was similar in the 2 treatment groups (paroxetine 17.5%, 17/98; placebo 18.1%, 19/105) (Table 13.13.1, Section 11; Listing 13.13.1, Appendix B). Note: As stated above, Table 13.13.1, Section 11, accounts for patients with unknown compliance. Therefore, it contains more patients than Listing PV15, Appendix B, which is based solely on the investigator's reporting of patients who missed more than 3 consecutive days study medication and does not account for patients with unknown compliance (Section 4.3.1).

Patients missing >3 consecutive days of dosing on more than one occasion were to be withdrawn from the study. No patients were reported by the investigators as meeting this criterion. Table 26 indicates, however, that 1 child and 1 adolescent in the paroxetine group and 1 child in the placebo group missed >3 consecutive days of dosing on more than one occasion. The apparent discrepancy between the investigator's reporting and Table 26 results from the fact that compliance was

unknown for these patients for at least one of the occasions recorded in Table 26, but the patient was not reported by the investigator as missing >3 consecutive days of dosing on that occasion.

Table 26 Summary of Patients Missing >3 Consecutive Days Study Medication, Excluding Taper Phase –Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group			
	Paroxetine		Placebo	
Missed >3 Consecutive Days	No	Yes	No	Yes
	n (%)	n (%)	n (%)	n (%)
Age Group: Total				
Week 1	96 (99.0)	1 (1.0)	105 (100.0)	0
Week 2	93 (98.9)	1 (1.1)	100 (99.0)	1 (1.0)
Week 3	91 (100.0)	0	95 (96.0)	4 (4.0)
Week 4	85 (96.6)	3 (3.4)	92 (97.9)	2 (2.1)
Week 6	76 (91.6)	7 (8.4)	92 (98.9)	1 (1.1)
Week 8	69 (94.5)	4 (5.5)	81 (92.0)	7 (8.0)
Week 10	64 (95.5)	3 (4.5)	76 (93.8)	5 (6.2)
Overall*	80 (82.5)	17 (17.5)	86 (81.9)	19 (18.1)
Age Group: Children				
Week 1	56 (98.2)	1 (1.8)	57 (100.0)	0
Week 2	53 (98.1)	1 (1.9)	54 (100.0)	0
Week 3	52 (100.0)	0	51 (92.7)	4 (7.3)
Week 4	50 (98.0)	1 (2.0)	51 (96.2)	2 (3.8)
Week 6	44 (91.7)	4 (8.3)	51 (98.1)	1 (1.9)
Week 8	40 (97.6)	1 (2.4)	47 (92.2)	4 (7.8)
Week 10	36 (94.7)	2 (5.3)	47 (97.9)	1 (2.1)
Overall*	48 (84.2)	9 (15.8)	46 (80.7)	11 (19.3)
Age Group:Adolescents				
Week 1	40 (100.0)	0	48 (100.0)	0
Week 2	40 (100.0)	0	46 (97.9)	1 (2.1)
Week 3	39 (100.0)	0	44 (100.0)	0
Week 4	35 (94.6)	2 (5.4)	41 (100.0)	0
Week 6	32 (91.4)	3 (8.6)	41 (100.0)	0
Week 8	29 (90.6)	3 (9.4)	34 (91.9)	3 (8.1)
Week 10	28 (96.6)	1 (3.4)	29 (87.9)	4 (12.1)
Overall*	32 (80.0)	8 (20.0)	40 (83.3)	8 (16.7)

*Number of patients who miss ≤ 3 or > 3 consecutive days at any time during the study.
Patients missing > 3 consecutive days on more than one occasion are only counted once.
Note: Percentages at each visit are based on the number of patients with study medication information for that visit.
Source: Table 13.13.1, Section 11; Listing 13.13.1, Appendix B

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

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

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

Between 74.6% and 89.9% of paroxetine patients and between 79.2% and 93.0% of placebo patients in the overall population fell within the range of 80% to 120% accountability at each visit (Table 27). The pattern of accountability was similar among placebo patients and paroxetine patients in both age groups, with one exception: Accountability at Week 10 fell to 66.7% (18/27 patients) among adolescents receiving paroxetine compared with 81.3% (26/32 patients) for adolescents receiving placebo.

Table 27 Tablet Accountability (Number [%] of Patients) at Each Visit–Age Group: Total/Adolescents/Children (ITT Population)

Accountability, n (%)	Treatment Group: Accountable*	Non-accountable	Accountable*	Non-accountable	Accountable*	Non-accountable
Age Group: Total	**Paroxetine (N = 98)**		**Placebo (N = 105)**		**Total (N = 203)**	
Week 1	80 (89.9)	9 (10.1)	93 (93.0)	7 (7.0)	173 (91.5)	16 (8.5)
Week 2	76 (82.6)	16 (17.4)	89 (89.0)	11 (11.0)	165 (85.9)	27 (14.1)
Week 3	70 (85.4)	12 (14.6)	83 (89.2)	10 (10.8)	153 (87.4)	22 (12.6)
Week 4	73 (86.9)	11 (13.1)	76 (85.4)	13 (14.6)	149 (86.1)	24 (13.9)
Week 6	64 (84.2)	12 (15.8)	79 (85.9)	13 (14.1)	143 (85.1)	25 (14.9)
Week 8	59 (84.3)	11 (15.7)	72 (86.7)	11 (13.3)	131 (85.6)	22 (14.4)
Week 10	47 (74.6)	16 (25.4)	61 (79.2)	16 (20.8)	108 (77.1)	32 (22.9)
Age Group: Children	**(N = 58)**		**(N = 57)**		**(N = 115)**	
Week 1	45 (88.2)	6 (11.8)	49 (92.5)	4 (7.5)	94 (90.4)	10 (9.6)
Week 2	43 (81.1)	10 (18.9)	51 (94.4)	3 (5.6)	94 (87.9)	13 (12.1)
Week 3	42 (87.5)	6 (12.5)	46 (86.8)	7 (13.2)	88 (87.1)	13 (12.9)
Week 4	45 (90.0)	5 (10.0)	41 (83.7)	8 (16.3)	86 (86.9)	13 (13.1)
Week 6	33 (76.7)	10 (23.3)	45 (86.5)	7 (13.5)	78 (82.1)	17 (17.9)
Week 8	32 (80.0)	8 (20.0)	42 (85.7)	7 (14.3)	74 (83.1)	15 (16.9)
Week 10	29 (80.6)	7 (19.4)	35 (77.8)	10 (22.2)	64 (79.0)	17 (21.0)

* Accountable is defined as the result of the following calculation falling within the 80%-120% band: ([No. of Tablets Dispensed - No. of Tablets Returned] / [No. of Days x No. of Tablets Per Day]) x 100. Accountability was calculated only if all data needed were present.
Note: Percentages at each visit are based on the number of patients with study medication information for that visit.
Source: Table 13.13.2, Section 11; Listing 13.13.1, Appendix B
(Continued)

Table 27 Tablet Accountability (Number [%] of Patients) at Each Visit–Age Group: Total/Adolescents/Children (ITT Population) (Continued)

	Treatment Group					
Accountability, n (%)	**Accountable***	**Non-accountable**	**Accountable***	**Non-accountable**	**Accountable***	**Non-accountable**
Age Group: Adolescents	**(N = 40)**		**(N = 48)**		**(N =88)**	
Week 1	35 (92.1)	3 (7.9)	44 (93.6)	3 (6.4)	79 (92.9)	6 (7.1)
Week 2	33 (84.6)	6 (15.4)	38 (82.6)	8 (17.4)	71 (83.5)	14 (16.5)
Week 3	28 (82.4)	6 (17.6)	37 (92.5)	3 (7.5)	65 (87.8)	9 (12.2)
Week 4	28 (82.4)	6 (17.6)	35 (87.5)	5 (12.5)	63 (85.1)	11 (14.9)
Week 6	31 (93.9)	2 (6.1)	34 (85.0)	6 (15.0)	65 (89.0)	8 (11.0)
Week 8	27 (90.0)	3 (10.0)	30 (88.2)	4 (11.8)	57 (89.1)	7 (10.9)
Week 10	18 (66.7)	9 (33.3)	26 (81.3)	6 (18.8)	44 (74.6)	15 (25.4)

* Accountable is defined as the result of the following calculation falling within the 80%-120% band: ([No. of Tablets Dispensed - No. of Tablets Returned] / [No. of Days x No. of Tablets Per Day]) x 100. Accountability was calculated only if all data needed were present.
Note: Percentages at each visit are based on the number of patients with study medication information for that visit.
Source: Table 13.13.2, Section 11; Listing 13.13.1, Appendix B

4.8.2 Titration of Dose

Dosing was initiated at 1 tablet/day of placebo or 10 mg/day of paroxetine, and if necessary, the dose could be titrated upward in 10 mg increments at weekly intervals to a maximum daily dose of 50 mg or 5 tablets. Dose escalation was to be based on therapeutic response and tolerability of the medication, according to the judgment of the investigator.

Table 28 presents the number of patients exposed to each daily dose of study medication both overall and by age subgroup. In the overall population, 26/98 (26.5%) paroxetine patients took a maximum dose of 50 mg per day, compared with 50/105 (47.6%) 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 per day and dose levels >DL 1. Among children, 11/58 (19.0%) paroxetine patients took a maximum dose of paroxetine (50 mg per day) for at least one dosing period compared with 23/57 (40.4%) placebo patients dosed at DL 5. Among adolescents, 15/40 (37.5%) paroxetine patients took a maximum dose of paroxetine (50 mg per day) for at least one dosing period compared with 27/48 (56.3%) placebo patients dosed at DL 5.

Table 28 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	**(N = 98)**	**(N = 58)**	**(N = 40)**
10 mg/day	98 (100.0)	58 (100.0)	40 (100.0)
20 mg/day	90 (91.8)	51 (87.9)	39 (97.5)
30 mg/day	63 (64.3)	29 (50.0)	34 (85.0)
40 mg/day	44 (44.9)	16 (27.6)	28 (70.0)
50 mg/day	26 (26.5)	11 (19.0)	15 (37.5)
Placebo	**(N = 105)**	**(N = 57)**	**(N = 48)**
DL 1	105 (100.0)	57 (100)	48 (100.0)
DL 2	100 (95.2)	54 (94.7)	46 (95.8)
DL 3	87 (82.9)	46 (80.7)	41 (85.4)
DL 4	67 (63.8)	35 (61.4)	32 (66.7)
DL 5	50 (47.6)	23 (40.4)	27 (56.3)

Source: Table 13.13.4, Section 11; Listing 13.13.1, Appendix B

Table 29 presents a summary of patient dosing by visit (excluding Taper Phase) and also maximum dose for the paroxetine group; Table 30 presents the same

summary for the placebo group. Patients in the placebo group reached higher dose levels earlier in the study compared with patients in the paroxetine group.

A total of 64.3% (63/98) of patients in the paroxetine group received a dose higher than 20 mg per day. Half the children (29/58, 50.0%) took a dose higher than 20 mg per day, compared with 85.0% (34/40) of the adolescents. Adolescents also reached higher doses earlier than children, with 61.5% (24/40) of adolescents receiving 30 mg per day at Week 3 compared with 34.6% (18/58) of children (Table 29).

Table 29 Summary of the Number (%) of Patients Exposed to Each Dose of Paroxetine by Visit–Age Group: Total/Children/Adolescents (ITT Population)

Daily Dose		Paroxetine				
		10 mg n (%)	**20 mg** n (%)	**30 mg** n (%)	**40 mg** n (%)	**50 mg** n (%)
Age Group: Total	**N***					
Week 1	98	98 (100.0)	0	0	0	0
Week 2	96	30 (31.3)	66 (68.8)	0	0	0
Week 3	91	17 (18.7)	32 (35.2)	42 (46.2)	0	0
Week 4	88	12 (13.6)	29 (33.0)	18 (20.5)	29 (33.0)	0
Week 6	84	8 (9.5)	28 (33.3)	13 (15.5)	19 (22.6)	16 (19.0)
Week 8	73	7 (9.6)	19 (26.0)	12 (16.4)	12 (16.4)	23 (31.5)
Week 10	68	6 (8.8)	18 (26.5)	8 (11.8)	18 (26.5)	18 (26.5)
Maximum **	**98**	8 (8.2)	27 (27.6)	19 (19.4)	18 (18.4)	26 (26.5)
Age Group: Children						
	N*					
Week 1	58	58 (100.0)	0	0	0	0
Week 2	56	22 (39.3)	34 (60.7)	0	0	0
Week 3	52	12 (23.1)	22 (42.3)	18 (34.6)	0	0
Week 4	51	8 (15.7)	23 (45.1)	11 (21.6)	9 (17.6)	0
Week 6	49	7 (14.3)	22 (44.9)	7 (14.3)	7 (14.3)	6 (12.2)
Week 8	41	6 (14.6)	16 (39.0)	5 (12.2)	5 (12.2)	9 (22.0)
Week 10	39	5 (12.8)	15 (38.5)	6 (15.4)	6 (15.4)	7 (17.9)
Maximum **	**58**	7 (12.1)	22 (37.9)	13 (22.4)	5 (8.6)	11 (19.0)
Age Group: Adolescents						
	N*					
Week 1	40	40 (100.0)	0	0	0	0
Week 2	40	8 (20.0)	32 (80.0)	0	0	0
Week 3	39	5 (12.8)	10 (25.6)	24 (61.5)	0	0
Week 4	37	4 (10.8)	6 (16.2)	7 (18.9)	20 (54.1)	0
Week 6	35	1 (2.9)	6 (17.1)	6 (17.1)	12 (34.3)	10 (28.6)
Week 8	32	1 (3.1)	3 (9.4)	7 (21.9)	7 (21.9)	14 (43.8)
Week 10	29	1 (3.4)	3 (10.3)	2 (6.9)	12 (41.4)	11 (37.9)
Maximum **	**40**	1 (2.5)	5 (12.5)	6 (15.0)	13 (32.5)	15 (37.5)

* N = The number of patients in the study at each visit; percentages are based on N.
**Represents the number of patients for whom that dose was the maximum dosing during the study.
Source: Tables 13.13.3, 13.13.4, Section 11; Listing 13.13.1, Appendix B

Table 30 presents a summary of patient dosing by visit (excluding Taper Phase) and also maximum dose for the placebo group.

A total of 82.9% of patients in the placebo group (87/105) took a dose higher than DL 2 per day, with comparable percentages among children (80.7%, 46/57) and adolescents (85.4%, 41/48). As in the paroxetine group, adolescents tended to reach higher dose levels earlier than children.

Table 30 Summary of the Number (%) of Patients Exposed to Each Dose Level of Placebo by Visit–Age Group: Total/Children/Adolescents (ITT Population)

		Placebo				
Dose Level		**1**	**2**	**3**	**4**	**5**
		n (%)	n (%)	n (%)	n (%)	n (%)
Age Group: Total	**N***					
Week 1	105	105 (100.0)	0	0	0	0
Week 2	103	26 (25.2)	77 (74.8)	0	0	0
Week 3	100	13 (13.0)	30 (30.0)	57 (57.0)	0	0
Week 4	95	6 (6.3)	22 (23.2)	22 (23.2)	45 (47.4)	0
Week 6	94	6 (6.4)	14 (14.9)	18 (19.1)	21 (22.3)	35 (37.2)
Week 8	88	4 (4.5)	10 (11.4)	16 (18.2)	17 (19.3)	41 (46.6)
Week 10	81	3 (3.7)	11 (13.6)	12 (14.8)	15 (18.5)	40 (49.4)
Maximum **	**105**	5 (4.8)	13 (12.4)	20 (19.0)	17 (16.2)	50 (47.6)
Age Group: Children						
	N*					
Week 1	57	57 (100.0)	0	0	0	0
Week 2	55	17 (30.9)	38 (69.1)	0	0	0
Week 3	55	9 (16.4)	19 (34.5)	27 (49.1)	0	0
Week 4	53	4 (7.5)	16 (30.2)	12 (22.6)	21 (39.6)	0
Week 6	53	4 (7.5)	10 (18.9)	12 (22.6)	12 (22.6)	15 (28.3)
Week 8	51	3 (5.9)	8 (15.7)	10 (19.6)	12 (23.5)	18 (35.3)
Week 10	48	3 (6.3)	9 (18.8)	6 (12.5)	11 (22.9)	19 (39.6)
Maximum **	**57**	3 (5.3)	8 (14.0)	11 (19.3)	12 (21.1)	23 (40.4)
Age Group: Adolescents						
	N*					
Week 1	48	48 (100)	0	0	0	0
Week 2	48	9 (18.8)	39 (81.3)	0	0	0
Week 3	45	4 (8.9)	11 (24.4)	30 (66.7)	0	0
Week 4	42	2 (4.8)	6 (14.3)	10 (23.8)	24 (57.1)	0
Week 6	41	2 (4.9)	4 (9.8)	6 (14.6)	9 (22.0)	20 (48.8)
Week 8	37	1 (2.7)	2 (5.4)	6 (16.2)	5 (13.5)	23 (62.2)
Week 10	33	0	2 (6.1)	6 (18.2)	4 (12.1)	21 (63.6)
Maximum **	**48**	2 (4.2)	5 (10.4)	9 (18.8)	5 (10.4)	27 (56.3)

* N = The number of patients in the study at each visit; percentages are based on N.
**Represents the number of patients for whom that dose level was the maximum dosing during the study.
Source: Tables 13.13.3, 13.13.4, Section 11; Listing 13.13.1, Appendix B

Table 31 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 23.0 mg per day for all patients: 20.3 mg per day for children and 26.8 mg per day for adolescents. The mean dose at Week 10 LOCF endpoint was 30.1 mg per day for all patients: 25.4 mg per day for children and 36.5 mg per day for adolescents (Tables 13.13.6 and 13.13.7, Section 11).

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 10 LOCF endpoint was DL 3.6 overall: DL 3.5 for children and DL 3.8 for adolescents (Tables 13.13.6 and 13.13.7, Section 11).

Table 31 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	98	10.0	0.00
Week 2	96	16.9	4.66
Week 3	91	22.7	7.61
Week 4	88	27.3	10.69
Week 6	84	30.8	13.10
Week 8	73	33.4	14.07
Week 10	68	33.5	13.58
Overall Mean	98	23.0	8.48
Week 10 LOCF Endpoint*	94	30.1	13.48
Age Group: Children			
Week 1	58	10.0	0.00
Week 2	56	16.1	4.93
Week 3	52	21.2	7.58
Week 4	51	24.1	9.63
Week 6	49	26.5	12.51
Week 8	41	28.8	14.18
Week 10	39	28.7	13.41
Overall Mean	58	20.3	7.92
Week 10 LOCF Endpoint*	54	25.4	13.28
Age Group: Adolescents			
Week 1	40	10.0	0.00
Week 2	40	18.0	4.05
Week 3	39	24.9	7.21
Week 4	37	31.6	10.68
Week 6	35	36.9	11.57
Week 8	32	39.4	11.62
Week 10	29	40.0	11.02
Overall Mean	40	26.8	7.84
Week 10 LOCF Endpoint*	40	36.5	10.99

*The Week 10 LOCF endpoint corresponds to the visit making up each patient's LOCF assessment for CY-BOCS Total Score.
Source: Tables 13.13.6, 13.13.7, Section 11; Listing 13.13.1, Appendix B

Overall duration of exposure to study medication (excluding taper) may be found in Table 50, Section 6.1, Extent of Exposure, and Table 13.13.5.1, Section 11.

5 Efficacy Results

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 98 patients in the paroxetine group and 105 patients in the placebo group.

Analysis of efficacy data derived from the PP population, which comprised 73 patients in the paroxetine group and 82 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.

Due to an audit finding of significant compliance violations, the participation of Center 055 in the study was terminated. Results of the analysis of the primary efficacy variable without data from patients at Center 055 in both the ITT and PP datasets are presented in Section 5.2.3 .

Section 3.14.5, Populations/Datasets to Be Evaluated, and Section 3.14.7, Defined Visit Timepoints, provide detailed descriptions of the populations, datasets and criteria used to define time periods. Additional details of the analyses may be found in the statistical appendix to this report (Appendix H).

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 10 LOCF dataset, the Week 10 OC dataset, and the 70% LOCF dataset. Primary inference is based on the Week 10 LOCF dataset for the ITT population. In the LOCF datasets for change in CY-BOCS total score and change in obsession and compulsion subscale score, the last known non-missing post-baseline score for each patient was carried forward to estimate missing data points. In the LOCF datasets for change in CGI Severity of Illness, change in GAF, and proportion of responders based on the CGI Global Improvement item, the last non-zero post-baseline score for each patient was

carried forward to estimate missing data points. The Week 10 LOCF dataset contains all data for the Week 10 visit, plus the last on-therapy 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 8; therefore, the 70% LOCF endpoint was analyzed.

5.2 Primary Efficacy Variable - Change from Baseline in Children's Yale-Brown Obsessive-Compulsive Scale (Total Score)

5.2.1 CY-BOCS (Total Score) - Intention-to-Treat Population

The protocol defined the primary efficacy variable as the change from Baseline in Children's Yale-Brown Obsessive-Compulsive Scale (CY-BOCS) total score at the Week 10 LOCF endpoint. The Week 10 LOCF dataset based on the ITT population for change from Baseline in CY-BOCS total score contained 94 patients treated with paroxetine and 102 patients given placebo. Seven patients in the ITT population were not included in the analysis of the primary efficacy variable. Five of these patients (704.009.25503, 704.020.25460 and 704.055.28176, randomized to paroxetine; 704.005.27053 and 704.015.25467, randomized to placebo) did not have any post-baseline data for the CY-BOCS, and two patients (704.002.25442, randomized to paroxetine; 704.016.25453, randomized to placebo) had no post-baseline CY-BOCS assessments during treatment or within 7 days of their last dose, although both had assessments more than 7 days after their last dose.

Table 32 presents the analysis of the primary variable at each assessment period for the Week 10 LOCF and OC datasets and the 70% LOCF dataset, based on the ITT population. The mean change from Baseline in each treatment group and the estimated mean differences between paroxetine and placebo were adjusted for the following pre-defined covariates: age group (children/adolescents), gender, Baseline CY-BOCS total score, and comorbidity (yes/no).

For the LOCF dataset, the adjusted mean change from Baseline at the Week 10 endpoint in CY-BOCS total score was –8.78 points (SE 0.82) for paroxetine patients and –5.34 points (SE 0.77) for placebo patients. The adjusted mean difference, -3.45 points in favor of paroxetine, was statistically significant (95% confidence interval [-5.60, -1.29], p = 0.002). The sample size for the study was

powered to detect a clinically meaningful difference of 4 units between paroxetine and placebo.

Therefore, there is statistically significant evidence that patients treated with paroxetine have a greater improvement in change from Baseline to Week 10 LOCF endpoint in CY-BOCS total score than patients given placebo. The Week 10 OC dataset and the 70% LOCF dataset analyses supported the conclusion of the Week 10 LOCF analysis, in that there was evidence of a statistically significant treatment effect.

Table 32 Summary of Analysis for Change from Baseline in CY-BOCS 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	98	24.4	4.95	105	25.3	5.05			
Change from Baseline to:									
Week 2	87	-3.7	0.50	87	-2.2	0.49			
Week 4	80	-6.6	0.69	83	-3.8	0.66			
Week 6	79	-8.1	0.81	90	-4.8	0.74			
Week 8	67	-9.3	0.88	82	-6.5	0.78			
Week 10 OC	67	-9.8	0.92	78	-7.2	0.84	-2.59	(-4.98, -0.20)	0.034
Week 10 LOCF	94	-8.8	0.82	102	-5.3	0.77	-3.45	(-5.60, -1.29)	0.002
70% LOCF‡	94	-8.2	0.77	102	-5.0	0.73	-3.19	(-5.21, -1.16)	0.002

*LOCF endpoint may have more patients than the first post-Baseline visit since early withdrawal data at unscheduled visits are not tabulated but are carried forward for LOCF endpoint.

* *Least square means. For Baseline, raw means are presented.

† For Baseline, standard deviations, not standard errors, are presented.

†† Differences in adjusted (least square) means (paroxetine minus placebo). Adjusted for baseline score, age group, gender and comorbidity.

‡ 70% LOCF endpoint was Week 8.

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

This primary model for the analysis of change from Baseline in CY-BOCS total score provided no evidence of any variation in response due to gender or presence/absence of comorbidity. However, it indicated that there were statistically significant differences in response between patients with varying Baseline CY-BOCS scores and between children and adolescents (Table 33). These differences were independent of which treatment the patient was receiving. Patients with a higher Baseline CY-BOCS total score had a greater change from Baseline than those with a lower Baseline CY-BOCS total score, irrespective of treatment group. Likewise, children had a greater change from baseline in CY-BOCS total score than adolescents, irrespective of treatment group.

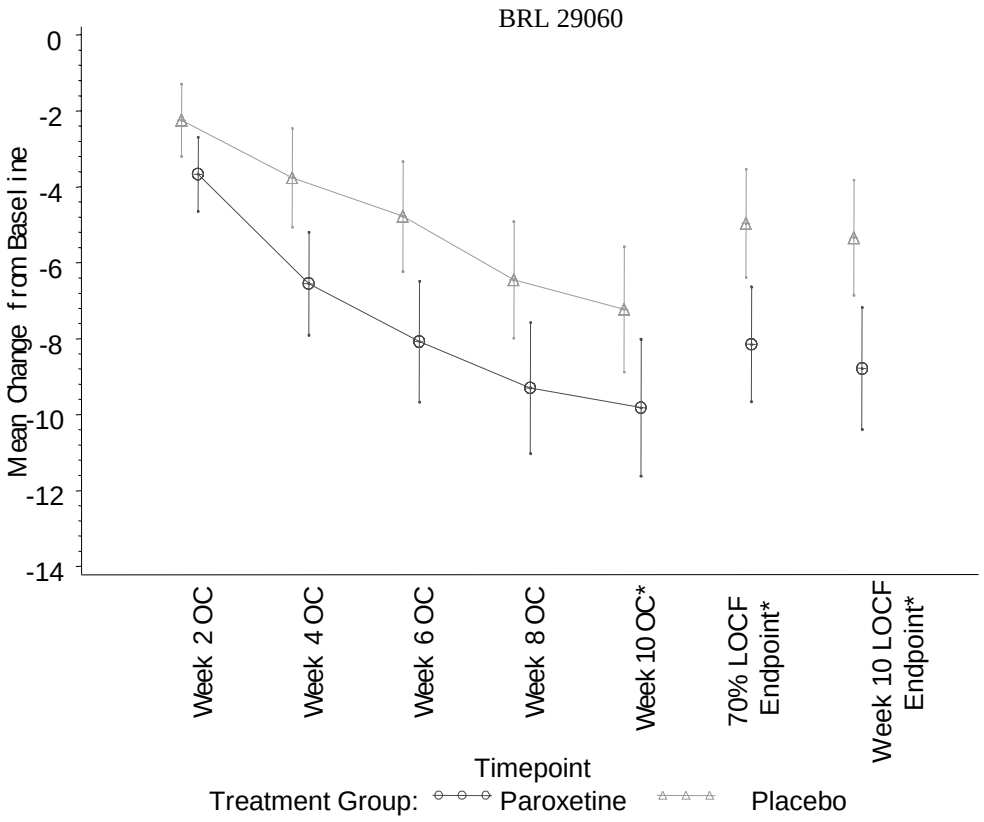
Table 33 Summary of Analysis for Change From Baseline in CY-BOCS Total Score - Covariate Significance, Week 10 LOCF (ITT Population)

Terms in Model	DF	Sum of Squares*	Mean Square	F-statistic	P-value
Baseline Score	1	577.35	577.35	10.17	0.002
Age Group	1	779.63	779.63	13.74	<0.001
Gender	1	7.93	7.93	0.14	0.709
Comorbidity	1	66.22	66.22	1.17	0.281

*Type III sum of squares.
Source: Table 14.1.2.1, Section 12

Figure 2 displays the adjusted mean change from Baseline (± 1.96 standard errors) in CY-BOCS total score at each visit by treatment group.

Figure 2 Change from Baseline in CY-BOCS Total Score at Each Visit-Age Group: Total (ITT Population)



* Statistically significant at 5% level.

Note: Mean change from Baseline adjusted for Baseline score, age group, gender, and comorbidity

Source: Table 14.1.2b, Section 12; Figure 14.1b, Section 14

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). This indicated that the treatment effect is consistent across Baseline CY-BOCS total score, age group, gender, and comorbidity.

Table 34 presents summary statistics for CY-BOCS total scores by visit for both age groups combined and separately for the ITT population. On average, scores decreased (improved) steadily over time in both treatment groups and in both age groups.

Table 34 Summary Statistics for CY-BOCS Total Score at Each Visit –Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group							
	Paroxetine				Placebo			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Age Group: Total			**(N = 98)**				**(N = 105)**	
Baseline	98	24.4	(4.95)	16 to 36	105	25.3	(5.05)	16 to 37
Week 2	87	20.5	(6.34)	4 to 36	87	23.0	(5.54)	7 to 37
Week 4	80	17.7	(7.56)	0 to 36	83	21.0	(5.85)	4 to 34
Week 6	79	16.0	(7.55)	0 to 36	90	19.8	(7.39)	2 to 38
Week 8	67	14.9	(8.12)	0 to 36	82	18.1	(7.48)	0 to 38
Week 10 OC	67	14.3	(8.58)	0 to 35	78	17.3	(7.52)	0 to 36
Week 10 LOCF	94	15.1	(8.62)	0 to 35	102	19.4	(8.21)	0 to 38
Age Group: Children			**(N = 58)**				**(N = 57)**	
Baseline	58	23.8	(5.00)	16 to 36	57	25.3	(5.31)	16 to 37
Week 2	49	19.3	(6.30)	4 to 36	48	22.7	(5.78)	7 to 37
Week 4	48	16.4	(7.07)	0 to 36	48	20.3	(6.12)	4 to 34
Week 6	45	14.2	(7.40)	0 to 36	51	18.7	(7.36)	2 to 37
Week 8	37	13.0	(8.43)	0 to 36	49	17.4	(8.07)	0 to 38
Week 10 OC	37	12.4	(8.41)	0 to 34	45	16.2	(7.59)	0 to 33
Week 10 LOCF	54	13.1	(8.38)	0 to 34	56	17.6	(7.91)	0 to 37
Age Group: Adolescents			**(N = 40)**				**(N = 48)**	
Baseline	40	25.2	(4.82)	18 to 36	48	25.3	(4.79)	16 to 37
Week 2	38	22.1	(6.11)	11 to 34	39	23.3	(5.28)	13 to 36
Week 4	32	19.8	(7.91)	3 to 34	35	22.0	(5.39)	12 to 34
Week 6	34	18.3	(7.23)	5 to 34	39	21.3	(7.25)	8 to 38
Week 8	30	17.2	(7.19)	8 to 34	33	19.2	(6.49)	5 to 35
Week 10 OC	30	16.6	(8.35)	3 to 35	33	18.7	(7.30)	0 to 36
Week 10 LOCF	40	17.9	(8.24)	3 to 35	46	21.6	(8.13)	0 to 38

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

Table 35 presents summary statistics for the change from Baseline in CY-BOCS total score at each visit for the two age groups (ITT population) combined and for each separately. The magnitude of the change from Baseline increased steadily over time in both treatment groups; however, the change was greater in patients who received paroxetine.

Table 35 Summary Statistics for Change from Baseline in CY-BOCS Total Score at Each Visit –Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group							
	Paroxetine				Placebo			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Age Group: Total			**(N = 98)**				**(N = 105)**	
Baseline	98	24.4	(4.95)	16 to 36	105	25.3	(5.05)	16 to 37
Change from Baseline to:								
Week 2	87	-3.9	(4.89)	-19 to 6	87	-2.3	(4.12)	-15 to 10
Week 4	80	-6.8	(6.53)	-30 to 8	83	-4.0	(5.66)	-24 to 7
Week 6	79	-8.3	(6.79)	-24 to 8	90	-5.2	(7.35)	-30 to 17
Week 8	67	-9.8	(6.80)	-25 to 6	82	-6.7	(7.12)	-25 to 7
Week 10 OC	67	-10.4	(7.16)	-27 to 10	78	-7.3	(7.56)	-25 to 6
Week 10 LOCF	94	-9.2	(7.61)	-27 to 10	102	-5.7	(8.15)	-25 to 17
Age Group: Children			**(N = 58)**				**(N = 57)**	
Baseline	58	23.8	(5.00)	16 to 36	57	25.3	(5.31)	16 to 37
Change from Baseline to:								
Week 2	49	-4.2	(4.63)	-16 to 6	48	-2.2	(4.57)	-15 to 10
Week 4	48	-7.2	(6.34)	-26 to 8	48	-4.4	(6.30)	-24 to 7
Week 6	45	-9.2	(6.76)	-21 to 8	51	-6.5	(7.83)	-30 to 10
Week 8	37	-11.0	(7.27)	-25 to 3	49	-7.6	(8.03)	-25 to 7
Week 10 OC	37	-11.5	(6.78)	-27 to 0	45	-8.4	(7.81)	-25 to 6
Week 10 LOCF	54	-10.6	(7.55)	-27 to 5	56	-7.6	(8.14)	-25 to 10
Age Group: Adolescents			**(N = 40)**				**(N = 48)**	
Baseline	40	25.2	(4.82)	18 to 36	48	25.3	(4.79)	16 to 37
Change from Baseline to:								
Week 2	38	-3.4	(5.24)	-19 to 4	39	-2.5	(3.55)	-10 to 3
Week 4	32	-6.2	(6.87)	-30 to 5	35	-3.3	(4.64)	-15 to 6
Week 6	34	-7.2	(6.77)	-24 to 6	39	-3.6	(6.42)	-15 to 17
Week 8	30	-8.3	(5.95)	-20 to 6	33	-5.4	(5.33)	-18 to 4
Week 10 OC	30	-9.0	(7.48)	-23 to 10	33	-5.7	(7.01)	-23 to 5
Week 10 LOCF	40	-7.3	(7.38)	-23 to 10	46	-3.5	(7.67)	-23 to 17

Source: Table 14.1.3b, Section 12; Listings 14.1.1, 14.1.2b, Appendix C

5.2.2 CY-BOCS (Total Score)–Per Protocol Population

The PP population for the Week 10 LOCF dataset for change from Baseline in CY-BOCS total score comprised 73 patients treated with paroxetine and 82 patients who received placebo. Table 36 presents results from the analysis of the PP population, which were similar to those seen in the ITT population. For the LOCF dataset, the adjusted mean change from Baseline at the Week 10 endpoint in CY-BOCS total score was –10.01 points (SE 0.86) for patients who

received paroxetine and –5.74 points (SE 0.79) for placebo patients. The adjusted mean difference between the two treatment groups at the Week 10 LOCF endpoint was –4.27 points in favor of paroxetine. This difference was statistically significant (95% confidence interval [-6.50, -2.04], p <0.001).

Therefore, there was statistically significant evidence from the PP analysis that patients on paroxetine had a greater improvement in change from Baseline to Week 10 LOCF endpoint in CY-BOCS total score than patients who received placebo, which is consistent with the ITT analysis.

The Week 10 OC and the 70% LOCF dataset analyses for the PP population supported the conclusion of the Week 10 LOCF analysis, in that there was evidence of a statistically significant treatment effect.

Summary statistics for CY-BOCS total score and for change from Baseline in CY-BOCS total score at each visit for the PP population may be found in Table 14.1.1c and Table 14.1.3c, Section 12, respectively.

Table 36 Summary of Analysis for Change from Baseline in CY-BOCS Total Score–Age Group: Total (PP Population)

	Treatment Group								
	Paroxetine			Placebo			Treatment Comparison		
	N*	LS Mean**	(SE) †	N*	LS Mean**	(SE)†	Difference††	95% CI	p-value
Baseline	73	24.0	(4.85)	82	24.9	(4.64)			
Change from Baseline to:									
Wk 2	70	-4.1	(0.54)	70	-2.4	(0.53)			
Wk 4	64	-7.2	(0.81)	68	-4.1	(0.77)			
Wk 6	66	-8.5	(0.82)	74	-5.0	(0.75)			
Wk 8	56	-9.7	(0.91)	70	-6.2	(0.80)			
Wk 10 OC	59	-10.5	(0.94)	68	-6.9	(0.84)	-3.55	(-5.97, -1.12)	0.005
Wk 10 LOCF	73	-10.0	(0.86)	82	-5.7	(0.79)	-4.27	(-6.50, -2.04)	<0.001
70% LOCF‡	73	-9.1	(0.81)	82	-5.5	(0.75)	-3.63	(-5.74, -1.53)	<0.001

* LOCF endpoint may have more patients than the first post-Baseline visit since early withdrawal data at unscheduled visits are not tabulated but are carried forward for LOCF endpoint.

** Least square means. For Baseline, raw means are presented.

† For Baseline, standard deviations, not standard errors, are presented.

†† Differences in adjusted (least square) means (paroxetine minus placebo). Adjusted for baseline score, age group, gender and comorbidity.

‡70% LOCF endpoint was Week 8.

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

5.2.3 CY-BOCS (Total Score) - Analyses Excluding Center 055

Due to an audit finding of significant compliance violations, the participation of Center 055 in the study was terminated. At the time of termination, the 7 patients randomized to each treatment group had completed the study. All 14 patients were included in the ITT population, and 7 were included in the PP population described throughout this Report. Additional analyses of the primary efficacy variable were conducted for the ITT and PP populations excluding all Center 055 patients.

5.2.3.1 ITT Population Excluding Center 055

The primary efficacy variable, change from Baseline in CY-BOCS total score at the Week 10 LOCF endpoint, was analyzed in the ITT population excluding patients from Center 055. Therefore, this population comprised 91 patients randomized to paroxetine and 98 patients randomized to placebo. The adjusted mean change from Baseline was -9.33 points (SE 0.84) for paroxetine patients and -5.45 points (SE 0.78) for placebo patients. The adjusted mean difference, -3.88 points in favor of paroxetine, was statistically significant (95% confidence interval [-6.08, -1.69], $p < 0.001$) (Table 14.1.2bZ, Section 12). These results were comparable to those obtained in the analysis for the ITT population including patients from Center 055.

5.2.3.2 Per Protocol Population Excluding Center 055

The PP population, excluding all patients from Center 055, for the Week 10 LOCF dataset for change from Baseline in CY-BOCS total score comprised 69 patients treated with paroxetine and 79 patients who received placebo. The adjusted mean change from Baseline was -10.30 points (SE 0.90) for patients who received paroxetine and -5.62 points (SE 0.81) for placebo patients. The adjusted mean difference between the two treatment groups was -4.68 points in favor of paroxetine. This difference was statistically significant (95% confidence interval [-6.99, -2.37], $p < 0.001$) (Table 14.1.2cZ, Section 12). These results were comparable to the results of the analysis for the PP population including patients from Center 055.

5.3 Secondary Efficacy Parameters

The protocol defined the following secondary efficacy variables to support the primary variable: the proportion of responders based on the CY-BOCS total score, proportion of responders based on the CGI Global Improvement item, change

from Baseline in CGI Severity of Illness score, change from Baseline in GAF score, and change from baseline in the CY-BOCS Obsession and Compulsion subscale scores.

5.3.1 Proportion of Responders Based on the Change in CY-BOCS Total Score from Baseline

Table 37 summarizes the analyses of responders based on the change from Baseline in CY-BOCS total score. Response was defined as a ≥25% reduction from Baseline in CY-BOCS total score. Percentages of responders at a particular visit are based on the total number of patients in the population at the particular visit with a CY-BOCS total score at Baseline. Results are presented for the Week 10 LOCF and OC datasets and for the 70% LOCF dataset, based on the ITT population.

The odds of being a CY-BOCS responder on paroxetine compared with placebo at Week 10 LOCF were 2.66 (95% CI: [1.45, 4.87], p = 0.002), indicating that the odds of responding on paroxetine were statistically significantly better than the odds of responding on placebo. This conclusion was supported by the results obtained from the Week 10 OC and the 70% LOCF analyses.

Table 37 Proportion of Responders Based on the CY-BOCS Total Score Change from Baseline–Age Group: Total (ITT Population)

	Treatment Groups						Treatment Comparisons		
	Paroxetine			Placebo					
Visit	N*	n**	%	N*	n**	%	Odds Ratio †	95% CI	p-value
Week 2	87	26	29.9	87	14	16.1			
Week 4	80	42	52.5	83	21	25.3			
Week 6	79	50	63.3	90	39	43.3			
Week 8	67	49	73.1	82	40	48.8			
Week 10 OC	67	50	74.6	78	38	48.7	2.78	(1.32, 5.85)	0.007
Week 10 LOCF	94	61	64.9	102	42	41.2	2.66	(1.45, 4.87)	0.002
70% LOCF ††	94	59	62.8	102	43	42.2	2.30	(1.27, 4.17)	0.006

*N is the total number of patients at a visit with a CY-BOCS total score at baseline.

**Responders (n) are defined as patients with a ≥25% reduction in CY-BOCS total score from Baseline.

†The odds ratio represents the odds of improving with paroxetine relative to that with placebo. Percentage of responders is unadjusted; odds ratio is adjusted for baseline score, age group, gender, and comorbidity.

†† 70% LOCF was Week 8.

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

Details of the distribution of responders versus non-responders in CY-BOCS total score at Week 10 LOCF are presented by treatment group for both age groups combined and by age subgroup in Table 38. The percentage of responders was higher in the paroxetine group overall (61/94, 64.9%) than in the placebo group (42/102, 41.2%). This pattern was also seen in the age subgroups. The highest percentage of responders was in the group of children who received paroxetine (40/54, 74.1%).

Table 38 Number (%) of Responders versus Non-Responders in CY-BOCS Total Score from Baseline at Week 10 LOCF–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group	
	Paroxetine (N = 98)	**Placebo (N = 105)**
	n (%)	**n (%)**
Age Group: Total	(N = 94)	(N = 102)
≥25% reduction	61 (64.9)	42 (41.2)
<25% reduction	33 (35.1)	60 (58.8)
Total	94 (100.0)	102 (100.0)
Age Group: Children	(N = 54)	(N = 56)
≥25% reduction	40 (74.1)	27 (48.2)
<25% reduction	14 (25.9)	29 (51.8)
Total	54 (100.0)	56 (100.0)
Age Group: Adolescents	(N = 40)	(N = 46)
≥25% reduction	21 (52.5)	15 (32.6)
<25% reduction	19 (47.5)	31 (67.4)
Total	40 (100.0)	46 (100.0)

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

5.3.2 Proportion of Responders Based on the Clinical Global Impression–Global Improvement Item

Table 39 summarizes the analyses of responders based on the 7-point CGI Global Improvement assessment for the ITT population. A responder was defined as a patient who scored 1 (very much improved) or 2 (much improved) at endpoint compared to baseline. Results are presented for the Week 10 LOCF and OC datasets and the 70% LOCF dataset. The odds ratio was adjusted for Baseline CGI Severity of Illness score, age group, gender, and comorbidity. Due to inadequate numbers of patients in some categories of the CGI Severity of Illness at Baseline, the classifications were collapsed for the analysis into Mild or

Moderately Ill, Markedly Ill, and Severely Ill or Among the Most Extremely Ill patients.

The odds of being a CGI responder on paroxetine compared with placebo at Week 10 LOCF were 1.69 (95% CI: [0.94, 3.07], p = 0.081), indicating that the odds of responding on paroxetine were not statistically significantly different from the odds of responding on placebo. However, the percentage of responders at Week 10 LOCF was higher for patients receiving paroxetine than for those receiving placebo (46.9% [45/96] vs. 33.3% [35/105], respectively). Similar results were obtained from the Week 10 OC analysis and the 70% LOCF analysis.

Table 39 Proportion of Responders Based on the CGI Global Improvement Item (ITT Population)

	Treatment Groups						Treatment Comparisons		
	Paroxetine			Placebo					
Visit	**N***	**n****	**%**	**N***	**n****	**%**	**Odds Ratio†**	**95% CI**	**p-value**
Week 1	93	3	3.2	99	2	2.0			
Week 2	89	16	18.0	92	6	6.5			
Week 3	89	28	31.5	84	13	15.5			
Week 4	84	27	32.1	92	15	16.			
Week 6	79	40	50.6	90	24	26.7			
Week 8	67	35	52.2	82	30	36.6			
Week 10 OC	67	38	56.7	78	33	42.3	1.65	(0.82, 3.33)	0.162
Week 10 LOCF	96	45	46.9	105	35	33.3	1.69	(0.94, 3.07)	0.081
70% LOCF††	96	42	43.8	105	31	29.5	1.74	(0.95, 3.18)	0.072

*N is 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 the visit or 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 comorbidity).

††70% LOCF endpoint was Week 8.

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

Details of the distribution of patient ratings in each global improvement category at Week 10 OC and LOCF are presented by treatment group for both age groups combined and separately in Table 40. In the LOCF dataset for the combined age groups, 46.9% of patients (45/96) treated with paroxetine were rated much or very much improved, compared with 33.3% of the placebo patients (35/105). Ten patients in the paroxetine group and 11 in the placebo group became worse over the course of the study, and 1 patient in the placebo group was rated very much worse. Within each treatment group, higher percentages of children (paroxetine, 51.8%, 29/56; placebo, 45.6%, 26/57) were rated much or very much improved compared with adolescents (paroxetine, 40.0%, 16/40; placebo, 18.8%, 9/48).

Table 40 Number (%) of Patients in Each Category of the CGI Global Improvement Item Score at Week 10–Age Group: Total/Children/Adolescents (ITT Population)

	Week 10 (OC)		Week 10 (LOCF)	
	Treatment Group		Treatment Group	
	Paroxetine n (%)	Placebo n (%)	Paroxetine n (%)	Placebo n (%)
Age Group: Total	(N = 67)	(N = 78)	(N = 96)	(N = 105)
Very much improved	17 (25.4)	9 (11.5)	20 (20.8)	9 (8.6)
Much improved	21 (31.3)	24 (30.8)	25 (26.0)	26 (24.8)
Minimally improved	14 (20.9)	18 (23.1)	23 (24.0)	20 (19.0)
No change	10 (14.9)	25 (32.1)	18 (18.8)	39 (37.1)
Minimally worse	3 (4.5)	2 (2.6)	4 (4.2)	7 (6.7)
Much worse	2 (3.0)	0	6 (6.3)	3 (2.9)
Very much worse	0	0	0	1 (1.0)
Total	67 (100.0)	78 (100.0)	96 (100.0)	105 (100.0)
Age Group: Children	(N = 37)	(N = 45)	(N = 56)	(N = 57)
Very much improved	10 (27.0)	6 (13.3)	13 (23.2)	6 (10.5)
Much improved	13 (35.1)	18 (40.0)	16 (28.6)	20 (35.1)
Minimally improved	8 (21.6)	7 (15.6)	14 (25.0)	8 (14.0)
No change	3 (8.1)	12 (26.7)	7 (12.5)	17 (29.8)
Minimally worse	2 (5.4)	2 (4.4)	2 (3.6)	5 (8.8)
Much worse	1 (2.7)	0	4 (7.1)	0
Very much worse	0	0	0	1 (1.8)
Total	37 (100.0)	45 (100.0)	56 (100.0)	57 (100.0)

N = number of patients with a Week 10 OC (Observed Cases) or LOCF (Last Observation Carried Forward) assessment.
Source: Table 14.3.1, Section 12; Listing 14.3.1, Appendix C
(Continued)

Table 40 Number (%) of Patients in Each Category of the CGI Global Improvement Item Score at Week 10–Age Group: Total/Children/Adolescents (ITT Population) (Continued)

	Week 10 (OC)		Week 10 (LOCF)	
	Treatment Group		Treatment Group	
	Paroxetine n (%)	Placebo n (%)	Paroxetine n (%)	Placebo n (%)
Age Group: Adolescents	(N = 30)	(N = 33)	(N = 40)	(N = 48)
Very much improved	7 (23.3)	3 (9.1)	7 (17.5)	3 (6.3)
Much improved	8 (26.7)	6 (18.2)	9 (22.5)	6 (12.5)
Minimally improved	6 (20.0)	11 (33.3)	9 (22.5)	12 (25.0)
No change	7 (23.3)	13 (39.4)	11 (27.5)	22 (45.8)
Minimally worse	1 (3.3)	0	2 (5.0)	2 (4.2)
Much worse	1 (3.3)	0	2 (5.0)	3 (6.3)
Very much worse	0	0	0	0
Total	30 (100.0)	33 (100.0)	40 (100.0)	48 (100.0)

N = number of patients with a Week 10 OC (Observed Cases) or LOCF (Last Observation Carried Forward) assessment.
Source: Table 14.3.1, Section 12; Listing 14.3.1, Appendix C

5.3.3 Change from Baseline in Clinical Global Impression Severity of Illness Score

Table 41 presents the analyses of the change from baseline in CGI Severity of Illness score for the Week 10 LOCF and OC datasets and the 70% LOCF dataset, based on the ITT population. No adjustment was made for covariates; however, the analysis was performed separately for each age group.

For children, the median difference between paroxetine and placebo at Week 10 LOCF was 0 ($p = 0.251$), indicating no evidence of a statistically significant benefit of paroxetine over placebo.

Similarly, for adolescents, the median difference between paroxetine and placebo at Week 10 LOCF was 0 ($p = 0.098$), again providing no evidence of a statistically significant benefit of paroxetine over placebo.

Similar results were observed for the Week 10 OC and 70% LOCF analyses.

Table 41 Summary of Analysis of Change from Baseline in CGI Severity of Illness Score–Age Group: Children/Adolescents (ITT Population)

	Treatment Group								Treatment Comparison	
	Paroxetine				Placebo				Median	
	N	Mean	Median	Range	N	Mean	Median	Range	Difference	p-value *
Children										
Baseline	58	4.4	4.0	4 to 7	57	4.6	4.0	3 to 6		
Change from Baseline to:										
Week 1	54	-0.1	0.0	-2 to 1	52	-0.1	0.0	-2 to 1		
Week 2	51	-0.5	0.0	-3 to 1	52	-0.2	0.0	-2 to 1		
Week 3	53	-0.8	-1.0	-3 to 2	48	-0.4	0.0	-3 to 1		
Week 4	50	-0.8	-1.0	-4 to 2	51	-0.7	0.0	-4 to 1		
Week 6	45	-1.2	-1.0	-4 to 2	51	-0.8	0.0	-4 to 1		
Week 8	37	-1.5	-2.0	-4 to 0	49	-1.1	-1.0	-4 to 1		
Week 10 OC	37	-1.5	-1.0	-4 to 0	45	-1.2	-1.0	-5 to 0	0	0.178
Week 10 LOCF	56	-1.3	-1.0	-4 to 2	57	-1.1	-1.0	-5 to 1	0	0.251
70% LOCF††	56	-1.2	-1.0	-4 to 2	57	-1.0	-1.0	-4 to 1	0	0.260

* P-value from Wilcoxon Rank Sum Test

†† 70% LOCF endpoint was Week 8

Source: Table 14.4.3, Section 12; Listings 14.4.1, 14.4.3, Appendix C

(Continued)

Table 41 Summary of Analysis of Change from Baseline in CGI Severity of Illness Score–Age Group: Children/Adolescents (ITT Population) (Continued)

	Treatment Group								Treatment Comparison	
	Paroxetine				Placebo				Median	
	N	Mean	Median	Range	N	Mean	Median	Range	Difference	p-value *
Adolescents										
Baseline	40	4.7	5.0	4 to 7	48	4.6	5.0	3 to 6		
Change from Baseline to:										
Week 1	39	-0.1	0.0	-1 to 1	47	-0.0	0.0	-1 to 1		
Week 2	38	-0.2	0.0	-2 to 1	40	-0.2	0.0	-2 to 1		
Week 3	36	-0.4	0.0	-2 to 0	36	-0.5	0.0	-3 to 0		
Week 4	34	-0.6	0.0	-3 to 1	41	-0.4	0.0	-3 to 1		
Week 6	34	-0.7	-1.0	-2 to 1	39	-0.6	0.0	-4 to 2		
Week 8	30	-0.8	-1.0	-3 to 0	33	-0.8	0.0	-3 to 0		
Week 10 OC	30	-1.0	-1.0	-3 to 0	33	-0.8	0.0	-4 to 0	0	0.247
Week 10 LOCF	40	-0.8	-1.0	-3 to 1	48	-0.5	0.0	-4 to 2	0	0.098
70% LOCF††	40	-0.7	-1.0	-3 to 1	48	-0.4	0.0	-3 to 2	0	0.129

* P-value from Wilcoxon Rank Sum Test

†† 70% LOCF endpoint was Week 8

Source: Table 14.4.3, Section 12; Listings 14.4.1, 14.4.3, Appendix C

Table 42 and Table 43 summarize the percentage of patients in each treatment group categorized by CGI Severity of Illness item score at Baseline and at Week 10 OC and LOCF for both age groups combined and for children and adolescents, respectively.

In the combined age groups, 26/96 paroxetine patients (27.1%) and 15/105 placebo patients (14.3%) were rated normal or borderline mentally ill at Week 10 LOCF, compared with no patients in either treatment group at Baseline. Eight of 98 patients (8.2%) in the paroxetine group and 16 of 105 patients (15.2%) in the placebo group had been rated severely ill or among the most extremely ill at Baseline. At Week 10 LOCF, 6 patients in the paroxetine group and 5 patients in the placebo group were rated severely ill, and no patients in either group were rated among the most extremely ill. Of note, at Week 10 OC, only 1 patient in each treatment group was rated severely ill, and no patients were rated among the most extremely ill.

Table 42 Number (%) of Patients in Each Category of the CGI Severity of Illness Item Score at Baseline and Week 10 –Age Group: Total (ITT Population)

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Baseline	**(N = 98)**		**(N =105)**	
Normal, not at all ill (1)	0	0	0	0
Borderline mentally ill (2)	0	0	0	0
Mildly ill (3)	0	0	4	(3.8)
Moderately ill (4)	57	(58.2)	49	(46.7)
Markedly ill (5)	33	(33.7)	36	(34.3)
Severely ill (6)	6	(6.1)	16	(15.2)
Among the most extremely ill (7)	2	(2.0)	0	0
Total	98	(100.0)	105	(100.0)
Week 10 OC	**(N = 67)**		**(N = 78)**	
Normal, not at all ill (1)	5	(7.5)	4	(5.1)
Borderline mentally ill (2)	16	(23.9)	11	(14.1)
Mildly ill (3)	17	(25.4)	17	(21.8)
Moderately ill (4)	19	(28.4)	34	(43.6)
Markedly ill (5)	9	(13.4)	11	(14.1)
Severely ill (6)	1	(1.5)	1	(1.3)
Among the most extremely ill (7)	0	0	0	0
Total	67	(100.0)	78	(100.0)
Week 10 LOCF	**(N = 96)**		**(N = 105)**	
Normal, not at all ill (1)	7	(7.3)	4	(3.8)
Borderline mentally ill (2)	19	(19.8)	11	(10.5)
Mildly ill (3)	19	(19.8)	20	(19.0)
Moderately ill (4)	31	(32.3)	43	(41.0)
Markedly ill (5)	14	(14.6)	22	(21.0)
Severely ill (6)	6	(6.3)	5	(4.8)
Among the most extremely ill (7)	0	0	0	0
Total	96	(100.0)	105	(100.0)

N = number of patients with a Week 10 OC (Observed Case) or LOCF (Last Observation Carried Forward) assessment.
Source: Table 14.4.1, Section 12; Listing 14.4.1, Appendix C

Among children, at Week 10 LOCF, 20/56 (35.7%) paroxetine patients were rated normal or borderline mentally ill compared with 11/57 (19.3%) placebo patients. Among adolescents, at Week 10 LOCF, 6/40 (15.0%) paroxetine patients were rated normal or borderline mentally ill compared with 4/48 (8.3%) placebo patients (Table 43). These data also show that within each treatment group, higher

percentages of children were rated normal or borderline mentally ill at Week 10 LOCF compared with adolescents.

Table 43 Number (%) of Patients in Each Category of the CGI Severity of Illness Item Score at Baseline and Week 10 –Age Group: Children/Adolescents (ITT Population)

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Age Group: Children	**(N = 58)**		**(N = 57)**	
Baseline				
Normal, not at all ill (1)	0	0	0	0
Borderline mentally ill (2)	0	0	0	0
Mildly ill (3)	0	0	3	(5.3)
Moderately ill (4)	39	(67.2)	28	(49.1)
Markedly ill (5)	15	(25.9)	16	(28.1)
Severely ill (6)	3	(5.2)	10	(17.5)
Among the most extremely ill (7)	1	(1.7)	0	0
Total	58	(100.0)	57	(100.0)
Week 10 OC	**(N = 37)**		**(N = 45)**	
Normal, not at all ill (1)	5	(13.5)	3	(6.7)
Borderline mentally ill (2)	10	(27.0)	8	(17.8)
Mildly ill (3)	9	(24.3)	12	(26.7)
Moderately ill (4)	11	(29.7)	16	(35.6)
Markedly ill (5)	1	(2.7)	6	(13.3)
Severely ill (6)	1	(2.7)	0	0
Among the most extremely ill (7)	0	0	0	0
Total	37	(100.0)	45	(100.0)
Week 10 LOCF	**(N = 56)**		**(N = 57)**	
Normal, not at all ill (1)	7	(12.5)	3	(5.3)
Borderline mentally ill (2)	13	(23.2)	8	(14.0)
Mildly ill (3)	10	(17.9)	15	(26.3)
Moderately ill (4)	20	(35.7)	20	(35.1)
Markedly ill (5)	2	(3.6)	11	(19.3)
Severely ill (6)	4	(7.1)	0	0
Among the most extremely ill (7)	0	0	0	0
Total	56	(100.0)	57	(100.0)

N = number of patients with a Week 10 OC (Observed Case) or LOCF (Last Observation Carried Forward) assessment.
Source: Table 14.4.1, Section 12; Listing 14.4.1, Appendix C
(Continued)

Table 43 Number (%) of Patients in Each Category of the CGI Severity of Illness Item Score at Baseline and Week 10 (Observed Cases)–Age Group: Children/Adolescents (ITT Population) (Continued)

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Age Group: Adolescents	**(N = 40)**		**(N = 48)**	
Baseline				
Normal, not at all ill (1)	0	0	0	0
Borderline mentally ill (2)	0	0	0	0
Mildly ill (3)	0	0	1	(2.1)
Moderately ill (4)	18	(45.0)	21	(43.8)
Markedly ill (5)	18	(45.0)	20	(41.7)
Severely ill (6)	3	(7.5)	6	(12.5)
Among the most extremely ill (7)	1	(2.5)	0	0
Total	40	(100.0)	48	(100.0)
Week 10 OC	**(N = 30)**		**(N = 33)**	
Normal, not at all ill (1)	0	0	1	(3.0)
Borderline mentally ill (2)	6	(20.0)	3	(9.1)
Mildly ill (3)	8	(26.7)	5	(15.2)
Moderately ill (4)	8	(26.7)	18	(54.5)
Markedly ill (5)	8	(26.7)	5	(15.2)
Severely ill (6)	0	0	1	(3.0)
Among the most extremely ill (7)	0	0	0	0
Total	30	(100.0)	33	(100.0)
Week 10 LOCF	**(N = 40**		**(N = 48)**	
Normal, not at all ill (1)	0	0	1	(2.1)
Borderline mentally ill (2)	6	(15.0)	3	(6.3)
Mildly ill (3)	9	(22.5)	5	(10.4)
Moderately ill (4)	11	(27.5)	23	(47.9)
Markedly ill (5)	12	(30.0)	11	(22.9)
Severely ill (6)	2	(5.0)	5	(10.4)
Among the most extremely ill (7)	0	0	0	0
Total	40	(100.0)	48	(100.0)

N = number of patients with a Week 10 OC (Observed Case) or LOCF (Last Observation Carried Forward) assessment.
Source: Table 14.4.1, Section 12; Listing 14.4.1, Appendix C

The number and percentage of patients in each category by change in CGI Severity of Illness from Baseline may be found in Table 14.4.2, Section 12, and Listing 14.4.1, Appendix C.

5.3.4 Change from Baseline in Global Assessment of Functioning Score

Table 44 presents the analysis for change from Baseline in the Global Assessment of Functioning (GAF) score for the Week 10 LOCF and OC datasets and for the 70% LOCF dataset, based on the ITT population.

The adjusted mean difference between paroxetine and placebo at Week 10 LOCF was 1.91 points in favor of paroxetine (95% CI: [-1.33, 5.15], p = 0.247), providing no evidence of a statistically significant benefit of paroxetine over placebo. Results for the Week 10 OC and the 70% LOCF analyses supported this conclusion.

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

	Treatment Groups						Treatment Comparisons		
	Paroxetine			Placebo					
Visit	**N ***	**LS Mean ****	**(SE) †**	**N ***	**LS Mean****	**(SE) †**	**Difference ††**	**95% CI**	**p-value**
Baseline	98	53.4	(6.59)	105	51.6	(7.18)			
Change from Baseline to:									
Wk 2	87	4.1	(0.68)	88	2.3	(0.66)			
Wk 4	80	6.4	(1.06)	83	5.4	(1.02)			
Wk 6	79	9.2	(1.19)	90	6.1	(1.07)			
Wk 8	67	10.4	(1.33)	82	7.7	(1.18)			
Wk 10 OC	67	11.9	(1.40)	78	9.6	(1.28)	2.35	(-1.29, 5.99)	0.205
Wk 10 LOCF	94	8.9	(1.23)	102	7.0	(1.16)	1.91	(-1.33, 5.15)	0.247
70% LOCF‡	94	7.7	(1.15)	102	5.9	(1.08)	1.86	(-1.17, 4.88)	0.227

***** LOCF Endpoint may have more patients than the first post-baseline visit as early withdrawal data at unscheduled visits are not tabulated but are carried forward for LOCF Endpoint.

** Least square means. For Baseline, raw means are presented.

† For Baseline, standard deviations, not standard errors, are presented.

†† Differences in adjusted least square means (paroxetine minus placebo). Adjusted for Baseline score, age group, gender, and comorbidity.

‡ 70% LOCF endpoint was Week 8.

Source: Table 14.5.2, Section 12; Listing 14.5.1, 14.5.2, Appendix C

Table 45 presents the summary statistics for GAF score at Baseline, Week 2, Week 4, Week 6, Week 8 and Week 10 and Week 10 LOCF by treatment group for both age groups combined and for each age subgroup.

Mean GAF scores increased (improved) similarly and steadily over time in both treatment groups for both age groups combined and separately, with the exception of children receiving placebo who had a small mean decrease between Weeks 4 and 6. In general, greater improvements were noted from Baseline to Week 4 than from Week 4 to Week 10.

Table 45 Summary Statistics for GAF Score at Each Visit –Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group							
	Paroxetine				Placebo			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Age Group: Total			**(N = 98)**				**(N = 105)**	
Baseline	98	53.4	(6.59)	40 to 70	105	51.6	(7.18)	32 to 78
Week 2	87	58.0	(8.25)	35 to 78	88	54.5	(7.54)	31 to 78
Week 4	80	60.7	(11.40)	30 to 90	83	58.0	(8.45)	37 to 81
Week 6	79	63.1	(12.25)	28 to 93	90	58.1	(9.37)	36 to 82
Week 8	67	64.9	(11.75)	42 to 91	82	60.0	(10.91)	35 to 85
Week 10 OC	67	66.4	(12.90)	34 to 91	78	61.9	(10.67)	40 to 90
Week 10 LOCF	94	63.4	(13.44)	30 to 91	102	59.6	(11.16)	31 to 90
Age Group: Children			**(N = 58)**				**(N = 57)**	
Baseline	58	53.2	(6.89)	40 to 70	57	52.3	(7.57)	32 to 78
Week 2	49	58.9	(9.18)	35 to 78	48	54.6	(7.96)	31 to 78
Week 4	48	61.0	(11.94)	30 to 90	48	58.9	(8.69)	40 to 81
Week 6	45	64.7	(13.08)	32 to 93	51	58.6	(9.57)	36 to 81
Week 8	37	67.0	(11.94)	45 to 91	49	60.8	(11.78)	35 to 85
Week 10 OC	37	68.7	(13.49)	45 to 91	45	63.2	(10.71)	40 to 90
Week 10 LOCF	54	65.1	(14.54)	30 to 91	56	61.6	(11.40)	31 to 90
Age Group: Adolescents			**(N = 40)**				**(N = 48)**	
Baseline	40	53.8	(6.19)	44 to 70	48	50.8	(6.67)	35 to 68
Week 2	38	56.7	(6.79)	44 to 70	40	54.3	(7.10)	36 to 70
Week 4	32	60.1	(10.71)	38 to 90	35	56.9	(8.10)	37 to 72
Week 6	34	61.1	(10.90)	28 to 80	39	57.4	(9.18)	40 to 82
Week 8	30	62.3	(11.16)	42 to 88	33	58.9	(9.54)	40 to 82
Week 10 OC	30	63.6	(11.75)	34 to 89	33	60.1	(10.53)	44 to 90
Week 10 LOCF	40	61.1	(11.57)	34 to 89	46	57.3	(10.51)	42 to 90

Source: Table 14.5.1, Section 12; Listing 14.5.1, Appendix C

Summary statistics for the change from Baseline in GAF score are presented in Table 14.5.3, Section 12. Individual patient information is provided in Listing 14.5.1, Appendix C.

5.3.5 Change from Baseline in the CY-BOCS Obsession and Compulsion Subscale Scores

5.3.5.1 CY-BOCS Obsession Subscale Score

Table 46 presents the analysis for change from Baseline in the CY-BOCS Obsession Subscale Score for the Week 10 LOCF and OC datasets and the 70% LOCF dataset, based on the ITT population.

The adjusted mean difference between paroxetine and placebo at Week 10 LOCF was -1.80 points in favor of paroxetine (95% CI: [-2.94, -0.67], p = 0.002), providing evidence of a statistically significant benefit of paroxetine over placebo. This conclusion was supported by similar results from the Week 10 OC and the 70% LOCF analyses.

Table 46 Summary of Analysis for Change from Baseline in CY-BOCS Obsession Subscale 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	98	11.5	(3.11)	105	12.2	(2.99)			
Change from Baseline to:									
Wk 2	87	-1.7	(0.28)	87	-1.0	(0.28)			
Wk 4	80	-3.3	(0.35)	83	-1.7	(0.34)			
Wk 6	79	-4.0	(0.45)	90	-2.0	(0.41)			
Wk 8	67	-4.6	(0.47)	82	-3.0	(0.42)			
Wk 10 OC	67	-4.7	(0.48)	78	-3.4	(0.44)	-1.37	(-2.62, -0.11)	0.033
Wk 10 LOCF	94	-4.2	(0.43)	102	-2.4	(0.41)	-1.80	(-2.94, -0.67)	0.002
70% LOCF‡	94	-3.9	(0.41)	102	-2.2	(0.39)	-1.75	(-2.83, -0.66)	0.002

***** LOCF Endpoint may have more patients than the first post-baseline visit as early withdrawal data at unscheduled visits are not tabulated but are carried forward for LOCF Endpoint.

** Least square means. For Baseline, raw means are presented.

† For Baseline, standard deviations, not standard errors, are presented.

†† Differences in adjusted least square means (paroxetine minus placebo). Adjusted for Baseline score, age group, gender, and comorbidity.

‡ 70% LOCF endpoint was Week 8.

Source: Table 14.6.2, Section 12; Listings 14.6.1 and 14.6.2, Appendix C

Table 47 presents the summary statistics for CY-BOCS Obsession Subscale score (sum of items 1 to 5, excluding 1b) at Baseline, Week 2, Week 4, Week 6, Week 8 and Week 10 and Week 10 LOCF by treatment group for both age groups combined and for each age subgroup.

Mean CY-BOCS Obsession Subscale scores decreased (improved) similarly and steadily over time in both treatment groups for both age groups combined and separately. In general, greater improvements were noted from Baseline to Week 4 than from Week 4 to Week 10, particularly in the paroxetine group.

Table 47 Summary Statistics for CY-BOCS Obsession Subscale Score at Each Visit-Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group							
	Paroxetine				Placebo			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Age Group: Total			**(N = 98)**				**(N = 105)**	
Baseline	98	11.5	(3.11)	0 to 19	105	12.2	(2.99)	5 to 20
Week 2	87	9.8	(3.64)	0 to 18	87	11.1	(3.01)	3 to 19
Week 4	80	8.2	(4.16)	0 to 18	83	10.3	(3.02)	3 to 17
Week 6	79	7.5	(4.03)	0 to 18	90	9.7	(4.05)	0 to 19
Week 8	67	7.0	(4.23)	0 to 18	82	8.8	(3.90)	0 to 20
Week 10 OC	67	6.8	(4.43)	0 to 18	78	8.3	(3.93)	0 to 18
Week 10 LOCF	94	7.2	(4.55)	0 to 18	102	9.4	(4.27)	0 to 19
Age Group: Children			**(N = 58)**				**(N = 57)**	
Baseline	58	11.2	(3.41)	0 to 18	57	12.1	(3.19)	5 to 20
Week 2	49	9.0	(3.83)	0 to 18	48	11.0	(3.12)	3 to 19
Week 4	48	7.4	(4.04)	0 to 18	48	9.8	(3.17)	3 to 17
Week 6	45	6.5	(4.15)	0 to 18	51	9.3	(4.16)	0 to 19
Week 8	37	5.9	(4.25)	0 to 18	49	8.7	(4.23)	0 to 20
Week 10 OC	37	5.7	(4.18)	0 to 17	45	7.8	(3.91)	0 to 16
Week 10 LOCF	54	6.0	(4.43)	0 to 17	56	8.6	(4.04)	0 to 17
Age Group: Adolescents			**(N = 40)**				**(N = 48)**	
Baseline	40	12.0	(2.59)	8 to 19	48	12.5	(2.74)	7 to 19
Week 2	38	10.7	(3.17)	5 to 17	39	11.1	(2.90)	5 to 17
Week 4	32	9.6	(4.02)	1 to 17	35	10.8	(2.73)	5 to 17
Week 6	34	8.8	(3.50)	2 to 17	39	10.4	(3.87)	2 to 19
Week 8	30	8.3	(3.90)	0 to 17	33	9.0	(3.40)	2 to 17
Week 10 OC	30	8.1	(4.44)	0 to 18	33	9.0	(3.92)	0 to 18
Week 10 LOCF	40	8.8	(4.29)	0 to 18	46	10.5	(4.34)	0 to 19

Source: Table 14.6.1, Section 12; Listing 14.6.1, Appendix C

Summary statistics for the change from Baseline in CY-BOCS Obsession Subscale score are presented in Table 14.6.3, Section 12. Individual patient information is provided in Listing 14.6.1, Appendix C.

5.3.5.2 CY-BOCS Compulsion Subscale Score

Table 48 presents the analysis for change from baseline in the CY-BOCS Compulsion Subscale Score for the Week 10 LOCF and OC datasets and the 70% LOCF dataset, based on the ITT population.

The adjusted mean difference between paroxetine and placebo at Week 10 LOCF was -1.72 points in favor of paroxetine (95% CI: [-2.85, -0.60], p = 0.003), providing evidence of a statistically significant benefit of paroxetine over placebo.

Similar results were observed for the 70% LOCF analysis; however, the Week 10 OC analysis provided no evidence of a statistically significant benefit of paroxetine over placebo at the 5% significance level.

Table 48 Summary of Analysis for Change from Baseline in CY-BOCS Compulsion Subscale Score-Age Group: Total (ITT Population)

	Treatment Groups						Treatment Comparisons		
	Paroxetine			Placebo					
Visit	**N ***	**LS Mean ****	**(SE) †**	**N ***	**LS Mean ****	**(SE) †**	**Difference ††**	**95% CI**	**p-value**
Baseline	98	12.8	(2.75)	105	13.1	(2.67)			
Change from Baseline to:									
Wk 2	86	-2.1	(0.28)	87	-1.2	(0.27)			
Wk 4	80	-3.3	(0.39)	83	-2.1	(0.37)			
Wk 6	79	-4.1	(0.42)	90	-2.7	(0.38)			
Wk 8	67	-4.7	(0.47)	82	-3.4	(0.42)			
Wk 10 OC	67	-5.1	(0.49)	78	-3.9	(0.45)	-1.21	(-2.48, 0.06)	0.062
Wk 10 LOCF	94	-4.6	(0.43)	102	-2.9	(0.40)	-1.72	(-2.85, -0.60)	0.003
70% LOCF‡	94	-4.3	(0.41)	102	-2.7	(0.38)	-1.54	(-2.61, -0.47)	0.005

***** LOCF Endpoint may have more patients than the first post-baseline visit as early withdrawal data at unscheduled visits are not tabulated but are carried forward for LOCF Endpoint.

** Least square means. For Baseline, raw means are presented.

† For Baseline, standard deviations, not standard errors, are presented.

†† Differences in adjusted least square means (paroxetine minus placebo). Adjusted for Baseline score, age group, gender, and comorbidity.

‡ 70% LOCF endpoint was Week 8.

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

Table 49 presents the summary statistics for CY-BOCS Compulsion Subscale score (sum of items 6 to 10, excluding 6b) at Baseline, Week 2, Week 4, Week 6, Week 8 and Week 10 and Week 10 LOCF by treatment group for both age groups combined and for each age subgroup.

Mean CY-BOCS Compulsion Subscale scores decreased (improved) similarly and steadily over time in both treatment groups for both age groups combined and separately. In general, greater improvements were noted from Baseline to Week 4 than from Week 4 to Week 10, particularly in the paroxetine group.

Table 49 Summary Statistics for CY-BOCS Compulsion Subscale Score at Each Visit–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group							
	Paroxetine				Placebo			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Age Group: Total			**(N = 98)**				**(N = 105)**	
Baseline	98	12.8	(2.75)	7 to 20	105	13.0	(2.67)	7 to 20
Week 2	86	10.7	(3.52)	1 to 18	87	11.9	(3.00)	4 to 19
Week 4	80	9.5	(4.11)	0 to 18	83	10.8	(3.28)	0 to 18
Week 6	79	8.5	(4.18)	0 to 18	90	10.1	(3.70)	2 to 19
Week 8	67	7.9	(4.24)	0 to 19	82	9.3	(3.90)	0 to 18
Week 10 OC	67	7.5	(4.59)	0 to 18	78	8.9	(3.90)	0 to 18
Week 10 LOCF	94	8.0	(4.50)	0 to 18	102	10.0	(4.21)	0 to 20
Age Group: Children			**(N = 58)**				**(N = 57)**	
Baseline	58	12.5	(2.78)	7 to 18	57	13.2	(2.67)	8 to 20
Week 2	49	10.2	(3.61)	1 to 18	48	11.7	(3.03)	4 to 18
Week 4	48	9.0	(4.11)	0 to 18	48	10.5	(3.41)	0 to 17
Week 6	45	7.8	(4.23)	0 to 18	51	9.4	(3.60)	2 to 18
Week 8	37	7.1	(4.56)	0 to 19	49	8.7	(4.08)	0 to 18
Week 10 OC	37	6.7	(4.77)	0 to 18	45	8.4	(4.01)	0 to 17
Week 10 LOCF	54	7.1	(4.52)	0 to 18	56	9.0	(4.16)	0 to 20
Age Group: Adolescents			**(N = 40)**				**(N = 48)**	
Baseline	40	13.3	(2.68)	10 to 20	48	12.8	(2.69)	7 to 19
Week 2	37	11.2	(3.35)	5 to 18	39	12.2	(2.97)	7 to 19
Week 4	32	10.2	(4.08)	2 to 18	35	11.2	(3.09)	5 to 18
Week 6	34	9.5	(3.94)	3 to 17	39	11.0	(3.69)	5 to 19
Week 8	30	8.9	(3.62)	3 to 17	33	10.2	(3.50)	2 to 18
Week 10 OC	30	8.5	(4.25)	0 to 17	33	9.7	(3.69)	0 to 18
Week 10 LOCF	40	9.2	(4.25)	0 to 17	46	11.1	(4.03)	0 to 19

Source: Table 14.7.1, Section 12; Listing 14.7.1, Appendix C

Summary statistics for the change from Baseline in CY-BOCS Compulsions Subscale score are presented in Table 14.7.3, Section 12. Individual patient information is provided in Listing 14.7.1, Appendix C.

6 Safety Results

This section describes the safety data for 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. Therefore, for this study, the ITT population is identical to the safety population. The safety data summarized include all AEs, vital signs, laboratory data, and ECGs.

6.1 Extent of Exposure

Table 50 shows the duration of time (excluding Taper Phase) for which each patient was exposed to paroxetine or placebo by treatment group, as well as an overall exposure and the range of exposure.

The overall mean number of days of exposure to study medication (excluding Taper) was 60.0 days for all patients who received paroxetine and 63.7 days for all patients who received placebo. The duration of exposure was similar for the adolescents across the 2 treatment groups. However, among children, the placebo group had a higher overall mean duration (placebo, 66.2 days; paroxetine, 58.5 days).

The extent of exposure (including the Taper Phase) is presented in Table 13.13.5.2, Section 11.

Table 50 Duration of Exposure to Study Medication by Time Intervals and Mean Treatment Duration (Excluding Taper)–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group			
Study Medication	**Paroxetine**		**Placebo**	
Exposure (Days)	n	**(%)**	**n**	**(%)**
Age Group: Total	**(N = 98)**		**(N = 105)**	
≥1	98	(100.0)	105	(100.0)
>7	96	(98.0)	103	(98.1)
>14	92	(93.9)	100	(95.2)
>21	90	(91.8)	97	(92.4)
>28	87	(88.8)	95	(90.5)
>42	77	(78.6)	90	(85.7)
>56	72	(73.5)	84	(80.0)
>70	34	(34.7)	50	(47.6)
>84	1	(1.0)	2	(1.9)
Overall mean duration	60.0		63.7	
Range	1 to 90		6 to 92	
Age Group: Children	**(N = 58)**		**(N = 57)**	
≥1	58	(100.0)	57	(100.0)
>7	56	(96.6)	57	(100.0)
>14	53	(91.4)	55	(96.5)
>21	51	(87.9)	54	(94.7)
>28	51	(87.9)	53	(93.0)
>42	44	(75.9)	51	(89.5)
>56	41	(70.7)	49	(86.0)
>70	20	(34.5)	29	(50.9)
>84	1	(1.7)	0	
Overall mean duration	58.5		66.2	
Range	1 to 90		8 to 81	

Source: Tables 13.13.5.1, Section 11; Patient Listing 13.13.1, Appendix B.

(Continued)

Table 50 Duration of Exposure to Study Medication by Time Intervals and Mean Treatment Duration (Excluding Taper)–Age Group: Total/Children/Adolescents (ITT Population) (Continued)

Study Medication Exposure (Days)	Treatment Group: Paroxetine n	Paroxetine (%)	Placebo n	Placebo (%)
Age Group: Adolescents	**(N = 40)**		**(N = 48)**	
≥1	40	(100.0)	48	(100.0)
>7	40	(100.0)	46	(95.8)
>14	39	(97.5)	45	(93.8)
>21	39	(97.5)	43	(89.6)
>28	36	(90.0)	42	(87.5)
>42	33	(82.5)	39	(81.3)
>56	31	(77.5)	35	(72.9)
>70	14	(35.0)	21	(43.8)
>84	0		2	(4.2)
Overall mean duration	62.2		60.7	
Range	14 to 81		6 to 92	

Source: Tables 13.13.5.1, Section 11; Patient Listing 13.13.1, Appendix B.

6.2 Adverse Events

The methodology for coding and tabulating AEs is described in Section 3.11.1. 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 10 or Early Withdrawal visit 1 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 15.1.1.6X for combined, Treatment, Taper, 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 and 15.1.2, 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-deemed relationship to study medication. See Section 3.14.6.1, Adverse Events, for a definition of emergent AEs in each treatment phase.

6.2.1 Treatment Phase-Emergent Adverse Events

Table 51 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 Tables 15.1.1.1, Section 13 (by body system and preferred term) and 15.1.1.1.X, Section 13 (by preferred term occurring in 1% or more of the population in descending order).

A total of 83/98 patients (84.7%) randomized to paroxetine reported gender-non-specific, emergent AEs during the Treatment Phase, compared with 77/105 patients receiving placebo (73.3%). Overall, the most common (>10%) gender-non-specific AEs for patients receiving paroxetine were headache, abdominal pain, nausea, respiratory disorder, somnolence, hyperkinesia, and trauma, while the most common AEs for patients receiving placebo were headache, abdominal pain, respiratory disorder, and infection.

The overall AE frequency was similar among children and adolescents. A total of 91/115 children (79.1%) reported gender-non-specific emergent AEs during the Treatment Phase, 49/58 (84.5%) on paroxetine and 42/57 (73.7%) on placebo. A total of 69/88 adolescents (78.4%) reported gender-non-specific emergent AEs

during the Treatment Phase, 34/40 (85.0%) on paroxetine and 35/48 (72.9%) on placebo.

No adolescent male patients in either treatment group reported a male-specific emergent AE during the Treatment Phase. Three adolescent female patients on paroxetine (3/18, 16.7%) and 1 adolescent female patient on placebo (1/19, 5.3%) reported a female-specific emergent AE (dysmenorrhea) during the Treatment Phase (Table 15.1.1.1, Section 13). There were no gender-specific AEs among children in either treatment group.

Table 51 Most Frequent (≥5% in Any Treatment Group) Treatment Phase-Emergent, Gender-non-specific Adverse Events–Age Group: Total/Children/Adolescents (ITT Population)

	Age Group: Total		Age Group: Children		Age Group: Adolescents	
AE Preferred Term*	**Paroxetine (N = 98)**	**Placebo (N = 105)**	**Paroxetine (N = 58)**	**Placebo (N = 57)**	**Paroxetine (N = 40)**	**Placebo (N = 48)**
Patients with AEs	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Total Patients with at least 1 AE	83 (84.7)	77 (73.3)	49 (84.5)	42 (73.7)	34 (85.0)	35 (72.9)
Headache	24 (24.5)	22 (21.0)	13 (22.4)	11 (19.3)	11 (27.5)	11 (22.9)
Abdominal Pain	17 (17.3)	12 (11.4)	13 (22.4)	9 (15.8)	4 (10.0)	3 (6.3)
Nausea	16 (16.3)	10 (9.5)	6 (10.3)	9 (15.8)	10 (25.0)	1 (2.1)
Respiratory Disorder	12 (12.2)	15 (14.3)	7 (12.1)	6 (10.5)	5 (12.5)	9 (18.8)
Somnolence	12 (12.2)	7 (6.7)	5 (8.6)	3 (5.3)	7 (17.5)	4 (8.3)
Hyperkinesia	12 (12.2)	6 (5.7)	10 (17.2)	4 (7.0)	2 (5.0)	2 (4.2)
Trauma	10 (10.2)	3 (2.9)	7 (12.1)	1 (1.8)	3 (7.5)	2 (4.2)
Insomnia	9 (9.2)	5 (4.8)	7 (12.1)	2 (3.5)	2 (5.0)	3 (6.3)
Decreased Appetite	9 (9.2)	1 (1.0)	6 (10.3)	1 (1.8)	3 (7.5)	0
Hostility	9 (9.2)	1 (1.0)	7 (12.1)	1 (1.8)	2 (5.0)	0
Pharyngitis	8 (8.2)	6 (5.7)	4 (6.9)	4 (7.0)	4 (10.0)	2 (4.2)
Diarrhea	8 (8.2)	2 (1.9)	5 (8.6)	2 (3.5)	3 (7.5)	0
Asthenia	8 (8.2)	1 (1.0)	3 (5.2)	1 (1.8)	5 (12.5)	0
Vomiting	6 (6.1)	2 (1.9)	5 (8.6)	2 (3.5)	1 (2.5)	0
Infection	5 (5.1)	12 (11.4)	3 (5.2)	9 (15.8)	2 (5.0)	3 (6.3)

*Sorted by decreasing frequency in the paroxetine group, age group = total.

Source: Table 15.1.1.1.X, Section 13; Listing 15.1.1, Appendix D

(Continued)

Table 51 Most Frequent (≥5% in Any Treatment Group) Treatment-Phase Emergent, Gender non-specific Adverse Events–Age Group: Total/Children/Adolescents (ITT Population) (Continued)

	Age Group: Total		Age Group: Children		Age Group: Adolescents	
AE Preferred Term*	Paroxetine (N = 98)	Placebo (N = 105)	Paroxetine (N = 58)	Placebo (N = 57)	Paroxetine (N = 40)	Placebo (N = 48)
Patients with AEs	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Dizziness	5 (5.1)	7 (6.7)	1 (1.7)	4 (7.0)	4 (10.0)	3 (6.3)
Nervousness	5 (5.1)	6 (5.7)	4 (6.9)	2 (3.5)	1 (2.5)	4 (8.3)
Sinusitis	5 (5.1)	5 (4.8)	4 (6.9)	2 (3.5)	1 (2.5)	3 (6.3)
Pain	5 (5.1)	3 (2.9)	3 (5.2)	3 (5.3)	2 (5.0)	0
Agitation	5 (5.1)	2 (1.9)	3 (5.2)	0	2 (5.0)	2 (4.2)
Neurosis	5 (5.1)	1 (1.0)	5 (8.6)	1 (1.8)	0	0
Rhinitis	4 (4.1)	10 (9.5)	2 (3.4)	6 (10.5)	2 (5.0)	4 (8.3)
Fever	4 (4.1)	7 (6.7)	4 (6.9)	4 (7.0)	0	3 (6.3)
Dry Mouth	4 (4.1)	5 (4.8)	1 (1.7)	3 (5.3)	3 (7.5)	2 (4.2)
Allergic Reaction	4 (4.1)	4 (3.8)	3 (5.2)	3 (5.3)	1 (2.5)	1 (2.1)
Chest Pain	3 (3.1)	0	3 (5.2)	0	0	0
Emotional Lability	3 (3.1)	0	1 (1.7)	0	2 (5.0)	0
Personality Disorder	3 (3.1)	0	3 (5.2)	0	0	0
Cough Increased	2 (2.0)	6 (5.7)	1 (1.7)	5 (8.8)	1 (2.5)	1 (2.1)
Constipation	2 (2.0)	3 (2.9)	1 (1.7)	3 (5.3)	1 (2.5)	0
Asthma	2 (2.0)	0	0	0	2 (5.0)	0

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

As shown in Table 52 for both age groups 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: hyperkinesia (12.2% vs. 5.7%), trauma (10.2% vs. 2.9%), decreased appetite (9.2% vs. 1.0%), hostility (9.2% vs. 1.0%), diarrhea (8.2% vs. 1.9%), asthenia (8.2% vs. 1.0%), vomiting (6.1% vs. 1.9%), agitation (5.1% vs. 1.9%), and neurosis (5.1% vs. 1.0%). In addition to these AEs, children receiving paroxetine also experienced insomnia, chest pain, and personality disorder (verbatim terms: disinhibited/oppositional, disinhibition, disinhibited) with an incidence of 5% or greater and with an incidence at least twice that of children receiving placebo. 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 nausea, somnolence, decreased appetite, hostility, pharyngitis, diarrhea, asthenia, pain, asthma, and emotional lability meeting these criteria (Table 51) .

Table 52 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	
	Paroxetine	Placebo
AE Preferred Term*	(N = 98)	(N = 105)
Patients with AEs	**n (%)**	**n (%)**
Hyperkinesia	12 (12.2)	6 (5.7)
Trauma	10 (10.2)	3 (2.9)
Decreased Appetite	9 (9.2)	1 (1.0)
Hostility	9 (9.2)	1 (1.0)
Diarrhea	8 (8.2)	2 (1.9)
Asthenia	8 (8.2)	1 (1.0)
Vomiting	6 (6.1)	2 (1.9)
Agitation	5 (5.1)	2 (1.9)
Neurosis	5 (5.1)	1 (1.0)

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

In the paroxetine group, 4 of the more commonly reported (i.e., >10%) AEs among adolescents occurred at an incidence at least twice that among children: nausea (25.0% vs. 10.3%), somnolence (17.5% vs. 8.6%), asthenia (12.5% vs. 5.2%), and dizziness (10.0% vs. 1.7%). However, in the placebo group, nausea was more frequent in children (15.8%) than in adolescents (2.1%), and the

incidences of somnolence, asthenia, and dizziness were comparable in the age groups (Table 53).

Likewise in the paroxetine group, 4 of the more commonly reported (i.e., >10%) AEs among children occurred at an incidence at least twice that among adolescents: abdominal pain (22.4% vs. 10.0%), hyperkinesia (17.2% vs. 5.0%), and insomnia and hostility (each 12.1% vs. 5.0%). In the placebo group, abdominal pain was also more frequent in children (15.8%) than in adolescents (6.3%), but the incidences of hyperkinesia, insomnia, and hostility were comparable in the age groups (Table 53).

Table 53 Treatment-Phase Emergent Gender-non-specific Adverse Events with Incidence ≥10% in Children or Adolescents in the Paroxetine Group and ≥Twice the Incidence in the Alternative Age Group - Age Group: Children/Adolescents (ITT Population)

	Age Group: Children		Age Group: Adolescents	
Preferred Term*	**Paroxetine (N = 58)**	**Placebo (N = 57)**	**Paroxetine (N = 40)**	**Placebo N = 48)**
Patients with AEs	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Abdominal Pain	13 (22.4)	9 (15.8)	4 (10.0)	3 (6.3)
Hyperkinesia	10 (17.2)	4 (7.0)	2 (5.0)	2 (4.2)
Hostility	7 (12.1)	1 (1.8)	2 (5.0)	0
Insomnia	7 (12.1)	2 (3.5)	2 (5.0)	3 (6.3)
Nausea	6 (10.3)	9 (15.8)	10 (25.0)	1 (2.1)
Somnolence	5 (8.6)	3 (5.3)	7 (17.5)	4 (8.3)
Asthenia	3 (5.2)	1 (1.8)	5 (12.5)	0
Dizziness	1 (1.7)	4 (7.0)	4 (10.0)	3 (6.3)

* Sorted by decreasing frequency in the paroxetine group, age group = children

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

Overall, AEs tended to be mild to moderate in intensity. Table 54 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, gender-non-specific severe AEs were reported in 8/98 patients (8.2%) in the paroxetine group and 5/105 patients (4.8%) in the placebo group. The only severe AEs occurring in more than one patient were hostility and trauma (each in 2/98 [2.0%] patients in the paroxetine group and no patients in the placebo group). The only severe gender-specific AE was dysmenorrhea, which occurred in 1 female in the paroxetine treatment group.

Table 54 Treatment Phase-Emergent Severe Gender-non-specific Adverse Events–Age Group: Total (ITT Population)

	Treatment Group			
	Paroxetine (N = 98)		Placebo (N = 105)	
AE Preferred Term*	**n**	**(%)**	**n**	**(%)**
Total Patients with at least 1 severe AE	8	(8.2)	5	(4.8)
Hostility	2	(2.0)	0	
Trauma	2	(2.0)	0	
Agitation	1	(1.0)	0	
Depression	1	(1.0)	0	
Emotional lability	1	(1.0)	0	
Headache	1	(1.0)	0	
Hyperkinesia	1	(1.0)	0	
Anxiety	0		1	(1.0)
Dizziness	0		1	(1.0)
Neurosis	0		1	(1.0)
Otitis media	0		1	(1.0)
Somnolence	0		1	(1.0)

*Sorted by decreasing frequency in the paroxetine group
Source: Table 15.1.3.1.X, Section 13; Listing 15.1.1, Appendix D

Three patients receiving paroxetine and 4 receiving placebo had severe AEs 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).

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

Table 55 presents 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.

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 Tables 15.1.4.1 (by body system and preferred term) and 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, 60/98 (61.2%) 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 with 44/105 (41.9%) patients in the placebo group. No males or females in either treatment group reported a gender-specific AE judged to be related or possibly related to study medication.

With the exception of headache, which was reported as related or possibly related to study medication in a comparable percentage of patients in each treatment group (paroxetine, 17.3%; placebo, 15.2%), the most frequent AEs reported to be related or possibly related to study medication in the paroxetine group had an incidence that approached or exceeded twice that in the placebo group: somnolence, 12.2% vs. 6.7%; hyperkinesia, 11.2% vs. 5.7%; abdominal pain, 10.2% vs. 5.7%; nausea, 10.2% vs. 3.8%. In addition, hostility, judged related or possibly related to study medication, was reported in 7/98 (7.1%) patients, all children, in the paroxetine group compared with no patients in either age group who received placebo.

Table 55 Treatment Phase-Emergent Adverse Events Considered Related or Possibly Related to Study Medication Occurring in ≥5% Patients in Either Treatment Group–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group	
	Paroxetine	**Placebo**
AE Preferred Term	**n (%)**	**n (%)**
Age Group: Total	**(N = 98)**	**(N = 105)**
Total Patients with at least 1 related or possibly related AE	60 (61.2)	44 (41.9)
Headache	17 (17.3)	16 (15.2)
Somnolence	12 (12.2)	7 (6.7)
Hyperkinesia	11 (11.2)	6 (5.7)
Abdominal pain	10 (10.2)	6 (5.7)
Nausea	10 (10.2)	4 (3.8)
Insomnia	8 (8.2)	5 (4.8)
Asthenia	8 (8.2)	1 (1.0)
Decreased appetite	8 (8.2)	1 (1.0)
Hostility	7 (7.1)	0
Nervousness	5 (5.1)	6 (5.7)
Age Group: Children	**(N = 58)**	**(N = 57)**
Total Patients with at least 1 related or possibly related AE	37 (63.8)	27 (47.4)
Headache	10 (17.2)	9 (15.8)
Hyperkinesia	9 (15.5)	4 (7.0)
Abdominal pain	7 (12.1)	5 (8.8)
Hostility	7 (12.1)	0
Insomnia	6 (10.3)	2 (3.5)
Somnolence	5 (8.6)	3 (5.3)
Decreased appetite	5 (8.6)	1 (1.8)
Nausea	4 (6.9)	4 (7.0)
Nervousness	4 (6.9)	2 (3.5)
Neurosis	4 (6.9)	1 (1.8)
Asthenia	3 (5.2)	1 (1.8)
Agitation	3 (5.2)	0
Personality disorder	3 (5.2)	0
Rhinitis	0	3 (5.3)

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

(Continued)

Table 55 Treatment Phase-Emergent Adverse Events Considered Related or Possibly Related to Study Medication Occurring in ≥5% Patients in Either Treatment Group–Age Group: Total/Children/Adolescents (ITT Population) (Continued)

	Treatment Group	
	Paroxetine	**Placebo**
AE Preferred Term	**n (%)**	**n (%)**
Age Group: Adolescents	**(N = 40)**	**(N = 48)**
Total Patients with at least 1 related or possibly related AE	23 (57.5)	17 (35.4)
Constipation	1 (1.7)	3 (5.3)
Dry mouth	1 (1.7)	3 (5.3)
Headache	7 (17.5)	7 (14.6)
Somnolence	7 (17.5)	4 (8.3)
Nausea	6 (15.0)	0
Asthenia	5 (12.5)	0
Dizziness	3 (7.5)	3 (6.3)
Abdominal pain	3 (7.5)	1 (2.1)
Decreased appetite	3 (7.5)	0
Insomnia	2 (5.0)	3 (6.3)
Dry mouth	2 (5.0)	2 (4.2)
Hyperkinesia	2 (5.0)	2 (4.2)
Nervousness	1 (2.5)	4 (8.3)

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

As shown in Table 56, 3 patients who received paroxetine and 4 patients who received placebo had one or more severe AEs that was considered related or possibly related to study medication by the investigator. As a result of severe AEs, 1 paroxetine patient and 2 placebo patients were withdrawn from the study, and study medication dose was reduced for 1 patient in each treatment group. None of these severe AEs was reported as an SAE.

Table 56 Treatment Phase-Emergent Severe Adverse Events Considered Related or Possibly Related to Study Medication (ITT Population)

Patient Number	Age (yrs)	Gender (M/F)	AE Preferred (Verbatim)	Relationship	Dose at Onset	Study Medication Action	Day of Onset *	Duration (days)
Paroxetine								
704.005.25409	8	F	Headache (Headache)	Possibly related	10 mg	Continued	Day 40 (-32)	1
704.016.25452	7	M	Hyperkinesia (Hyperactive)	Related	20 mg	Stopped	Day 29 (-1)	4
704.019.25384	10	M	Agitation (Increased Agitation)	Possibly related	30 mg	Continued	Day 22 (-21)	Ongoing
			Hostility (Aggressive Behavior)	Possibly related	30 mg	Dose decreased	Day 22 (-21)	5
Placebo								
704.006.25421	15	M	Anxiety (Anxiety)	Possibly related	DL 5	Dose decreased	Day 39 (-5)	Ongoing
704.016.25453	17	F	Somnolence (Sedation)	Related	DL 1	Stopped	Day 6 (-1)	6
704.020.25455	15	F	Dizziness (Dizziness)	Possibly related	DL 2	Continued	Day 13 (-58)	6
704.025.27036	6	M	Neurosis (Increased Anxiety Due to OCD Symptoms)	Related	DL 2	Stopped	Day 9 (0)	3

* Relative to the first day of study medication (relative to the last dose of study medication, excluding taper). The patient had not necessarily withdrawn from study medication at that time.

Source: Tables 15.1.3.1.x and 15.1.4.1x, Section 13; Listings 13.5.1 and 13.13.1, Appendix B; Listing 15.1.1, Appendix D

6.2.1.3 Treatment Phase-Emergent Adverse Events by Time of First Occurrence

Table 57 and Table 58 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 the paroxetine and placebo groups, respectively. Table 15.1.6.1.X, Section 13, presents the time of first occurrence for all Treatment Phase-emergent AEs, by preferred term in descending order.

The time to first occurrence for many of the common AEs tended to be within the first 3 weeks of study medication, especially for headache, abdominal pain, nausea, dizziness, and pharyngitis in both treatment groups; for hyperkinesia, decreased appetite, insomnia, and asthenia in the paroxetine group; and for somnolence in the placebo group. Nervousness and infection appeared to occur later in the study in both treatment groups. Trauma occurred later in the study in patients who received paroxetine; fewer than 5% of placebo patients experienced trauma.

Table 57 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)

	Time of First Occurrence*							
AE Preferred Term, n (%)	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 6**	**Week 8**	**Week 10**	**Total**
Paroxetine (N = 98)								
Headache	5 (5.1)	6 (6.1)	3 (3.1)	1 (1.0)	3 (3.1)	3 (3.1)	3 (3.1)	24 (24.5)
Abdominal pain	7 (7.1)	4 (4.1)	2 (2.0)	2 (2.0)	1 (1.0)	1 (1.0)	0	17 (17.3)
Nausea	7 (7.1)	2 (2.0)	3 (3.1)	3 (3.1)	0	0	1 (1.0)	16 (16.3)
Hyperkinesia	6 (6.1)	3 (3.1)	1 (1.0)	1 (1.0)	0	1 (1.0)	0	12 (12.2)
Respiratory disorder	1 (1.0)	3 (3.1)	1 (1.0)	1 (1.0)	3 (3.1)	2 (2.0)	1 (1.0)	12 (12.2)
Somnolence	4 (4.1)	2 (2.0)	1 (1.0)	3 (3.1)	1 (1.0)	1 (1.0)	0	12 (12.2)
Trauma	1 (1.0)	2 (2.0)	0	2 (2.0)	3 (3.1)	0	2 (2.0)	10 (10.2)
Decreased appetite	5 (5.1)	1 (1.0)	0	3 (3.1)	0	0	0	9 (9.2)
Hostility	0	2 (2.0)	2 (2.0)	1 (1.0)	2 (2.0)	1 (1.0)	1 (1.0)	9 (9.2)
Insomnia	3 (3.1)	2 (2.0)	1 (1.0)	2 (2.0)	0	1 (1.0)	0	9 (9.2)
Asthenia	4 (4.1)	1 (1.0)	1 (1.0)	2 (2.0)	0	0	0	8 (8.2)
Diarrhea	2 (2.0)	0	2 (2.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	8 (8.2)
Pharyngitis	3 (3.1)	2 (2.0)	1 (1.0)	0	0	1 (1.0)	1 (1.0)	8 (8.2)
Dysmenorrhea**	0	1 (2.2)	0	2 (4.4)	0	0	0	3 (6.7)
Vomiting	2 (2.0)	0	1 (1.0)	1 (1.0)	0	2 (2.0)	0	6 (6.1)
Agitation	0	1 (1.0)	2 (2.0)	0	2 (2.0)	0	0	5 (5.1)

* No AEs fell within the Post-Week 10 Time Interval.

** Percentages are based on 45 females in the paroxetine group.

Source: Table 15.1.6.1.X, Section 13; Listing 15.1.1, Appendix D

(Continued)

Table 57 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) (Continued)

	Time of First Occurrence							
AE Preferred Term, n (%)	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 6**	**Week 8**	**Week 10**	**Total**
Dizziness	3 (3.1)	1 (1.0)	0	0	0	0	1 (1.0)	5 (5.1)
Infection	1 (1.0)	0	0	1 (1.0)	2 (2.0)	1 (1.0)	0	5 (5.1)
Nervousness	0	0	1 (1.0)	1 (1.0)	0	3 (3.1)	0	5 (5.1)
Neurosis	2 (2.0)	1 (1.0)	0	1 (1.0)	1 (1.0)	0	0	5 (5.1)
Pain	2 (2.0)	0	1 (1.0)	0	0	2 (2.0)	0	5 (5.1)
Sinusitis	1 (1.0)	1 (1.0)	0	1 (1.0)	2 (2.0)	0	0	5 (5.1)

* No AEs fell within the Post-Week 10 Time Interval.
** Percentages are based on 45 females in the paroxetine group.
Source: Table 15.1.6.1.X, Section 13; Listing 15.1.1, Appendix D

Table 58 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)

	Time of First Occurrence*							
AE Preferred Term, n (%)	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 6**	**Week 8**	**Week 10**	**Total**
Placebo (N = 105)								
Headache	11 (10.5)	3 (2.9)	4 (3.8)	0	2 (1.9)	1 (1.0)	1 (1.0)	22 (21.0)
Respiratory disorder	4 (3.8)	2 (1.9)	1 (1.0)	3 (2.9)	2 (1.9)	1 (1.0)	2 (1.9)	15 (14.3)
Abdominal pain	3 (2.9)	6 (5.7)	2 (1.9)	0	0	1 (1.0)	0	12 (11.4)
Infection	4 (3.8)	1 (1.0)	0	2 (1.9)	1 (1.0)	2 (1.9)	2 (1.9)	12 (11.4)
Nausea	4 (3.8)	3 (2.9)	2 (1.9)	1 (1.0)	0	0	0	10 (9.5)
Rhinitis	1 (1.0)	2 (1.9)	1 (1.0)	3 (2.9)	0	2 (1.9)	1 (1.0)	10 (9.5)
Dizziness	2 (1.9)	3 (2.9)	2 (1.9)	0	0	0	0	7 (6.7)
Fever	1 (1.0)	1 (1.0)	2 (1.9)	1 (1.0)	1 (1.0)	0	1 (1.0)	7 (6.7)
Somnolence	3 (2.9)	2 (1.9)	2 (1.9)	0	0	0	0	7 (6.7)
Cough increased	0	2 (1.9)	1 (1.0)	1 (1.0)	0	1 (1.0)	1 (1.0)	6 (5.7)
Hyperkinesia	1 (1.0)	1 (1.0)	0	2 (1.9)	2 (1.9)	0	0	6 (5.7)
Nervousness	2 (1.9)	0	0	3 (2.9)	1 (1.0)	0	0	6 (5.7)
Pharyngitis	1 (1.0)	3 (2.9)	2 (1.9)	0	0	0	0	6 (5.7)

* No AEs fell within the Post-Week 10 Time Interval.

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 59 presents the number (%) of patients in both age groups combined by treatment group whose dose of study medication was decreased during the Treatment Phase due to an AE. Twenty of 98 patients (20.4%) in the paroxetine group had dose reductions due to an AE compared with 8 of 105 patients (7.6%) in the placebo group.

The AEs that most frequently led to a dose reduction in patients in the paroxetine group were hyperkinesia (7/98, 7.1% vs. 3/105, 2.9% in the placebo group), somnolence (4/98, 4.1% vs. 0 in the placebo group), and hostility (3/98, 3.1% vs. 0 in the placebo group). In the placebo group, the AE that most frequently led to a dose reduction was nervousness in 4 of 105 (3.8%) patients, compared with 2 of 98 patients (2.0%) in the paroxetine group.

AEs leading to dose reduction occurred with greatest frequency in the Nervous System body system. There were no gender-specific AEs that led to dose reduction. No patient had more than one dose reduction during the Treatment Phase. However, 2 patients (704.020.27028 and 704.029.27009) in the paroxetine group and 1 patient (704.006.25421) in the placebo group had their dose reduced by 2 dose levels simultaneously. All of these patients were at the maximum dose level allowed in the study. One patient in the placebo group who was at DL 1 had dosing interrupted for 3 days rather than reduced as a result of AEs.

Table 59 Treatment Phase-Emergent Adverse Events That Led to Dose Reductions by Body System–Age Group: Total (ITT Population)

Body system	AE Preferred Term	Treatment Group: Paroxetine (N = 98) n (%)	Treatment Group: Placebo (N = 105) n (%)
Total Patients with Dose Reductions*		20 (20.4)	8 (7.6)
Nervous System	Total	18 (18.4)	7 (6.7)
	Hyperkinesia	7 (7.1)	3 (2.9)
	Somnolence	4 (4.1)	0
	Hostility	3 (3.1)	0
	Nervousness	2 (2.0)	4 (3.8)
	Insomnia	2 (2.0)	2 (1.9)
	Anxiety	2 (2.0)	1 (1.0)
	Neurosis	2 (2.0)	0
	Agitation	1 (1.0)	1 (1.0)
	Personality disorder	1 (1.0)	0
	Concentration impaired	0	1 (1.0)
Body as a Whole	Total	2 (2.0)	1 (1.0)
	Asthenia	1 (1.0)	0
	Trauma	1 (1.0)	0
	Headache	0	1 (1.0)
Digestive System	Total	2 (2.0)	1 (1.0)
	Bruxism	1 (1.0)	0
	Increased appetite	1 (1.0)	0
	Nausea	0	1 (1.0)
	Vomiting	0	1 (1.0)

*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 60 presents a listing of specific patients who had an AE identified as leading to a dose reduction. All dose reductions during the course of the study, except for those in 2 patients who received paroxetine, were for AEs considered related or possibly related to study medication. Sixteen of the 20 paroxetine patients and 5 of the 8 placebo patients with dose reductions were children.

Table 60 Treatment Phase-Emergent Adverse Events That Led to Dose Reductions by Patient (ITT Population)

Patient Number	Gender (M/F)	Age (yrs)	Dose Reduction From	Dose Reduction To	AE Preferred Term	Intensity	Relationship
Paroxetine							
704.005.27054	M	10	30 mg	20 mg	Hostility	Moderate	Possibly Related
					Personality disorder	Moderate	Possibly Related
704.006.25417	F	10	50 mg	40 mg	Increased appetite	Mild	Probably Unrelated
					Somnolence	Mild	Possibly Related
704.006.25420	F	14	40 mg	30 mg	Anxiety	Mild	Possibly Related
					Nervousness	Mild	Possibly Related
704.008.25361	F	16	30 mg	20 mg	Somnolence	Moderate	Possibly Related
704.008.25366	M	9	20 mg	10 mg	Agitation	Moderate	Possibly Related
					Nervousness	Moderate	Possibly Related
704.012.25480	M	9	30 mg*	20 mg	Neurosis	Moderate	Related
704.015.27095	M	10	20 mg	10 mg	Hyperkinesia	Moderate	Related
704.016.25448	F	11	40 mg	30 mg	Hyperkinesia	Mild	Possibly Related
					Neurosis	Mild	Possibly Related
704.016.25451	M	9	20 mg	10 mg	Hyperkinesia	Mild	Possibly Related
704.016.25452**	M	7	20 mg	10 mg	Hyperkinesia	Moderate	Related

*Dose at AE onset was 10 mg/day.
** Patient was later withdrawn from the study due to severe hyperkinesia.
†Dose at AE onset was 30 mg/day.
†† Dose at AE onset was 20 mg/day.
‡ Dose at AE onset was DL 1; dosing was interrupted due to the AEs.
Source: Table 15.1.8, Section 13; Listings 13.5.1, 13.13.1, Appendix B; Listing 15.1.1, Appendix D
(Continued)

Table 60 Treatment Phase-Emergent Adverse Events That Led to Dose Reductions by Patient (ITT Population) (Continued)

Patient Number	Gender (M/F)	Age (yrs)	Dose Reduction From	Dose Reduction To	AE Preferred Term	Intensity	Relationship
Paroxetine							
704.016.27018	F	6	20 mg	10 mg	Somnolence	Moderate	Possibly Related
704.016.27022	M	7	20 mg	10 mg	Hyperkinesia	Moderate	Possibly Related
					Insomnia	Moderate	Possibly Related
704.016.27182	M	15	30 mg	20 mg	Bruxism	Moderate	Related
					Hyperkinesia	Moderate	Related
704.019.25384	M	10	30 mg	20 mg	Hostility	Severe	Possibly Related
704.019.25386	F	9	20 mg	10 mg	Hostility	Moderate	Possibly Related
704.020.27028	M	7	50 mg†	30 mg	Anxiety	Mild	Possibly Related
					Insomnia	Mild	Possibly Related
704.025.27032	F	7	20 mg	10 mg	Trauma	Severe	Not Related
704.029.27009	F	12	50 mg	30 mg	Somnolence	Moderate	Possibly Related
704.051.28104	M	11	50 mg	40 mg	Asthenia	Moderate	Related
704.052.28101	M	7	30 mg††	20 mg	Hyperkinesia	Moderate	Possibly Related

*** Dose at AE onset was 10 mg/day.**
**** Patient was later withdrawn from the study due to severe hyperkinesia.**
†Dose at AE onset was 30 mg/day.
†† Dose at AE onset was 20 mg/day.
‡Dose at AE onset was DL 1; dosing was interrupted due to the AEs.
Source: Table 15.1.8, Section 13; Listings 13.5.1, 13.13.1, Appendix B; Listing 15.1.1, Appendix D
(*Continued*)

Table 60 Treatment Phase-Emergent Adverse Events That Led to Dose Reductions by Patient (ITT Population) (Continued)

Patient Number	Gender (M/F)	Age (yrs)	Dose Reduction From	Dose Reduction To	AE Preferred Term	Intensity	Relationship
Placebo							
704.006.25421	M	15	DL 5	DL 3	Anxiety	Severe	Possibly Related
					Nervousness	Moderate	Possibly Related
704.008.25364	F	15	DL 2	DL 1	Insomnia	Mild	Possibly Related
					Nervousness	Mild	Possibly Related
704.016.25454	F	7	DL 3	DL 2	Hyperkinesia	Moderate	Possibly Related
704.016.27017	M	12	DL 4	DL 3	Agitation	Moderate	Related
					Hyperkinesia	Moderate	Related
					Insomnia	Moderate	Related
					Nervousness	Moderate	Related
704.016.27019	M	11	DL 3	DL 2	Hyperkinesia	Moderate	Possibly Related
704.016.27023	M	8	DL 3	DL 2	Concentration Impaired	Moderate	Related
704.020.27185	M	8	DL 5	DL 4	Nervousness	Moderate	Possibly Related
704.031.25535	M	10	DL 1‡	DL 1	Headache	Moderate	Possibly Related
					Nausea	Moderate	Possibly Related
					Vomiting	Moderate	Possibly Related

* Dose at AE onset was 10 mg/day.
** Patient was later withdrawn from the study due to severe hyperkinesia.
†Dose at AE onset was 30 mg/day.
†† Dose at AE onset was 20 mg/day.
‡ Dose at AE onset was DL 1; dosing was interrupted due to the AEs.
Source: Table 15.1.8, Section 13; Listings 13.5.1, 13.13.1, Appendix B; Listing 15.1.1, Appendix D

6.2.2 Taper/Follow-up Phase-Emergent Adverse Events

Patients in both treatment groups were to be down-titrated 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. 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 Treatment or Taper study medication unless they entered open-label extension study 29060/716.

Of the 98 paroxetine patients in the Treatment Phase, 80 (81.6%) entered the Taper Phase and/or the Follow-up Phase. Of the 105 placebo patients in the Treatment Phase, 89 (84.8%) entered the Taper Phase and/or the Follow-up Phase.

Table 61 presents the number and percent of patients with the most frequent (≥2%) Taper Phase or Follow-up Phase-emergent AEs regardless of treatment attribution. The proportions of patients in each treatment group having gender-non-specific AEs during the Taper or Follow-up Phase were similar, 15/80 (18.8%) in the paroxetine group and 15/89 (16.9%) in the placebo group. The most common AE was headache, which occurred in 4/80 patients in the paroxetine group (5.0%) and in 4/89 patients in the placebo group (4.5%). Vomiting was reported only in the paroxetine group (3/80 patients, 3.8%), and neurosis was reported only in the placebo group (3/89 patients, 3.4%). No other AEs occurred in more than 2 patients in either treatment group.

No gender-specific AEs were reported in either treatment group during the Taper or Follow-up Phases.

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 descending order and preferred term). 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 descending order and preferred term).

Table 61 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	
	Paroxetine (N = 80)	Placebo (N = 89)
AE Preferred Term	**n (%)**	**n (%)**
Total Patients with at Least 1 AE	15 (18.8)	15 (16.9)
Headache	4 (5.0)	4 (4.5)
Vomiting	3 (3.8)	0
Nervousness	2 (2.5)	2 (2.2)
Nausea	2 (2.5)	1 (1.1)
Infection	1 (1.3)	2 (2.2)
Rhinitis	1 (1.3)	2 (2.2)
Neurosis	0	3 (3.4)
Asthenia	0	2 (2.2)

N = number of patients entering the Taper Phase or Follow-up Phase.
Source: Table 15.1.1.5.X, Section 13; Listing 15.1.2, Appendix D

6.2.2.1 Taper Phase-Emergent Adverse Events

Table 62 presents a summary of all AEs that emerged during the Taper Phase. The proportions of patients in each treatment group having non-gender-specific AEs during the Taper Phase were similar, 9/60 patients in the paroxetine group (15.0%) and 12/74 patients in the placebo group (16.2%). The only event experienced by more than 1 patient in the paroxetine treatment group was headache, which occurred in 2 patients; 4 patients in the placebo group reported headache. No gender-specific Taper Phase-emergent AEs were reported.

One AE emerged during the Taper Phase that had not occurred in either treatment group during the Treatment Phase. In the paroxetine group, patient 704.008.25361 had paresthesia 1 day after the last dose of study medication in the Treatment Phase. The paresthesia was considered by the investigator to be mild and possibly related to study medication (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 62 Number (%) of Patients with Taper Phase-Emergent Adverse Events–Age Group: Total (ITT Population Entering the Taper Phase)

	Treatment Group	
AE Preferred Term	**Paroxetine (N = 60) n (%)**	**Placebo (N = 74) n (%)**
Total Patients with at least 1 AE	9 (15.0)	12 (16.2)
Headache	2 (3.3)	4 (5.4)
Infection	1 (1.7)	2 (2.7)
Nervousness	1 (1.7)	2 (2.7)
Rhinitis	1 (1.7)	2 (2.7)
Allergic reaction	1 (1.7)	0
Anxiety	1 (1.7)	0
Arthralgia	1 (1.7)	0
Diarrhea	1 (1.7)	0
Dizziness	1 (1.7)	0
Myalgia	1 (1.7)	0
Paresthesia	1 (1.7)	0
Sinusitis	1 (1.7)	0
Ulcerative stomatitis	1 (1.7)	0
Neurosis	0	3 (4.1)
Asthenia	0	2 (2.7)
Abdominal pain	0	1 (1.4)
Conjunctivitis	0	1 (1.4)
Decreased appetite	0	1 (1.4)
Ear pain	0	1 (1.4)
Nausea	0	1 (1.4)
Otitis media	0	1 (1.4)
Vasodilatation	0	1 (1.4)

N = number of patients entering the Taper Phase.
Source: Table 15.1.1.2.X, Section 13; Listing 15.1.2, Appendix D

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.

Table 15.1.4.2, Section 13, presents Taper Phase-emergent AEs that are related or possibly related to study medication by body system. Five 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 63). The only events judged to be related or possibly related to study medication and experienced by 2 or more patients in either treatment group were headache in 2 patients in each group, neurosis in 3 patients who received placebo, and asthenia and nervousness, each in 2 patients who received placebo. No patients who received paroxetine reported related or possibly related neurosis, asthenia, or nervousness as emergent during the Taper Phase.

Table 63 Number (%) of Patients with 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 = 60) n (%)**	**Placebo (N = 74) n (%)**
Total patients with at least 1 related or possibly related AE	5 (8.3)	7 (9.5)
Headache	2 (3.3)	2 (2.7)
Diarrhea	1 (1.7)	0
Dizziness	1 (1.7)	0
Myalgia	1 (1.7)	0
Paresthesia	1 (1.7)	0
Neurosis	0	3 (4.1)
Asthenia	0	2 (2.7)
Nervousness	0	2 (2.7)
Conjunctivitis	0	1 (1.4)
Decreased appetite	0	1 (1.4)
Nausea	0	1 (1.4)
Rhinitis	0	1 (1.4)
Vasodilatation	0	1 (1.4)

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 AEs during the Treatment Phase or Taper Phase by body system. 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. Tables 15.1.3.3 and 15.1.7.3, Section 13, present patients with emergent AEs

during the Treatment Phase or Taper Phase by intensity by body system, and by maximum intensity, respectively.

One patient in each treatment group had a Taper Phase-emergent AE that was considered severe by the investigator. Patient 704.029.27009, in the paroxetine group, had 2 episodes of anxiety, one while taking a 30-mg dose and one while at a 20-mg dose. Both episodes were judged to be severe and probably unrelated to treatment with study medication. Patient 704.016.25447, in the placebo group, had a Taper Phase-emergent AE of neurosis (verbatim: fear of germs, handwashing) judged to be severe and related to treatment with study medication by the investigator.

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) unless they entered open-label extension study 29060/716. Thirty-seven paroxetine patients and 39 placebo patients entered the Follow-up Phase. Forty-six patients in the paroxetine group and 62 patients in the placebo group did not have a Follow-up Visit because they entered the open-label extension study. (Note: Information about the extension study is accurate at the time of this Report.)

Of the patients who entered the Follow-up Phase, 7 of 37 patients in the paroxetine group (18.9%) and 3 of 39 patients in the placebo group (7.7%) had an AE during the Follow-up Phase (Table 64). Vomiting was experienced by 3 patients in the paroxetine group and headache and nausea were each experienced by 2 patients in the paroxetine group; no patients in the placebo group reported these AEs. No other AEs were experienced by more than one patient in either treatment group, and no patients had a gender-specific AE. In the paroxetine treatment group, 5 of the 10 AEs reported were in the Digestive Body System compared with 1 of the 4 AEs reported for 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.

All of the AEs that emerged during the Follow-up Phase had occurred in at least one of the treatment groups during the Treatment or Taper Phase (Tables 15.1.1.3X and 15.1.1.4.X, Section 13).

Table 64 Number (%) of Patients with Follow-up Phase-Emergent Adverse Events–Age Group: Total (ITT Population Entering the Follow-up Phase)

	Treatment Group	
AE Preferred Term	**Paroxetine (N = 37) n (%)**	**Placebo (N = 39) n (%)**
Total Patients with at least 1 AE	7 (18.9)	3 (7.7)
Vomiting	3 (8.1)	0
Headache	2 (5.4)	0
Nausea	2 (5.4)	0
Hostility	1 (2.7)	0
Nervousness	1 (2.7)	0
Respiratory disorder	1 (2.7)	0
Albuminuria	0	1 (2.6)
Dry mouth	0	1 (2.6)
Hematuria	0	1 (2.6)
Insomnia	0	1 (2.6)

N = Patients entering the Follow-up Phase
Source: Tables 15.1.1.4.X, Section 13; Listing 15.1.2, Appendix D

Three patients in the paroxetine group had AEs during the Follow-up Phase that were considered by the investigator to be related or possibly related to study medication: headache, 2 patients; nausea, 2 patients; vomiting, 1 patient; and nervousness, 1 patient. No patient in the placebo group had an AE during the Follow-up Phase that was judged by the investigator to be related or possibly related 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.

During the Follow-up Phase, 2 patients in the paroxetine group had severe AEs. Vomiting was reported as a non-serious AE and hostility was reported as an SAE (see Section 6.4). No patients in the placebo group had a severe AE during follow-up. AEs emergent in the Follow-up Phase, described by intensity, may be found in Table 15.1.3.4, Section 13, by body system, and in Table 15.1.3.4.X, Section 13, ordered by preferred term occurring in 1% or more of the population in descending order. Table 15.1.7.4, Section 13, presents Follow-up Phase-emergent AEs by maximum intensity by body system.

6.3 Deaths

There were no deaths during the course of the study or at any time since the last dose of study medication (Listing 15.1.5, Appendix D.)

6.4 Serious Adverse Events

A serious AE was defined as any event which was fatal, life threatening, disabling/incapacitating or resulted in hospitalization,[6] prolonged a hospital stay or was associated with congenital abnormality, cancer or overdose (either accidental or intentional). In addition any experience which the investigator regarded as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be 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 may be considered a serious adverse drug experience when, based upon appropriate medical judgement, they may jeopardize the patient or patients and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

As shown in Table 65, 3 patients (3.0%) of the 100 patients randomized to paroxetine reported SAEs during the Treatment Phase or within 30 days post-therapy (including Taper medication) compared with 1 of 107 placebo patients (0.9%). (Note: The total number of patients randomized included 1 patient who did not receive study medication and 3 patients who did not have any post-Baseline assessments.) Hostility occurred in 2 patients in the paroxetine group (2 occurrences in 1 patient) and in 1 patient in the placebo group. Emotional lability occurred in 1 patient in the paroxetine group. No gender-specific SAEs were reported for either treatment group. No patient had an SAE during the Pre-treatment Phase of the study (Listing 15.1.3.1, Appendix D).

[6] Elective surgery or routine clinical procedures which 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.

Table 65 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 = 100)	**Placebo (N = 107)**
SAE Preferred Term	n (%)	n (%)
Total Patients with at least 1 SAE *	3 (3.0)	1 (0.9)
Hostility	2 (2.0)	1 (0.9)
Emotional lability	1 (1.0)	0

N = Number of patients randomized. This includes 1 patient who was randomized but did not receive any study medication and 3 patients who were randomized but did not have any post-baseline assessments.
* Serious AEs up to 30 days after the last dose of randomized treatment are included in this summary.
Source: Table 15.1.2.1, Section 13; Listing 15.1.3.2, 15.1.3.3, Appendix D

Table 66 presents a listing of all patients, 3 from the paroxetine group and 1 from the placebo group, with an SAE occurring at any time post-randomization up to 30 days after the last dose of randomized medication. None of these patients had any psychiatric conditions reported other than OCD. All of the SAEs were considered unrelated or probably unrelated to study medication by the investigator.

Of the 3 paroxetine patients who experienced SAEs, Patient 704.033.25513, was withdrawn from the study as a result. This 15-year-old male was randomized to paroxetine and titrated up to a dose of 40 mg/day. On Day 25 of study medication, 1 day after reaching his maximum dose level, the patient began to have suicidal thoughts (preferred term: emotional lability) while staying at a youth shelter. He was hospitalized for evaluation, and, as a result of this event, study medication was stopped. The event lasted 8 days. The investigator considered the SAE severe and probably unrelated to treatment with study medication.

Patient 704.048.27175, an 11-year-old female, was randomized to paroxetine and titrated up to a dose of 50 mg/day. On Day 55 of study medication, about 3 weeks after reaching the maximum dose level, the patient began to experience irritability and hostile and aggressive behavior; the patient claimed to be upset because her grandmother had come to live with her family. This behavior was reported as a non-serious AE (preferred term: hostility), lasting 16 days. This

non-serious AE was considered of moderate intensity and possibly related to study medication by the investigator. On Day 71, 3 days after receiving the last dose of study medication in the Treatment Phase and 1 day after stopping the Taper Phase, the patient's irritable, hostile, and aggressive behavior worsened; she became "out of control" and was taken to the emergency room and hospitalized. Taper Phase study medication was stopped and the event resolved in 2 days. The investigator considered the SAE (preferred term: hostility) to be severe and probably unrelated to treatment with study medication.

Patient 704.055.28174, a 14-year-old male, was randomized to paroxetine and titrated up to a dose of 40 mg/day. On Day 39 of study medication, about 3 weeks after reaching his maximum dose level, the patient had a "bad altercation" with his mother and was hospitalized for a "time-out" due to aggressive behavior. The patient continued in the study and this SAE resolved in 18 days. The patient completed the study on Day 63 and entered the Taper Phase. On that same day, the patient had another altercation with his mother and was again hospitalized for aggressive behavior. He was discharged in stable condition after 1 day and the event resolved in 26 days. The investigator considered both SAEs (preferred term: hostility) to be severe, unrelated to treatment with study medication, and associated with the patient's dysfunctional family.

One patient randomized to placebo experienced an SAE. Patient 704.055.28171, a 9-year-old male, was titrated up to study medication Dose Level 5. On Day 42 of study medication, 13 days after reaching the maximum dose level, the patient had a conflict with his mother and was hospitalized for a "time-out" due to aggressive behavior. The event resolved in 15 days and the patient completed the study. The investigator considered the SAE (preferred term: hostility) to be of moderate severity and unrelated to treatment with study medication.

Complete narratives for these patients may be found in Table 15.1.2, Section 13. There may be minor discrepancies in the details of the SAEs included in the clinical narratives compared with the safety tabulations, because the data come from two different databases and have been collected at different points in time. However, it is considered that these differences, if any, are minor in nature and do not change the overall clinical significance or understanding of the SAEs. In the safety tabulations, SAEs were coded by the WHO ART dictionary and mapped by ADECS for preferred term. In the separate database used for preparing the clinical narratives, SAEs were coded by the WHO ART dictionary, but not mapped by ADECS for preferred term. The following preferred terms in the two systems are equivalent: aggressive reaction and hostility; suicide attempt and emotional lability.

Table 66 Randomized Patients with Serious Nonfatal Adverse Events (On-therapy Plus 30 Days Post-Therapy) (ITT Population)

Patient Number	Age (yrs)	Gender (M/F)	SAE (Preferred Term)	SAE (Verbatim Term)	Intensity	Relationship	Day of Onset *	Duration (days)
Paroxetine								
704.033.25513**	15	M	Emotional Lability	Hospitalization due to suicidal thoughts	Severe	Probably Unrelated	25 (0)	8
704.048.27175†	11	F	Hostility	Irritable/hostile aggressive behavior worsened	Severe	Probably Unrelated	71 (3)	2
704.055.28174	14	M	Hostility	"Time-out" hospitalization (aggressive behavior)	Severe	Unrelated	39 (-24)	18
			Hostility	Aggressive behavior	Severe	Unrelated	63 (0)	26
Placebo								
704.055.28171	9	M	Hostility	"Time-out" hospitalization (aggressive behavior)	Moderate	Unrelated	42 (-28)	15

* Relative to the first day of study medication (relative to the last dose of study medication, excluding taper). The patient had not necessarily withdrawn from study medication at that time.
** Patient was withdrawn from the study because of this AE.
† SAE occurred during the Taper Phase.
Source: Table 15.1.2.1, 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

A total of 10/98 patients randomized to paroxetine (10.2%) and 3/105 patients randomized to placebo (2.9%) were withdrawn from the study because of one or more AEs. Table 67 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 order of decreasing frequency, 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. One patient (704.040.27110) was withdrawn from the study due to an AE (iritis) prior to randomization (Listing 13.3.1a).

The only AE leading to withdrawal that occurred in more than 1 patient in the same treatment group for both age groups combined was hyperkinesia, experienced by 3 patients in the paroxetine group and no patients in the placebo group. Two patients, 1 in each treatment group, experienced neurosis that led to withdrawal. All other AEs leading to withdrawal were each experienced by a single patient. No gender-specific AEs led to withdrawal.

Table 67 Number (%) of Patients Withdrawn During the Treatment Phase Due to an AE–Age Group: Total (ITT Population)

Adverse Events by Preferred Term	Treatment Group: Paroxetine (N = 98) n	(%)	Placebo (N = 105) n	(%)
Total Patients with an AE Leading to Withdrawal	10	(10.2)	3	(2.9)
Hyperkinesia	3	(3.1)	0	
Neurosis	1	(1.0)	1	(1.0)
Concentration impaired	1	(1.0)	0	
Depression	1	(1.0)	0	
Dyspepsia	1	(1.0)	0	
Emotional Lability	1	(1.0)	0	
Gastrointestinal disorder	1	(1.0)	0	
Hostility	1	(1.0)	0	
Nervousness	1	(1.0)	0	
Personality disorder	1	(1.0)	0	
Urinary retention	1	(1.0)	0	
Agitation	0		1	(1.0)
Somnolence	0		1	(1.0)

Note: A patient may have more than one AE leading to withdrawal.
Source: Table 15.1.5.1.X, Section 13; Listing 15.1.4, Appendix D.

Table 68 presents per-patient information about patients withdrawn from the study due to an AE. Nine of the 13 patients withdrawn were children, and 10 of the 13 were males. All but 2 of the AEs leading to withdrawal (14/16) were considered moderate or severe in intensity, and 10 of these 14 moderate or severe AEs were considered by the investigator to be related or possibly related to study medication.

One patient in the paroxetine group (704.033.25513) and none in the placebo group experienced a serious AE that led to withdrawal. A detailed narrative for this patient may be found in Table 15.1.2, Section 13. Detailed narratives for patients with non-serious adverse events that led to withdrawal may be found in Table 15.1.5, Section 13.

Table 68 Patients Withdrawn from the Study Due to an Adverse Event (ITT Population)

Patient Number	Gender (M/F)	Age (yrs)	Dose at Onset	AE Leading to Withdrawal Preferred Term (Verbatim Term)	Intensity	Relationship to Study Medication	Day of Onset *	Duration (days)
Paroxetine								
704.002.25442	M	8	10 mg	Hyperkinesia (Increase in hyperactive & impulsive behavior)	Moderate	Probably Unrelated	1 (-3)	7
			10 mg	Neurosis (Increase in hyperactive & impulsive behavior)	Moderate	Probably Unrelated	1 (-3)	7
704.010.25367	M	12	20 mg	Depression (Depression)	Severe	Unrelated	13 (-1)	5
704.010.25369	F	7	10 mg	Urinary retention (Urinary retention)	Moderate	Possibly Related	11 (-7)	14
704.010.25372	F	9	30 mg	Personality disorder (Disinhibition)	Mild	Possibly Related	32 (-5)	15
704.014.25357	M	9	20 mg	Concentration Impaired (Increase in ADHD Symptoms, "Fidgety," Inattentive, Distractable)	Moderate	Possibly Related	61 (-3)	Ongoing
				Nervousness (Increase in ADHD Symptoms, "Fidgety," Inattentive, Distractable)	Moderate	Possibly Related	61 (-3)	Ongoing
704.015.27044	M	7	10 mg	Hostility (Oppositional defiant disorder)	Mild	Related	14 (-28)	37
704.016.25452	M	7	20 mg	Hyperkinesia (Hyperactive)	Severe	Related	29 (-1)	4

* Relative to the first day of study medication (relative to the last dose of study medication, excluding taper).

** AE leading to withdrawal was an SAE.

†AE onset during interruption in study medication.

Source: Table 15.1.5.1, Section 13; Listings 13.5.1, 13.13.1, Appendix B, Listing 15.1.4, Appendix D

Continued

Table 68 Patients Withdrawn from the Study Due to an Adverse Event (ITT Population) (Continued)

Patient Number	Gender (M/F)	Age (yrs)	Dose at Onset	AE Leading to Withdrawal Preferred Term (Verbatim Term)	Intensity	Relationship to Study Medication	Day of Onset *	Duration (days)
Paroxetine								
704.016.27020	M	8	10 mg	Dyspepsia (Heartburn/acid reflux)	Moderate	Possibly Related	8 (-13)	Ongoing
			10 mg	Gastrointestinal disorder (Heartburn/acid reflux)	Moderate	Possibly Related	8 (-13)	Ongoing
704.016.27022	M	7	10 mg	Hyperkinesia (Hyperactivity)	Moderate	Related	25 (-10)	26
704.033.25513	M	15	40 mg	Emotional Lability (Hospitalization due to suicidal thoughts)**	Severe	Probably Unrelated	25 (0)	8
Placebo								
704.006.25421	M	15	0†	Agitation (Panic Attacks)	Moderate	Possibly Related	42 (-2)	15
704.016.25453	F	17	DL 1	Somnolence (Sedation)	Severe	Related	6 (-1)	6
704.025.27036	M	6	DL 2	Neurosis (Increased anxiety due to obsessive compulsive disorder symptoms)	Severe	Related	9 (0)	3

* Relative to the first day of study medication (relative to the last dose of study medication, excluding taper).
** AE leading to withdrawal was an SAE.
†AE onset during interruption in study medication.
Source: Table 15.1.5.1, Section 13; Listings 13.5.1, 13.13.1, Appendix B, Listing 15.1.4, Appendix D

6.6 Medical Procedures

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. A listing of non-medication therapeutic, diagnostic or surgical procedures performed during this study can be found in Listing 15.5.1, Appendix D.

Of the 13 paroxetine patients (23 procedures) and the 15 placebo patients (19 procedures) in Listing 15.5.1, Appendix D, 4 patients from the paroxetine group and 5 patients from the placebo group had procedures that were elective and were not associated with an on-therapy adverse event.

One patient in each treatment group (704.055.28174 in the paroxetine group and 704.055.28171 in the placebo group) had medical procedures of diagnostic laboratory work and/or EEG consequent to SAEs of hostility leading to hospitalization. Detailed narratives for these patients may be found in Table 15.1.2, Section 13.

Three patients, all children, had procedures in connection with events that were not reported as adverse events. Patient 704.051.28104, in the paroxetine group, had a 24-hour Holter monitor due to anxiety with heart palpitations. No concurrent adverse event was reported and no results were provided. The patient was subsequently lost to follow-up. Patient 704.015.25464, in the placebo group, had portable ECG arrhythmia monitoring to rule out tachycardia; the patient had a history of tachycardia and irregular heartbeat. No concurrent adverse event was reported and no results were provided. Patient 704.028.27079, in the placebo group, had liquid nitrogen treatment for a plantar wart on the right palm. The latter two patients completed the study as planned (Listing 13.6.1, Appendix B, and Listing 15.1.1, Appendix D).

Two patients in the placebo group had minor procedures for adverse events: patient 704.004.25401 had removal of ear wax to treat ear pain, and patient 704.029.27071 had osteopathic back therapy to treat headaches. 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 adverse events.

6.7 Pregnancy

None of the patients enrolled in the study had a positive serum HCG pregnancy test at screening, and none of the randomized patients had a positive serum HCG pregnancy test or became pregnant during the course of the study (Listing 15.3.2, Appendix F; Listing PV13, 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 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 69 shows the pre-determined absolute values and changes from Baseline of potential clinical concern.

Table 69 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
Heart Rate	bpm (beats per minute)	Ages 7 to 12: <65 or >115 Ages 13 to 17: <55 or >110			Increase≥30 Decrease ≥30
Weight *	kgs	Age	Boys	Girls	
		7/8	<18.2 or >36.8	<17.3 or >36.8	Increase ≥7%
		9	<20.0 or >41.8	<19.5 or >42.7	Decrease ≥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	

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

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 10 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. All vital signs data by patient are provided in Listing 15.2.1, Appendix E.

Table 70 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 during the Treatment or

Taper Phase). All of these measurements were recorded during the Treatment Phase. 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.

Table 70 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	Paroxetine n (%)	Placebo N	Placebo n (%)
Total Patients with a Vital Sign of Clinical Concern	98	9 (9.2)	105	11 (10.5)
Systolic BP (mmHg)				
>145, and increase ≥40	96	0	105	1 (1.0)
<95, and decrease ≥30	96	0	105	3 (2.9)
Diastolic BP (mmHg)				
>85, and increase ≥30	96	2 (2.1)	105	1 (1.0)
<50, and decrease ≥20	96	4 (4.2)	105	1 (1.0)
Heart Rate (bpm [beats per minute])				
Ages 7 to 12 >115, ages 13 to 17 >110, and increase ≥30	96	3 (3.1)	105	0
Ages 7 to 12 <65, ages 13 to 17, <55, and decrease ≥30	96	0	105	2 (1.9)
Weight (kg)				
Above normal range,* and increase ≥7%	72	0	81	3 (3.7)
Below normal range,* and decrease ≥7%	72	0	81	0

N = Number of patients with Baseline and post-Baseline assessment.
* Normal ranges for weight may be found in Table 69.
Source: Table 15.2.2.1, Section 13; Listing 15.2.1, Appendix E

As shown in Table 70 and Table 71, 9 patients in the paroxetine group and 11 in the placebo group were identified as having a change and absolute value in one or more of the vital signs that met the concern criteria during the Treatment or Taper Phase. Three patients in the paroxetine treatment group had more than one value of concern. In addition, 1 patient in each treatment group had a vital sign change and absolute value meeting concern criteria during the Follow-up Phase (Table 15.2.2.2, Section 13). Patient 704.025.27040, a 7-year-old female, had a decrease from Baseline of 30 mmHg in diastolic BP to 49 mmHg, 5 days after stopping paroxetine. Patient 704.015.25464, a 7-year-old male, had an increase

from Baseline of 32 bpm in heart rate to 120 bpm, 1 day after stopping placebo (Listing 13.13.1, Appendix B, and Listing 15.2.1, Appendix E).

Table 71 Patients With Vital Signs Values Meeting Predefined Clinical Concern Criteria (Treatment or Taper Phase) (ITT Population)

Patient Number	Gender (M/F)	Age (yrs)	Vital Sign of Concern	Baseline Value	Value of Concern	Visit
Paroxetine						
704.004.25404	M	15	Diastolic BP low/decrease	78 mm Hg	45 mm Hg	Week 1
704.004.25405	F	7	Diastolic BP low/decrease	71 mm Hg	47 mm Hg	Week 2
					49 mm Hg	Week 3
					49 mm Hg	Week 4
					46 mm Hg	Week 8
704.012.25480	M	9	Diastolic BP high/increase	72 mm Hg	119 mm Hg	Week 2
704.015.25469	M	8	Heart Rate high/increase	72 bpm	120 bpm	Week 4
					120 bpm	Post Week 10
704.015.27043	F	16	Heart Rate high/increase	80 bpm	116 bpm	Week 3
704.015.27095	M	10	Heart Rate high/increase	80 bpm	120 bpm	Week 3
704.019.25384	M	10	Diastolic BP low/decrease	70 mm Hg	47 mm Hg	Week 6
704.055.28137	F	10	Diastolic BP low/decrease	85 mm Hg	46 mm Hg	Week 1
					43 mm Hg	Week 4
704.055.28174	M	14	Diastolic BP high/increase	57 mm Hg	100 mm Hg	Week 1
					92 mm Hg	Post Week 10

Source: Table 15.2.2.1, Section 13; Listing 15.2.1, Appendix E
(Continued)

Table 71 Patients With Vital Signs Values Meeting Predefined Clinical Concern Criteria (Treatment or Taper Phase) (ITT Population) (Continued)

Patient Number	Gender (M/F)	Age (yrs)	Vital Sign of Concern	Baseline Value	Value of Concern	Visit
Placebo						
704.002.25439	M	14	Systolic BP high/increase	126 mm Hg	166 mm Hg	Week 10
704.006.25421	M	15	Systolic BP low/decrease	124 mm Hg	90 mm Hg	Week 3
704.016.27017	M	12	Weight high/increase	54.2 kg	60.5 kg	Week 10
704.016.27021	M	8	Systolic BP low/decrease	122 mm Hg	90 mm Hg	Week 2
704.020.25461	F	11	Systolic BP low/decrease	110 mm Hg	77 mm Hg	Week 1
704.025.27059	M	14	Weight high/increase	69.5 kg	76.3 kg	Post Week 10
704.025.28115	M	8	Weight high/increase	37.2 kg	40.4 kg	Week 10
704.040.27112	F	8	Heart Rate low/decrease	84 bpm	52 bpm	Week 2
704.052.27200	M	7	Heart Rate low/decrease	101 bpm	62 bpm	Week 2
704.055.28172	M	9	Diastolic BP high/increase	56 mm Hg	88 mm Hg	Week 3
704.055.28189	F	11	Diastolic BP low/decrease	86 mm Hg	46 mm Hg	Week 1

Source: Table 15.2.2.1, Section 13; Listing 15.2.1, Appendix E

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 CRF. Patient 704.048.27173, a 13-year-old male, was reported as having intermittent hypertension, judged of moderate intensity and possibly related to study medication, on Day 21 of treatment with paroxetine. His diastolic BP was above the normal range (diastolic, 50 to 85 mm Hg; systolic, 95 to 145 mm Hg) at Week 8 (diastolic, 94 mm Hg; systolic 142 mm Hg) and post-Week 10 (diastolic, 90 mm Hg; systolic 130 mm Hg); BP was within the normal range at Baseline (diastolic, 80 mm Hg; systolic 120 mm Hg). Patient 704.049.28148, a 13-year-old female, was reported as having weight loss, judged of moderate intensity and possibly related to study medication on Day 21 of treatment with paroxetine. The patient's weight, measured at Screening (50.1 kg) and Week 10 (48.1 kg), was within the normal range (≥31.8 to ≤69.5 kg) (Listing 15.2.1, Appendix E).

Detailed patient narratives were to have been 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. No patients met this combination of criteria.

6.8.2 Changes in Vital Signs

Table 72 presents a summary of BP, heart rate and body weight values at Baseline and change from Baseline at Week 10. Data are included in the summary for those patients who had a value both at Baseline and at Week 10. Approximately 57% of the patients in the paroxetine group and approximately 63% of patients in the placebo group contributed to this analysis.

Baseline values were comparable in both treatment groups, and mean changes in all vital sign parameters were very small and comparable between groups.

Table 72 Mean Change from Baseline to Week 10 in Vital Signs, Weight, and BMI–Age Group: Total (ITT Population)

	Treatment Group			
	Paroxetine (N = 98)		Placebo (N = 105)	
Vital Sign	**n**	**Mean (SD)**	**n**	**Mean (SD)**
Systolic BP (mmHg)				
Baseline	98	106.5 (11.32)	105	108.1 (12.33)
Change at Week 10	56	1.0 (9.94)	66	1.4 (13.00)
BP Diastolic (mmHg)				
Baseline	98	66.2 (8.97)	105	66.5 (8.65)
Change at Week 10	56	2.0 (10.79)	66	1.2 (10.92)
Heart rate (bpm)				
Baseline	98	82.1 (11.86)	105	79.4 (11.29)
Change at Week 10	56	2.7 (9.59)	66	1.1 (10.84)
Weight (kg)				
Baseline	98	46.3 (20.52)	104	48.9 (19.51)
Change at Week 10	53	1.0 (1.95)	60	0.8 (2.71)
BMI (kg/m^2)				
Baseline	98	20.15 (5.294)	104	20.85 (5.321)
Change at Week 10	53	-0.01 (1.639)	59	0.10 (1.140)

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 and body weight may be found in Table 15.2.1.2, Section 13.

6.9 Laboratory Data

6.9.1 Laboratory Values of Potential Clinical Concern

Laboratory values meeting potential clinical concern criteria defined by the sponsor were identified and tabulated. Table 73 shows these values.

Table 73 Sponsor-Defined Laboratory Values of Potential Clinical Concern

Laboratory Parameter		Units	Value of Potential Clinical Concern
Hematology			
Hemoglobin	males	g/L	<115
	females	g/L	<95
Hematocrit	6 to 11 years	%	<35
	12 to 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	>0.40
Eosinophils		$x10^{9}$/L	>0.79
Neutrophils		$x10^{9}$/L	<1.58 or >8.64
Platelet Count		$x10^{9}$/L	<75 or >700
Liver Function			
SGOT (AST)		IU/L	>150
SGPT (ALT)		IU/L	>165
Total Bilirubin		mcmol/L	>34.2
Renal Function			
Creatinine		mcmol/L	>176.8
Blood Urea Nitrogen		mmol/L	>10.71
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

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 10 or Early Withdrawal visit one or more days after the last dose of study medication), were coded as occurring during the Taper Phase if the patient entered the Taper Phase, and in the Follow-up Phase if the patient did not enter the Taper Phase. The number and percentage of patients with laboratory values of potential clinical concern by post-randomization treatment phase may be found in Tables 15.3.1.2 (Treatment and

Taper), 15.3.1.3 (Follow-up), and 15.3.1.4 (Treatment, Taper, and Follow-up), Section 13. 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 concern are provided in Listing 15.3.3, Appendix F.

Table 74 presents a summary of the number and percentage of patients with post-randomization laboratory values meeting sponsor-defined criteria for potential clinical concern during the study. A maximum of 71 patients in the paroxetine group and 81 patients in the placebo group had at least one laboratory assessment for any parameter during the Treatment or Taper Phase. A total of 14 patients in the paroxetine group and 11 patients in the placebo group had a laboratory value during the Treatment Phase or Taper Phase that met the sponsor-defined value of potential clinical concern (Table 74). Low hematocrit values of potential concern were reported in more patients (11) in the paroxetine group than in the placebo group (7); of these, 5 paroxetine patients and 2 placebo patients had low hematocrit values of concern at Screening (Listing 15.3.2, Appendix F). Other values of potential concern occurred with comparable frequency in the two treatment groups.

During the Follow-up Phase, 1 patient in the placebo group had a low hematocrit of potential concern, and 1 patient in the paroxetine group had high neutrophils of potential concern (Table 15.3.1.3, Section 13). In addition, 1 patient (704.005.25407) who received paroxetine had a low hematocrit of potential concern 19 days after the last dose of study medication, (Listing 15.3.3).

Table 74 Number (%) of Patients with Laboratory Values Meeting Sponsor-Defined Criteria for Potential Clinical Concern During the Treatment or Taper Phase–Age Group: Total (ITT Population)

Laboratory Parameter		Treatment Group			
		Paroxetine		Placebo	
Patients with at least one value of clinical concern	**High/Low**	**N**	**n (%)**	**N**	**n (%)**
		98	14 (14.3)	105	11 (10.5)
Hemoglobin	Low	71	3 (4.2)	81	2 (2.5)
Hematocrit	Low	71	11 (15.5)	81	7 (8.6)
WBC	Low	71	1 (1.4)	81	0
Neutrophils, Absolute	Low	71	2 (2.8)	81	1 (1.2)
Eosinophils, Absolute	High	71	0	81	2 (2.5)
Lymphocytes, Absolute	High	71	1 (1.4)	81	1 (1.2)

N = Number of patients who had an assessment for this parameter at any time during the Treatment or Taper Phase.
Source: Table 15.3.1.2, Section 13; Listing 15.3.3, Appendix F

Laboratory values by patient and by parameter may be found in Listings 15.3.1 and 15.3.2, Appendix F, respectively. A per-patient listing of laboratory values meeting potential clinical concern criteria predefined by the sponsor may be found in Listing 15.3.3, Appendix F.

Table 74 does not necessarily include all 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 CRF. Two patients who received paroxetine and 1 patient who received placebo had AEs related to laboratory findings. Patient 704.048.27164 had mild anemia, considered unrelated to study medication by the investigator, reported on Day 5 of treatment with paroxetine; the patient's hematocrit was below the normal range at Screening (33.7%, normal range low = 35.0%) and within the normal range at Week 10 (35.1%). Patient 704.005.28196 had thyroid disorder (verbatim: high TSH) reported as an AE on Day 65 of treatment with paroxetine. The investigator considered the AE of moderate intensity and probably unrelated to study medication; the patient's TSH level at Screening (17 mU/L) was high and of potential clinical concern (>10 mU/L). Patient 704.016.27017 had mild leukopenia (verbatim: slight decrease in WBC), considered possibly related to study medication by the investigator, reported on Day 66 (Week 10) of placebo. The patient's white blood cell count decreased from normal at Screening (4.8 x

10^9/L) to below the normal range at Week 10 (4.0 x 10^9/L, normal range low = 4.5 x 10^9/L).

Detailed narratives were to have been prepared for patients with a post-randomization laboratory value meeting potential clinical concern criteria and with an AE that was related to that laboratory parameter; no patients had laboratory values and related AEs that met those criteria.

6.9.2 Changes in Laboratory Values

Table 75 presents descriptive statistics (means, standard deviations, and ranges) for Baseline, Week 10, endpoint (last on-therapy assessment including Taper Phase), and change at endpoint for each of the laboratory parameters monitored during the study. Summary statistics for thyroid tests are not presented because they were not required to be performed at endpoint (See Errata, Section 15.). The treatment groups were comparable at Baseline with respect to laboratory parameters, and there were no substantial differences between the paroxetine and the placebo groups at Week 10, at endpoint, or in the change from Baseline at endpoint.

Table 75 Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 98) n	Mean	(SD)	Range	Placebo (N = 105) n	Mean	(SD)	Range
Hemoglobin (g/L)								
Baseline	97	131.2	(9.96)	106.0 to 164.0	105	133.5	(10.48)	104.0 to 163.0
Week 10	64	129.7	(11.06)	104.0 to 165.0	71	131.7	(11.08)	103.0 to 165.0
Endpoint	71	129.8	(11.05)	104.0 to 165.0	81	131.3	(10.76)	103.0 to 165.0
Change at Endpoint	70	-2.1	(7.35)	-16.0 to 14.0	81	-1.7	(6.49)	-16.0 to 18.0
Hematocrit (%)								
Baseline	97	38.7	(2.89)	32.5 to 48.9	105	39.3	(2.89)	31.8 to 46.2
Week 10	64	38.3	(3.09)	31.8 to 48.5	71	38.9	(3.07)	33.0 to 48.8
Endpoint	71	38.4	(3.14)	31.8 to 48.5	81	38.8	(3.00)	33.0 to 48.8
Change at Endpoint	70	-0.4	(2.07)	-4.9 to 4.3	81	-0.4	(2.27)	-6.7 to 4.8
RBC Count (10^{12}/L)								
Baseline	97	4.5	(0.32)	3.9 to 5.6	105	4.6	(0.34)	3.8 to 5.3
Week 10	64	4.5	(0.36)	3.9 to 5.8	71	4.5	(0.37)	3.9 to 5.4
Endpoint	71	4.5	(0.37)	3.7 to 5.8	81	4.5	(0.37)	3.9 to 5.4
Change at Endpoint	70	-0.1	(0.24)	-0.5 to 0.5	81	-0.1	(0.25)	-0.7 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
(Continued)

Table75 Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population) (continued)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 98) n	Mean	(SD)	Range	Placebo (N = 105) n	Mean	(SD)	Range
WBC (10^9/L)								
Baseline	97	7.0	(2.11)	2.5 to 17.3	105	6.6	(1.74)	3.3 to 13.1
Week 10	64	6.5	(1.61)	2.7 to 10.1	71	6.7	(1.78)	4.0 to 13.6
Endpoint	71	6.6	(1.47)	3.9 to 10.1	81	6.7	(1.80)	4.0 to 13.6
Change at Endpoint	70	-0.3	(1.90)	-11.0 to 2.4	81	0.1	(1.96)	-5.8 to 6.3
Platelets (10^9/L)								
Baseline	97	280.3	(64.74)	142.0 to 433.0	105	295.1	(63.53)	177.0 to 463.0
Week 10	64	284.8	(60.45)	184.0 to 433.0	70	291.5	(73.19)	157.0 to 525.0
Endpoint	71	287.7	(60.79)	184.0 to 433.0	80	289.9	(71.34)	157.0 to 525.0
Change at Endpoint	70	3.2	(41.74)	-80.0 to 148.0	80	-3.4	(45.94)	-131.0 to 132.0
Basophils (10^9/L)								
Baseline	97	0.020	(0.0148)	0.00 to 0.08	105	0.020	(0.0150)	0.00 to 0.09
Week 10	64	0.017	(0.0099)	0.00 to 0.05	71	0.019	(0.0191)	0.00 to 0.14
Endpoint	71	0.018	(0.0129)	0.00 to 0.09	81	0.019	(0.0184)	0.00 to 0.14
Change at Endpoint	70	0.000	(0.0167)	-0.04 to 0.06	81	-0.001	(0.0195)	-0.07 to 0.07

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
(Continued)

Table 75 Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population) (continued)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 98) n	Mean	(SD)	Range	Placebo (N = 105) n	Mean	(SD)	Range
Eosinophils (10^9/L)								
Baseline	97	0.226	(0.1976)	0.03 to 1.44	105	0.238	(0.1820)	0.00 to 0.98
Week 10	64	0.224	(0.1570)	0.01 to 0.66	71	0.245	(0.1982)	0.00 to 1.17
Endpoint	71	0.224	(0.1497)	0.01 to 0.66	81	0.231	(0.1940)	0.00 to 1.17
Change at Endpoint	70	-0.005	(0.1900)	-0.97 to 0.31	81	-0.009	(0.1360)	-0.39 to 0.39
Lymphocytes (10^9/L)								
Baseline	97	2.52	(0.741)	1.39 to 5.02	105	2.38	(0.680)	1.04 to 4.60
Week 10	64	2.39	(0.763)	0.96 to 4.86	71	2.28	(0.668)	0.84 to 4.54
Endpoint	71	2.42	(0.741)	0.96 to 4.86	81	2.30	(0.724)	0.84 to 4.54
Change at Endpoint	70	-0.02	(0.665)	-2.57 to 1.81	81	0.00	(0.465)	-1.04 to 1.58
Monocytes (10^9/L)								
Baseline	97	0.41	(0.193)	0.03 to 1.00	105	0.36	(0.177)	0.01 to 1.40
Week 10	64	0.35	(0.164)	0.02 to 0.69	71	0.35	(0.150)	0.00 to 0.66
Endpoint	71	0.36	(0.165)	0.02 to 0.77	81	0.35	(0.153)	0.00 to 0.72
Change at Endpoint	70	-0.05	(0.207)	-0.61 to 0.36	81	-0.00	(0.220)	-1.05 to 0.53

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
(Continued)

Table 75 Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population) (continued)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 98) n	Mean	(SD)	Range	Placebo (N = 105) n	Mean	(SD)	Range
Neutrophils (10^9/L)								
Baseline	97	3.8	(1.66)	0.8 to 11.8	105	3.6	(1.43)	1.0 to 8.7
Week 10	64	3.6	(1.20)	0.9 to 6.7	71	3.8	(1.44)	1.2 to 8.3
Endpoint	71	3.6	(1.17)	1.5 to 6.7	81	3.8	(1.40)	1.2 to 8.3
Change at Endpoint	70	-0.3	(1.59)	-8.7 to 2.2	81	0.2	(1.75)	-4.5 to 4.8
Sodium (mmol/L)								
Baseline	98	141.5	(2.33)	137.0 to 149.0	105	141.9	(2.52)	137.0 to 149.0
Week 10	63	141.8	(1.70)	138.0 to 145.0	73	141.1	(2.17)	135.0 to 146.0
Endpoint	72	141.7	(1.78)	138.0 to 147.0	80	141.2	(2.22)	135.0 to 146.0
Change at Endpoint	72	0.2	(2.68)	-7.0 to 7.0	80	-1.0	(3.15)	-11.0 to 5.0
Potassium (mmol/L)								
Baseline	98	4.31	(0.357)	3.60 to 5.60	105	4.40	(0.357)	3.70 to 5.50
Week 10	63	4.35	(0.410)	3.50 to 5.50	73	4.37	(0.392)	3.70 to 5.80
Endpoint	72	4.38	(0.400)	3.50 to 5.50	80	4.38	(0.387)	3.70 to 5.80
Change at Endpoint	72	0.07	(0.418)	-0.90 to 1.20	80	-0.03	(0.453)	-1.00 to 1.80

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
(Continued)

Table 75 Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population) (continued)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 98) N	Mean	(SD)	Range	Placebo (N = 105) N	Mean	(SD)	Range
BUN (mmol/L)								
Baseline	98	4.8	(1.21)	2.5 to 7.9	105	4.5	(1.23)	1.4 to 8.9
Week 10	63	4.9	(1.21)	1.8 to 7.9	73	4.7	(1.38)	2.1 to 9.6
Endpoint	72	4.8	(1.15)	1.8 to 7.9	80	4.7	(1.36)	2.1 to 9.6
Change at Endpoint	72	0.1	(0.99)	-2.1 to 2.9	80	0.2	(1.28)	-3.2 to 2.9
Creatinine (umol/L)								
Baseline	98	49.3	(13.55)	26.5 to 88.4	105	50.1	(13.35)	26.5 to 79.6
Week 10	63	51.4	(12.08)	26.5 to 79.6	73	52.1	(13.22)	26.5 to 79.6
Endpoint	72	50.3	(11.46)	26.5 to 79.6	80	52.3	(12.83)	26.5 to 79.6
Change at Endpoint	72	0.7	(11.47)	-35.4 to 26.5	80	1.8	(10.28)	-35.4 to 26.5
Alkaline Phosphatase (IU/L)								
Baseline	98	225.7	(85.86)	48.0 to 448.0	105	235.5	(96.58)	55.0 to 548.0
Week 10	63	216.9	(87.45)	68.0 to 433.0	73	230.6	(85.91)	66.0 to 426.0
Endpoint	72	218.8	(84.72)	68.0 to 433.0	80	227.7	(88.38)	60.0 to 426.0
Change at Endpoint	72	-9.4	(35.34)	-124.0 to 104.0	80	-8.5	(43.87)	-142.0 to 102.0

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
(Continued)

Table 75 Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population) (continued)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 98) N	Mean	(SD)	Range	Placebo (N = 105) N	Mean	(SD)	Range
SGOT (AST) (IU/L)								
Baseline	98	24.3	(6.35)	13.0 to 42.0	105	24.6	(7.13)	9.0 to 43.0
Week 10	63	25.0	(5.33)	15.0 to 36.0	73	24.8	(7.10)	12.0 to 46.0
Endpoint	72	25.2	(5.17)	15.0 to 36.0	80	24.2	(7.25)	11.0 to 46.0
Change at Endpoint	72	1.7	(5.69)	-15.0 to 17.0	80	-0.1	(5.05)	-13.0 to 16.0
SGPT (ALT) (IU/L)								
Baseline	98	15.2	(6.47)	6.0 to 53.0	105	17.1	(8.71)	7.0 to 59.0
Week 10	63	17.7	(8.00)	10.0 to 54.0	73	16.4	(6.60)	7.0 to 37.0
Endpoint	72	17.6	(7.66)	10.0 to 54.0	80	15.9	(6.53)	7.0 to 37.0
Change at Endpoint	72	2.3	(8.89)	-36.0 to 44.0	80	-0.8	(5.62)	-20.0 to 16.0
Total Bilirubin (umol/L)								
Baseline	98	7.7	(5.23)	0.0 to 41.0	105	7.8	(4.50)	3.4 to 34.2
Week 10	63	6.7	(3.95)	0.0 to 29.1	73	7.8	(4.57)	3.4 to 32.5
Endpoint	72	6.8	(3.90)	0.0 to 29.1	80	7.8	(4.39)	3.4 to 32.5
Change at Endpoint	72	-1.2	(3.59)	-12.0 to 8.6	80	0.1	(3.32)	-15.4 to 12.0

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

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 per parameter (that is, whose laboratory value changed categories) from Baseline to endpoint and from Baseline to Follow-up. Transitions occurred infrequently and were generally comparable between the treatment groups. In the paroxetine group, more values transitioned from normal to abnormal than normalized during the study (i.e., transitioned from a low or high value at Baseline to an in-range value at endpoint or Follow-up). The most frequent transitions from normal to abnormal were decreases in hematocrit and monocyte values in patients who received paroxetine and decreases in RBC and monocyte values in patients who received placebo.

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. Urinalysis results for each patient are provided by patient and by parameter in Listings 15.3.1 and 15.3.2, Appendix F.

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 704.006.27177, a 9-year-old female, had mild albuminuria (verbatim: urine positive for trace protein), judged probably unrelated to treatment with study medication by the investigator, on Day 70 of treatment. At Screening and on Day 70, generic urine dipstick results were positive; however, protein dipstick results were negative. Other positive urinalysis results on Day 70 were calcium oxalate crystals, amorphous sediment, and squamous epithelial cells. Patient 704.008.25361, a 16-year-old female, had mild hematuria (verbatim: positive for blood on urine dipstick), considered unrelated to treatment with study medication by the investigator, on Day 69 of treatment. Positive urinalysis results on that day were blood dipstick, RBCs, generic dipstick, trace protein dipstick, calcium oxalate crystals, and mucous threads. In addition, Patient 704.005.25407 had mild albuminuria (verbatim: trace protein in urine) reported 19 days after the last dose of paroxetine.

Urine abnormalities associated with an AE were reported for 2 patients in the placebo group during the Treatment Phase and in 1 placebo patient during the Follow-up Phase (Listings 15.1.1 and 15.1.2, Appendix D). Patient 704.005.27055, a 14-year-old male, had mild hematuria (verbatim: high blood in urine), judged possibly related to treatment with study medication by the investigator, on Day 75 of the Treatment Phase. Generic dipstick results were positive; however, blood dipstick results were negative and RBCs were not present; amorphous sediment and mucous threads were present. Patient 704.025.27038, a 15-year-old female, had a mild urinary tract infection, considered unrelated to treatment with study medication by the investigator, on Day 1 of the Treatment Phase. At Screening, 7 days earlier, urinalysis findings were few white blood cells, few squamous epithelial cells, moderate bacteria, and positive generic dipstick. Five days after the last dose of study medication, Patient 704.006.25421, a 15-year-old male, had mild albuminuria and mild hematuria (verbatim: positive urine protein and blood), both considered probably unrelated to treatment with study medication by the investigator. At Screening, urinalysis results included positive blood dipstick, positive generic dipstick, few RBCs, few mucous threads, few squamous epithelial cells, and many amorphous sediment; protein dipstick results were negative. Five days after the last dose of study medication, urinalysis results included trace blood dipstick, positive generic dipstick, few RBCs, few calcium oxalate crystals, and many amorphous sediment; protein dipstick results were negative.

6.10 Electrocardiographic Data

A 12-lead ECG was carried out at Screening on all patients, and if clinically significant abnormalities were found, the ECG was repeated at Baseline. An additional ECG was performed at Week 10 or Early Withdrawal; a repeat ECG was performed at Taper End and 14-day Follow-up if clinically significant abnormalities were identified at the previous visit. Table 15.4.1, Section 13, presents summary data for all patients with ECG assessments during the study.

No patients in the study had abnormal ECG assessments at Screening or Baseline (Table 15.4.1, Section 13; Listing 15.4.1, Appendix E).

During the study, only 1 patient, 704.025.27038 in the placebo group, had an abnormal ECG assessment (as assessed by the investigator) at the end of study treatment. The patient's ECG was normal at the end of the Taper Phase, 16 days later (Listing 15.4.1, Appendix E).

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. Approximately 90 patients in this study provided blood samples for PK evaluation at Weeks 4 and/or 10.

Paroxetine plasma concentration data from this study will be combined with similar data from studies 209060/701 and 209060/676 [19], [20]. 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 [21].

8 Discussion

This 10-week, double-blind, placebo-controlled, randomized study evaluated the efficacy and tolerability of paroxetine in the treatment of 203 children and adolescents who met the DSM-IV criteria for OCD. The study objectives were prospectively defined and the trial used four different rating instruments to assess OCD treatment response: the Children's Yale-Brown Obsessive-Compulsive Scale (CY-BOCS), the Clinical Global Impression (CGI) Severity of Illness scale, the CGI Global Improvement scale, and the Global Assessment of Functioning (GAF) scale. The methodology used to statistically analyze the results employed standard practices. Although only 30% of patients withdrew from the study, conservative analytical techniques, such as last observation carried forward, were used to estimate missing data.

Efficacy

Analysis of the primary efficacy endpoint, change from Baseline in CY-BOCS total score, for the ITT population provided statistically significant evidence that paroxetine was more efficacious than placebo in the treatment of children and adolescents with OCD. The magnitude of the reduction of 8.78 points in the CY-BOCS total score at the Week 10 LOCF endpoint for patients who received paroxetine compared favorably with reductions reported in pediatric OCD trials with sertraline[18], fluvoxamine[22], and fluoxetine[23] that also utilized the CY-BOCS. In each of these studies, the active medication was also statistically superior to placebo in improving OCD symptoms. The adjusted mean difference between the paroxetine and placebo groups in change from Baseline in CY-BOCS total score at Week 10 LOCF for the ITT population was -3.45 points in favor of paroxetine (95% confidence interval [-5.60, -1.29], p = 0.002). Statistically significant differences in the CY-BOCS total score between paroxetine and placebo were also observed at the Week 10 OC and 70% LOCF endpoints. Furthermore, the per-protocol analysis supported these findings. There was no evidence of any statistically significant treatment by covariate interactions for the primary endpoint (ITT Week 10 LOCF), indicating that the treatment effect was consistent across age group, gender, comorbidity, and Baseline CY-BOCS total score.

Among the secondary efficacy parameters, the odds of being a CY-BOCS responder and the change from baseline in CY-BOCS obsession and compulsion subscale scores also showed a statistically significant treatment effect favoring paroxetine. The results of the other secondary efficacy parameters, while not

showing statistically significant superiority of paroxetine over placebo at the Week 10 LOCF endpoint, showed numerical superiority.

Of interest, children received a lower overall mean daily dose of paroxetine, 20.3 mg/day compared with 26.8 mg/day for adolescents, as well as a lower mean dose at the Week 10 LOCF endpoint, 25.4 mg/day compared with 36.5 mg/day for adolescents. Only half of the children who received paroxetine received more than 20 mg/day as compared with 85% of adolescents, and the mean duration of exposure for children (58.5 days) was also somewhat lower than that for adolescents (62.2 days). When compared with adolescents receiving paroxetine, the group of children had a higher percentage of responders based on the CY-BOCS total score (children 74%, adolescents 53%), a higher percentage of patients rated much or very much improved on the CGI Global Improvement Item score (children 52%, adolescents 40%), and a higher percentage of patients rated normal or borderline mentally ill on the CGI Severity of Illness Item score (children 36%, adolescents 15%) at the Week 10 LOCF endpoint. It should also be noted, however, that the same pattern was observed when comparing results for children and adolescents receiving placebo.

Safety

This study indicates that paroxetine is safe when used in children and adolescents over a period of up to 10 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 2 treatment groups reported at least 1 emergent AE during the Treatment Phase (85% in the paroxetine group vs. 73% in the placebo group). More paroxetine patients than placebo patients experienced AEs judged to be severe (9 patients vs. 5 patients, respectively) and/or AEs that led to withdrawal from the study (10 patients vs. 3 patients, respectively). However, there were few patients with SAEs in either group (3 patients vs. 1 patient, respectively), and none of the SAEs was considered related to treatment by the investigator. 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 (hyperkinesia, hostility, agitation, and neurosis) and digestive (decreased appetite, diarrhea, and vomiting) body systems.

Taper and Follow-up Phase emergent AEs were unremarkable. The percentages of patients in each treatment group having Taper or Follow-up Phase emergent AEs were similar, 19% (15/80) in the paroxetine group and 17% (15/89) in the

placebo group. One serious AE occurred during the Follow-up Phase: A patient in the paroxetine group experienced hostility (verbatim: irritable/hostile aggressive behavior worsened) 1 day after stopping taper medication. The only AE during the Taper Phase that occurred in more than 1 patient in the paroxetine group was headache, which occurred in 2 paroxetine patients and 4 placebo patients. During the Follow-up Phase, the only AEs that occurred in more than 1 patient receiving paroxetine were vomiting (3 patients), headache (2 patients), and nausea (2 patients); no patients in the placebo group reported these AEs.

The safety profile of paroxetine observed in pediatric patients with OCD in this 10-week trial appears to differ somewhat from that observed in adult patients with OCD who participated in 12-week paroxetine trials[24]. As expected, there were few gender-specific adverse events reported in adolescents and none in children. However, seven of the nine AEs 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 did not meet these criteria in adult OCD studies of paroxetine (hyperkinesia, trauma, asthenia, hostility, vomiting, neurosis, and agitation). However, these findings are not inconsistent with the reported occurrence of AEs with the use of other SSRIs for the treatment of pediatric patients with OCD. [18][22][23]

Data from this study suggest that some younger children (i.e., less than age 12) may not tolerate paroxetine treatment as well as adolescents and that the safety profile of paroxetine may differ somewhat in children and adolescents. The incidence of AEs leading to withdrawal was 14% (8/58) in children who received paroxetine, compared with 5% (2/40) in adolescents who received paroxetine. In the placebo group, 1 of 57 children (2%) and 2 of 48 adolescents (4%) were withdrawn due to AEs. The overall incidence of AEs in patients who received paroxetine was the same in both age subgroups. However, review of specific AEs by age group in paroxetine patients showed that the incidence of abdominal pain, hyperkinesia, insomnia, and hostility in children was at least twice that in adolescents while nausea, somnolence, asthenia, and dizziness occurred at least twice as frequently in adolescents than in children. In the placebo group, both nausea and abdominal pain were more likely to occur in children, while the incidences of the other AEs were comparable in the age subgroups.

Three patients in the paroxetine group and 1 in the placebo group had a total of 5 AEs that were classified as serious. All of the SAEs were psychiatric in nature, and all were considered unrelated or probably unrelated to treatment with study medication by the investigators. Emotional lability led to the withdrawal of 1 adolescent paroxetine patient from the study. One adolescent receiving

paroxetine was hospitalized twice due to hostility, and hostility resulting in hospitalization was also reported in 1 child receiving paroxetine and in 1 child receiving placebo.

Clinical laboratory abnormalities meeting predefined potential concern criteria were few in number and similar in both treatment groups. Similarly, there were few vital sign measurements that met potential clinical concern criteria. No laboratory or vital sign measurements meeting the potential concern criteria were reported as AEs by investigators. The only abnormal ECG assessment reported during the study was in a patient who received placebo.

9 Conclusions

Assessment of the primary efficacy variable, change from Baseline in the CY-BOCS Total score at the Week 10 LOCF endpoint, provided statistically significant evidence that paroxetine was more efficacious than placebo in treating children and adolescents with OCD. This conclusion was supported by statistically significant results from analysis of 3 of the 6 secondary efficacy variables and numerical results indicating a benefit of paroxetine over placebo for the other secondary variables.

Data from this study demonstrated that paroxetine was safe and generally well tolerated when used in children and adolescents with OCD over a period of up to 10 weeks. There was some indication that the AE profile in children may differ slightly from that in adolescents.

10 References

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11 Source Tables: Study Population

Table 13.0 Investigators, the SB Assigned Center Number and the Investigator Hospital or University Affiliation and Location

Investigator	Center	Affiliated Institution	City	State
United States				
	002		Minneapolis	MN
	004		Dallas	TX
	005		Belmont	MA
	006		Charlotte	NC
	008		Salem	OR
	009		n Piscataway	NJ
	010		Lake Jackson	TX
	011		Portland	OR
	012		Madison	WI
	013		Baltimore	MD
	014		Boise	ID
	015		Lexington	KY
	016		Phoenix	AZ
	017		Cincinnati	OH
	019		ı Galveston	TX
	020		Gainesville	FL
	021		Memphis	TN
	022		Cleveland	OH
	023		Milwaukee	WI
	025		Terre Haute	IN
	026		Medina	OH
	027		Washington	DC
	028		Richmond	VA

Table 13.0 Investigators, the SB Assigned Center Number and the Investigator Hospital or University Affiliation and Location

Investigator	Center	Affiliated Institution	City	State
	029		Seattle	WA
	040		Baltimore	MD
	041		Bethesda	MD
	043		Clearwater	FL
	044		Maitland	FL
	047		Elkins Park	PA
	048		Prairie Village	KS
	049		Hershey	PA
	051		Fort Walton Beach	FL
	052		Mobile	AL
	053		Sioux Falls	SD
	055		New Orleans	LA
	056		San Antonio	TX
	058		Vernon Hills	IL
	031		Halifax	Nova Scotia
	033	Grey Nuns Hospital	Edmonton	Alberta

* Patients were screened but not randomized.

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Table 13.1.1

Number (%) of Patients by Population
All Patients

Age Group : Children

Study Stage/Population	Treatment Group: Paroxetine (N=60)		Placebo (N=58)		Total (N=151)	
Screened Only	0		0		33	
Randomised	60	(100.0%)	58	(100.0%)	118	(100.0%)
Completed	36	(60.0%)	48	(82.8%)	84	(71.2%)
Early Withdrawal	24	(40.0%)	10	(17.2%)	34	(28.8%)
Intention-to-Treat Population	58	(96.7%)	57	(98.3%)	115	(97.5%)
Per-Protocol Population	40	(66.7%)	45	(77.6%)	85	(72.0%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Completed = Subjects who completed a week 10 visit CRF, note 3 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10

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Table 13.1.1

Number (%) of Patients by Population
All Patients

Age Group : Adolescents

Study Stage/Population	Paroxetine (N=40)		Placebo (N=49)		Total (N=114)	
	Treatment Group					
Screened Only	0		0		25	
Randomised	40	(100.0%)	49	(100.0%)	89	(100.0%)
Completed	29	(72.5%)	32	(65.3%)	61	(68.5%)
Early Withdrawal	11	(27.5%)	17	(34.7%)	28	(31.5%)
Intention-to-Treat Population	40	(100.0%)	48	(98.0%)	88	(98.9%)
Per-Protocol Population	33	(82.5%)	37	(75.5%)	70	(78.7%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Completed = Subjects who completed a week 10 visit CRF, note 3 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10

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Table 13.1.1

Number (%) of Patients by Population
All Patients

Age Group : Total

Study Stage/Population	Paroxetine (N=100)		Placebo (N=107)		Total (N=265)	
	Treatment Group					
Screened Only	0		0		58	
Randomised	100	(100.0%)	107	(100.0%)	207	(100.0%)
Completed	65	(65.0%)	80	(74.8%)	145	(70.0%)
Early Withdrawal	35	(35.0%)	27	(25.2%)	62	(30.0%)
Intention-to-Treat Population	98	(98.0%)	105	(98.1%)	203	(98.1%)
Per-Protocol Population	73	(73.0%)	82	(76.6%)	155	(74.9%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Completed = Subjects who completed a week 10 visit CRF, note 3 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : Canada (2 Centres)
Age Group : Children

Study Stage/Population	Treatment Group: Paroxetine (N=1)	Placebo (N=3)	Total (N=5)
Screened Only	0	0	1
Randomised	1 (100.0%)	3 (100.0%)	4 (100.0%)
Completed	1 (100.0%)	3 (100.0%)	4 (100.0%)
Early Withdrawal	0	0	0
Intention-to-Treat Population	1 (100.0%)	3 (100.0%)	4 (100.0%)
Per-Protocol Population	1 (100.0%)	3 (100.0%)	4 (100.0%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Completed = Subjects who completed a week 10 visit CRF, note 3 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : Canada (2 Centres)
Age Group : Adolescents

Study Stage / Population	Treatment Group: Paroxetine (N=1)	Placebo (N=3)	Total (N=4)
Screened Only	0	0	0
Randomised	1 (100.0%)	3 (100.0%)	4 (100.0%)
Completed	0	3 (100.0%)	3 (75.0%)
Early Withdrawal	1 (100.0%)	0	1 (25.0%)
Intention-to-Treat Population	1 (100.0%)	3 (100.0%)	4 (100.0%)
Per-Protocol Population	0	2 (66.7%)	2 (50.0%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Completed = Subjects who completed a week 10 visit CRF, note 3 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : Canada (2 Centres)
Age Group : Total

Study Stage / Population	Paroxetine (N=2)		Placebo (N=6)		Total (N=9)	
	Treatment Group					
Screened Only	0		0		1	
Randomised	2	(100.0%)	6	(100.0%)	8	(100.0%)
Completed	1	(50.0%)	6	(100.0%)	7	(87.5%)
Early Withdrawal	1	(50.0%)	0		1	(12.5%)
Intention-to-Treat Population	2	(100.0%)	6	(100.0%)	8	(100.0%)
Per-Protocol Population	1	(50.0%)	5	(83.3%)	6	(75.0%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Completed = Subjects who completed a week 10 visit CRF, note 3 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : United States of America (37 Centres)
Age Group : Children

Study Stage/Population	Treatment Group: Paroxetine (N=59)		Placebo (N=55)		Total (N=146)	
Screened Only	0		0		32	
Randomised	59	(100.0%)	55	(100.0%)	114	(100.0%)
Completed	35	(59.3%)	45	(81.8%)	80	(70.2%)
Early Withdrawal	24	(40.7%)	10	(18.2%)	34	(29.8%)
Intention-to-Treat Population	57	(96.6%)	54	(98.2%)	111	(97.4%)
Per-Protocol Population	39	(66.1%)	42	(76.4%)	81	(71.1%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Completed = Subjects who completed a week 10 visit CRF, note 3 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : United States of America (37 Centres)
Age Group : Adolescents

Study Stage / Population	Treatment Group: Paroxetine (N=39)		Placebo (N=46)		Total (N=110)	
Screened Only	0		0		25	
Randomised	39	(100.0%)	46	(100.0%)	85	(100.0%)
Completed	29	(74.4%)	29	(63.0%)	58	(68.2%)
Early Withdrawal	10	(25.6%)	17	(37.0%)	27	(31.8%)
Intention-to-Treat Population	39	(100.0%)	45	(97.8%)	84	(98.8%)
Per-Protocol Population	33	(84.6%)	35	(76.1%)	68	(80.0%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Completed = Subjects who completed a week 10 visit CRF, note 3 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : United States of America (37 Centres)
Age Group : Total

Study Stage / Population	Treatment Group: Paroxetine (N=98)		Placebo (N=101)		Total (N=256)	
Screened Only	0		0		57	
Randomised	98	(100.0%)	101	(100.0%)	199	(100.0%)
Completed	64	(65.3%)	74	(73.3%)	138	(69.3%)
Early Withdrawal	34	(34.7%)	27	(26.7%)	61	(30.7%)
Intention-to-Treat Population	96	(98.0%)	99	(98.0%)	195	(98.0%)
Per-Protocol Population	72	(73.5%)	77	(76.2%)	149	(74.9%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)
Completed = Subjects who completed a week 10 visit CRF, note 3 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10

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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=58)	Placebo (N=57)	Total (N=115)
Total number of patients excluded*	18(31.0%)	12(21.1%)	30(26.1%)
Patient is taking or has taken psychoactive medications	5(8.6%)	6(10.5%)	11(9.6%)
Illicit drug use -Urine Drug Screening	0	1(1.8%)	1(0.9%)
Patient Requiring > 1 Dosage Reduction	2(3.4%)	0	2(1.7%)
Patient Missed more than 3 Consecutive days Medication	8(13.8%)	5(8.8%)	13(11.3%)
Patient had exposure to less than 2 weeks Duration of Randomised Study Medication	4(6.9%)	2(3.5%)	6(5.2%)
Total number of patients with no protocol violations	40(69.0%)	45(78.9%)	85(73.9%)

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

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=40)	Placebo (N=48)	Total (N=88)
Total number of patients excluded*	7(17.5%)	11(22.9%)	18(20.5%)
Patient is taking or has taken psychoactive medications	1(2.5%)	5(10.4%)	6(6.8%)
Illicit drug use -Urine Drug Screening	0	1(2.1%)	1(1.1%)
Patient Missed more than 3 Consecutive days Medication	7(17.5%)	5(10.4%)	12(13.6%)
Patient had exposure to less than 2 weeks Duration of Randomised Study Medication	0	2(4.2%)	2(2.3%)
Total number of patients with no protocol violations	33(82.5%)	37(77.1%)	70(79.5%)

* 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=98)	Placebo (N=105)	Total (N=203)
Total number of patients excluded*	25(25.5%)	23(21.9%)	48(23.6%)
Patient is taking or has taken psychoactive medications	6(6.1%)	11(10.5%)	17(8.4%)
Illicit drug use -Urine Drug Screening	0	2(1.9%)	2(1.0%)
Patient Requiring > 1 Dosage Reduction	2(2.0%)	0	2(1.0%)
Patient Missed more than 3 Consecutive days Medication	15(15.3%)	10(9.5%)	25(12.3%)
Patient had exposure to less than 2 weeks Duration of Randomised Study Medication	4(4.1%)	4(3.8%)	8(3.9%)
Total number of patients with no protocol violations	73(74.5%)	82(78.1%)	155(76.4%)

* 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=58)	Placebo (N=57)	Total (N=115)
Total number of patients included with a deviation**	0	0	0
Total number of patients with no protocol deviations	58(100.0%)	57(100.0%)	115(100.0%)

** 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=40)	Placebo (N=48)	Total (N=88)
Total number of patients included with a deviation**	0	1(2.1%)	1(1.1%)
Is the patient medically healthy as determined by specified criteria?	0	1(2.1%)	1(1.1%)
Total number of patients with no protocol deviations	40(100.0%)	47(97.9%)	87(98.9%)

** 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=98)	Placebo (N=105)	Total (N=203)
Total number of patients included with a deviation**	0	1(1.0%)	1(0.5%)
Is the patient medically healthy as determined by specified criteria?	0	1(1.0%)	1(0.5%)
Total number of patients with no protocol deviations	98(100.0%)	104(99.0%)	202(99.5%)

** 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=58)	
Baseline Adverse Experience	1	(1.7%)
Does not meet inclusion/exclusion criteria	36	(62.1%)
Protocol deviation	0	
Lost to Follow-up	5	(8.6%)
Other+	16	(27.6%)
Total withdrawn	58	(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	Paroxetine (N=58)		Placebo (N=57)		Total (N=115)	
	Treatment Group					
Completed Study*	36	(62.1%)	48	(84.2%)	84	(73.0%)
Adverse Experience	8	(13.8%)	1	(1.8%)	9	(7.8%)
Lack of Efficacy	3	(5.2%)	4	(7.0%)	7	(6.1%)
Protocol deviation (including non-compliance)	1	(1.7%)	1	(1.8%)	2	(1.7%)
Lost to Follow-up	5	(8.6%)	2	(3.5%)	7	(6.1%)
Other+	5	(8.6%)	1	(1.8%)	6	(5.2%)
Total withdrawn	22	(37.9%)	9	(15.8%)	31	(27.0%)

* Completed = Subjects who completed a week 10 visit CRF, note 3 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10
+ 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	Paroxetine (N=40)		Placebo (N=48)		Total (N=88)	
	Treatment Group					
Completed Study*	29	(72.5%)	32	(66.7%)	61	(69.3%)
Adverse Experience	2	(5.0%)	2	(4.2%)	4	(4.5%)
Lack of Efficacy	2	(5.0%)	10	(20.8%)	12	(13.6%)
Protocol deviation (including non-compliance)	4	(10.0%)	2	(4.2%)	6	(6.8%)
Lost to Follow-up	1	(2.5%)	1	(2.1%)	2	(2.3%)
Other+	2	(5.0%)	1	(2.1%)	3	(3.4%)
Total withdrawn	11	(27.5%)	16	(33.3%)	27	(30.7%)

* Completed = Subjects who completed a week 10 visit CRF, note 3 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10
+ 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	Paroxetine (N=98)		Placebo (N=105)		Total (N=203)	
	Treatment Group					
Completed Study*	65	(66.3%)	80	(76.2%)	145	(71.4%)
Adverse Experience	10	(10.2%)	3	(2.9%)	13	(6.4%)
Lack of Efficacy	5	(5.1%)	14	(13.3%)	19	(9.4%)
Protocol deviation (including non-compliance)	5	(5.1%)	3	(2.9%)	8	(3.9%)
Lost to Follow-up	6	(6.1%)	3	(2.9%)	9	(4.4%)
Other+	7	(7.1%)	2	(1.9%)	9	(4.4%)
Total withdrawn	33	(33.7%)	25	(23.8%)	58	(28.6%)

* Completed = Subjects who completed a week 10 visit CRF, note 3 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10

+ 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	Paroxetine (N=40)		Placebo (N=45)		Total (N=85)	
Completed Study*	32	(80.0%)	41	(91.1%)	73	(85.9%)
Adverse Experience	4	(10.0%)	0		4	(4.7%)
Lack of Efficacy	1	(2.5%)	4	(8.9%)	5	(5.9%)
Protocol deviation (including non-compliance)	1	(2.5%)	0		1	(1.2%)
Lost to Follow-up	1	(2.5%)	0		1	(1.2%)
Other+	1	(2.5%)	0		1	(1.2%)
Total withdrawn	8	(20.0%)	4	(8.9%)	12	(14.1%)

* Completed = Subjects who completed a week 10 visit CRF, note 2 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10

+ 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=33)		Placebo (N=37)		Total (N=70)	
Completed Study*	27	(81.8%)	28	(75.7%)	55	(78.6%)
Adverse Experience	1	(3.0%)	0		1	(1.4%)
Lack of Efficacy	1	(3.0%)	8	(21.6%)	9	(12.9%)
Protocol deviation (including non-compliance)	2	(6.1%)	0		2	(2.9%)
Lost to Follow-up	1	(3.0%)	1	(2.7%)	2	(2.9%)
Other+	1	(3.0%)	0		1	(1.4%)
Total withdrawn	6	(18.2%)	9	(24.3%)	15	(21.4%)

* Completed = Subjects who completed a week 10 visit CRF, note 2 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10
+ 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=73)		Placebo (N=82)		Total (N=155)	
Completed Study*	59	(80.8%)	69	(84.1%)	128	(82.6%)
Adverse Experience	5	(6.8%)	0		5	(3.2%)
Lack of Efficacy	2	(2.7%)	12	(14.6%)	14	(9.0%)
Protocol deviation (including non-compliance)	3	(4.1%)	0		3	(1.9%)
Lost to Follow-up	2	(2.7%)	1	(1.2%)	3	(1.9%)
Other+	2	(2.7%)	0		2	(1.3%)
Total withdrawn	14	(19.2%)	13	(15.9%)	27	(17.4%)

* Completed = Subjects who completed a week 10 visit CRF, note 2 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10
+ 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=98)		Placebo (N=105)		Total (N=203)	
Baseline	Entered	98	(100.0%)	105	(100.0%)	203	(100.0%)
Week 1	Still in Study	95	(96.9%)	101	(96.2%)	196	(96.6%)
	Withdrawn	3	(3.1%)	4	(3.8%)	7	(3.4%)
Week 2	Still in Study	92	(93.9%)	98	(93.3%)	190	(93.6%)
	Withdrawn	3	(3.2%)	3	(3.0%)	6	(3.1%)
Week 3	Still in Study	88	(89.8%)	96	(91.4%)	184	(90.6%)
	Withdrawn	4	(4.3%)	2	(2.0%)	6	(3.2%)
Week 4	Still in Study	83	(84.7%)	92	(87.6%)	175	(86.2%)
	Withdrawn	5	(5.7%)	4	(4.2%)	9	(4.9%)
Week 6	Still in Study	72	(73.5%)	86	(81.9%)	158	(77.8%)
	Withdrawn	11	(13.3%)	6	(6.5%)	17	(9.7%)
Week 8	Still in Study	67	(68.4%)	80	(76.2%)	147	(72.4%)
	Withdrawn	3	(4.2%)	5	(5.8%)	8	(5.1%)
	Completed	2	(2.0%)	1	(1.0%)	3	(1.5%)
Week 10	Still in Study	0		1	(1.0%)	1	(0.5%)
	Withdrawn	4	(6.0%)	1	(1.3%)	5	(3.4%)
	Completed	63	(64.3%)	78	(74.3%)	141	(69.5%)
Post Week 10	Completed	0		1	(1.0%)	1	(0.5%)

Completed = Subjects who completed a week 10 visit CRF, note 3 subjects took their last dose of non-taper study medication before relative day 64 and hence had their visit re-categorised as Week 8 and 1 subject took their last dose of non-taper study medication after relative day 91 and hence had their visit re-categorised as post week 10
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, whilst 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 = 58)								Placebo (N = 57)								Total (N = 115)							
	AE		LE		Other		Total		AE		LE		Other		Total		AE		LE		Other		Total	
Visit	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Baseline	0	0.0	0	0.0	0	0.0	0	0.0	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 1	1	1.7	0	0.0	2	3.4	3	5.2	1	1.8	0	0.0	1	1.8	2	3.5	2	1.7	0	0.0	3	2.6	5	4.3
Week 2	1	1.7	1	1.7	3	5.2	5	8.6	1	1.8	0	0.0	2	3.5	3	5.3	2	1.7	1	0.9	5	4.3	8	7.0
Week 3	3	5.2	1	1.7	3	5.2	7	12.1	1	1.8	0	0.0	2	3.5	3	5.3	4	3.5	1	0.9	5	4.3	10	8.7
Week 4	5	8.6	1	1.7	4	6.9	10	17.2	1	1.8	0	0.0	4	7.0	5	8.8	6	5.2	1	0.9	8	7.0	15	13.0
Week 6	7	12.1	2	3.4	8	13.8	17	29.3	1	1.8	2	3.5	4	7.0	7	12.3	8	7.0	4	3.5	12	10.4	24	20.9
Week 8	7	12.1	3	5.2	9	15.5	19	32.8	1	1.8	4	7.0	4	7.0	9	15.8	8	7.0	7	6.1	13	11.3	28	24.3
Week 10	8	13.8	3	5.2	11	19.0	22	37.9	1	1.8	4	7.0	4	7.0	9	15.8	9	7.8	7	6.1	15	13.0	31	27.0

AE = adverse experience LE = lack of efficacy
Other = Protocol Deviation (including non-compliance), Lost to follow-up, Unknown and non-study related personal reasons

Table 13.3.3

Cumulative Number (%) of All Randomised Patients Withdrawn During the Study by Reason for Withdrawal

Intention-To-Treat Population
Age Group : Adolescents

	Treatment Group																							
	Paroxetine (N = 40)								Placebo (N = 48)								Total (N = 88)							
	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																								
Baseline	0	0.0	0	0.0	0	0.0	0	0.0	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 1	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	1	2.1	2	4.2	1	1.1	0	0.0	1	1.1	2	2.3
Week 2	1	2.5	0	0.0	0	0.0	1	2.5	1	2.1	2	4.2	1	2.1	4	8.3	2	2.3	2	2.3	1	1.1	5	5.7
Week 3	1	2.5	0	0.0	2	5.0	3	7.5	1	2.1	4	8.3	1	2.1	6	12.5	2	2.3	4	4.5	3	3.4	9	10.2
Week 4	2	5.0	0	0.0	3	7.5	5	12.5	1	2.1	5	10.4	2	4.2	8	16.7	3	3.4	5	5.7	5	5.7	13	14.8
Week 6	2	5.0	1	2.5	6	15.0	9	22.5	2	4.2	7	14.6	3	6.3	12	25.0	4	4.5	8	9.1	9	10.2	21	23.9
Week 8	2	5.0	1	2.5	7	17.5	10	25.0	2	4.2	9	18.8	4	8.3	15	31.3	4	4.5	10	11.4	11	12.5	25	28.4
Week 10	2	5.0	2	5.0	7	17.5	11	27.5	2	4.2	10	20.8	4	8.3	16	33.3	4	4.5	12	13.6	11	12.5	27	30.7

AE = adverse experience LE = lack of efficacy
Other = Protocol Deviation (including non-compliance), Lost to follow-up, Unknown and non-study related personal reasons

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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 = 98)								Placebo (N = 105)								Total (N = 203)							
	AE		LE		Other		Total		AE		LE		Other		Total		AE		LE		Other		Total	
Visit	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Baseline	0	0.0	0	0.0	0	0.0	0	0.0	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 1	1	1.0	0	0.0	2	2.0	3	3.1	2	1.9	0	0.0	2	1.9	4	3.8	3	1.5	0	0.0	4	2.0	7	3.4
Week 2	2	2.0	1	1.0	3	3.1	6	6.1	2	1.9	2	1.9	3	2.9	7	6.7	4	2.0	3	1.5	6	3.0	13	6.4
Week 3	4	4.1	1	1.0	5	5.1	10	10.2	2	1.9	4	3.8	3	2.9	9	8.6	6	3.0	5	2.5	8	3.9	19	9.4
Week 4	7	7.1	1	1.0	7	7.1	15	15.3	2	1.9	5	4.8	6	5.7	13	12.4	9	4.4	6	3.0	13	6.4	28	13.8
Week 6	9	9.2	3	3.1	14	14.3	26	26.5	3	2.9	9	8.6	7	6.7	19	18.1	12	5.9	12	5.9	21	10.3	45	22.2
Week 8	9	9.2	4	4.1	16	16.3	29	29.6	3	2.9	13	12.4	8	7.6	24	22.9	12	5.9	17	8.4	24	11.8	53	26.1
Week 10	10	10.2	5	5.1	18	18.4	33	33.7	3	2.9	14	13.3	8	7.6	25	23.8	13	6.4	19	9.4	26	12.8	58	28.6

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

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=58)	Placebo (N=57)	Total (N=115)
002	xxxxxxxxxxxxxxxxx	Randomised	2 (3.4%)	1 (1.8%)	3 (2.6%)
		Completed	0	1 (1.8%)	1 (0.9%)
004	xxxxxxxxxxxxxx	Randomised	3 (5.2%)	3 (5.3%)	6 (5.2%)
		Completed	3 (5.2%)	2 (3.5%)	5 (4.3%)
005	xxxxxxxxxxxxxxxx	Randomised	3 (5.2%)	2 (3.5%)	5 (4.3%)
		Completed	3 (5.2%)	2 (3.5%)	5 (4.3%)
006	xxxxxxxxxxxx	Randomised	2 (3.4%)	1 (1.8%)	3 (2.6%)
		Completed	2 (3.4%)	1 (1.8%)	3 (2.6%)
008	xxxxxxxxxxxx	Randomised	2 (3.4%)	2 (3.5%)	4 (3.5%)
		Completed	2 (3.4%)	1 (1.8%)	3 (2.6%)
009	xxxxxxxxxxxxxx	Randomised	1 (1.7%)	1 (1.8%)	2 (1.7%)
		Completed	0	1 (1.8%)	1 (0.9%)
010	xxxxxxxxxxxx	Randomised	2 (3.4%)	0	2 (1.7%)
012	xxxxxxxxxxxxxx	Randomised	1 (1.7%)	0	1 (0.9%)
		Completed	1 (1.7%)	0	1 (0.9%)
013	xxxxxxxxxxxxxxxxxxxxx	Randomised	0	1 (1.8%)	1 (0.9%)
014	xxxxxxxxxxxxxxx	Randomised	1 (1.7%)	2 (3.5%)	3 (2.6%)
		Completed	0	2 (3.5%)	2 (1.7%)
015	xxxxxxxxxxxxxxxxx	Randomised	4 (6.9%)	3 (5.3%)	7 (6.1%)
		Completed	2 (3.4%)	2 (3.5%)	4 (3.5%)
016	xxxxxxxxxxxxxxx	Randomised	6 (10.3%)	7 (12.3%)	13 (11.3%)
		Completed	3 (5.2%)	7 (12.3%)	10 (8.7%)
019	xxxxxxxxxxxxxxx	Randomised	4 (6.9%)	3 (5.3%)	7 (6.1%)
		Completed	2 (3.4%)	3 (5.3%)	5 (4.3%)
020	xxxxxxxxxxxx	Randomised	4 (6.9%)	4 (7.0%)	8 (7.0%)
		Completed	2 (3.4%)	4 (7.0%)	6 (5.2%)
022	xxxxxxxxxxxxx	Randomised	0	1 (1.8%)	1 (0.9%)
		Completed	0	1 (1.8%)	1 (0.9%)
025	xxxxxxxxxxxxxxx	Randomised	6 (10.3%)	6 (10.5%)	12 (10.4%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population

Age Group : Children

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=58)	Placebo (N=57)	Total (N=115)
025	xxxxxxxxxxxxxxxx	Completed	3 (5.2%)	4 (7.0%)	7 (6.1%)
026	xxxxxxxxxxxxxx	Randomised	1 (1.7%)	2 (3.5%)	3 (2.6%)
		Completed	1 (1.7%)	1 (1.8%)	2 (1.7%)
027	xxxxxxxxxxxxxx	Randomised	2 (3.4%)	2 (3.5%)	4 (3.5%)
		Completed	2 (3.4%)	2 (3.5%)	4 (3.5%)
028	xxxxxxxxxxxxx	Randomised	1 (1.7%)	1 (1.8%)	2 (1.7%)
		Completed	1 (1.7%)	1 (1.8%)	2 (1.7%)
029	xxxxxxxxxxxxxxxxxxxx	Randomised	1 (1.7%)	1 (1.8%)	2 (1.7%)
		Completed	1 (1.7%)	1 (1.8%)	2 (1.7%)
031	xxxxxxxxxxxxx	Randomised	1 (1.7%)	2 (3.5%)	3 (2.6%)
		Completed	1 (1.7%)	2 (3.5%)	3 (2.6%)
033	xxxxxxxxxxxxxx	Randomised	0	1 (1.8%)	1 (0.9%)
		Completed	0	1 (1.8%)	1 (0.9%)
040	xxxxxxxxxxxxxx	Randomised	1 (1.7%)	2 (3.5%)	3 (2.6%)
		Completed	1 (1.7%)	2 (3.5%)	3 (2.6%)
043	xxxxxxxxxxxxxxxxxxx	Randomised	1 (1.7%)	0	1 (0.9%)
		Completed	1 (1.7%)	0	1 (0.9%)
044	xxxxxxxxxxxx	Randomised	0	1 (1.8%)	1 (0.9%)
		Completed	0	1 (1.8%)	1 (0.9%)
048	xxxxxxxxxxxxxxxxx	Randomised	3 (5.2%)	2 (3.5%)	5 (4.3%)
		Completed	3 (5.2%)	2 (3.5%)	5 (4.3%)
051	xxxxxxxxxxxxxxx	Randomised	1 (1.7%)	0	1 (0.9%)
052	xxxxxxxxxxxxxx	Randomised	1 (1.7%)	2 (3.5%)	3 (2.6%)
		Completed	0	1 (1.8%)	1 (0.9%)
055	xxxxxxxxxxxxxxxx	Randomised	4 (6.9%)	4 (7.0%)	8 (7.0%)
		Completed	2 (3.4%)	3 (5.3%)	5 (4.3%)

BRL 29060 - 704

Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population

Age Group : Adolescents

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=40)	Placebo (N=48)	Total (N=88)
002	xxxxxxxxxxxxxxxxx	Randomised	1 (2.5%)	1 (2.1%)	2 (2.3%)
		Completed	1 (2.5%)	1 (2.1%)	2 (2.3%)
004	xxxxxxxxxxxxxx	Randomised	1 (2.5%)	1 (2.1%)	2 (2.3%)
		Completed	1 (2.5%)	1 (2.1%)	2 (2.3%)
005	xxxxxxxxxxxxxxx.	Randomised	3 (7.5%)	2 (4.2%)	5 (5.7%)
		Completed	1 (2.5%)	1 (2.1%)	2 (2.3%)
006	xxxxxxxxxxx	Randomised	2 (5.0%)	2 (4.2%)	4 (4.5%)
		Completed	2 (5.0%)	1 (2.1%)	3 (3.4%)
008	xxxxxxxxxxx	Randomised	2 (5.0%)	1 (2.1%)	3 (3.4%)
		Completed	2 (5.0%)	1 (2.1%)	3 (3.4%)
009	xxxxxxxxxxxxxx	Randomised	1 (2.5%)	0	1 (1.1%)
		Completed	1 (2.5%)	0	1 (1.1%)
010	xxxxxxxxxxxx	Randomised	3 (7.5%)	4 (8.3%)	7 (8.0%)
		Completed	2 (5.0%)	3 (6.3%)	5 (5.7%)
014	xxxxxxxxxxxxxxx	Randomised	2 (5.0%)	1 (2.1%)	3 (3.4%)
		Completed	2 (5.0%)	1 (2.1%)	3 (3.4%)
015	xxxxxxxxxxxxxxxxx	Randomised	1 (2.5%)	2 (4.2%)	3 (3.4%)
		Completed	1 (2.5%)	1 (2.1%)	2 (2.3%)
016	xxxxxxxxxxxxxxx	Randomised	2 (5.0%)	2 (4.2%)	4 (4.5%)
		Completed	2 (5.0%)	1 (2.1%)	3 (3.4%)
017	xxxxxxxxxxxxxxx	Randomised	1 (2.5%)	0	1 (1.1%)
		Completed	1 (2.5%)	0	1 (1.1%)
019	xxxxxxxxxxxxxxx	Randomised	0	1 (2.1%)	1 (1.1%)
020	xxxxxxxxxxxxxxx	Randomised	3 (7.5%)	4 (8.3%)	7 (8.0%)
		Completed	3 (7.5%)	2 (4.2%)	5 (5.7%)
021	xxxxxxxxxxxxxxx	Randomised	0	1 (2.1%)	1 (1.1%)
025	xxxxxxxxxxxxxxx	Randomised	4 (10.0%)	4 (8.3%)	8 (9.1%)
		Completed	1 (2.5%)	3 (6.3%)	4 (4.5%)
027	xxxxxxxxxxxxxxx	Randomised	1 (2.5%)	0	1 (1.1%)

BRL 29060 - 704

Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population

Age Group : Adolescents

Centre Number	Investigator	Status	Treatment Group: Paroxetine (N=40)	Placebo (N=48)	Total (N=88)
027	xxxxxxxxxxxxxxx	Completed	1 (2.5%)	0	1 (1.1%)
028	xxxxxxxxxxxxxxx	Randomised	0	1 (2.1%)	1 (1.1%)
		Completed	0	1 (2.1%)	1 (1.1%)
029	xxxxxxxxxxxxxxxxxx	Randomised	3 (7.5%)	2 (4.2%)	5 (5.7%)
		Completed	1 (2.5%)	1 (2.1%)	2 (2.3%)
031	xxxxxxxxxxxxxxx	Randomised	0	1 (2.1%)	1 (1.1%)
		Completed	0	1 (2.1%)	1 (1.1%)
033	xxxxxxxxxxxxxxx	Randomised	1 (2.5%)	2 (4.2%)	3 (3.4%)
		Completed	0	2 (4.2%)	2 (2.3%)
040	xxxxxxxxxxxxxxx	Randomised	0	1 (2.1%)	1 (1.1%)
041	xxxxxxxxxxxxxxx	Randomised	0	1 (2.1%)	1 (1.1%)
044	xxxxxxxxxxxxxxx	Randomised	0	1 (2.1%)	1 (1.1%)
		Completed	0	1 (2.1%)	1 (1.1%)
047	xxxxxxxxxxxxxxx	Randomised	1 (2.5%)	2 (4.2%)	3 (3.4%)
		Completed	1 (2.5%)	2 (4.2%)	3 (3.4%)
048	xxxxxxxxxxxxxxxxx	Randomised	2 (5.0%)	2 (4.2%)	4 (4.5%)
		Completed	1 (2.5%)	2 (4.2%)	3 (3.4%)
049	xxxxxxxxxxxxxxxxx	Randomised	2 (5.0%)	3 (6.3%)	5 (5.7%)
		Completed	2 (5.0%)	3 (6.3%)	5 (5.7%)
051	xxxxxxxxxxxxxxxxx	Randomised	1 (2.5%)	0	1 (1.1%)
052	xxxxxxxxxxxxxxxxx	Randomised	0	1 (2.1%)	1 (1.1%)
053	xxxxxxxxxxxxxxxxx	Randomised	0	1 (2.1%)	1 (1.1%)
055	xxxxxxxxxxxxxxxxx	Randomised	3 (7.5%)	3 (6.3%)	6 (6.8%)
		Completed	3 (7.5%)	2 (4.2%)	5 (5.7%)
056	xxxxxxxxxxxxxxxxx	Randomised	0	1 (2.1%)	1 (1.1%)
		Completed	0	1 (2.1%)	1 (1.1%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population

Age Group : Total

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
002	xxxxxxxxxxxxxxxxx	Randomised	3 (3.1%)	2 (1.9%)	5 (2.5%)
		Completed	1 (1.0%)	2 (1.9%)	3 (1.5%)
004	xxxxxxxxxxxxxxxxx	Randomised	4 (4.1%)	4 (3.8%)	8 (3.9%)
		Completed	4 (4.1%)	3 (2.9%)	7 (3.4%)
005	xxxxxxxxxxxxxxxxx	Randomised	6 (6.1%)	4 (3.8%)	10 (4.9%)
		Completed	4 (4.1%)	3 (2.9%)	7 (3.4%)
006	xxxxxxxxxxxxxxxxx	Randomised	4 (4.1%)	3 (2.9%)	7 (3.4%)
		Completed	4 (4.1%)	2 (1.9%)	6 (3.0%)
008	xxxxxxxxxxxxxxxxx	Randomised	4 (4.1%)	3 (2.9%)	7 (3.4%)
		Completed	4 (4.1%)	2 (1.9%)	6 (3.0%)
009	xxxxxxxxxxxxxxxxx	Randomised	2 (2.0%)	1 (1.0%)	3 (1.5%)
		Completed	1 (1.0%)	1 (1.0%)	2 (1.0%)
010	xxxxxxxxxxxxxxxx	Randomised	5 (5.1%)	4 (3.8%)	9 (4.4%)
		Completed	2 (2.0%)	3 (2.9%)	5 (2.5%)
012	xxxxxxxxxxxxxxxx	Randomised	1 (1.0%)	0	1 (0.5%)
		Completed	1 (1.0%)	0	1 (0.5%)
013	xxxxxxxxxxxxxxxxxxxx	Randomised	0	1 (1.0%)	1 (0.5%)
014	xxxxxxxxxxxxxxxxx	Randomised	3 (3.1%)	3 (2.9%)	6 (3.0%)
		Completed	2 (2.0%)	3 (2.9%)	5 (2.5%)
015	xxxxxxxxxxxxxxxxx	Randomised	5 (5.1%)	5 (4.8%)	10 (4.9%)
		Completed	3 (3.1%)	3 (2.9%)	6 (3.0%)
016	xxxxxxxxxxxxxxxxx	Randomised	8 (8.2%)	9 (8.6%)	17 (8.4%)
		Completed	5 (5.1%)	8 (7.6%)	13 (6.4%)
017	Sxxxxxxxxxxxxxxxxx	Randomised	1 (1.0%)	0	1 (0.5%)
		Completed	1 (1.0%)	0	1 (0.5%)
019	xxxxxxxxxxxxxxxxx	Randomised	4 (4.1%)	4 (3.8%)	8 (3.9%)
		Completed	2 (2.0%)	3 (2.9%)	5 (2.5%)
020	xxxxxxxxxxxxxxxxx	Randomised	7 (7.1%)	8 (7.6%)	15 (7.4%)
		Completed	5 (5.1%)	6 (5.7%)	11 (5.4%)

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Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population

Age Group : Total

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
021	xxxxxxxxxxxxxxx	Randomised	0	1 (1.0%)	1 (0.5%)
022	xxxxxxxxxxxxxxx	Randomised	0	1 (1.0%)	1 (0.5%)
		Completed	0	1 (1.0%)	1 (0.5%)
025	xxxxxxxxxxxxxxxxxx	Randomised	10 (10.2%)	10 (9.5%)	20 (9.9%)
		Completed	4 (4.1%)	7 (6.7%)	11 (5.4%)
026	xxxxxxxxxxxxxxxx	Randomised	1 (1.0%)	2 (1.9%)	3 (1.5%)
		Completed	1 (1.0%)	1 (1.0%)	2 (1.0%)
027	xxxxxxxxxxxxxxxx	Randomised	3 (3.1%)	2 (1.9%)	5 (2.5%)
		Completed	3 (3.1%)	2 (1.9%)	5 (2.5%)
028	xxxxxxxxxxxxxxxx	Randomised	1 (1.0%)	2 (1.9%)	3 (1.5%)
		Completed	1 (1.0%)	2 (1.9%)	3 (1.5%)
029	xxxxxxxxxxxxxxxxxx	Randomised	4 (4.1%)	3 (2.9%)	7 (3.4%)
		Completed	2 (2.0%)	2 (1.9%)	4 (2.0%)
031	xxxxxxxxxxxxxxxxx	Randomised	1 (1.0%)	3 (2.9%)	4 (2.0%)
		Completed	1 (1.0%)	3 (2.9%)	4 (2.0%)
033	xxxxxxxxxxxxxxxxx	Randomised	1 (1.0%)	3 (2.9%)	4 (2.0%)
		Completed	0	3 (2.9%)	3 (1.5%)
040	xxxxxxxxxxxxxxxxx	Randomised	1 (1.0%)	3 (2.9%)	4 (2.0%)
		Completed	1 (1.0%)	2 (1.9%)	3 (1.5%)
041	xxxxxxxxxxxxxxxxx	Randomised	0	1 (1.0%)	1 (0.5%)
043	xxxxxxxxxxxxxxxxxx	Randomised	1 (1.0%)	0	1 (0.5%)
		Completed	1 (1.0%)	0	1 (0.5%)
044	xxxxxxxxxxxxxxxxx	Randomised	0	2 (1.9%)	2 (1.0%)
		Completed	0	2 (1.9%)	2 (1.0%)
047	xxxxxxxxxxxxxxxxx	Randomised	1 (1.0%)	2 (1.9%)	3 (1.5%)
		Completed	1 (1.0%)	2 (1.9%)	3 (1.5%)
048	Vxxxxxxxxxxxxxxxxx	Randomised	5 (5.1%)	4 (3.8%)	9 (4.4%)
		Completed	4 (4.1%)	4 (3.8%)	8 (3.9%)
049	Kxxxxxxxxxxxxxxxxx	Randomised	2 (2.0%)	3 (2.9%)	5 (2.5%)

Table 13.4.1

Number (%) of Patients Randomised and Completed by Centre

Intention-To-Treat Population

Age Group : Total

Centre Number	Investigator	Status	Treatment Group Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
049	xxxxxxxxxxxxxxxxx	Completed	2 (2.0%)	3 (2.9%)	5 (2.5%)
051	xxxxxxxxxxxxxxxxx	Randomised	2 (2.0%)	0	2 (1.0%)
052	xxxxxxxxxxxxxxxxx	Randomised	1 (1.0%)	3 (2.9%)	4 (2.0%)
		Completed	0	1 (1.0%)	1 (0.5%)
053	xxxxxxxxxxxxxxxxx	Randomised	0	1 (1.0%)	1 (0.5%)
055	xxxxxxxxxxxxxxxxx	Randomised	7 (7.1%)	7 (6.7%)	14 (6.9%)
		Completed	5 (5.1%)	5 (4.8%)	10 (4.9%)
056	xxxxxxxxxxxxxxxxx	Randomised	0	1 (1.0%)	1 (0.5%)
		Completed	0	1 (1.0%)	1 (0.5%)

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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=58)	Placebo (N=57)	Total (N=115)
Gender	Female	27 (46.6%)	22 (38.6%)	49 (42.6%)
	Male	31 (53.4%)	35 (61.4%)	66 (57.4%)
Race	White	49 (84.5%)	51 (89.5%)	100 (87.0%)
	Black	6 (10.3%)	4 (7.0%)	10 (8.7%)
	Oriental	0	0	0
	Other	3 (5.2%)	2 (3.5%)	5 (4.3%)

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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=40)	Placebo (N=48)	Total (N=88)
Gender	Female	18 (45.0%)	19 (39.6%)	37 (42.0%)
	Male	22 (55.0%)	29 (60.4%)	51 (58.0%)
Race	White	36 (90.0%)	43 (89.6%)	79 (89.8%)
	Black	2 (5.0%)	1 (2.1%)	3 (3.4%)
	Oriental	0	0	0
	Other	2 (5.0%)	4 (8.3%)	6 (6.8%)

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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=98)	Placebo (N=105)	Total (N=203)
Gender	Female	45 (45.9%)	41 (39.0%)	86 (42.4%)
	Male	53 (54.1%)	64 (61.0%)	117 (57.6%)
Race	White	85 (86.7%)	94 (89.5%)	179 (88.2%)
	Black	8 (8.2%)	5 (4.8%)	13 (6.4%)
	Oriental	0	0	0
	Other	5 (5.1%)	6 (5.7%)	11 (5.4%)

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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=40)	Placebo (N=45)	Total (N=85)
Gender	Female	19 (47.5%)	17 (37.8%)	36 (42.4%)
	Male	21 (52.5%)	28 (62.2%)	49 (57.6%)
Race	White	33 (82.5%)	44 (97.8%)	77 (90.6%)
	Black	5 (12.5%)	1 (2.2%)	6 (7.1%)
	Oriental	0	0	0
	Other	2 (5.0%)	0	2 (2.4%)

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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=33)	Placebo (N=37)	Total (N=70)
Gender	Female	15 (45.5%)	13 (35.1%)	28 (40.0%)
	Male	18 (54.5%)	24 (64.9%)	42 (60.0%)
Race	White	30 (90.9%)	33 (89.2%)	63 (90.0%)
	Black	1 (3.0%)	1 (2.7%)	2 (2.9%)
	Oriental	0	0	0
	Other	2 (6.1%)	3 (8.1%)	5 (7.1%)

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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=73)	Placebo (N=82)	Total (N=155)
Gender	Female	34 (46.6%)	30 (36.6%)	64 (41.3%)
	Male	39 (53.4%)	52 (63.4%)	91 (58.7%)
Race	White	63 (86.3%)	77 (93.9%)	140 (90.3%)
	Black	6 (8.2%)	2 (2.4%)	8 (5.2%)
	Oriental	0	0	0
	Other	4 (5.5%)	3 (3.7%)	7 (4.5%)

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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=58)	Placebo (N=57)	Total (N=115)
Age (years)	N	58	57	115
	MEAN	8.9	9.2	9.1
	MEDIAN	9.0	9.0	9.0
	STDDEV	1.47	1.51	1.49
	MINIMUM	6	6	6
	MAXIMUM	11	11	11
	MISSING	0	0	0
Height (cm)	N	58	57	115
	MEAN	136.41	138.05	137.22
	MEDIAN	136.45	139.70	138.00
	STDDEV	12.532	10.804	11.684
	MINIMUM	106.6	106.6	106.6
	MAXIMUM	161.3	161.0	161.3
	MISSING	0	0	0
Weight (kg)	N	58	57	115
	MEAN	35.03	36.28	35.65
	MEDIAN	30.60	33.60	33.10
	STDDEV	13.683	12.674	13.150
	MINIMUM	18.6	19.0	18.6
	MAXIMUM	79.5	104.0	104.0
	MISSING	0	0	0
BMI (kg/m2)	N	58	57	115
	MEAN	18.23	18.70	18.46
	MEDIAN	17.05	17.40	17.20
	STDDEV	4.274	4.328	4.288
	MINIMUM	13.0	13.7	13.0
	MAXIMUM	32.8	40.1	40.1
	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=40)	Placebo (N=48)	Total (N=88)
Age (years)	N	40	48	88
	MEAN	14.2	14.3	14.3
	MEDIAN	14.0	14.0	14.0
	STDDEV	1.67	1.59	1.62
	MINIMUM	12	12	12
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	40	47	87
	MEAN	164.69	165.66	165.21
	MEDIAN	167.30	167.60	167.60
	STDDEV	12.590	10.697	11.546
	MINIMUM	135.9	127.0	127.0
	MAXIMUM	188.0	192.0	192.0
	MISSING	0	1	1
Weight (kg)	N	40	47	87
	MEAN	62.72	64.31	63.58
	MEDIAN	60.00	63.60	61.80
	STDDEV	17.556	14.728	16.013
	MINIMUM	32.5	37.7	32.5
	MAXIMUM	110.9	100.9	110.9
	MISSING	0	1	1
BMI (kg/m2)	N	40	47	87
	MEAN	22.93	23.47	23.22
	MEDIAN	21.50	22.80	21.90
	STDDEV	5.440	5.274	5.326
	MINIMUM	16.2	16.1	16.1
	MAXIMUM	41.9	37.7	41.9
	MISSING	0	1	1

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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=98)	Placebo (N=105)	Total (N=203)
Age (years)	N	98	105	203
	MEAN	11.1	11.6	11.3
	MEDIAN	11.0	11.0	11.0
	STDDEV	3.03	2.97	3.00
	MINIMUM	6	6	6
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	98	104	202
	MEAN	147.95	150.52	149.28
	MEDIAN	148.60	149.90	149.05
	STDDEV	18.737	17.470	18.096
	MINIMUM	106.6	106.6	106.6
	MAXIMUM	188.0	192.0	192.0
	MISSING	0	1	1
Weight (kg)	N	98	104	202
	MEAN	46.33	48.94	47.68
	MEDIAN	42.00	43.80	43.40
	STDDEV	20.520	19.512	20.000
	MINIMUM	18.6	19.0	18.6
	MAXIMUM	110.9	104.0	110.9
	MISSING	0	1	1
BMI (kg/m2)	N	98	104	202
	MEAN	20.15	20.85	20.51
	MEDIAN	19.35	19.65	19.40
	STDDEV	5.294	5.321	5.306
	MINIMUM	13.0	13.7	13.0
	MAXIMUM	41.9	40.1	41.9
	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 : Children

		Treatment Group		
	Statistic	Paroxetine (N=40)	Placebo (N=45)	Total (N=85)
Age (years)	N	40	45	85
	MEAN	9.0	9.2	9.1
	MEDIAN	9.0	9.0	9.0
	STDDEV	1.49	1.46	1.47
	MINIMUM	6	7	6
	MAXIMUM	11	11	11
	MISSING	0	0	0
Height (cm)	N	40	45	85
	MEAN	136.52	138.88	137.77
	MEDIAN	136.45	140.00	138.00
	STDDEV	13.078	10.256	11.658
	MINIMUM	106.6	119.0	106.6
	MAXIMUM	161.3	161.0	161.3
	MISSING	0	0	0
Weight (kg)	N	40	45	85
	MEAN	35.10	36.17	35.66
	MEDIAN	29.50	33.40	33.00
	STDDEV	15.061	13.292	14.077
	MINIMUM	18.6	20.5	18.6
	MAXIMUM	79.5	104.0	104.0
	MISSING	0	0	0
BMI (kg/m2)	N	40	45	85
	MEAN	18.16	18.38	18.28
	MEDIAN	16.60	17.20	17.00
	STDDEV	4.797	4.418	4.574
	MINIMUM	13.0	13.7	13.0
	MAXIMUM	32.8	40.1	40.1
	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=33)	Placebo (N=37)	Total (N=70)
Age (years)	N	33	37	70
	MEAN	14.3	14.3	14.3
	MEDIAN	14.0	14.0	14.0
	STDDEV	1.73	1.63	1.66
	MINIMUM	12	12	12
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	33	36	69
	MEAN	165.35	165.16	165.25
	MEDIAN	168.00	167.60	167.60
	STDDEV	13.392	11.197	12.204
	MINIMUM	135.9	127.0	127.0
	MAXIMUM	188.0	192.0	192.0
	MISSING	0	1	1
Weight (kg)	N	33	36	69
	MEAN	63.99	64.02	64.01
	MEDIAN	60.80	64.25	62.70
	STDDEV	18.825	14.386	16.531
	MINIMUM	32.5	38.2	32.5
	MAXIMUM	110.9	98.2	110.9
	MISSING	0	1	1
BMI (kg/m2)	N	33	36	69
	MEAN	23.20	23.58	23.40
	MEDIAN	21.10	22.85	22.50
	STDDEV	5.935	5.497	5.671
	MINIMUM	16.2	16.1	16.1
	MAXIMUM	41.9	37.7	41.9
	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=73)	Placebo (N=82)	Total (N=155)
Age (years)	N	73	82	155
	MEAN	11.4	11.5	11.5
	MEDIAN	11.0	11.0	11.0
	STDDEV	3.12	2.97	3.03
	MINIMUM	6	7	6
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	73	81	154
	MEAN	149.55	150.56	150.08
	MEDIAN	148.60	149.90	149.70
	STDDEV	19.523	16.892	18.133
	MINIMUM	106.6	119.0	106.6
	MAXIMUM	188.0	192.0	192.0
	MISSING	0	1	1
Weight (kg)	N	73	81	154
	MEAN	48.16	48.55	48.36
	MEDIAN	42.70	43.60	43.40
	STDDEV	22.137	19.535	20.741
	MINIMUM	18.6	20.5	18.6
	MAXIMUM	110.9	104.0	110.9
	MISSING	0	1	1
BMI (kg/m2)	N	73	81	154
	MEAN	20.44	20.69	20.57
	MEDIAN	19.40	19.10	19.15
	STDDEV	5.874	5.541	5.684
	MINIMUM	13.0	13.7	13.0
	MAXIMUM	41.9	40.1	41.9
	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=98)	Placebo (N=105)	Total (N=203)
Patients with at least one Prior Condition		54 (55.1%)	64 (61.0%)	118 (58.1%)
CARDIOVASCULAR	Total	8 (8.2%)	6 (5.7%)	14 (6.9%)
	CARDIAC MURMURS	2 (2.0%)	1 (1.0%)	3 (1.5%)
	CONG ANOM, CIRC SYST	1 (1.0%)	0	1 (0.5%)
	CONG ANOM, HEART	0	1 (1.0%)	1 (0.5%)
	FLUSHING	0	1 (1.0%)	1 (0.5%)
	MIGRAINE	2 (2.0%)	1 (1.0%)	3 (1.5%)
	MITRAL VALVE DISORD	1 (1.0%)	1 (1.0%)	2 (1.0%)
	OPERATION, HEART VALVE/SEPTA	1 (1.0%)	0	1 (0.5%)
	OPERATION, OTHER HEART	1 (1.0%)	0	1 (0.5%)
	PALPITATIONS	1 (1.0%)	1 (1.0%)	2 (1.0%)
CAUSES OF INJURY	Total	2 (2.0%)	5 (4.8%)	7 (3.4%)
	ACCIDENT/MOTOR VEHICLE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	ADVERSE EFF/ANALGESIC	1 (1.0%)	0	1 (0.5%)
	ADVERSE EFF/ANTI-INFECT	1 (1.0%)	0	1 (0.5%)
	ADVERSE EFF/ANTIBIOTIC	1 (1.0%)	4 (3.8%)	5 (2.5%)
DIGESTIVE	Total	5 (5.1%)	8 (7.6%)	13 (6.4%)
	CONSTIPATION	0	1 (1.0%)	1 (0.5%)
	DIGESTIVE DISORD, OTHER	0	1 (1.0%)	1 (0.5%)
	ENTERITIS/COLITIS	0	1 (1.0%)	1 (0.5%)
	GASTROINTEST PROB, NEC	1 (1.0%)	0	1 (0.5%)
	HEARTBURN	0	1 (1.0%)	1 (0.5%)
	INTEST INFECT DIS	1 (1.0%)	0	1 (0.5%)
	NAUSEA	1 (1.0%)	0	1 (0.5%)
	NAUSEA AND VOMITING	0	1 (1.0%)	1 (0.5%)
	NEOPLASMS BENIGN	1 (1.0%)	0	1 (0.5%)
	OPERATION, APPENDIX	0	1 (1.0%)	1 (0.5%)
	OPERATION, NOSE/MOUTH	2 (2.0%)	0	2 (1.0%)
	ORAL SOFT TISSUE DIS	1 (1.0%)	0	1 (0.5%)
	STOMACH/DUODENUM DISORD	0	1 (1.0%)	1 (0.5%)
	TONGUE DISORD	0	1 (1.0%)	1 (0.5%)
ENDOCRINE	Total	0	2 (1.9%)	2 (1.0%)
	HYPOTHYROIDISM	0	1 (1.0%)	1 (0.5%)
	HYPOTHYROIDISM, CONGENITAL	0	1 (1.0%)	1 (0.5%)
GENERAL BODY OR SYS UNSPEC	Total	15 (15.3%)	24 (22.9%)	39 (19.2%)
	ALLERGIC REACTION, FOOD	0	1 (1.0%)	1 (0.5%)
	ALLERGY, NEC	2 (2.0%)	3 (2.9%)	5 (2.5%)
	BACT DIS, OTHER	1 (1.0%)	2 (1.9%)	3 (1.5%)
	CONG ANOM, MUSCULOSKEL	1 (1.0%)	0	1 (0.5%)
	HEADACHE	4 (4.1%)	5 (4.8%)	9 (4.4%)

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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=98)	Placebo (N=105)	Total (N=203)
GENERAL BODY OR SYS UNSPEC	HERNIA, ABDOMINAL	1 (1.0%)	0	1 (0.5%)
	INJURY/POIS, OTHER	0	2 (1.9%)	2 (1.0%)
	MOTION SICKNESS	1 (1.0%)	0	1 (0.5%)
	MYCOSES	0	1 (1.0%)	1 (0.5%)
	OPEN WOUND	1 (1.0%)	0	1 (0.5%)
	OPERATION, HERNIA REPAIR	0	3 (2.9%)	3 (1.5%)
	PAIN, ABDOMINO-PELVIC	0	1 (1.0%)	1 (0.5%)
	PROCEDURE, SURGERY UNSP	1 (1.0%)	0	1 (0.5%)
	TOXIC EFFECTS, NONMEDICINAL	0	1 (1.0%)	1 (0.5%)
	TRAUMA/INJURIES, UNSPEC	0	1 (1.0%)	1 (0.5%)
	VIRAL DIS/EXANTHEM	4 (4.1%)	6 (5.7%)	10 (4.9%)
	VIRAL INFECTION	0	1 (1.0%)	1 (0.5%)
GENITOURINARY	Total	6 (6.1%)	7 (6.7%)	13 (6.4%)
	CONG ANOM, GU	1 (1.0%)	1 (1.0%)	2 (1.0%)
	GENITAL FEMALE DISORD, OTHER	0	2 (1.9%)	2 (1.0%)
	GENITAL MALE DISORD, OTHER	1 (1.0%)	0	1 (0.5%)
	GLYCOSURIA	0	1 (1.0%)	1 (0.5%)
	KIDNEY DISORD	1 (1.0%)	0	1 (0.5%)
	OPERATION, FEM GENITAL	0	1 (1.0%)	1 (0.5%)
	OPERATION, MALE GENITAL	1 (1.0%)	1 (1.0%)	2 (1.0%)
	OPERATION, OTHER URINARY	1 (1.0%)	1 (1.0%)	2 (1.0%)
	PROTEINURIA	1 (1.0%)	0	1 (0.5%)
	URETHRAL DISORD	1 (1.0%)	1 (1.0%)	2 (1.0%)
	URINARY TRACT INFECTION	0	1 (1.0%)	1 (0.5%)
HEMATIC/HEMATOPOIETIC/LYMPH	Total	0	1 (1.0%)	1 (0.5%)
	LYMPHADENOPATHY	0	1 (1.0%)	1 (0.5%)
INTEGUMENTARY	Total	5 (5.1%)	10 (9.5%)	15 (7.4%)
	CYST, SEBACEOUS	0	1 (1.0%)	1 (0.5%)
	DYSCHROMIA	1 (1.0%)	0	1 (0.5%)
	HYPERHIDROSIS	1 (1.0%)	0	1 (0.5%)
	INFLAM SKIN/SUBCUT	1 (1.0%)	4 (3.8%)	5 (2.5%)
	OPERATION, SKIN/SUBCUT	0	1 (1.0%)	1 (0.5%)
	SCARRING	1 (1.0%)	0	1 (0.5%)
	SKIN/SUBCUT DISORD, OTHER	2 (2.0%)	3 (2.9%)	5 (2.5%)
	URTICARIA	0	1 (1.0%)	1 (0.5%)
	VIRUS/CHLAMYD DIS, OTHER	0	1 (1.0%)	1 (0.5%)
METABOLIC/NUTRITIONAL/IMMUNE	Total	0	2 (1.9%)	2 (1.0%)
	OBESITY	0	1 (1.0%)	1 (0.5%)
	POTASSIUM ELEVATED, SERUM	0	1 (1.0%)	1 (0.5%)
MUSCULOSKELETAL	Total	7 (7.1%)	12 (11.4%)	19 (9.4%)
	CRAMP, LIMB	1 (1.0%)	1 (1.0%)	2 (1.0%)

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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=98)	Placebo (N=105)	Total (N=203)
MUSCULOSKELETAL	DEFORMITY, ACQUIRED	1 (1.0%)	0	1 (0.5%)
	FRACTURE, LOWER LIMB	3 (3.1%)	4 (3.8%)	7 (3.4%)
	FRACTURE, NECK/TRUNK	1 (1.0%)	0	1 (0.5%)
	FRACTURE, UPPER LIMB	1 (1.0%)	5 (4.8%)	6 (3.0%)
	OPERATION, BONE/JOINT	1 (1.0%)	2 (1.9%)	3 (1.5%)
	SPRAINS/STRAINS	1 (1.0%)	0	1 (0.5%)
NERVOUS/SENSE ORGANS	Total	21 (21.4%)	23 (21.9%)	44 (21.7%)
	BRAIN CONDIT, OTHER	0	1 (1.0%)	1 (0.5%)
	CATARACT	1 (1.0%)	0	1 (0.5%)
	CONGEN ANOM, EAR	0	1 (1.0%)	1 (0.5%)
	CONGEN ANOM, HEAD/NECK	0	1 (1.0%)	1 (0.5%)
	CONTUSION	1 (1.0%)	0	1 (0.5%)
	CONVULSIONS	1 (1.0%)	0	1 (0.5%)
	EAR/MASTOID DISORD	2 (2.0%)	1 (1.0%)	3 (1.5%)
	EYE DISORD, OTHER	2 (2.0%)	6 (5.7%)	8 (3.9%)
	HEARING LOSS	2 (2.0%)	0	2 (1.0%)
	HYPERACTIVITY	0	1 (1.0%)	1 (0.5%)
	INJURY, INTRACRANIAL	1 (1.0%)	0	1 (0.5%)
	MENINGITIS	0	1 (1.0%)	1 (0.5%)
	OPERATION, EAR	7 (7.1%)	9 (8.6%)	16 (7.9%)
	OPERATION, EYE	1 (1.0%)	3 (2.9%)	4 (2.0%)
	OTITIS MEDIA	7 (7.1%)	10 (9.5%)	17 (8.4%)
	VISUAL DISTURB	1 (1.0%)	0	1 (0.5%)
PSYCHOLOGICAL DISORDERS	Total	2 (2.0%)	0	2 (1.0%)
	ANXIETY	1 (1.0%)	0	1 (0.5%)
	MENTAL STATUS, IMPAIRED	1 (1.0%)	0	1 (0.5%)
RESPIRATORY	Total	23 (23.5%)	30 (28.6%)	53 (26.1%)
	ASTHMA	8 (8.2%)	6 (5.7%)	14 (6.9%)
	BRONCHITIS, OTHER	1 (1.0%)	1 (1.0%)	2 (1.0%)
	CONDITIONS, PERINATAL	1 (1.0%)	0	1 (0.5%)
	CONG ANOM, RESP SYST	1 (1.0%)	0	1 (0.5%)
	EPISTAXIS	2 (2.0%)	2 (1.9%)	4 (2.0%)
	INFECTION, BACTERIAL	2 (2.0%)	2 (1.9%)	4 (2.0%)
	NASOPHARYNGITIS, ACUTE	0	1 (1.0%)	1 (0.5%)
	OPERATION, NOSE/MOUTH	2 (2.0%)	10 (9.5%)	12 (5.9%)
	PNEUMONIA, OTHER	1 (1.0%)	5 (4.8%)	6 (3.0%)
	RHINITIS, ALLERGIC	7 (7.1%)	9 (8.6%)	16 (7.9%)
	RHINITIS,NOS	1 (1.0%)	0	1 (0.5%)
	SINUSITIS,NOS	1 (1.0%)	2 (1.9%)	3 (1.5%)
	TONSILLITIS, ACUTE	2 (2.0%)	2 (1.9%)	4 (2.0%)
	UPPER RESP DISORD, OTHER	1 (1.0%)	0	1 (0.5%)

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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=98)	Placebo (N=105)	Total (N=203)
Patients with at least one Prior Condition	54 (55.1%)	64 (61.0%)	118 (58.1%)
ASTHMA	8 (8.2%)	6 (5.7%)	14 (6.9%)
OTITIS MEDIA	7 (7.1%)	10 (9.5%)	17 (8.4%)
OPERATION, EAR	7 (7.1%)	9 (8.6%)	16 (7.9%)
RHINITIS, ALLERGIC	7 (7.1%)	9 (8.6%)	16 (7.9%)
OPERATION, NOSE/MOUTH	4 (4.1%)	10 (9.5%)	14 (6.9%)
VIRAL DIS/EXANTHEM	4 (4.1%)	6 (5.7%)	10 (4.9%)
HEADACHE	4 (4.1%)	5 (4.8%)	9 (4.4%)
FRACTURE, LOWER LIMB	3 (3.1%)	4 (3.8%)	7 (3.4%)
EYE DISORD, OTHER	2 (2.0%)	6 (5.7%)	8 (3.9%)
ALLERGY, NEC	2 (2.0%)	3 (2.9%)	5 (2.5%)
SKIN/SUBCUT DISORD, OTHER	2 (2.0%)	3 (2.9%)	5 (2.5%)
EPISTAXIS	2 (2.0%)	2 (1.9%)	4 (2.0%)
INFECTION, BACTERIAL	2 (2.0%)	2 (1.9%)	4 (2.0%)
TONSILLITIS, ACUTE	2 (2.0%)	2 (1.9%)	4 (2.0%)
CARDIAC MURMURS	2 (2.0%)	1 (1.0%)	3 (1.5%)
EAR/MASTOID DISORD	2 (2.0%)	1 (1.0%)	3 (1.5%)
MIGRAINE	2 (2.0%)	1 (1.0%)	3 (1.5%)
HEARING LOSS	2 (2.0%)	0	2 (1.0%)
FRACTURE, UPPER LIMB	1 (1.0%)	5 (4.8%)	6 (3.0%)
PNEUMONIA, OTHER	1 (1.0%)	5 (4.8%)	6 (3.0%)
ADVERSE EFF/ANTIBIOTIC	1 (1.0%)	4 (3.8%)	5 (2.5%)
INFLAM SKIN/SUBCUT	1 (1.0%)	4 (3.8%)	5 (2.5%)
OPERATION, EYE	1 (1.0%)	3 (2.9%)	4 (2.0%)
BACT DIS, OTHER	1 (1.0%)	2 (1.9%)	3 (1.5%)
OPERATION, BONE/JOINT	1 (1.0%)	2 (1.9%)	3 (1.5%)
SINUSITIS,NOS	1 (1.0%)	2 (1.9%)	3 (1.5%)
ACCIDENT/MOTOR VEHICLE	1 (1.0%)	1 (1.0%)	2 (1.0%)
BRONCHITIS, OTHER	1 (1.0%)	1 (1.0%)	2 (1.0%)
CONG ANOM, GU	1 (1.0%)	1 (1.0%)	2 (1.0%)
CRAMP, LIMB	1 (1.0%)	1 (1.0%)	2 (1.0%)
MITRAL VALVE DISORD	1 (1.0%)	1 (1.0%)	2 (1.0%)
OPERATION, MALE GENITAL	1 (1.0%)	1 (1.0%)	2 (1.0%)
OPERATION, OTHER URINARY	1 (1.0%)	1 (1.0%)	2 (1.0%)
PALPITATIONS	1 (1.0%)	1 (1.0%)	2 (1.0%)
URETHRAL DISORD	1 (1.0%)	1 (1.0%)	2 (1.0%)
ADVERSE EFF/ANALGESIC	1 (1.0%)	0	1 (0.5%)
ADVERSE EFF/ANTI-INFECT	1 (1.0%)	0	1 (0.5%)
ANXIETY	1 (1.0%)	0	1 (0.5%)
CATARACT	1 (1.0%)	0	1 (0.5%)
CONDITIONS, PERINATAL	1 (1.0%)	0	1 (0.5%)
CONG ANOM, CIRC SYST	1 (1.0%)	0	1 (0.5%)
CONG ANOM, MUSCULOSKEL	1 (1.0%)	0	1 (0.5%)
CONG ANOM, RESP SYST	1 (1.0%)	0	1 (0.5%)
CONTUSION	1 (1.0%)	0	1 (0.5%)

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=98)	Placebo (N=105)	Total (N=203)
CONVULSIONS	1 (1.0%)	0	1 (0.5%)
DEFORMITY, ACQUIRED	1 (1.0%)	0	1 (0.5%)
DYSCHROMIA	1 (1.0%)	0	1 (0.5%)
FRACTURE, NECK/TRUNK	1 (1.0%)	0	1 (0.5%)
GASTROINTEST PROB, NEC	1 (1.0%)	0	1 (0.5%)
GENITAL MALE DISORD, OTHER	1 (1.0%)	0	1 (0.5%)
HERNIA, ABDOMINAL	1 (1.0%)	0	1 (0.5%)
HYPERHIDROSIS	1 (1.0%)	0	1 (0.5%)
INJURY, INTRACRANIAL	1 (1.0%)	0	1 (0.5%)
INTEST INFECT DIS	1 (1.0%)	0	1 (0.5%)
KIDNEY DISORD	1 (1.0%)	0	1 (0.5%)
MENTAL STATUS, IMPAIRED	1 (1.0%)	0	1 (0.5%)
MOTION SICKNESS	1 (1.0%)	0	1 (0.5%)
NAUSEA	1 (1.0%)	0	1 (0.5%)
NEOPLASMS BENIGN	1 (1.0%)	0	1 (0.5%)
OPEN WOUND	1 (1.0%)	0	1 (0.5%)
OPERATION, HEART VALVE/SEPTA	1 (1.0%)	0	1 (0.5%)
OPERATION, OTHER HEART	1 (1.0%)	0	1 (0.5%)
ORAL SOFT TISSUE DIS	1 (1.0%)	0	1 (0.5%)
PROCEDURE, SURGERY UNSP	1 (1.0%)	0	1 (0.5%)
PROTEINURIA	1 (1.0%)	0	1 (0.5%)
RHINITIS,NOS	1 (1.0%)	0	1 (0.5%)
SCARRING	1 (1.0%)	0	1 (0.5%)
SPRAINS/STRAINS	1 (1.0%)	0	1 (0.5%)
UPPER RESP DISORD, OTHER	1 (1.0%)	0	1 (0.5%)
VISUAL DISTURB	1 (1.0%)	0	1 (0.5%)
OPERATION, HERNIA REPAIR	0	3 (2.9%)	3 (1.5%)
GENITAL FEMALE DISORD, OTHER	0	2 (1.9%)	2 (1.0%)
INJURY/POIS, OTHER	0	2 (1.9%)	2 (1.0%)
ALLERGIC REACTION, FOOD	0	1 (1.0%)	1 (0.5%)
BRAIN CONDIT, OTHER	0	1 (1.0%)	1 (0.5%)
CONG ANOM, HEART	0	1 (1.0%)	1 (0.5%)
CONGEN ANOM, EAR	0	1 (1.0%)	1 (0.5%)
CONGEN ANOM, HEAD/NECK	0	1 (1.0%)	1 (0.5%)
CONSTIPATION	0	1 (1.0%)	1 (0.5%)
CYST, SEBACEOUS	0	1 (1.0%)	1 (0.5%)
DIGESTIVE DISORD, OTHER	0	1 (1.0%)	1 (0.5%)
ENTERITIS/COLITIS	0	1 (1.0%)	1 (0.5%)
FLUSHING	0	1 (1.0%)	1 (0.5%)
GLYCOSURIA	0	1 (1.0%)	1 (0.5%)
HEARTBURN	0	1 (1.0%)	1 (0.5%)
HYPERACTIVITY	0	1 (1.0%)	1 (0.5%)
HYPOTHYROIDISM	0	1 (1.0%)	1 (0.5%)
HYPOTHYROIDISM, CONGENITAL	0	1 (1.0%)	1 (0.5%)
LYMPHADENOPATHY	0	1 (1.0%)	1 (0.5%)
MENINGITIS	0	1 (1.0%)	1 (0.5%)

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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=98)	Placebo (N=105)	Total (N=203)
MYCOSES	0	1 (1.0%)	1 (0.5%)
NASOPHARYNGITIS, ACUTE	0	1 (1.0%)	1 (0.5%)
NAUSEA AND VOMITING	0	1 (1.0%)	1 (0.5%)
OBESITY	0	1 (1.0%)	1 (0.5%)
OPERATION, APPENDIX	0	1 (1.0%)	1 (0.5%)
OPERATION, FEM GENITAL	0	1 (1.0%)	1 (0.5%)
OPERATION, SKIN/SUBCUT	0	1 (1.0%)	1 (0.5%)
PAIN, ABDOMINO-PELVIC	0	1 (1.0%)	1 (0.5%)
POTASSIUM ELEVATED, SERUM	0	1 (1.0%)	1 (0.5%)
STOMACH/DUODENUM DISORD	0	1 (1.0%)	1 (0.5%)
TONGUE DISORD	0	1 (1.0%)	1 (0.5%)
TOXIC EFFECTS, NONMEDICINAL	0	1 (1.0%)	1 (0.5%)
TRAUMA/INJURIES, UNSPEC	0	1 (1.0%)	1 (0.5%)
URINARY TRACT INFECTION	0	1 (1.0%)	1 (0.5%)
URTICARIA	0	1 (1.0%)	1 (0.5%)
VIRAL INFECTION	0	1 (1.0%)	1 (0.5%)
VIRUS/CHLAMYD DIS, OTHER	0	1 (1.0%)	1 (0.5%)

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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=98)	Placebo (N=105)	Total (N=203)
Patients with at least one Active Condition		54 (55.1%)	68 (64.8%)	122 (60.1%)
CARDIOVASCULAR	Total	7 (7.1%)	9 (8.6%)	16 (7.9%)
	ARRHYTHMIA	1 (1.0%)	0	1 (0.5%)
	CARDIAC MURMURS	1 (1.0%)	2 (1.9%)	3 (1.5%)
	CONDUCTION DISORD	1 (1.0%)	0	1 (0.5%)
	CONG ANOM, HEART	1 (1.0%)	1 (1.0%)	2 (1.0%)
	CONG ANOM, INTEGUMENT	1 (1.0%)	1 (1.0%)	2 (1.0%)
	FLUSHING	0	1 (1.0%)	1 (0.5%)
	MIGRAINE	2 (2.0%)	1 (1.0%)	3 (1.5%)
	MITRAL VALVE DISORD	1 (1.0%)	1 (1.0%)	2 (1.0%)
	PALPITATIONS	0	1 (1.0%)	1 (0.5%)
	TACHYCARDIA, UNSPEC	0	1 (1.0%)	1 (0.5%)
CAUSES OF INJURY	Total	8 (8.2%)	9 (8.6%)	17 (8.4%)
	ADVERSE EFF/ANALGESIC	2 (2.0%)	0	2 (1.0%)
	ADVERSE EFF/ANTI-INFECT	2 (2.0%)	2 (1.9%)	4 (2.0%)
	ADVERSE EFF/ANTIBIOTIC	4 (4.1%)	8 (7.6%)	12 (5.9%)
	ADVERSE EFF/PSYCHOTROPICS	1 (1.0%)	0	1 (0.5%)
	ADVERSE EFF/VACCINE	1 (1.0%)	0	1 (0.5%)
DIGESTIVE	Total	3 (3.1%)	10 (9.5%)	13 (6.4%)
	CONSTIPATION	0	1 (1.0%)	1 (0.5%)
	DIGESTIVE DISORD, OTHER	1 (1.0%)	2 (1.9%)	3 (1.5%)
	DRY MOUTH	1 (1.0%)	0	1 (0.5%)
	DYSPEPSIA	0	1 (1.0%)	1 (0.5%)
	ENTERITIS/COLITIS	0	1 (1.0%)	1 (0.5%)
	ESOPHAGITIS	0	1 (1.0%)	1 (0.5%)
	GASTROINTEST PROB, NEC	1 (1.0%)	0	1 (0.5%)
	HEARTBURN	0	1 (1.0%)	1 (0.5%)
	INTEST MALABSORPTION	0	1 (1.0%)	1 (0.5%)
	NAUSEA	1 (1.0%)	2 (1.9%)	3 (1.5%)
	NAUSEA AND VOMITING	0	1 (1.0%)	1 (0.5%)
	TEETH DISORD	0	1 (1.0%)	1 (0.5%)
ENDOCRINE	Total	0	2 (1.9%)	2 (1.0%)
	HYPOTHYROIDISM	0	1 (1.0%)	1 (0.5%)
	HYPOTHYROIDISM, CONGENITAL	0	1 (1.0%)	1 (0.5%)
GENERAL BODY OR SYS UNSPEC	Total	19 (19.4%)	22 (21.0%)	41 (20.2%)
	ALLERGIC REACTION, FOOD	3 (3.1%)	4 (3.8%)	7 (3.4%)
	ALLERGY, NEC	3 (3.1%)	5 (4.8%)	8 (3.9%)
	BACT DIS, OTHER	1 (1.0%)	0	1 (0.5%)
	HEADACHE	9 (9.2%)	10 (9.5%)	19 (9.4%)
	INJURY, SUPERFICIAL	1 (1.0%)	0	1 (0.5%)

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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=98)	Placebo (N=105)	Total (N=203)
GENERAL BODY OR SYS UNSPEC	MOTION SICKNESS	1 (1.0%)	0	1 (0.5%)
	MYCOSES	0	1 (1.0%)	1 (0.5%)
	PAIN UNSP, CHEST	0	1 (1.0%)	1 (0.5%)
	PAIN, ABDOMINO-PELVIC	3 (3.1%)	2 (1.9%)	5 (2.5%)
	PAIN, LIMB	1 (1.0%)	0	1 (0.5%)
	SOFT TISSUE DISORD	1 (1.0%)	1 (1.0%)	2 (1.0%)
	TOXIC EFFECTS, VENOM	0	1 (1.0%)	1 (0.5%)
	VIRAL DIS/EXANTHEM	1 (1.0%)	0	1 (0.5%)
GENITOURINARY	Total	3 (3.1%)	6 (5.7%)	9 (4.4%)
	CONG ANOM, GU	0	1 (1.0%)	1 (0.5%)
	GENITAL FEMALE DISORD, OTHER	1 (1.0%)	1 (1.0%)	2 (1.0%)
	GYNECOMASTIA	0	1 (1.0%)	1 (0.5%)
	HEMATURIA	2 (2.0%)	2 (1.9%)	4 (2.0%)
	MASS, BREAST	1 (1.0%)	0	1 (0.5%)
	URINE, ABN, OTHER	0	1 (1.0%)	1 (0.5%)
HEMATIC/HEMATOPOIETIC/LYMPH	Total	2 (2.0%)	1 (1.0%)	3 (1.5%)
	ANEMIA, OTHER	1 (1.0%)	0	1 (0.5%)
	LEUCOCYTOSIS	1 (1.0%)	0	1 (0.5%)
	LYMPHADENOPATHY	0	1 (1.0%)	1 (0.5%)
INTEGUMENTARY	Total	11 (11.2%)	11 (10.5%)	22 (10.8%)
	DYSCHROMIA	1 (1.0%)	0	1 (0.5%)
	HYPERHIDROSIS	1 (1.0%)	0	1 (0.5%)
	INFLAM SKIN/SUBCUT	2 (2.0%)	4 (3.8%)	6 (3.0%)
	NEOPLASMS BENIGN	0	1 (1.0%)	1 (0.5%)
	OPERATION, SKIN/SUBCUT	1 (1.0%)	1 (1.0%)	2 (1.0%)
	RASH/OTHER SKIN ERUPTION	0	1 (1.0%)	1 (0.5%)
	SKIN/SUBCUT DISORD, OTHER	6 (6.1%)	5 (4.8%)	11 (5.4%)
	URTICARIA	0	1 (1.0%)	1 (0.5%)
	VIRUS/CHLAMYD DIS, OTHER	0	1 (1.0%)	1 (0.5%)
METABOLIC/NUTRITIONAL/IMMUNE	Total	2 (2.0%)	5 (4.8%)	7 (3.4%)
	ANOREXIA	0	1 (1.0%)	1 (0.5%)
	CARBOHYDRATE DISORD	1 (1.0%)	1 (1.0%)	2 (1.0%)
	HYPOGLYCEMIA	1 (1.0%)	0	1 (0.5%)
	OBESITY	0	3 (2.9%)	3 (1.5%)
MUSCULOSKELETAL	Total	2 (2.0%)	4 (3.8%)	6 (3.0%)
	ARTHRITIS, RHEUMATOID	0	1 (1.0%)	1 (0.5%)
	CONG ANOM, MUSCULOSKEL	0	1 (1.0%)	1 (0.5%)
	CRAMP, LIMB	1 (1.0%)	1 (1.0%)	2 (1.0%)
	DEFORMITY, ACQUIRED	1 (1.0%)	1 (1.0%)	2 (1.0%)
	FRACTURE, UPPER LIMB	0	1 (1.0%)	1 (0.5%)

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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=98)	Placebo (N=105)	Total (N=203)
NERVOUS/SENSE ORGANS	Total	7 (7.1%)	18 (17.1%)	25 (12.3%)
	AUT NERV SYST DISORD	0	1 (1.0%)	1 (0.5%)
	BRAIN CONDIT, OTHER	0	1 (1.0%)	1 (0.5%)
	CONGEN ANOM, EAR	0	1 (1.0%)	1 (0.5%)
	CONGEN ANOM, HEAD/NECK	0	1 (1.0%)	1 (0.5%)
	DISTURBANCE, SPEECH	1 (1.0%)	0	1 (0.5%)
	DYSFUNCTION, SYMBOLIC	0	2 (1.9%)	2 (1.0%)
	EAR/MASTOID DISORD	0	3 (2.9%)	3 (1.5%)
	EYE DISORD, OTHER	0	1 (1.0%)	1 (0.5%)
	HEARING LOSS	1 (1.0%)	2 (1.9%)	3 (1.5%)
	HYPERACTIVITY	0	1 (1.0%)	1 (0.5%)
	INSOMNIA	1 (1.0%)	1 (1.0%)	2 (1.0%)
	LACK OF COORDINATION	0	1 (1.0%)	1 (0.5%)
	OTITIS MEDIA	1 (1.0%)	5 (4.8%)	6 (3.0%)
	REFLEX, ABN	0	1 (1.0%)	1 (0.5%)
	TICS	1 (1.0%)	0	1 (0.5%)
	VISUAL DISTURB	2 (2.0%)	2 (1.9%)	4 (2.0%)
PSYCHOLOGICAL DISORDERS	Total	2 (2.0%)	1 (1.0%)	3 (1.5%)
	MENTAL DEVELOP DISORD	0	1 (1.0%)	1 (0.5%)
	MENTAL STATUS, IMPAIRED	1 (1.0%)	0	1 (0.5%)
	STAMMERING/STUTTERING	1 (1.0%)	0	1 (0.5%)
RESPIRATORY	Total	26 (26.5%)	33 (31.4%)	59 (29.1%)
	ASTHMA	10 (10.2%)	8 (7.6%)	18 (8.9%)
	BRONCHITIS, OTHER	1 (1.0%)	1 (1.0%)	2 (1.0%)
	EPISTAXIS	2 (2.0%)	0	2 (1.0%)
	INFECTION, BACTERIAL	0	2 (1.9%)	2 (1.0%)
	INFLUENZA	0	1 (1.0%)	1 (0.5%)
	RHINITIS, ALLERGIC	18 (18.4%)	22 (21.0%)	40 (19.7%)
	RHINITIS,NOS	1 (1.0%)	0	1 (0.5%)
	SINUSITIS,NOS	0	3 (2.9%)	3 (1.5%)
	UPPER RESP INFECT, ACUTE	1 (1.0%)	0	1 (0.5%)

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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=98)	Placebo (N=105)	Total (N=203)
Patients with at least one Active Condition	54 (55.1%)	68 (64.8%)	122 (60.1%)
RHINITIS, ALLERGIC	18 (18.4%)	22 (21.0%)	40 (19.7%)
ASTHMA	10 (10.2%)	8 (7.6%)	18 (8.9%)
HEADACHE	9 (9.2%)	10 (9.5%)	19 (9.4%)
SKIN/SUBCUT DISORD, OTHER	6 (6.1%)	5 (4.8%)	11 (5.4%)
ADVERSE EFF/ANTIBIOTIC	4 (4.1%)	8 (7.6%)	12 (5.9%)
ALLERGY, NEC	3 (3.1%)	5 (4.8%)	8 (3.9%)
ALLERGIC REACTION, FOOD	3 (3.1%)	4 (3.8%)	7 (3.4%)
PAIN, ABDOMINO-PELVIC	3 (3.1%)	2 (1.9%)	5 (2.5%)
INFLAM SKIN/SUBCUT	2 (2.0%)	4 (3.8%)	6 (3.0%)
ADVERSE EFF/ANTI-INFECT	2 (2.0%)	2 (1.9%)	4 (2.0%)
HEMATURIA	2 (2.0%)	2 (1.9%)	4 (2.0%)
VISUAL DISTURB	2 (2.0%)	2 (1.9%)	4 (2.0%)
MIGRAINE	2 (2.0%)	1 (1.0%)	3 (1.5%)
ADVERSE EFF/ANALGESIC	2 (2.0%)	0	2 (1.0%)
EPISTAXIS	2 (2.0%)	0	2 (1.0%)
OTITIS MEDIA	1 (1.0%)	5 (4.8%)	6 (3.0%)
CARDIAC MURMURS	1 (1.0%)	2 (1.9%)	3 (1.5%)
DIGESTIVE DISORD, OTHER	1 (1.0%)	2 (1.9%)	3 (1.5%)
HEARING LOSS	1 (1.0%)	2 (1.9%)	3 (1.5%)
NAUSEA	1 (1.0%)	2 (1.9%)	3 (1.5%)
BRONCHITIS, OTHER	1 (1.0%)	1 (1.0%)	2 (1.0%)
CARBOHYDRATE DISORD	1 (1.0%)	1 (1.0%)	2 (1.0%)
CONG ANOM, HEART	1 (1.0%)	1 (1.0%)	2 (1.0%)
CONG ANOM, INTEGUMENT	1 (1.0%)	1 (1.0%)	2 (1.0%)
CRAMP, LIMB	1 (1.0%)	1 (1.0%)	2 (1.0%)
DEFORMITY, ACQUIRED	1 (1.0%)	1 (1.0%)	2 (1.0%)
GENITAL FEMALE DISORD, OTHER	1 (1.0%)	1 (1.0%)	2 (1.0%)
INSOMNIA	1 (1.0%)	1 (1.0%)	2 (1.0%)
MITRAL VALVE DISORD	1 (1.0%)	1 (1.0%)	2 (1.0%)
OPERATION, SKIN/SUBCUT	1 (1.0%)	1 (1.0%)	2 (1.0%)
SOFT TISSUE DISORD	1 (1.0%)	1 (1.0%)	2 (1.0%)
ADVERSE EFF/PSYCHOTROPICS	1 (1.0%)	0	1 (0.5%)
ADVERSE EFF/VACCINE	1 (1.0%)	0	1 (0.5%)
ANEMIA, OTHER	1 (1.0%)	0	1 (0.5%)
ARRHYTHMIA	1 (1.0%)	0	1 (0.5%)
BACT DIS, OTHER	1 (1.0%)	0	1 (0.5%)
CONDUCTION DISORD	1 (1.0%)	0	1 (0.5%)
DISTURBANCE, SPEECH	1 (1.0%)	0	1 (0.5%)
DRY MOUTH	1 (1.0%)	0	1 (0.5%)
DYSCHROMIA	1 (1.0%)	0	1 (0.5%)
GASTROINTEST PROB, NEC	1 (1.0%)	0	1 (0.5%)
HYPERHIDROSIS	1 (1.0%)	0	1 (0.5%)
HYPOGLYCEMIA	1 (1.0%)	0	1 (0.5%)
INJURY, SUPERFICIAL	1 (1.0%)	0	1 (0.5%)

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=98)	Placebo (N=105)	Total (N=203)
LEUCOCYTOSIS	1 (1.0%)	0	1 (0.5%)
MASS, BREAST	1 (1.0%)	0	1 (0.5%)
MENTAL STATUS, IMPAIRED	1 (1.0%)	0	1 (0.5%)
MOTION SICKNESS	1 (1.0%)	0	1 (0.5%)
PAIN, LIMB	1 (1.0%)	0	1 (0.5%)
RHINITIS,NOS	1 (1.0%)	0	1 (0.5%)
STAMMERING/STUTTERING	1 (1.0%)	0	1 (0.5%)
TICS	1 (1.0%)	0	1 (0.5%)
UPPER RESP INFECT, ACUTE	1 (1.0%)	0	1 (0.5%)
VIRAL DIS/EXANTHEM	1 (1.0%)	0	1 (0.5%)
EAR/MASTOID DISORD	0	3 (2.9%)	3 (1.5%)
OBESITY	0	3 (2.9%)	3 (1.5%)
SINUSITIS,NOS	0	3 (2.9%)	3 (1.5%)
DYSFUNCTION, SYMBOLIC	0	2 (1.9%)	2 (1.0%)
INFECTION, BACTERIAL	0	2 (1.9%)	2 (1.0%)
ANOREXIA	0	1 (1.0%)	1 (0.5%)
ARTHRITIS, RHEUMATOID	0	1 (1.0%)	1 (0.5%)
AUT NERV SYST DISORD	0	1 (1.0%)	1 (0.5%)
BRAIN CONDIT, OTHER	0	1 (1.0%)	1 (0.5%)
CONG ANOM, GU	0	1 (1.0%)	1 (0.5%)
CONG ANOM, MUSCULOSKEL	0	1 (1.0%)	1 (0.5%)
CONGEN ANOM, EAR	0	1 (1.0%)	1 (0.5%)
CONGEN ANOM, HEAD/NECK	0	1 (1.0%)	1 (0.5%)
CONSTIPATION	0	1 (1.0%)	1 (0.5%)
DYSPEPSIA	0	1 (1.0%)	1 (0.5%)
ENTERITIS/COLITIS	0	1 (1.0%)	1 (0.5%)
ESOPHAGITIS	0	1 (1.0%)	1 (0.5%)
EYE DISORD, OTHER	0	1 (1.0%)	1 (0.5%)
FLUSHING	0	1 (1.0%)	1 (0.5%)
FRACTURE, UPPER LIMB	0	1 (1.0%)	1 (0.5%)
GYNECOMASTIA	0	1 (1.0%)	1 (0.5%)
HEARTBURN	0	1 (1.0%)	1 (0.5%)
HYPERACTIVITY	0	1 (1.0%)	1 (0.5%)
HYPOTHYROIDISM	0	1 (1.0%)	1 (0.5%)
HYPOTHYROIDISM, CONGENITAL	0	1 (1.0%)	1 (0.5%)
INFLUENZA	0	1 (1.0%)	1 (0.5%)
INTEST MALABSORPTION	0	1 (1.0%)	1 (0.5%)
LACK OF COORDINATION	0	1 (1.0%)	1 (0.5%)
LYMPHADENOPATHY	0	1 (1.0%)	1 (0.5%)
MENTAL DEVELOP DISORD	0	1 (1.0%)	1 (0.5%)
MYCOSES	0	1 (1.0%)	1 (0.5%)
NAUSEA AND VOMITING	0	1 (1.0%)	1 (0.5%)
NEOPLASMS BENIGN	0	1 (1.0%)	1 (0.5%)
PAIN UNSP, CHEST	0	1 (1.0%)	1 (0.5%)
PALPITATIONS	0	1 (1.0%)	1 (0.5%)
RASH/OTHER SKIN ERUPTION	0	1 (1.0%)	1 (0.5%)

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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=98)	Placebo (N=105)	Total (N=203)
REFLEX, ABN	0	1 (1.0%)	1 (0.5%)
TACHYCARDIA, UNSPEC	0	1 (1.0%)	1 (0.5%)
TEETH DISORD	0	1 (1.0%)	1 (0.5%)
TOXIC EFFECTS, VENOM	0	1 (1.0%)	1 (0.5%)
URINE, ABN, OTHER	0	1 (1.0%)	1 (0.5%)
URTICARIA	0	1 (1.0%)	1 (0.5%)
VIRUS/CHLAMYD DIS, OTHER	0	1 (1.0%)	1 (0.5%)

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Table 13.7.1

History of OCD - Summary Statistics For Age at First Onset and Overall Duration

Intention-To-Treat Population

Age Group : Children

		Treatment Group		
		Paroxetine (N=58)	Placebo (N=57)	Total (N=115)
Age at First Onset of OCD(Years)	N	57	57	114
	MEAN	6.1	6.0	6.1
	MEDIAN	6.0	6.0	6.0
	STDDEV	2.32	2.55	2.43
	MINIMUM	2	2	2
	MAXIMUM	11	11	11
	MISSING	1	0	1
Overall Duration of OCD(Days)*	N	57	57	114
	MEAN	1178.4	1300.8	1239.6
	MEDIAN	1049.0	1135.0	1105.0
	STDDEV	808.49	796.93	801.53
	MINIMUM	98	90	90
	MAXIMUM	3648	3497	3648
	MISSING	1	0	1

* Overall Duration = Screening Date - Date of First Onset of OCD + 1
Note: Date of first onset of OCD = Age at First Onset (years and months) + Date of Birth
e.g. DOB=26-Oct-86, Age at first Onset 12yrs 11 mths and therefore Date of First Onset=26-Sep-99

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Table 13.7.1

History of OCD - Summary Statistics For Age at First Onset and Overall Duration

Intention-To-Treat Population

Age Group : Adolescents

		Treatment Group		
		Paroxetine (N=40)	Placebo (N=48)	Total (N=88)
Age at First Onset of OCD(Years)	N	40	48	88
	MEAN	9.3	9.3	9.3
	MEDIAN	9.0	9.5	9.0
	STDDEV	3.10	2.81	2.93
	MINIMUM	2	4	2
	MAXIMUM	14	14	14
	MISSING	0	0	0
Overall Duration of OCD(Days)*	N	40	48	88
	MEAN	1948.7	1954.6	1951.9
	MEDIAN	1658.5	1743.0	1710.0
	STDDEV	1275.32	1148.48	1200.70
	MINIMUM	191	52	52
	MAXIMUM	5495	4968	5495
	MISSING	0	0	0

* Overall Duration = Screening Date - Date of First Onset of OCD + 1
Note: Date of first onset of OCD = Age at First Onset (years and months) + Date of Birth
e.g. DOB=26-Oct-86, Age at first Onset 12yrs 11 mths and therefore Date of First Onset=26-Sep-99

Table 13.7.1

History of OCD - Summary Statistics For Age at First Onset and Overall Duration

Intention-To-Treat Population

Age Group : Total

		Treatment Group		
		Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
Age at First Onset of OCD(Years)	N	97	105	202
	MEAN	7.4	7.5	7.5
	MEDIAN	7.0	8.0	7.0
	STDDEV	3.08	3.12	3.09
	MINIMUM	2	2	2
	MAXIMUM	14	14	14
	MISSING	1	0	1
Overall Duration of OCD(Days)*	N	97	105	202
	MEAN	1496.0	1599.7	1549.9
	MEDIAN	1390.0	1347.0	1384.0
	STDDEV	1089.64	1022.35	1053.83
	MINIMUM	98	52	52
	MAXIMUM	5495	4968	5495
	MISSING	1	0	1

* Overall Duration = Screening Date - Date of First Onset of OCD + 1
Note: Date of first onset of OCD = Age at First Onset (years and months) + Date of Birth
e.g. DOB=26-Oct-86, Age at first Onset 12yrs 11 mths and therefore Date of First Onset=26-Sep-99

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Table 13.7.2

History of OCD - Frequency Distribution for Family History, Hospitalisation, Tic Disorder and Current Treatment
Intention-To-Treat Population

Age Group : Children

		Treatment Group Paroxetine (N=58)	Placebo (N=57)	Total (N=115)
Family Members History*	None	20 (34.5%)	27 (47.4%)	47 (40.9%)
	Mother	17 (29.3%)	15 (26.3%)	32 (27.8%)
	Father	7 (12.1%)	9 (15.8%)	16 (13.9%)
	Sibling	11 (19.0%)	7 (12.3%)	18 (15.7%)
	Grandparent	9 (15.5%)	13 (22.8%)	22 (19.1%)
	Other	9 (15.5%)	2 (3.5%)	11 (9.6%)
No. of times Hospitalised for OCD	Never	58 (100.0%)	57 (100.0%)	115 (100.0%)
	1 time	0	0	0
	2 times	0	0	0
	3 times	0	0	0
	4 times	0	0	0
	>=5 times	0	0	0
Tic Disorder or Fam.hist. of Tic Disorder	Yes	5 (8.6%)	7 (12.3%)	12 (10.4%)
	No	53 (91.4%)	50 (87.7%)	103 (89.6%)
Treatment for Current Episode	No Therapy	41 (70.7%)	42 (73.7%)	83 (72.2%)
	Psychotherapy	8 (13.8%)	3 (5.3%)	11 (9.6%)
	Pharmacotherapy	6 (10.3%)	10 (17.5%)	16 (13.9%)
	Both Psychotherapy and Pharmacotherapy	3 (5.2%)	2 (3.5%)	5 (4.3%)

* More than one response possible

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Table 13.7.2

History of OCD - Frequency Distribution for Family History, Hospitalisation, Tic Disorder and Current Treatment
Intention-To-Treat Population

Age Group : Adolescents

		Treatment Group Paroxetine (N=40)	Placebo (N=48)	Total (N=88)
Family Members History*	None	20 (50.0%)	20 (41.7%)	40 (45.5%)
	Mother	11 (27.5%)	10 (20.8%)	21 (23.9%)
	Father	9 (22.5%)	13 (27.1%)	22 (25.0%)
	Sibling	6 (15.0%)	5 (10.4%)	11 (12.5%)
	Grandparent	8 (20.0%)	9 (18.8%)	17 (19.3%)
	Other	2 (5.0%)	6 (12.5%)	8 (9.1%)
No. of times Hospitalised for OCD	Never	40 (100.0%)	46 (95.8%)	86 (97.7%)
	1 time	0	1 (2.1%)	1 (1.1%)
	2 times	0	1 (2.1%)	1 (1.1%)
	3 times	0	0	0
	4 times	0	0	0
	>=5 times	0	0	0
Tic Disorder or Fam.hist. of Tic Disorder	Yes	5 (12.5%)	9 (18.8%)	14 (15.9%)
	No	35 (87.5%)	39 (81.3%)	74 (84.1%)
Treatment for Current Episode	No Therapy	29 (72.5%)	29 (60.4%)	58 (65.9%)
	Psychotherapy	5 (12.5%)	4 (8.3%)	9 (10.2%)
	Pharmacotherapy	1 (2.5%)	8 (16.7%)	9 (10.2%)
	Both Psychotherapy and Pharmacotherapy	5 (12.5%)	7 (14.6%)	12 (13.6%)

* More than one response possible

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Table 13.7.2

History of OCD - Frequency Distribution for Family History, Hospitalisation, Tic Disorder and Current Treatment
Intention-To-Treat Population

Age Group : Total

		Treatment Group Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
Family Members History*	None	40 (40.8%)	47 (44.8%)	87 (42.9%)
	Mother	28 (28.6%)	25 (23.8%)	53 (26.1%)
	Father	16 (16.3%)	22 (21.0%)	38 (18.7%)
	Sibling	17 (17.3%)	12 (11.4%)	29 (14.3%)
	Grandparent	17 (17.3%)	22 (21.0%)	39 (19.2%)
	Other	11 (11.2%)	8 (7.6%)	19 (9.4%)
No. of times Hospitalised for OCD	Never	98 (100.0%)	103 (98.1%)	201 (99.0%)
	1 time	0	1 (1.0%)	1 (0.5%)
	2 times	0	1 (1.0%)	1 (0.5%)
	3 times	0	0	0
	4 times	0	0	0
	>=5 times	0	0	0
Tic Disorder or Fam.hist. of Tic Disorder	Yes	10 (10.2%)	16 (15.2%)	26 (12.8%)
	No	88 (89.8%)	89 (84.8%)	177 (87.2%)
Treatment for Current Episode	No Therapy	70 (71.4%)	71 (67.6%)	141 (69.5%)
	Psychotherapy	13 (13.3%)	7 (6.7%)	20 (9.9%)
	Pharmacotherapy	7 (7.1%)	18 (17.1%)	25 (12.3%)
	Both Psychotherapy and Pharmacotherapy	8 (8.2%)	9 (8.6%)	17 (8.4%)

* More than one response possible

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Table 13.8.1

Psychiatric History from the KSADS-PL

Intention-To-Treat Population

Age Group : Children

Psychiatric Disorder	Past/Current/Both/NA	Treatment Group Paroxetine (N=58)	Placebo (N=57)	Total (N=115)
Major Depressive Disorder	Past	1 (1.7%)	1 (1.8%)	2 (1.7%)
	N/A	57 (98.3%)	56 (98.2%)	113 (98.3%)
Psychotic Features	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Dysthymia	Both	0	1 (1.8%)	1 (0.9%)
	N/A	58 (100.0%)	56 (98.2%)	114 (99.1%)
Depressive Disorder NOS	Past	1 (1.7%)	0	1 (0.9%)
	N/A	57 (98.3%)	57 (100.0%)	114 (99.1%)
Adj. Disorder w Depressed Mood	Past	1 (1.7%)	0	1 (0.9%)
	Both	0	1 (1.8%)	1 (0.9%)
	N/A	57 (98.3%)	56 (98.2%)	113 (98.3%)
Mania	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Hypomania	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Cyclothymia	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Bipolar NOS	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Bipolar I	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Bipolar II	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Schizoaffective Disorder - Manic	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Schizoaffective Disorder - Depressed	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Schizophrenia	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Schizophreniform Disorder	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Brief Reactive Psychosis	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Panic Disorder	Current	0	1 (1.8%)	1 (0.9%)
	Both	1 (1.7%)	1 (1.8%)	2 (1.7%)
	N/A	57 (98.3%)	55 (96.5%)	112 (97.4%)
Separation Anxiety Disorder	Past	2 (3.4%)	1 (1.8%)	3 (2.6%)

N/A = no prior/current history or information not available

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Table 13.8.1

Psychiatric History from the KSADS-PL

Intention-To-Treat Population

Age Group : Children

Psychiatric Disorder	Past/Current/Both/NA	Treatment Group Paroxetine (N=58)	Placebo (N=57)	Total (N=115)
Separation Anxiety Disorder	Current	2 (3.4%)	1 (1.8%)	3 (2.6%)
	Both	1 (1.7%)	3 (5.3%)	4 (3.5%)
	N/A	53 (91.4%)	52 (91.2%)	105 (91.3%)
Avoidant Disorder of Childhood	Past	0	2 (3.5%)	2 (1.7%)
	Both	1 (1.7%)	0	1 (0.9%)
	N/A	57 (98.3%)	55 (96.5%)	112 (97.4%)
Simple Phobia	Past	1 (1.7%)	1 (1.8%)	2 (1.7%)
	Current	3 (5.2%)	0	3 (2.6%)
	Both	0	1 (1.8%)	1 (0.9%)
	N/A	54 (93.1%)	55 (96.5%)	109 (94.8%)
Social Phobia	Past	1 (1.7%)	1 (1.8%)	2 (1.7%)
	Both	0	1 (1.8%)	1 (0.9%)
	N/A	57 (98.3%)	55 (96.5%)	112 (97.4%)
Agoraphobia	Past	0	1 (1.8%)	1 (0.9%)
	N/A	58 (100.0%)	56 (98.2%)	114 (99.1%)
Overanxious Disorder	Current	0	3 (5.3%)	3 (2.6%)
	Both	1 (1.7%)	2 (3.5%)	3 (2.6%)
	N/A	57 (98.3%)	52 (91.2%)	109 (94.8%)
Generalized Anxiety Disorder	Past	0	1 (1.8%)	1 (0.9%)
	Current	2 (3.4%)	2 (3.5%)	4 (3.5%)
	Both	1 (1.7%)	2 (3.5%)	3 (2.6%)
	N/A	55 (94.8%)	52 (91.2%)	107 (93.0%)
Obsessive-Compulsive Disorder	Current	28 (48.3%)	19 (33.3%)	47 (40.9%)
	Both	30 (51.7%)	38 (66.7%)	68 (59.1%)
Post-Traumatic Stress Disorder	Past	1 (1.7%)	0	1 (0.9%)
	Both	0	1 (1.8%)	1 (0.9%)
	N/A	57 (98.3%)	56 (98.2%)	113 (98.3%)
Acute Stress Disorder	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Adj. Disorder w Anxious Mood	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Enuresis	Past	2 (3.4%)	3 (5.3%)	5 (4.3%)
	Current	1 (1.7%)	0	1 (0.9%)

N/A = no prior/current history or information not available

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Table 13.8.1

Psychiatric History from the KSADS-PL

Intention-To-Treat Population

Age Group : Children

Psychiatric Disorder	Past/Current/Both/NA	Treatment Group Paroxetine (N=58)	Placebo (N=57)	Total (N=115)
Enuresis	Both	4 (6.9%)	6 (10.5%)	10 (8.7%)
	N/A	51 (87.9%)	48 (84.2%)	99 (86.1%)
Encopresis	Both	1 (1.7%)	1 (1.8%)	2 (1.7%)
	N/A	57 (98.3%)	56 (98.2%)	113 (98.3%)
Anorexia Nervosa	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Bulimia	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Attention Deficit Disorder	Past	2 (3.4%)	0	2 (1.7%)
	Current	4 (6.9%)	5 (8.8%)	9 (7.8%)
	Both	4 (6.9%)	5 (8.8%)	9 (7.8%)
	N/A	48 (82.8%)	47 (82.5%)	95 (82.6%)
Conduct Disorder	Past	0	1 (1.8%)	1 (0.9%)
	Current	0	1 (1.8%)	1 (0.9%)
	Both	1 (1.7%)	0	1 (0.9%)
	N/A	57 (98.3%)	55 (96.5%)	112 (97.4%)
Oppositional Defiant Disorder	Current	1 (1.7%)	0	1 (0.9%)
	Both	1 (1.7%)	2 (3.5%)	3 (2.6%)
	N/A	56 (96.6%)	55 (96.5%)	111 (96.5%)
Adj. Disorder w Dist. of Conduct	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Adj. Dis w. Mixed Mood & Conduct	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Tourettes	Both	1 (1.7%)	0	1 (0.9%)
	N/A	57 (98.3%)	57 (100.0%)	114 (99.1%)
Chronic Motor or Vocal Tic Disorder	Past	0	1 (1.8%)	1 (0.9%)
	Current	0	1 (1.8%)	1 (0.9%)
	N/A	58 (100.0%)	55 (96.5%)	113 (98.3%)
Transient Tic Disorder	Current	2 (3.4%)	1 (1.8%)	3 (2.6%)
	Both	0	2 (3.5%)	2 (1.7%)
	N/A	56 (96.6%)	54 (94.7%)	110 (95.7%)
Alcohol Abuse	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Alcohol Dependence	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)

N/A = no prior/current history or information not available

Table 13.8.1

Psychiatric History from the KSADS-PL

Intention-To-Treat Population

Age Group : Children

Psychiatric Disorder	Past/Current/Both/NA	Treatment Group Paroxetine (N=58)	Placebo (N=57)	Total (N=115)
Substance Abuse	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Substance Dependence	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Mental Retardation	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
Other Psychiatric Disorder	N/A	58 (100.0%)	57 (100.0%)	115 (100.0%)
No Psychiatric Disorder	Past	0	1 (1.8%)	1 (0.9%)
	N/A	58 (100.0%)	56 (98.2%)	114 (99.1%)

N/A = no prior/current history or information not available

Table 13.8.1

Psychiatric History from the KSADS-PL

Intention-To-Treat Population

Age Group : Adolescents

Psychiatric Disorder	Past/Current/Both/NA	Treatment Group Paroxetine (N=40)	Placebo (N=48)	Total (N=88)
Major Depressive Disorder	Past	6 (15.0%)	3 (6.3%)	9 (10.2%)
	N/A	34 (85.0%)	45 (93.8%)	79 (89.8%)
Psychotic Features	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Dysthymia	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Depressive Disorder NOS	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Adj. Disorder w Depressed Mood	Current	0	1 (2.1%)	1 (1.1%)
	N/A	40 (100.0%)	47 (97.9%)	87 (98.9%)
Mania	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Hypomania	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Cyclothymia	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Bipolar NOS	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Bipolar I	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Bipolar II	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Schizoaffective Disorder - Manic	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Schizoaffective Disorder - Depressed	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Schizophrenia	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Schizophreniform Disorder	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Brief Reactive Psychosis	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Panic Disorder	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Separation Anxiety Disorder	Past	1 (2.5%)	2 (4.2%)	3 (3.4%)
	Current	0	1 (2.1%)	1 (1.1%)
	N/A	39 (97.5%)	45 (93.8%)	84 (95.5%)
Avoidant Disorder of Childhood	Both	0	1 (2.1%)	1 (1.1%)
	N/A	40 (100.0%)	47 (97.9%)	87 (98.9%)

N/A = no prior/current history or information not available

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Table 13.8.1

Psychiatric History from the KSADS-PL

Intention-To-Treat Population

Age Group : Adolescents

Psychiatric Disorder	Past/Current/Both/NA	Treatment Group Paroxetine (N=40)	Placebo (N=48)	Total (N=88)
Simple Phobia	Current	1 (2.5%)	4 (8.3%)	5 (5.7%)
	Both	0	1 (2.1%)	1 (1.1%)
	N/A	39 (97.5%)	43 (89.6%)	82 (93.2%)
Social Phobia	Current	1 (2.5%)	1 (2.1%)	2 (2.3%)
	Both	0	2 (4.2%)	2 (2.3%)
	N/A	39 (97.5%)	45 (93.8%)	84 (95.5%)
Agoraphobia	Past	0	1 (2.1%)	1 (1.1%)
	Current	0	1 (2.1%)	1 (1.1%)
	N/A	40 (100.0%)	46 (95.8%)	86 (97.7%)
Overanxious Disorder	Current	2 (5.0%)	1 (2.1%)	3 (3.4%)
	Both	2 (5.0%)	1 (2.1%)	3 (3.4%)
	N/A	36 (90.0%)	46 (95.8%)	82 (93.2%)
Generalized Anxiety Disorder	Current	2 (5.0%)	2 (4.2%)	4 (4.5%)
	Both	2 (5.0%)	1 (2.1%)	3 (3.4%)
	N/A	36 (90.0%)	45 (93.8%)	81 (92.0%)
Obsessive-Compulsive Disorder	Current	14 (35.0%)	21 (43.8%)	35 (39.8%)
	Both	26 (65.0%)	25 (52.1%)	51 (58.0%)
	N/A	0	2 (4.2%)	2 (2.3%)
Post-Traumatic Stress Disorder	Past	0	2 (4.2%)	2 (2.3%)
	N/A	40 (100.0%)	46 (95.8%)	86 (97.7%)
Acute Stress Disorder	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Adj. Disorder w Anxious Mood	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Enuresis	Past	1 (2.5%)	3 (6.3%)	4 (4.5%)
	Both	1 (2.5%)	2 (4.2%)	3 (3.4%)
	N/A	38 (95.0%)	43 (89.6%)	81 (92.0%)
Encopresis	Past	2 (5.0%)	0	2 (2.3%)
	N/A	38 (95.0%)	48 (100.0%)	86 (97.7%)
Anorexia Nervosa	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Bulimia	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)

N/A = no prior/current history or information not available

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Table 13.8.1

Psychiatric History from the KSADS-PL

Intention-To-Treat Population

Age Group : Adolescents

Psychiatric Disorder	Past/Current/Both/NA	Treatment Group Paroxetine (N=40)	Placebo (N=48)	Total (N=88)
Attention Deficit Disorder	Past	1 (2.5%)	5 (10.4%)	6 (6.8%)
	Current	1 (2.5%)	0	1 (1.1%)
	N/A	38 (95.0%)	43 (89.6%)	81 (92.0%)
Conduct Disorder	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Oppositional Defiant Disorder	Current	0	3 (6.3%)	3 (3.4%)
	Both	0	3 (6.3%)	3 (3.4%)
	N/A	40 (100.0%)	42 (87.5%)	82 (93.2%)
Adj. Disorder w Dist. of Conduct	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Adj. Dis w. Mixed Mood & Conduct	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Tourettes	Current	0	2 (4.2%)	2 (2.3%)
	Both	0	1 (2.1%)	1 (1.1%)
	N/A	40 (100.0%)	45 (93.8%)	85 (96.6%)
Chronic Motor or Vocal Tic Disorder	Past	0	2 (4.2%)	2 (2.3%)
	Current	0	1 (2.1%)	1 (1.1%)
	N/A	40 (100.0%)	45 (93.8%)	85 (96.6%)
Transient Tic Disorder	Past	0	1 (2.1%)	1 (1.1%)
	Both	0	1 (2.1%)	1 (1.1%)
	N/A	40 (100.0%)	46 (95.8%)	86 (97.7%)
Alcohol Abuse	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Alcohol Dependence	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Substance Abuse	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Substance Dependence	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Mental Retardation	N/A	40 (100.0%)	48 (100.0%)	88 (100.0%)
Other Psychiatric Disorder	Past	1 (2.5%)	0	1 (1.1%)
	N/A	39 (97.5%)	48 (100.0%)	87 (98.9%)
No Psychiatric Disorder	Past	1 (2.5%)	0	1 (1.1%)
	N/A	39 (97.5%)	48 (100.0%)	87 (98.9%)

N/A = no prior/current history or information not available

Table 13.8.1

Psychiatric History from the KSADS-PL

Intention-To-Treat Population

Age Group : Total

Psychiatric Disorder	Past/Current/Both/NA	Treatment Group Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
Major Depressive Disorder	Past	7 (7.1%)	4 (3.8%)	11 (5.4%)
	N/A	91 (92.9%)	101 (96.2%)	192 (94.6%)
Psychotic Features	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Dysthymia	Both	0	1 (1.0%)	1 (0.5%)
	N/A	98 (100.0%)	104 (99.0%)	202 (99.5%)
Depressive Disorder NOS	Past	1 (1.0%)	0	1 (0.5%)
	N/A	97 (99.0%)	105 (100.0%)	202 (99.5%)
Adj. Disorder w Depressed Mood	Past	1 (1.0%)	0	1 (0.5%)
	Current	0	1 (1.0%)	1 (0.5%)
	Both	0	1 (1.0%)	1 (0.5%)
	N/A	97 (99.0%)	103 (98.1%)	200 (98.5%)
Mania	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Hypomania	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Cyclothymia	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Bipolar NOS	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Bipolar I	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Bipolar II	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Schizoaffective Disorder - Manic	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Schizoaffective Disorder - Depressed	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Schizophrenia	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Schizophreniform Disorder	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Brief Reactive Psychosis	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Panic Disorder	Current	0	1 (1.0%)	1 (0.5%)
	Both	1 (1.0%)	1 (1.0%)	2 (1.0%)
	N/A	97 (99.0%)	103 (98.1%)	200 (98.5%)

N/A = no prior/current history or information not available

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Table 13.8.1

Psychiatric History from the KSADS-PL

Intention-To-Treat Population

Age Group : Total

Psychiatric Disorder	Past/Current/Both/NA	Treatment Group Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
Separation Anxiety Disorder	Past	3 (3.1%)	3 (2.9%)	6 (3.0%)
	Current	2 (2.0%)	2 (1.9%)	4 (2.0%)
	Both	1 (1.0%)	3 (2.9%)	4 (2.0%)
	N/A	92 (93.9%)	97 (92.4%)	189 (93.1%)
Avoidant Disorder of Childhood	Past	0	2 (1.9%)	2 (1.0%)
	Both	1 (1.0%)	1 (1.0%)	2 (1.0%)
	N/A	97 (99.0%)	102 (97.1%)	199 (98.0%)
Simple Phobia	Past	1 (1.0%)	1 (1.0%)	2 (1.0%)
	Current	4 (4.1%)	4 (3.8%)	8 (3.9%)
	Both	0	2 (1.9%)	2 (1.0%)
	N/A	93 (94.9%)	98 (93.3%)	191 (94.1%)
Social Phobia	Past	1 (1.0%)	1 (1.0%)	2 (1.0%)
	Current	1 (1.0%)	1 (1.0%)	2 (1.0%)
	Both	0	3 (2.9%)	3 (1.5%)
	N/A	96 (98.0%)	100 (95.2%)	196 (96.6%)
Agoraphobia	Past	0	2 (1.9%)	2 (1.0%)
	Current	0	1 (1.0%)	1 (0.5%)
	N/A	98 (100.0%)	102 (97.1%)	200 (98.5%)
Overanxious Disorder	Current	2 (2.0%)	4 (3.8%)	6 (3.0%)
	Both	3 (3.1%)	3 (2.9%)	6 (3.0%)
	N/A	93 (94.9%)	98 (93.3%)	191 (94.1%)
Generalized Anxiety Disorder	Past	0	1 (1.0%)	1 (0.5%)
	Current	4 (4.1%)	4 (3.8%)	8 (3.9%)
	Both	3 (3.1%)	3 (2.9%)	6 (3.0%)
	N/A	91 (92.9%)	97 (92.4%)	188 (92.6%)
Obsessive-Compulsive Disorder	Current	42 (42.9%)	40 (38.1%)	82 (40.4%)
	Both	56 (57.1%)	63 (60.0%)	119 (58.6%)
	N/A	0	2 (1.9%)	2 (1.0%)
Post-Traumatic Stress Disorder	Past	1 (1.0%)	2 (1.9%)	3 (1.5%)
	Both	0	1 (1.0%)	1 (0.5%)
	N/A	97 (99.0%)	102 (97.1%)	199 (98.0%)
Acute Stress Disorder	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)

N/A = no prior/current history or information not available

Table 13.8.1

Psychiatric History from the KSADS-PL

Intention-To-Treat Population

Age Group : Total

Psychiatric Disorder	Past/Current/Both/NA	Treatment Group Paroxetine (N=98)		Placebo (N=105)		Total (N=203)	
Adj. Disorder w Anxious Mood	N/A	98	(100.0%)	105	(100.0%)	203	(100.0%)
Enuresis	Past	3	(3.1%)	6	(5.7%)	9	(4.4%)
	Current	1	(1.0%)	0		1	(0.5%)
	Both	5	(5.1%)	8	(7.6%)	13	(6.4%)
	N/A	89	(90.8%)	91	(86.7%)	180	(88.7%)
Encopresis	Past	2	(2.0%)	0		2	(1.0%)
	Both	1	(1.0%)	1	(1.0%)	2	(1.0%)
	N/A	95	(96.9%)	104	(99.0%)	199	(98.0%)
Anorexia Nervosa	N/A	98	(100.0%)	105	(100.0%)	203	(100.0%)
Bulimia	N/A	98	(100.0%)	105	(100.0%)	203	(100.0%)
Attention Deficit Disorder	Past	3	(3.1%)	5	(4.8%)	8	(3.9%)
	Current	5	(5.1%)	5	(4.8%)	10	(4.9%)
	Both	4	(4.1%)	5	(4.8%)	9	(4.4%)
	N/A	86	(87.8%)	90	(85.7%)	176	(86.7%)
Conduct Disorder	Past	0		1	(1.0%)	1	(0.5%)
	Current	0		1	(1.0%)	1	(0.5%)
	Both	1	(1.0%)	0		1	(0.5%)
	N/A	97	(99.0%)	103	(98.1%)	200	(98.5%)
Oppositional Defiant Disorder	Current	1	(1.0%)	3	(2.9%)	4	(2.0%)
	Both	1	(1.0%)	5	(4.8%)	6	(3.0%)
	N/A	96	(98.0%)	97	(92.4%)	193	(95.1%)
Adj. Disorder w Dist. of Conduct	N/A	98	(100.0%)	105	(100.0%)	203	(100.0%)
Adj. Dis w. Mixed Mood & Conduct	N/A	98	(100.0%)	105	(100.0%)	203	(100.0%)
Tourettes	Current	0		2	(1.9%)	2	(1.0%)
	Both	1	(1.0%)	1	(1.0%)	2	(1.0%)
	N/A	97	(99.0%)	102	(97.1%)	199	(98.0%)
Chronic Motor or Vocal Tic Disorder	Past	0		3	(2.9%)	3	(1.5%)
	Current	0		2	(1.9%)	2	(1.0%)
	N/A	98	(100.0%)	100	(95.2%)	198	(97.5%)
Transient Tic Disorder	Past	0		1	(1.0%)	1	(0.5%)

N/A = no prior/current history or information not available

Table 13.8.1

Psychiatric History from the KSADS-PL

Intention-To-Treat Population

Age Group : Total

Psychiatric Disorder	Past/Current/Both/NA	Treatment Group: Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
Transient Tic Disorder	Current	2 (2.0%)	1 (1.0%)	3 (1.5%)
	Both	0	3 (2.9%)	3 (1.5%)
	N/A	96 (98.0%)	100 (95.2%)	196 (96.6%)
Alcohol Abuse	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Alcohol Dependence	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Substance Abuse	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Substance Dependence	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Mental Retardation	N/A	98 (100.0%)	105 (100.0%)	203 (100.0%)
Other Psychiatric Disorder	Past	1 (1.0%)	0	1 (0.5%)
	N/A	97 (99.0%)	105 (100.0%)	202 (99.5%)
No Psychiatric Disorder	Past	1 (1.0%)	1 (1.0%)	2 (1.0%)
	N/A	97 (99.0%)	104 (99.0%)	201 (99.0%)

N/A = no prior/current history or information not available

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Table 13.9.1

Summary Statistics for CY-BOCS Total Score at Screening and Baseline

Intention-To-Treat Population

Age Group : Children

Visit	Statistic	Treatment Group Paroxetine (N=58)	Placebo (N=57)	Total (N=115)
Screening	N	58	56	114
	MEAN	23.5	25.3	24.4
	MEDIAN	23.0	25.0	24.0
	STDDEV	4.65	4.84	4.81
	MINIMUM	16	16	16
	MAXIMUM	36	37	37
	MISSING	0	1	1
Baseline	N	58	57	115
	MEAN	23.8	25.3	24.5
	MEDIAN	23.0	25.0	24.0
	STDDEV	5.00	5.31	5.19
	MINIMUM	16	16	16
	MAXIMUM	36	37	37
	MISSING	0	0	0

Note: 'MISSING' row indicates number of patients with either missing data at screening/baseline or insufficient data to calculate total.

Table 13.9.1

Summary Statistics for CY-BOCS Total Score at Screening and Baseline

Intention-To-Treat Population

Age Group : Adolescents

Visit	Statistic	Treatment Group: Paroxetine (N=40)	Placebo (N=48)	Total (N=88)
Screening	N	40	47	87
	MEAN	25.4	24.8	25.1
	MEDIAN	25.0	25.0	25.0
	STDDEV	4.96	4.57	4.74
	MINIMUM	16	16	16
	MAXIMUM	35	35	35
	MISSING	0	1	1
Baseline	N	40	48	88
	MEAN	25.2	25.3	25.3
	MEDIAN	24.5	25.0	25.0
	STDDEV	4.82	4.79	4.77
	MINIMUM	18	16	16
	MAXIMUM	36	37	37
	MISSING	0	0	0

Note: 'MISSING' row indicates number of patients with either missing data at screening/baseline or insufficient data to calculate total.

Table 13.9.1

Summary Statistics for CY-BOCS Total Score at Screening and Baseline

Intention-To-Treat Population

Age Group : Total

Visit	Statistic	Treatment Group Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
Screening	N	98	103	201
	MEAN	24.3	25.1	24.7
	MEDIAN	24.0	25.0	24.0
	STDDEV	4.85	4.70	4.78
	MINIMUM	16	16	16
	MAXIMUM	36	37	37
	MISSING	0	2	2
Baseline	N	98	105	203
	MEAN	24.4	25.3	24.8
	MEDIAN	23.5	25.0	24.0
	STDDEV	4.95	5.05	5.01
	MINIMUM	16	16	16
	MAXIMUM	36	37	37
	MISSING	0	0	0

Note: 'MISSING' row indicates number of patients with either missing data at screening/baseline or insufficient data to calculate total.

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Table 13.10.1

Number (%) of Patients With Each CGI Severity of Illness Score at Baseline

Intention-To-Treat Population

Age Group : Children

	Treatment Group					
	Paroxetine (N = 58)		Placebo (N = 57)		Total (N = 115)	
	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)	0	0.0	3	5.3	3	2.6
Moderately ill (4)	39	67.2	28	49.1	67	58.3
Markedly ill (5)	15	25.9	16	28.1	31	27.0
Severely ill (6)	3	5.2	10	17.5	13	11.3
Among the most extremely ill patients (7)	1	1.7	0	0.0	1	0.9

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Table 13.10.1

Number (%) of Patients With Each CGI Severity of Illness Score at Baseline

Intention-To-Treat Population

Age Group : Adolescents

	Treatment Group					
	Paroxetine (N = 40)		Placebo (N = 48)		Total (N = 88)	
	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)	0	0.0	1	2.1	1	1.1
Moderately ill (4)	18	45.0	21	43.8	39	44.3
Markedly ill (5)	18	45.0	20	41.7	38	43.2
Severely ill (6)	3	7.5	6	12.5	9	10.2
Among the most extremely ill patients (7)	1	2.5	0	0.0	1	1.1

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Table 13.10.1

Number (%) of Patients With Each CGI Severity of Illness Score at Baseline

Intention-To-Treat Population

Age Group : Total

	Treatment Group					
	Paroxetine (N = 98)		Placebo (N = 105)		Total (N = 203)	
	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)	0	0.0	4	3.8	4	2.0
Moderately ill (4)	57	58.2	49	46.7	106	52.2
Markedly ill (5)	33	33.7	36	34.3	69	34.0
Severely ill (6)	6	6.1	16	15.2	22	10.8
Among the most extremely ill patients (7)	2	2.0	0	0.0	2	1.0

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Table 13.11.1

Summary Statistics for GAF Score at Baseline

Intention-To-Treat Population

Age Group : Children

Visit	Statistic	Treatment Group Paroxetine (N=58)	Placebo (N=57)	Total (N=115)
Baseline	N	58	57	115
	MEAN	53.2	52.3	52.7
	MEDIAN	52.5	51.0	52.0
	STDDEV	6.89	7.57	7.22
	MINIMUM	40	32	32
	MAXIMUM	70	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 13.11.1

Summary Statistics for GAF Score at Baseline

Intention-To-Treat Population

Age Group : Adolescents

Visit	Statistic	Treatment Group Paroxetine (N=40)	Placebo (N=48)	Total (N=88)
Baseline	N	40	48	88
	MEAN	53.8	50.8	52.1
	MEDIAN	52.5	50.0	51.0
	STDDEV	6.19	6.67	6.59
	MINIMUM	44	35	35
	MAXIMUM	70	68	70
	MISSING	0	0	0

Note: 'MISSING' row indicates number of patients with missing data or inadequate information at baseline

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Table 13.11.1

Summary Statistics for GAF Score at Baseline

Intention-To-Treat Population

Age Group : Total

Visit	Statistic	Treatment Group Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
Baseline	N	98	105	203
	MEAN	53.4	51.6	52.5
	MEDIAN	52.5	50.0	52.0
	STDDEV	6.59	7.18	6.94
	MINIMUM	40	32	32
	MAXIMUM	70	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 13.12.1.1

OCD Medication History by Psychoactive Class Identification and Generic Term

Intention-To-Treat Population

Age Group : Children

Psychoactive Class	Generic Term(s)	Treatment Group Paroxetine (N=58)	Placebo (N=57)	Total (N=115)
SSRI	Total	7(12.1%)	8(14.0%)	15(13.0%)
	FLUOXETINE	2(3.4%)	1(1.8%)	3(2.6%)
	FLUVOXAMINE MALEATE	2(3.4%)	4(7.0%)	6(5.2%)
	PAROXETINE	3(5.2%)	3(5.3%)	6(5.2%)
	SERTRALINE HYDROCHLORIDE	2(3.4%)	2(3.5%)	4(3.5%)
MAOI	Total	0	0	0
TCA	Total	1(1.7%)	2(3.5%)	3(2.6%)
	CLOMIPRAMINE HYDROCHLORIDE	1(1.7%)	0	1(0.9%)
	IMIPRAMINE HYDROCHLORIDE	0	2(3.5%)	2(1.7%)
Benzodiazepines	Total	0	1(1.8%)	1(0.9%)
	ALPRAZOLAM	0	1(1.8%)	1(0.9%)
Other psychoactive medications	Total	2(3.4%)	5(8.8%)	7(6.1%)
	AMFEBUTAMONE HYDROCHLORIDE	0	2(3.5%)	2(1.7%)
	AMPHETAMINE ASPARTATE	0	1(1.8%)	1(0.9%)
	AMPHETAMINE SULFATE	0	1(1.8%)	1(0.9%)
	BUSPIRONE HYDROCHLORIDE	1(1.7%)	0	1(0.9%)
	CLONIDINE	0	1(1.8%)	1(0.9%)
	DEXTROAMPHETAMINE SACCHARATE	0	1(1.8%)	1(0.9%)
	DEXTROAMPHETAMINE SULFATE	0	1(1.8%)	1(0.9%)
	HYPERICUM EXTRACT	1(1.7%)	1(1.8%)	2(1.7%)
	NEFAZODONE	1(1.7%)	0	1(0.9%)
	RISPERIDONE	0	1(1.8%)	1(0.9%)
Total *		9(15.5%)	14(24.6%)	23(20.0%)
None		49(84.5%)	43(75.4%)	92(80.0%)

* Total number of patients in one or more psychoactive class

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Table 13.12.1.1

OCD Medication History by Psychoactive Class Identification and Generic Term

Intention-To-Treat Population

Age Group : Adolescents

Psychoactive Class	Generic Term(s)	Treatment Group Paroxetine (N=40)	Placebo (N=48)	Total (N=88)
SSRI	Total	7(17.5%)	14(29.2%)	21(23.9%)
	CITALOPRAM	1(2.5%)	1(2.1%)	2(2.3%)
	FLUOXETINE	4(10.0%)	5(10.4%)	9(10.2%)
	FLUVOXAMINE MALEATE	3(7.5%)	9(18.8%)	12(13.6%)
	PAROXETINE	2(5.0%)	1(2.1%)	3(3.4%)
	SERTRALINE HYDROCHLORIDE	1(2.5%)	4(8.3%)	5(5.7%)
MAOI	Total	0	0	0
TCA	Total	1(2.5%)	4(8.3%)	5(5.7%)
	CLOMIPRAMINE HYDROCHLORIDE	1(2.5%)	4(8.3%)	5(5.7%)
Benzodiazepines	Total	0	1(2.1%)	1(1.1%)
	CLONAZEPAM	0	1(2.1%)	1(1.1%)
Other psychoactive medications	Total	1(2.5%)	3(6.3%)	4(4.5%)
	AMFEBUTAMONE HYDROCHLORIDE	1(2.5%)	0	1(1.1%)
	BUSPIRONE HYDROCHLORIDE	0	1(2.1%)	1(1.1%)
	QUETIAPINE	0	1(2.1%)	1(1.1%)
	RISPERIDONE	0	1(2.1%)	1(1.1%)
	VENLAFAXINE	0	1(2.1%)	1(1.1%)
Total *		7(17.5%)	14(29.2%)	21(23.9%)
None		33(82.5%)	34(70.8%)	67(76.1%)

* Total number of patients in one or more psychoactive class

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Table 13.12.1.1

OCD Medication History by Psychoactive Class Identification and Generic Term

Intention-To-Treat Population

Age Group : Total

Psychoactive Class	Generic Term(s)	Treatment Group Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
SSRI	Total	14(14.3%)	22(21.0%)	36(17.7%)
	CITALOPRAM	1(1.0%)	1(1.0%)	2(1.0%)
	FLUOXETINE	6(6.1%)	6(5.7%)	12(5.9%)
	FLUVOXAMINE MALEATE	5(5.1%)	13(12.4%)	18(8.9%)
	PAROXETINE	5(5.1%)	4(3.8%)	9(4.4%)
	SERTRALINE HYDROCHLORIDE	3(3.1%)	6(5.7%)	9(4.4%)
MAOI	Total	0	0	0
TCA	Total	2(2.0%)	6(5.7%)	8(3.9%)
	CLOMIPRAMINE HYDROCHLORIDE	2(2.0%)	4(3.8%)	6(3.0%)
	IMIPRAMINE HYDROCHLORIDE	0	2(1.9%)	2(1.0%)
Benzodiazepines	Total	0	2(1.9%)	2(1.0%)
	ALPRAZOLAM	0	1(1.0%)	1(0.5%)
	CLONAZEPAM	0	1(1.0%)	1(0.5%)
Other psychoactive medications	Total	3(3.1%)	8(7.6%)	11(5.4%)
	AMFEBUTAMONE HYDROCHLORIDE	1(1.0%)	2(1.9%)	3(1.5%)
	AMPHETAMINE ASPARTATE	0	1(1.0%)	1(0.5%)
	AMPHETAMINE SULFATE	0	1(1.0%)	1(0.5%)
	BUSPIRONE HYDROCHLORIDE	1(1.0%)	1(1.0%)	2(1.0%)
	CLONIDINE	0	1(1.0%)	1(0.5%)
	DEXTROAMPHETAMINE SACCHARATE	0	1(1.0%)	1(0.5%)
	DEXTROAMPHETAMINE SULFATE	0	1(1.0%)	1(0.5%)
	HYPERICUM EXTRACT	1(1.0%)	1(1.0%)	2(1.0%)
	NEFAZODONE	1(1.0%)	0	1(0.5%)
	QUETIAPINE	0	1(1.0%)	1(0.5%)
	RISPERIDONE	0	2(1.9%)	2(1.0%)
	VENLAFAXINE	0	1(1.0%)	1(0.5%)
Total *		16(16.3%)	28(26.7%)	44(21.7%)
None		82(83.7%)	77(73.3%)	159(78.3%)

* Total number of patients in one or more psychoactive class

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Table 13.12.1.2

Number(%) of Patients with Prior OCD Medication by Generic Term ordered by decreasing frequency

Intention-To-Treat Population

Generic Term	Treatment Group Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
Total number of patients with at least one prior psychoactive medication	16 (16.3%)	28 (26.7%)	44 (21.7%)
FLUOXETINE	6 (6.1%)	6 (5.7%)	12 (5.9%)
FLUVOXAMINE MALEATE	5 (5.1%)	13 (12.4%)	18 (8.9%)
PAROXETINE	5 (5.1%)	4 (3.8%)	9 (4.4%)
SERTRALINE HYDROCHLORIDE	3 (3.1%)	6 (5.7%)	9 (4.4%)
CLOMIPRAMINE HYDROCHLORIDE	2 (2.0%)	4 (3.8%)	6 (3.0%)
AMFEBUTAMONE HYDROCHLORIDE	1 (1.0%)	2 (1.9%)	3 (1.5%)
BUSPIRONE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
CITALOPRAM	1 (1.0%)	1 (1.0%)	2 (1.0%)
HYPERICUM EXTRACT	1 (1.0%)	1 (1.0%)	2 (1.0%)
NEFAZODONE	1 (1.0%)	0	1 (0.5%)
IMIPRAMINE HYDROCHLORIDE	0	2 (1.9%)	2 (1.0%)
RISPERIDONE	0	2 (1.9%)	2 (1.0%)
ALPRAZOLAM	0	1 (1.0%)	1 (0.5%)
AMPHETAMINE ASPARTATE	0	1 (1.0%)	1 (0.5%)
AMPHETAMINE SULFATE	0	1 (1.0%)	1 (0.5%)
CLONAZEPAM	0	1 (1.0%)	1 (0.5%)
CLONIDINE	0	1 (1.0%)	1 (0.5%)
DEXTROAMPHETAMINE SACCHARATE	0	1 (1.0%)	1 (0.5%)
DEXTROAMPHETAMINE SULFATE	0	1 (1.0%)	1 (0.5%)
QUETIAPINE	0	1 (1.0%)	1 (0.5%)
VENLAFAXINE	0	1 (1.0%)	1 (0.5%)

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Table 13.12.2.1

Psychoactive Medication History (for Indications Other Than OCD) by Psychoactive Class Identification and Generic Term

Intention-To-Treat Population

Age Group : Children

Psychoactive Class	Generic Term(s)	Treatment Group Paroxetine (N=58)	Placebo (N=57)	Total (N=115)
SSRI	Total	1(1.7%)	0	1(0.9%)
	SERTRALINE HYDROCHLORIDE	1(1.7%)	0	1(0.9%)
MAOI	Total	0	0	0
TCA	Total	0	1(1.8%)	1(0.9%)
	IMIPRAMINE HYDROCHLORIDE	0	1(1.8%)	1(0.9%)
Benzodiazepines	Total	0	0	0
Other psychoactive medications	Total	9(15.5%)	11(19.3%)	20(17.4%)
	AMFEBUTAMONE HYDROCHLORIDE	0	1(1.8%)	1(0.9%)
	AMPHETAMINE ASPARTATE	3(5.2%)	5(8.8%)	8(7.0%)
	AMPHETAMINE SULFATE	3(5.2%)	5(8.8%)	8(7.0%)
	CARBAMAZEPINE	1(1.7%)	0	1(0.9%)
	CLONIDINE	0	1(1.8%)	1(0.9%)
	CYPROHEPTADINE HYDROCHLORIDE	0	1(1.8%)	1(0.9%)
	DEXTROAMPHETAMINE SACCHARATE	3(5.2%)	5(8.8%)	8(7.0%)
	DEXTROAMPHETAMINE SULFATE	3(5.2%)	6(10.5%)	9(7.8%)
	DIPHENHYDRAMINE HYDROCHLORIDE	0	1(1.8%)	1(0.9%)
	HYDROXYZINE EMBONATE	0	1(1.8%)	1(0.9%)
	HYPERICUM EXTRACT	1(1.7%)	0	1(0.9%)
	METHYLPHENIDATE HYDROCHLORIDE	3(5.2%)	4(7.0%)	7(6.1%)
	OLANZAPINE	2(3.4%)	0	2(1.7%)
	RISPERIDONE	1(1.7%)	0	1(0.9%)
	TRAZODONE	0	1(1.8%)	1(0.9%)
	VALPROATE SEMISODIUM	1(1.7%)	0	1(0.9%)
Total *		10(17.2%)	12(21.1%)	22(19.1%)
None		48(82.8%)	45(78.9%)	93(80.9%)

* Total number of patients in one or more psychoactive class
Note that this tabulates medication taken during the three months prior to screening

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Table 13.12.2.1

Psychoactive Medication History (for Indications Other Than OCD) by Psychoactive Class Identification and Generic Term

Intention-To-Treat Population

Age Group : Adolescents

Psychoactive Class	Generic Term(s)	Treatment Group: Paroxetine (N=40)	Placebo (N=48)	Total (N=88)
SSRI	Total	1(2.5%)	2(4.2%)	3(3.4%)
	FLUOXETINE	0	1(2.1%)	1(1.1%)
	PAROXETINE	1(2.5%)	1(2.1%)	2(2.3%)
MAOI	Total	0	0	0
TCA	Total	0	0	0
Benzodiazepines	Total	0	1(2.1%)	1(1.1%)
	DIAZEPAM	0	1(2.1%)	1(1.1%)
Other psychoactive medications	Total	7(17.5%)	3(6.3%)	10(11.4%)
	AMFEBUTAMONE HYDROCHLORIDE	1(2.5%)	1(2.1%)	2(2.3%)
	AMPHETAMINE ASPARTATE	1(2.5%)	0	1(1.1%)
	AMPHETAMINE SULFATE	1(2.5%)	0	1(1.1%)
	BUSPIRONE HYDROCHLORIDE	1(2.5%)	0	1(1.1%)
	CARBAMAZEPINE	0	1(2.1%)	1(1.1%)
	DEXTROAMPHETAMINE SACCHARATE	1(2.5%)	0	1(1.1%)
	DEXTROAMPHETAMINE SULFATE	1(2.5%)	0	1(1.1%)
	GUANFACINE HYDROCHLORIDE	0	1(2.1%)	1(1.1%)
	HYPERICUM EXTRACT	2(5.0%)	0	2(2.3%)
	METHYLPHENIDATE HYDROCHLORIDE	1(2.5%)	0	1(1.1%)
	OLANZAPINE	0	1(2.1%)	1(1.1%)
	VALPROATE SEMISODIUM	1(2.5%)	0	1(1.1%)
	VENLAFAXINE HYDROCHLORIDE	1(2.5%)	0	1(1.1%)
Total *		7(17.5%)	6(12.5%)	13(14.8%)
None		33(82.5%)	42(87.5%)	75(85.2%)

* Total number of patients in one or more psychoactive class
Note that this tabulates medication taken during the three months prior to screening

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Table 13.12.2.1

Psychoactive Medication History (for Indications Other Than OCD) by Psychoactive Class Identification and Generic Term

Intention-To-Treat Population

Age Group : Total

Psychoactive Class	Generic Term(s)	Treatment Group: Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
SSRI	Total	2(2.0%)	2(1.9%)	4(2.0%)
	FLUOXETINE	0	1(1.0%)	1(0.5%)
	PAROXETINE	1(1.0%)	1(1.0%)	2(1.0%)
	SERTRALINE HYDROCHLORIDE	1(1.0%)	0	1(0.5%)
MAOI	Total	0	0	0
TCA	Total	0	1(1.0%)	1(0.5%)
	IMIPRAMINE HYDROCHLORIDE	0	1(1.0%)	1(0.5%)
Benzodiazepines	Total	0	1(1.0%)	1(0.5%)
	DIAZEPAM	0	1(1.0%)	1(0.5%)
Other psychoactive medications	Total	16(16.3%)	14(13.3%)	30(14.8%)
	AMFEBUTAMONE HYDROCHLORIDE	1(1.0%)	2(1.9%)	3(1.5%)
	AMPHETAMINE ASPARTATE	4(4.1%)	5(4.8%)	9(4.4%)
	AMPHETAMINE SULFATE	4(4.1%)	5(4.8%)	9(4.4%)
	BUSPIRONE HYDROCHLORIDE	1(1.0%)	0	1(0.5%)
	CARBAMAZEPINE	1(1.0%)	1(1.0%)	2(1.0%)
	CLONIDINE	0	1(1.0%)	1(0.5%)
	CYPROHEPTADINE HYDROCHLORIDE	0	1(1.0%)	1(0.5%)
	DEXTROAMPHETAMINE SACCHARATE	4(4.1%)	5(4.8%)	9(4.4%)
	DEXTROAMPHETAMINE SULFATE	4(4.1%)	6(5.7%)	10(4.9%)
	DIPHENHYDRAMINE HYDROCHLORIDE	0	1(1.0%)	1(0.5%)
	GUANFACINE HYDROCHLORIDE	0	1(1.0%)	1(0.5%)
	HYDROXYZINE EMBONATE	0	1(1.0%)	1(0.5%)
	HYPERICUM EXTRACT	3(3.1%)	0	3(1.5%)
	METHYLPHENIDATE HYDROCHLORIDE	4(4.1%)	4(3.8%)	8(3.9%)
	OLANZAPINE	2(2.0%)	1(1.0%)	3(1.5%)
	RISPERIDONE	1(1.0%)	0	1(0.5%)
	TRAZODONE	0	1(1.0%)	1(0.5%)
	VALPROATE SEMISODIUM	2(2.0%)	0	2(1.0%)
	VENLAFAXINE HYDROCHLORIDE	1(1.0%)	0	1(0.5%)
Total *		17(17.3%)	18(17.1%)	35(17.2%)
None		81(82.7%)	87(82.9%)	168(82.8%)

* Total number of patients in one or more psychoactive class
Note that this tabulates medication taken during the three months prior to screening

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Table 13.12.2.2

Number (%) of Patients with Prior Psychoactive Medication (for indications other than OCD)
by Generic Term Ordered by Decreasing Frequency
Intention-To-Treat Population

Generic Term	Treatment Group: Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
Total number of patients with at least one prior psychoactive medication	17 (17.3%)	18 (17.1%)	35 (17.2%)
DEXTROAMPHETAMINE SULFATE	4 (4.1%)	6 (5.7%)	10 (4.9%)
AMPHETAMINE ASPARTATE	4 (4.1%)	5 (4.8%)	9 (4.4%)
AMPHETAMINE SULFATE	4 (4.1%)	5 (4.8%)	9 (4.4%)
DEXTROAMPHETAMINE SACCHARATE	4 (4.1%)	5 (4.8%)	9 (4.4%)
METHYLPHENIDATE HYDROCHLORIDE	4 (4.1%)	4 (3.8%)	8 (3.9%)
HYPERICUM EXTRACT	3 (3.1%)	0	3 (1.5%)
OLANZAPINE	2 (2.0%)	1 (1.0%)	3 (1.5%)
VALPROATE SEMISODIUM	2 (2.0%)	0	2 (1.0%)
AMFEBUTAMONE HYDROCHLORIDE	1 (1.0%)	2 (1.9%)	3 (1.5%)
CARBAMAZEPINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
PAROXETINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
BUSPIRONE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
RISPERIDONE	1 (1.0%)	0	1 (0.5%)
SERTRALINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
VENLAFAXINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
CLONIDINE	0	1 (1.0%)	1 (0.5%)
CYPROHEPTADINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
DIAZEPAM	0	1 (1.0%)	1 (0.5%)
DIPHENHYDRAMINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
FLUOXETINE	0	1 (1.0%)	1 (0.5%)
GUANFACINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
HYDROXYZINE EMBONATE	0	1 (1.0%)	1 (0.5%)
IMIPRAMINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
TRAZODONE	0	1 (1.0%)	1 (0.5%)

Note that this tabulates medication taken during the three months prior to screening

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Table 13.12.3.1

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=98)	Placebo (N=105)	Total (N=203)
Total number of patients with at least one prior non-psychoactive medication	Total	38 (38.8%)	49 (46.7%)	87 (42.9%)
ALIMENTARY TRACT/METAB	Total	10 (10.2%)	12 (11.4%)	22 (10.8%)
	ACETYLSALICYLIC ACID	1 (1.0%)	1 (1.0%)	2 (1.0%)
	ALUMINIUM HYDROXIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	ASCORBIC ACID	2 (2.0%)	0	2 (1.0%)
	BISMUTH SUBSALICYLATE	2 (2.0%)	0	2 (1.0%)
	CALCIUM	1 (1.0%)	0	1 (0.5%)
	CALCIUM CARBONATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	DIMETICONE, ACTIVATED	1 (1.0%)	1 (1.0%)	2 (1.0%)
	MAGNESIUM HYDROXIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	MINERALS NOS	1 (1.0%)	0	1 (0.5%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	RANITIDINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
	SENNA FRUIT	0	1 (1.0%)	1 (0.5%)
	TOCOPHEROL	1 (1.0%)	0	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	1 (1.0%)	3 (2.9%)	4 (2.0%)
	VITAMINS NOS	5 (5.1%)	4 (3.8%)	9 (4.4%)
ANTIINFECTIVES,SYSTEMIC	Total	8 (8.2%)	6 (5.7%)	14 (6.9%)
	ACICLOVIR	1 (1.0%)	0	1 (0.5%)
	AMOXICILLIN	2 (2.0%)	1 (1.0%)	3 (1.5%)
	AMOXICILLIN TRIHYDRATE	0	1 (1.0%)	1 (0.5%)
	ANTIBIOTIC NOS	0	1 (1.0%)	1 (0.5%)
	AZITHROMYCIN	0	1 (1.0%)	1 (0.5%)
	CEFALEXIN MONOHYDRATE	1 (1.0%)	0	1 (0.5%)
	CEFIXIME	1 (1.0%)	0	1 (0.5%)
	CLAVULANIC ACID	0	1 (1.0%)	1 (0.5%)
	ERYTHROMYCIN	1 (1.0%)	0	1 (0.5%)
	ERYTHROMYCIN ETHYLSUCCINATE	1 (1.0%)	0	1 (0.5%)
	LORACARBEF	1 (1.0%)	0	1 (0.5%)
	MINOCYCLINE	0	1 (1.0%)	1 (0.5%)
	SULFAMETHOXAZOLE	0	1 (1.0%)	1 (0.5%)
	TRIMETHOPRIM	0	1 (1.0%)	1 (0.5%)
ANTINEOPLASTIC & IMMUNOSUP	Total	1 (1.0%)	1 (1.0%)	2 (1.0%)
	TAMOXIFEN	0	1 (1.0%)	1 (0.5%)
	TRETINOIN	1 (1.0%)	0	1 (0.5%)
BLOOD/BLOOD FORM ORGANS	Total	2 (2.0%)	1 (1.0%)	3 (1.5%)
	ACETYLSALICYLIC ACID	1 (1.0%)	1 (1.0%)	2 (1.0%)
	FISH OIL	1 (1.0%)	0	1 (0.5%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.12.3.1

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=98)	Placebo (N=105)	Total (N=203)
CENTRAL NERVOUS SYSTEM	Total	21 (21.4%)	19 (18.1%)	40 (19.7%)
	ACETYLSALICYLIC ACID	3 (3.1%)	1 (1.0%)	4 (2.0%)
	CAFFEINE	2 (2.0%)	0	2 (1.0%)
	CHLORPHENAMINE MALEATE	0	1 (1.0%)	1 (0.5%)
	DEXTROMETHORPHAN HYDROBROMIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	DOXYLAMINE SUCCINATE	1 (1.0%)	0	1 (0.5%)
	HYDROXYZINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	IBUPROFEN	8 (8.2%)	11 (10.5%)	19 (9.4%)
	IMIPRAMINE	0	1 (1.0%)	1 (0.5%)
	IMIPRAMINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	LIDOCAINE	0	3 (2.9%)	3 (1.5%)
	PARACETAMOL	10 (10.2%)	4 (3.8%)	14 (6.9%)
	PRILOCAINE	0	3 (2.9%)	3 (1.5%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
DERMATOLOGICALS	Total	7 (7.1%)	13 (12.4%)	20 (9.9%)
	BENZOYL PEROXIDE	1 (1.0%)	0	1 (0.5%)
	BUDESONIDE	2 (2.0%)	2 (1.9%)	4 (2.0%)
	CORTISONE	0	1 (1.0%)	1 (0.5%)
	DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	ERYTHROMYCIN	1 (1.0%)	0	1 (0.5%)
	FLUTICASONE PROPIONATE	1 (1.0%)	3 (2.9%)	4 (2.0%)
	LIDOCAINE	0	3 (2.9%)	3 (1.5%)
	PRILOCAINE	0	3 (2.9%)	3 (1.5%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	SALICYLIC ACID	1 (1.0%)	0	1 (0.5%)
	TOCOPHEROL	1 (1.0%)	0	1 (0.5%)
	TRETINOIN	1 (1.0%)	0	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	1 (1.0%)	3 (2.9%)	4 (2.0%)
GU SYSTEM/SEX HORMONES	Total	1 (1.0%)	3 (2.9%)	4 (2.0%)
	ANTIBIOTIC NOS	0	1 (1.0%)	1 (0.5%)
	ETHINYLESTRADIOL	1 (1.0%)	1 (1.0%)	2 (1.0%)
	LEVONORGESTREL	1 (1.0%)	0	1 (0.5%)
	NORGESTREL	0	1 (1.0%)	1 (0.5%)
	ORAL CONTRACEPTIVE	0	1 (1.0%)	1 (0.5%)
MUSCULO-SKELETAL	Total	10 (10.2%)	11 (10.5%)	21 (10.3%)
	IBUPROFEN	8 (8.2%)	11 (10.5%)	19 (9.4%)
	NAPROXEN	1 (1.0%)	0	1 (0.5%)
	NAPROXEN SODIUM	1 (1.0%)	0	1 (0.5%)
	SALICYLIC ACID	1 (1.0%)	0	1 (0.5%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.12.3.1

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=98)	Placebo (N=105)	Total (N=203)
RESPIRATORY	Total	20 (20.4%)	22 (21.0%)	42 (20.7%)
	BECLOMETASONE DIPROPIONATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	BROMPHENIRAMINE MALEATE	1 (1.0%)	0	1 (0.5%)
	BUDESONIDE	2 (2.0%)	2 (1.9%)	4 (2.0%)
	CETIRIZINE HYDROCHLORIDE	2 (2.0%)	4 (3.8%)	6 (3.0%)
	CHLORPHENAMINE MALEATE	1 (1.0%)	2 (1.9%)	3 (1.5%)
	CHLORPHENAMINE TANNATE	0	1 (1.0%)	1 (0.5%)
	CODEINE PHOSPHATE	0	1 (1.0%)	1 (0.5%)
	CROMOGLICATE SODIUM	0	1 (1.0%)	1 (0.5%)
	CROMOGLICIC ACID	0	1 (1.0%)	1 (0.5%)
	DEXTROMETHORPHAN HYDROBROMIDE	2 (2.0%)	3 (2.9%)	5 (2.5%)
	DIMENHYDRINATE	2 (2.0%)	0	2 (1.0%)
	DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	DIPROPHYLLINE	1 (1.0%)	0	1 (0.5%)
	DOXYLAMINE SUCCINATE	1 (1.0%)	0	1 (0.5%)
	FEXOFENADINE HYDROCHLORIDE	3 (3.1%)	1 (1.0%)	4 (2.0%)
	FLUTICASONE PROPIONATE	1 (1.0%)	3 (2.9%)	4 (2.0%)
	GUAIFENESIN	2 (2.0%)	1 (1.0%)	3 (1.5%)
	IPRATROPIUM BROMIDE	0	1 (1.0%)	1 (0.5%)
	LORATADINE	5 (5.1%)	6 (5.7%)	11 (5.4%)
	MEPYRAMINE MALEATE	1 (1.0%)	0	1 (0.5%)
	MEPYRAMINE TANNATE	0	1 (1.0%)	1 (0.5%)
	MONTELUKAST SODIUM	0	1 (1.0%)	1 (0.5%)
	PARACETAMOL	1 (1.0%)	1 (1.0%)	2 (1.0%)
	PHENIRAMINE MALEATE	1 (1.0%)	0	1 (0.5%)
	PHENYLEPHRINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	PHENYLEPHRINE TANNATE	0	1 (1.0%)	1 (0.5%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	3 (3.1%)	1 (1.0%)	4 (2.0%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.0%)	2 (1.9%)	3 (1.5%)
	SALBUTAMOL	4 (4.1%)	5 (4.8%)	9 (4.4%)
	TRIAMCINOLONE ACETONIDE	1 (1.0%)	3 (2.9%)	4 (2.0%)
	TRIPROLIDINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
SENSORY ORGANS	Total	2 (2.0%)	5 (4.8%)	7 (3.4%)
	CORTISONE	0	1 (1.0%)	1 (0.5%)
	CROMOGLICATE SODIUM	0	1 (1.0%)	1 (0.5%)
	ERYTHROMYCIN	1 (1.0%)	0	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	1 (1.0%)	3 (2.9%)	4 (2.0%)
SYSTEMIC HORMONAL	Total	2 (2.0%)	8 (7.6%)	10 (4.9%)
	CORTISONE	0	1 (1.0%)	1 (0.5%)
	DESMOPRESSIN	1 (1.0%)	2 (1.9%)	3 (1.5%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.12.3.1

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=98)	Placebo (N=105)	Total (N=203)
SYSTEMIC HORMONAL	LEVOTHYROXINE SODIUM	0	2 (1.9%)	2 (1.0%)
	TRIAMCINOLONE ACETONIDE	1 (1.0%)	3 (2.9%)	4 (2.0%)
VARIOUS	Total	1 (1.0%)	2 (1.9%)	3 (1.5%)
	ECHINACEA EXTRACT	1 (1.0%)	0	1 (0.5%)
	GARLIC	0	1 (1.0%)	1 (0.5%)
	GLYCEROL	0	1 (1.0%)	1 (0.5%)
	HERBAL MEDICATION	0	1 (1.0%)	1 (0.5%)
	SOYA OIL	0	1 (1.0%)	1 (0.5%)
	SPIRULINA	1 (1.0%)	0	1 (0.5%)
	WATER	0	1 (1.0%)	1 (0.5%)
	WHEY PROTEIN	0	1 (1.0%)	1 (0.5%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.12.3.2

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=98)	Placebo (N=105)	Total (N=203)
Total number of patients with at least one prior non-psychoactive medication	38 (38.8%)	49 (46.7%)	87 (42.9%)
PARACETAMOL	10 (10.2%)	4 (3.8%)	14 (6.9%)
IBUPROFEN	8 (8.2%)	11 (10.5%)	19 (9.4%)
LORATADINE	5 (5.1%)	6 (5.7%)	11 (5.4%)
VITAMINS NOS	5 (5.1%)	4 (3.8%)	9 (4.4%)
SALBUTAMOL	4 (4.1%)	5 (4.8%)	9 (4.4%)
ACETYLSALICYLIC ACID	3 (3.1%)	1 (1.0%)	4 (2.0%)
FEXOFENADINE HYDROCHLORIDE	3 (3.1%)	1 (1.0%)	4 (2.0%)
PHENYLPROPANOLAMINE HYDROCHLORIDE	3 (3.1%)	1 (1.0%)	4 (2.0%)
CETIRIZINE HYDROCHLORIDE	2 (2.0%)	4 (3.8%)	6 (3.0%)
DEXTROMETHORPHAN HYDROBROMIDE	2 (2.0%)	3 (2.9%)	5 (2.5%)
BUDESONIDE	2 (2.0%)	2 (1.9%)	4 (2.0%)
AMOXICILLIN	2 (2.0%)	1 (1.0%)	3 (1.5%)
GUAIFENESIN	2 (2.0%)	1 (1.0%)	3 (1.5%)
ASCORBIC ACID	2 (2.0%)	0	2 (1.0%)
BISMUTH SUBSALICYLATE	2 (2.0%)	0	2 (1.0%)
CAFFEINE	2 (2.0%)	0	2 (1.0%)
DIMENHYDRINATE	2 (2.0%)	0	2 (1.0%)
FLUTICASONE PROPIONATE	1 (1.0%)	3 (2.9%)	4 (2.0%)
TRIAMCINOLONE ACETONIDE	1 (1.0%)	3 (2.9%)	4 (2.0%)
CHLORPHENAMINE MALEATE	1 (1.0%)	2 (1.9%)	3 (1.5%)
DESMOPRESSIN	1 (1.0%)	2 (1.9%)	3 (1.5%)
PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.0%)	2 (1.9%)	3 (1.5%)
ALUMINIUM HYDROXIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
BECLOMETASONE DIPROPIONATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
CALCIUM CARBONATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
DIMETICONE, ACTIVATED	1 (1.0%)	1 (1.0%)	2 (1.0%)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
ETHINYLESTRADIOL	1 (1.0%)	1 (1.0%)	2 (1.0%)
MAGNESIUM HYDROXIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
ACICLOVIR	1 (1.0%)	0	1 (0.5%)
BENZOYL PEROXIDE	1 (1.0%)	0	1 (0.5%)
BROMPHENIRAMINE MALEATE	1 (1.0%)	0	1 (0.5%)
CALCIUM	1 (1.0%)	0	1 (0.5%)
CEFALEXIN MONOHYDRATE	1 (1.0%)	0	1 (0.5%)
CEFIXIME	1 (1.0%)	0	1 (0.5%)
DIPROPHYLLINE	1 (1.0%)	0	1 (0.5%)
DOXYLAMINE SUCCINATE	1 (1.0%)	0	1 (0.5%)
ECHINACEA EXTRACT	1 (1.0%)	0	1 (0.5%)
ERYTHROMYCIN	1 (1.0%)	0	1 (0.5%)
ERYTHROMYCIN ETHYLSUCCINATE	1 (1.0%)	0	1 (0.5%)
FISH OIL	1 (1.0%)	0	1 (0.5%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.12.3.2

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=98)	Placebo (N=105)	Total (N=203)
HYDROXYZINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
IMIPRAMINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
LEVONORGESTREL	1 (1.0%)	0	1 (0.5%)
LORACARBEF	1 (1.0%)	0	1 (0.5%)
MEPYRAMINE MALEATE	1 (1.0%)	0	1 (0.5%)
MINERALS NOS	1 (1.0%)	0	1 (0.5%)
NAPROXEN	1 (1.0%)	0	1 (0.5%)
NAPROXEN SODIUM	1 (1.0%)	0	1 (0.5%)
PHENIRAMINE MALEATE	1 (1.0%)	0	1 (0.5%)
PHENYLEPHRINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
PROMETHAZINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
SALICYLIC ACID	1 (1.0%)	0	1 (0.5%)
SPIRULINA	1 (1.0%)	0	1 (0.5%)
TOCOPHEROL	1 (1.0%)	0	1 (0.5%)
TRETINOIN	1 (1.0%)	0	1 (0.5%)
LIDOCAINE	0	3 (2.9%)	3 (1.5%)
PRILOCAINE	0	3 (2.9%)	3 (1.5%)
LEVOTHYROXINE SODIUM	0	2 (1.9%)	2 (1.0%)
AMOXICILLIN TRIHYDRATE	0	1 (1.0%)	1 (0.5%)
ANTIBIOTIC NOS	0	1 (1.0%)	1 (0.5%)
AZITHROMYCIN	0	1 (1.0%)	1 (0.5%)
CHLORPHENAMINE TANNATE	0	1 (1.0%)	1 (0.5%)
CLAVULANIC ACID	0	1 (1.0%)	1 (0.5%)
CODEINE PHOSPHATE	0	1 (1.0%)	1 (0.5%)
CORTISONE	0	1 (1.0%)	1 (0.5%)
CROMOGLICATE SODIUM	0	1 (1.0%)	1 (0.5%)
CROMOGLICIC ACID	0	1 (1.0%)	1 (0.5%)
GARLIC	0	1 (1.0%)	1 (0.5%)
GLYCEROL	0	1 (1.0%)	1 (0.5%)
HERBAL MEDICATION	0	1 (1.0%)	1 (0.5%)
IMIPRAMINE	0	1 (1.0%)	1 (0.5%)
IPRATROPIUM BROMIDE	0	1 (1.0%)	1 (0.5%)
MEPYRAMINE TANNATE	0	1 (1.0%)	1 (0.5%)
MINOCYCLINE	0	1 (1.0%)	1 (0.5%)
MONTELUKAST SODIUM	0	1 (1.0%)	1 (0.5%)
NORGESTREL	0	1 (1.0%)	1 (0.5%)
ORAL CONTRACEPTIVE	0	1 (1.0%)	1 (0.5%)
PHENYLEPHRINE TANNATE	0	1 (1.0%)	1 (0.5%)
RANITIDINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
SENNA FRUIT	0	1 (1.0%)	1 (0.5%)
SOYA OIL	0	1 (1.0%)	1 (0.5%)
SULFAMETHOXAZOLE	0	1 (1.0%)	1 (0.5%)
TAMOXIFEN	0	1 (1.0%)	1 (0.5%)
TRIMETHOPRIM	0	1 (1.0%)	1 (0.5%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.12.3.2

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=98)	Placebo (N=105)	Total (N=203)
TRIPROLIDINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
WATER	0	1 (1.0%)	1 (0.5%)
WHEY PROTEIN	0	1 (1.0%)	1 (0.5%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.12.3.3

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=98)	Placebo (N=105)	Total (N=203)
Total number of patients with at least one concomitant medication	Total	61 (62.2%)	73 (69.5%)	134 (66.0%)
ALIMENTARY TRACT/METAB	Total	19 (19.4%)	16 (15.2%)	35 (17.2%)
	ACETYLSALICYLIC ACID	2 (2.0%)	0	2 (1.0%)
	ALUMINIUM HYDROXIDE	1 (1.0%)	2 (1.9%)	3 (1.5%)
	ASCORBIC ACID	4 (4.1%)	1 (1.0%)	5 (2.5%)
	BISMUTH SUBSALICYLATE	2 (2.0%)	2 (1.9%)	4 (2.0%)
	CALCIUM	1 (1.0%)	0	1 (0.5%)
	CALCIUM CARBONATE	3 (3.1%)	4 (3.8%)	7 (3.4%)
	CITRIC ACID	1 (1.0%)	0	1 (0.5%)
	CYANOCOBALAMIN	1 (1.0%)	0	1 (0.5%)
	DIMETICONE, ACTIVATED	2 (2.0%)	2 (1.9%)	4 (2.0%)
	ERGOCALCIFEROL	1 (1.0%)	0	1 (0.5%)
	FERROUS FUMARATE	1 (1.0%)	0	1 (0.5%)
	FLUORIDE NOS	1 (1.0%)	0	1 (0.5%)
	HYDROCHLORIC ACID	1 (1.0%)	0	1 (0.5%)
	KAOLIN	1 (1.0%)	0	1 (0.5%)
	LIDOCAINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	LOPERAMIDE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	MAGNESIUM HYDROXIDE	1 (1.0%)	2 (1.9%)	3 (1.5%)
	METHYLPARABEN	1 (1.0%)	0	1 (0.5%)
	METRONIDAZOLE	1 (1.0%)	0	1 (0.5%)
	MINERALS NOS	1 (1.0%)	0	1 (0.5%)
	NEOMYCIN	0	1 (1.0%)	1 (0.5%)
	NICOTINAMIDE	1 (1.0%)	0	1 (0.5%)
	PARAFFIN, LIQUID	1 (1.0%)	0	1 (0.5%)
	PECTIN	1 (1.0%)	0	1 (0.5%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	PYRIDOXINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	RANITIDINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	RETINOL	1 (1.0%)	0	1 (0.5%)
	RIBOFLAVIN	1 (1.0%)	0	1 (0.5%)
	SENNA FRUIT	0	1 (1.0%)	1 (0.5%)
	SODIUM BICARBONATE	1 (1.0%)	0	1 (0.5%)
	SODIUM CHLORIDE	2 (2.0%)	0	2 (1.0%)
	SODIUM HYDROXIDE	1 (1.0%)	0	1 (0.5%)
	THIAMINE MONONITRATE	1 (1.0%)	0	1 (0.5%)
	TOCOPHEROL	1 (1.0%)	0	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	0	3 (2.9%)	3 (1.5%)
	VITAMINS NOS	6 (6.1%)	4 (3.8%)	10 (4.9%)
ANTIINFECTIVES,SYSTEMIC	Total	16 (16.3%)	16 (15.2%)	32 (15.8%)
	ACICLOVIR	1 (1.0%)	0	1 (0.5%)
	AMOXICILLIN	2 (2.0%)	2 (1.9%)	4 (2.0%)
	AMOXICILLIN TRIHYDRATE	3 (3.1%)	3 (2.9%)	6 (3.0%)

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Table 13.12.3.3

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=98)	Placebo (N=105)	Total (N=203)
ANTIINFECTIVES,SYSTEMIC	AZITHROMYCIN	0	2 (1.9%)	2 (1.0%)
	CEFADROXIL MONOHYDRATE	1 (1.0%)	0	1 (0.5%)
	CEFALEXIN	0	1 (1.0%)	1 (0.5%)
	CEFIXIME	1 (1.0%)	0	1 (0.5%)
	CEFPROZIL MONOHYDRATE	1 (1.0%)	0	1 (0.5%)
	CLARITHROMYCIN	1 (1.0%)	0	1 (0.5%)
	CLAVULANIC ACID	2 (2.0%)	3 (2.9%)	5 (2.5%)
	DOXYCYCLINE	1 (1.0%)	0	1 (0.5%)
	ERYTHROMYCIN	1 (1.0%)	1 (1.0%)	2 (1.0%)
	ERYTHROMYCIN ETHYLSUCCINATE	1 (1.0%)	0	1 (0.5%)
	IMMUNOGLOBULIN HUMAN ANTI-RABIES	0	1 (1.0%)	1 (0.5%)
	LORACARBEF	1 (1.0%)	0	1 (0.5%)
	METRONIDAZOLE	1 (1.0%)	0	1 (0.5%)
	MINOCYCLINE	0	1 (1.0%)	1 (0.5%)
	NEOMYCIN	0	1 (1.0%)	1 (0.5%)
	OFLOXACIN	1 (1.0%)	0	1 (0.5%)
	PENICILLIN NOS	2 (2.0%)	0	2 (1.0%)
	RABIES VACCINE	0	1 (1.0%)	1 (0.5%)
	RIMANTADINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
	SULFAMETHOXAZOLE	2 (2.0%)	4 (3.8%)	6 (3.0%)
	TRIMETHOPRIM	2 (2.0%)	3 (2.9%)	5 (2.5%)
ANTINEOPLASTIC & IMMUNOSUP	Total	1 (1.0%)	1 (1.0%)	2 (1.0%)
	TAMOXIFEN	0	1 (1.0%)	1 (0.5%)
	TRETINOIN	1 (1.0%)	0	1 (0.5%)
BLOOD/BLOOD FORM ORGANS	Total	4 (4.1%)	0	4 (2.0%)
	ACETYLSALICYLIC ACID	1 (1.0%)	0	1 (0.5%)
	FISH OIL	1 (1.0%)	0	1 (0.5%)
	SODIUM CHLORIDE	2 (2.0%)	0	2 (1.0%)
CARDIOVASCULAR	Total	1 (1.0%)	0	1 (0.5%)
	HYDROCHLORIC ACID	1 (1.0%)	0	1 (0.5%)
	LIDOCAINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	METHYLPARABEN	1 (1.0%)	0	1 (0.5%)
	SODIUM HYDROXIDE	1 (1.0%)	0	1 (0.5%)
CENTRAL NERVOUS SYSTEM	Total	38 (38.8%)	42 (40.0%)	80 (39.4%)
	ACETYLSALICYLIC ACID	5 (5.1%)	1 (1.0%)	6 (3.0%)
	CAFFEINE	3 (3.1%)	1 (1.0%)	4 (2.0%)
	CHLORPHENAMINE MALEATE	2 (2.0%)	2 (1.9%)	4 (2.0%)
	CHLORPROMAZINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	CINNAMEDRINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	CITRIC ACID	1 (1.0%)	0	1 (0.5%)
	DEXTROMETHORPHAN HYDROBROMIDE	2 (2.0%)	2 (1.9%)	4 (2.0%)

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Table 13.12.3.3

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=98)	Placebo (N=105)	Total (N=203)
CENTRAL NERVOUS SYSTEM	DIPHENHYDRAMINE CITRATE	1 (1.0%)	0	1 (0.5%)
	DIPHENHYDRAMINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
	DOXYLAMINE SUCCINATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	FLUOXETINE	0	1 (1.0%)	1 (0.5%)
	FLUVOXAMINE MALEATE	1 (1.0%)	0	1 (0.5%)
	HYDROCHLORIC ACID	1 (1.0%)	0	1 (0.5%)
	IBUPROFEN	14 (14.3%)	21 (20.0%)	35 (17.2%)
	IMIPRAMINE	0	1 (1.0%)	1 (0.5%)
	IMIPRAMINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	LIDOCAINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	LIDOCAINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	LORAZEPAM	0	1 (1.0%)	1 (0.5%)
	METHYLPARABEN	1 (1.0%)	0	1 (0.5%)
	METHYLPHENIDATE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	NITROUS OXIDE	0	1 (1.0%)	1 (0.5%)
	PARACETAMOL	26 (26.5%)	25 (23.8%)	51 (25.1%)
	PAROXETINE	1 (1.0%)	0	1 (0.5%)
	PHENAZONE	0	1 (1.0%)	1 (0.5%)
	PRILOCAINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	PROCAINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	4 (4.1%)	4 (3.8%)	8 (3.9%)
	SODIUM BICARBONATE	1 (1.0%)	0	1 (0.5%)
	SODIUM HYDROXIDE	1 (1.0%)	0	1 (0.5%)
DERMATOLOGICALS	Total	15 (15.3%)	19 (18.1%)	34 (16.7%)
	BENZOYL PEROXIDE	1 (1.0%)	0	1 (0.5%)
	BUDESONIDE	2 (2.0%)	2 (1.9%)	4 (2.0%)
	CHLOROXYLENOL	0	1 (1.0%)	1 (0.5%)
	CORTISONE	0	1 (1.0%)	1 (0.5%)
	DIPHENHYDRAMINE CITRATE	1 (1.0%)	0	1 (0.5%)
	DIPHENHYDRAMINE HYDROCHLORIDE	6 (6.1%)	4 (3.8%)	10 (4.9%)
	ERYTHROMYCIN	1 (1.0%)	1 (1.0%)	2 (1.0%)
	FLUTICASONE PROPIONATE	1 (1.0%)	3 (2.9%)	4 (2.0%)
	HYDROCHLORIC ACID	1 (1.0%)	0	1 (0.5%)
	LIDOCAINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	LIDOCAINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	METHYLPARABEN	1 (1.0%)	0	1 (0.5%)
	METRONIDAZOLE	1 (1.0%)	0	1 (0.5%)
	MOMETASONE FUROATE	0	2 (1.9%)	2 (1.0%)
	NEOMYCIN	0	1 (1.0%)	1 (0.5%)
	PARACETAMOL	1 (1.0%)	0	1 (0.5%)
	PARAFFIN, LIQUID	1 (1.0%)	0	1 (0.5%)
	PRILOCAINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	SALICYLIC ACID	1 (1.0%)	0	1 (0.5%)

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Table 13.12.3.3

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=98)	Placebo (N=105)	Total (N=203)
DERMATOLOGICALS	SODIUM HYDROXIDE	1 (1.0%)	0	1 (0.5%)
	SULFACETAMIDE SODIUM	1 (1.0%)	0	1 (0.5%)
	TOCOPHEROL	1 (1.0%)	0	1 (0.5%)
	TRETINOIN	1 (1.0%)	0	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	0	3 (2.9%)	3 (1.5%)
GU SYSTEM/SEX HORMONES	Total	3 (3.1%)	2 (1.9%)	5 (2.5%)
	ETHINYLESTRADIOL	1 (1.0%)	1 (1.0%)	2 (1.0%)
	LEVONORGESTREL	1 (1.0%)	0	1 (0.5%)
	METRONIDAZOLE	1 (1.0%)	0	1 (0.5%)
	NORGESTREL	0	1 (1.0%)	1 (0.5%)
	OFLOXACIN	1 (1.0%)	0	1 (0.5%)
	ORAL CONTRACEPTIVE	0	1 (1.0%)	1 (0.5%)
MUSCULO-SKELETAL	Total	16 (16.3%)	21 (20.0%)	37 (18.2%)
	DICLOFENAC SODIUM	0	1 (1.0%)	1 (0.5%)
	IBUPROFEN	14 (14.3%)	21 (20.0%)	35 (17.2%)
	NAPROXEN	1 (1.0%)	0	1 (0.5%)
	NAPROXEN SODIUM	1 (1.0%)	1 (1.0%)	2 (1.0%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	SALICYLIC ACID	1 (1.0%)	0	1 (0.5%)
PARASITOLOGY	Total	1 (1.0%)	0	1 (0.5%)
	METRONIDAZOLE	1 (1.0%)	0	1 (0.5%)
RESPIRATORY	Total	35 (35.7%)	44 (41.9%)	79 (38.9%)
	AZELASTINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	BECLOMETASONE DIPROPIONATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	BROMPHENIRAMINE MALEATE	3 (3.1%)	6 (5.7%)	9 (4.4%)
	BUDESONIDE	2 (2.0%)	2 (1.9%)	4 (2.0%)
	CETIRIZINE HYDROCHLORIDE	2 (2.0%)	4 (3.8%)	6 (3.0%)
	CHLORPHENAMINE MALEATE	2 (2.0%)	3 (2.9%)	5 (2.5%)
	CHLORPHENAMINE TANNATE	0	1 (1.0%)	1 (0.5%)
	CLEMASTINE FUMARATE	0	1 (1.0%)	1 (0.5%)
	CODEINE	0	1 (1.0%)	1 (0.5%)
	CODEINE PHOSPHATE	0	1 (1.0%)	1 (0.5%)
	COUGH COLD PREPARATIONS NOS	1 (1.0%)	1 (1.0%)	2 (1.0%)
	CYPROHEPTADINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
	DEXTROMETHORPHAN	0	1 (1.0%)	1 (0.5%)
	DEXTROMETHORPHAN HYDROBROMIDE	5 (5.1%)	6 (5.7%)	11 (5.4%)
	DIMENHYDRINATE	1 (1.0%)	2 (1.9%)	3 (1.5%)
	DIPHENHYDRAMINE CITRATE	1 (1.0%)	0	1 (0.5%)
	DIPHENHYDRAMINE HYDROCHLORIDE	6 (6.1%)	5 (4.8%)	11 (5.4%)
	DIPROPHYLLINE	1 (1.0%)	0	1 (0.5%)
	DOXYLAMINE SUCCINATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	ETHANOL	1 (1.0%)	0	1 (0.5%)

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Table 13.12.3.3

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=98)	Placebo (N=105)	Total (N=203)
RESPIRATORY	FEXOFENADINE HYDROCHLORIDE	5 (5.1%)	3 (2.9%)	8 (3.9%)
	FLUTICASONE PROPIONATE	1 (1.0%)	3 (2.9%)	4 (2.0%)
	GUAIFENESIN	5 (5.1%)	5 (4.8%)	10 (4.9%)
	IBUPROFEN	1 (1.0%)	0	1 (0.5%)
	IPRATROPIUM BROMIDE	0	1 (1.0%)	1 (0.5%)
	LORATADINE	8 (8.2%)	8 (7.6%)	16 (7.9%)
	MEPYRAMINE MALEATE	3 (3.1%)	3 (2.9%)	6 (3.0%)
	MEPYRAMINE TANNATE	0	1 (1.0%)	1 (0.5%)
	MOMETASONE FUROATE	0	2 (1.9%)	2 (1.0%)
	MONTELUKAST SODIUM	1 (1.0%)	1 (1.0%)	2 (1.0%)
	PARACETAMOL	7 (7.1%)	4 (3.8%)	11 (5.4%)
	PHENIRAMINE MALEATE	3 (3.1%)	3 (2.9%)	6 (3.0%)
	PHENYLEPHRINE HYDROCHLORIDE	3 (3.1%)	5 (4.8%)	8 (3.9%)
	PHENYLEPHRINE TANNATE	0	1 (1.0%)	1 (0.5%)
	PHENYLPROPANOLAMINE BITARTRATE	0	1 (1.0%)	1 (0.5%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	6 (6.1%)	10 (9.5%)	16 (7.9%)
	PREDNISONE	1 (1.0%)	0	1 (0.5%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	9 (9.2%)	8 (7.6%)	17 (8.4%)
	SALBUTAMOL	4 (4.1%)	5 (4.8%)	9 (4.4%)
	SODIUM CHLORIDE	2 (2.0%)	0	2 (1.0%)
	TRIAMCINOLONE ACETONIDE	0	3 (2.9%)	3 (1.5%)
	TRIPROLIDINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
SENSORY ORGANS	Total	7 (7.1%)	9 (8.6%)	16 (7.9%)
	BROMPHENIRAMINE MALEATE	0	1 (1.0%)	1 (0.5%)
	CIPROFLOXACIN HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
	CORTISONE	0	1 (1.0%)	1 (0.5%)
	DEXTRAN	1 (1.0%)	0	1 (0.5%)
	DICLOFENAC SODIUM	0	1 (1.0%)	1 (0.5%)
	ERYTHROMYCIN	1 (1.0%)	1 (1.0%)	2 (1.0%)
	HYDROCORTISONE	0	1 (1.0%)	1 (0.5%)
	HYPROMELLOSE	1 (1.0%)	0	1 (0.5%)
	NEOMYCIN	0	1 (1.0%)	1 (0.5%)
	OFLOXACIN	1 (1.0%)	0	1 (0.5%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
	PREDNISOLONE ACETATE	1 (1.0%)	0	1 (0.5%)
	SODIUM CHLORIDE	2 (2.0%)	0	2 (1.0%)
	SULFACETAMIDE SODIUM	2 (2.0%)	0	2 (1.0%)
	TRIAMCINOLONE ACETONIDE	0	3 (2.9%)	3 (1.5%)
SYSTEMIC HORMONAL	Total	3 (3.1%)	8 (7.6%)	11 (5.4%)
	CORTISONE	0	1 (1.0%)	1 (0.5%)
	DESMOPRESSIN	1 (1.0%)	2 (1.9%)	3 (1.5%)

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Table 13.12.3.3

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=98)	Placebo (N=105)	Total (N=203)
SYSTEMIC HORMONAL	LEVOTHYROXINE SODIUM	1 (1.0%)	2 (1.9%)	3 (1.5%)
	PREDNISONE	1 (1.0%)	0	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	0	3 (2.9%)	3 (1.5%)
UNCLASSIFIABLE	Total	0	1 (1.0%)	1 (0.5%)
	UNKNOWN MEDICATION	0	1 (1.0%)	1 (0.5%)
VARIOUS	Total	2 (2.0%)	3 (2.9%)	5 (2.5%)
	ACONITE	0	1 (1.0%)	1 (0.5%)
	GARLIC	0	1 (1.0%)	1 (0.5%)
	GLYCEROL	0	1 (1.0%)	1 (0.5%)
	GNAPHALIUM	0	1 (1.0%)	1 (0.5%)
	HERBAL MEDICATION	0	1 (1.0%)	1 (0.5%)
	HYDROCHLORIC ACID	1 (1.0%)	0	1 (0.5%)
	LEDUM PALUSTRE	0	1 (1.0%)	1 (0.5%)
	LIDOCAINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	MAGNESIUM PHOSPHATE	0	1 (1.0%)	1 (0.5%)
	METHYLPARABEN	1 (1.0%)	0	1 (0.5%)
	MISTLETOE EXTRACT	0	1 (1.0%)	1 (0.5%)
	RHUS TOXICODENDRON	0	1 (1.0%)	1 (0.5%)
	SODIUM HYDROXIDE	1 (1.0%)	0	1 (0.5%)
	SOYA OIL	0	1 (1.0%)	1 (0.5%)
	SPIRULINA	1 (1.0%)	0	1 (0.5%)
	WATER	0	1 (1.0%)	1 (0.5%)
	WHEY PROTEIN	0	1 (1.0%)	1 (0.5%)

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Table 13.12.3.4

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=98)	Placebo (N=105)	Total (N=203)
Total number of patients with at least one concomitant medication	61 (62.2%)	73 (69.5%)	134 (66.0%)
PARACETAMOL	28 (28.6%)	25 (23.8%)	53 (26.1%)
IBUPROFEN	14 (14.3%)	21 (20.0%)	35 (17.2%)
PSEUDOEPHEDRINE HYDROCHLORIDE	9 (9.2%)	8 (7.6%)	17 (8.4%)
LORATADINE	8 (8.2%)	8 (7.6%)	16 (7.9%)
PHENYLPROPANOLAMINE HYDROCHLORIDE	6 (6.1%)	10 (9.5%)	16 (7.9%)
DIPHENHYDRAMINE HYDROCHLORIDE	6 (6.1%)	5 (4.8%)	11 (5.4%)
VITAMINS NOS	6 (6.1%)	4 (3.8%)	10 (4.9%)
DEXTROMETHORPHAN HYDROBROMIDE	5 (5.1%)	6 (5.7%)	11 (5.4%)
GUAIFENESIN	5 (5.1%)	5 (4.8%)	10 (4.9%)
FEXOFENADINE HYDROCHLORIDE	5 (5.1%)	3 (2.9%)	8 (3.9%)
ACETYLSALICYLIC ACID	5 (5.1%)	1 (1.0%)	6 (3.0%)
SALBUTAMOL	4 (4.1%)	5 (4.8%)	9 (4.4%)
ASCORBIC ACID	4 (4.1%)	1 (1.0%)	5 (2.5%)
BROMPHENIRAMINE MALEATE	3 (3.1%)	6 (5.7%)	9 (4.4%)
PHENYLEPHRINE HYDROCHLORIDE	3 (3.1%)	5 (4.8%)	8 (3.9%)
CALCIUM CARBONATE	3 (3.1%)	4 (3.8%)	7 (3.4%)
AMOXICILLIN TRIHYDRATE	3 (3.1%)	3 (2.9%)	6 (3.0%)
MEPYRAMINE MALEATE	3 (3.1%)	3 (2.9%)	6 (3.0%)
PHENIRAMINE MALEATE	3 (3.1%)	3 (2.9%)	6 (3.0%)
CAFFEINE	3 (3.1%)	1 (1.0%)	4 (2.0%)
CETIRIZINE HYDROCHLORIDE	2 (2.0%)	4 (3.8%)	6 (3.0%)
SULFAMETHOXAZOLE	2 (2.0%)	4 (3.8%)	6 (3.0%)
CHLORPHENAMINE MALEATE	2 (2.0%)	3 (2.9%)	5 (2.5%)
CLAVULANIC ACID	2 (2.0%)	3 (2.9%)	5 (2.5%)
TRIMETHOPRIM	2 (2.0%)	3 (2.9%)	5 (2.5%)
AMOXICILLIN	2 (2.0%)	2 (1.9%)	4 (2.0%)
BISMUTH SUBSALICYLATE	2 (2.0%)	2 (1.9%)	4 (2.0%)
BUDESONIDE	2 (2.0%)	2 (1.9%)	4 (2.0%)
DIMETICONE, ACTIVATED	2 (2.0%)	2 (1.9%)	4 (2.0%)
PENICILLIN NOS	2 (2.0%)	0	2 (1.0%)
SODIUM CHLORIDE	2 (2.0%)	0	2 (1.0%)
SULFACETAMIDE SODIUM	2 (2.0%)	0	2 (1.0%)
FLUTICASONE PROPIONATE	1 (1.0%)	3 (2.9%)	4 (2.0%)
ALUMINIUM HYDROXIDE	1 (1.0%)	2 (1.9%)	3 (1.5%)
DESMOPRESSIN	1 (1.0%)	2 (1.9%)	3 (1.5%)
DIMENHYDRINATE	1 (1.0%)	2 (1.9%)	3 (1.5%)
LEVOTHYROXINE SODIUM	1 (1.0%)	2 (1.9%)	3 (1.5%)
MAGNESIUM HYDROXIDE	1 (1.0%)	2 (1.9%)	3 (1.5%)
BECLOMETASONE DIPROPIONATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
COUGH COLD PREPARATIONS NOS	1 (1.0%)	1 (1.0%)	2 (1.0%)
DOXYLAMINE SUCCINATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
ERYTHROMYCIN	1 (1.0%)	1 (1.0%)	2 (1.0%)
ETHINYLESTRADIOL	1 (1.0%)	1 (1.0%)	2 (1.0%)

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Table 13.12.3.4

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=98)	Placebo (N=105)	Total (N=203)
LIDOCAINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
LOPERAMIDE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
MONTELUKAST SODIUM	1 (1.0%)	1 (1.0%)	2 (1.0%)
NAPROXEN SODIUM	1 (1.0%)	1 (1.0%)	2 (1.0%)
PRILOCAINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
PROCAINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
PROMETHAZINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
RANITIDINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
ACICLOVIR	1 (1.0%)	0	1 (0.5%)
AZELASTINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
BENZOYL PEROXIDE	1 (1.0%)	0	1 (0.5%)
CALCIUM	1 (1.0%)	0	1 (0.5%)
CEFADROXIL MONOHYDRATE	1 (1.0%)	0	1 (0.5%)
CEFIXIME	1 (1.0%)	0	1 (0.5%)
CEFPROZIL MONOHYDRATE	1 (1.0%)	0	1 (0.5%)
CHLORPROMAZINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
CINNAMEDRINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
CITRIC ACID	1 (1.0%)	0	1 (0.5%)
CLARITHROMYCIN	1 (1.0%)	0	1 (0.5%)
CYANOCOBALAMIN	1 (1.0%)	0	1 (0.5%)
DEXTRAN	1 (1.0%)	0	1 (0.5%)
DIPHENHYDRAMINE CITRATE	1 (1.0%)	0	1 (0.5%)
DIPROPHYLLINE	1 (1.0%)	0	1 (0.5%)
DOXYCYCLINE	1 (1.0%)	0	1 (0.5%)
ERGOCALCIFEROL	1 (1.0%)	0	1 (0.5%)
ERYTHROMYCIN ETHYLSUCCINATE	1 (1.0%)	0	1 (0.5%)
ETHANOL	1 (1.0%)	0	1 (0.5%)
FERROUS FUMARATE	1 (1.0%)	0	1 (0.5%)
FISH OIL	1 (1.0%)	0	1 (0.5%)
FLUORIDE NOS	1 (1.0%)	0	1 (0.5%)
FLUVOXAMINE MALEATE	1 (1.0%)	0	1 (0.5%)
HYDROCHLORIC ACID	1 (1.0%)	0	1 (0.5%)
HYPROMELLOSE	1 (1.0%)	0	1 (0.5%)
IMIPRAMINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
KAOLIN	1 (1.0%)	0	1 (0.5%)
LEVONORGESTREL	1 (1.0%)	0	1 (0.5%)
LIDOCAINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
LORACARBEF	1 (1.0%)	0	1 (0.5%)
METHYLPARABEN	1 (1.0%)	0	1 (0.5%)
METHYLPHENIDATE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
METRONIDAZOLE	1 (1.0%)	0	1 (0.5%)
MINERALS NOS	1 (1.0%)	0	1 (0.5%)
NAPROXEN	1 (1.0%)	0	1 (0.5%)
NICOTINAMIDE	1 (1.0%)	0	1 (0.5%)
OFLOXACIN	1 (1.0%)	0	1 (0.5%)
PARAFFIN, LIQUID	1 (1.0%)	0	1 (0.5%)

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Table 13.12.3.4

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=98)	Placebo (N=105)	Total (N=203)
PAROXETINE	1 (1.0%)	0	1 (0.5%)
PECTIN	1 (1.0%)	0	1 (0.5%)
PREDNISOLONE ACETATE	1 (1.0%)	0	1 (0.5%)
PREDNISONE	1 (1.0%)	0	1 (0.5%)
PYRIDOXINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
RETINOL	1 (1.0%)	0	1 (0.5%)
RIBOFLAVIN	1 (1.0%)	0	1 (0.5%)
SALICYLIC ACID	1 (1.0%)	0	1 (0.5%)
SODIUM BICARBONATE	1 (1.0%)	0	1 (0.5%)
SODIUM HYDROXIDE	1 (1.0%)	0	1 (0.5%)
SPIRULINA	1 (1.0%)	0	1 (0.5%)
THIAMINE MONONITRATE	1 (1.0%)	0	1 (0.5%)
TOCOPHEROL	1 (1.0%)	0	1 (0.5%)
TRETINOIN	1 (1.0%)	0	1 (0.5%)
TRIAMCINOLONE ACETONIDE	0	3 (2.9%)	3 (1.5%)
AZITHROMYCIN	0	2 (1.9%)	2 (1.0%)
MOMETASONE FUROATE	0	2 (1.9%)	2 (1.0%)
ACONITE	0	1 (1.0%)	1 (0.5%)
CEFALEXIN	0	1 (1.0%)	1 (0.5%)
CHLOROXYLENOL	0	1 (1.0%)	1 (0.5%)
CHLORPHENAMINE TANNATE	0	1 (1.0%)	1 (0.5%)
CIPROFLOXACIN HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
CLEMASTINE FUMARATE	0	1 (1.0%)	1 (0.5%)
CODEINE	0	1 (1.0%)	1 (0.5%)
CODEINE PHOSPHATE	0	1 (1.0%)	1 (0.5%)
CORTISONE	0	1 (1.0%)	1 (0.5%)
CYPROHEPTADINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
DEXTROMETHORPHAN	0	1 (1.0%)	1 (0.5%)
DICLOFENAC SODIUM	0	1 (1.0%)	1 (0.5%)
FLUOXETINE	0	1 (1.0%)	1 (0.5%)
GARLIC	0	1 (1.0%)	1 (0.5%)
GLYCEROL	0	1 (1.0%)	1 (0.5%)
GNAPHALIUM	0	1 (1.0%)	1 (0.5%)
HERBAL MEDICATION	0	1 (1.0%)	1 (0.5%)
HYDROCORTISONE	0	1 (1.0%)	1 (0.5%)
IMIPRAMINE	0	1 (1.0%)	1 (0.5%)
IMMUNOGLOBULIN HUMAN ANTI-RABIES	0	1 (1.0%)	1 (0.5%)
IPRATROPIUM BROMIDE	0	1 (1.0%)	1 (0.5%)
LEDUM PALUSTRE	0	1 (1.0%)	1 (0.5%)
LORAZEPAM	0	1 (1.0%)	1 (0.5%)
MAGNESIUM PHOSPHATE	0	1 (1.0%)	1 (0.5%)
MEPYRAMINE TANNATE	0	1 (1.0%)	1 (0.5%)
MINOCYCLINE	0	1 (1.0%)	1 (0.5%)
MISTLETOE EXTRACT	0	1 (1.0%)	1 (0.5%)
NEOMYCIN	0	1 (1.0%)	1 (0.5%)
NITROUS OXIDE	0	1 (1.0%)	1 (0.5%)

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Table 13.12.3.4

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=98)	Placebo (N=105)	Total (N=203)
NORGESTREL	0	1 (1.0%)	1 (0.5%)
ORAL CONTRACEPTIVE	0	1 (1.0%)	1 (0.5%)
PHENAZONE	0	1 (1.0%)	1 (0.5%)
PHENYLEPHRINE TANNATE	0	1 (1.0%)	1 (0.5%)
PHENYLPROPANOLAMINE BITARTRATE	0	1 (1.0%)	1 (0.5%)
RABIES VACCINE	0	1 (1.0%)	1 (0.5%)
RHUS TOXICODENDRON	0	1 (1.0%)	1 (0.5%)
RIMANTADINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
SENNA FRUIT	0	1 (1.0%)	1 (0.5%)
SOYA OIL	0	1 (1.0%)	1 (0.5%)
TAMOXIFEN	0	1 (1.0%)	1 (0.5%)
TRIPROLIDINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
UNKNOWN MEDICATION	0	1 (1.0%)	1 (0.5%)
WATER	0	1 (1.0%)	1 (0.5%)
WHEY PROTEIN	0	1 (1.0%)	1 (0.5%)

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Table 13.12.3.5

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=80)	Placebo (N=89)	Total (N=169)
Total number of patients with at least one concomitant medication during taper or follow-up	Total	42 (52.5%)	48 (53.9%)	90 (53.3%)
ALIMENTARY TRACT/METAB	Total	11 (13.8%)	11 (12.4%)	22 (13.0%)
	ALUMINIUM HYDROXIDE	1 (1.3%)	0	1 (0.6%)
	ASCORBIC ACID	3 (3.8%)	0	3 (1.8%)
	BISMUTH SUBSALICYLATE	2 (2.5%)	0	2 (1.2%)
	CALCIUM	1 (1.3%)	0	1 (0.6%)
	CALCIUM CARBONATE	1 (1.3%)	2 (2.2%)	3 (1.8%)
	CYANOCOBALAMIN	1 (1.3%)	0	1 (0.6%)
	DIMETICONE, ACTIVATED	2 (2.5%)	0	2 (1.2%)
	ERGOCALCIFEROL	1 (1.3%)	0	1 (0.6%)
	FERROUS FUMARATE	1 (1.3%)	0	1 (0.6%)
	FLUORIDE NOS	1 (1.3%)	0	1 (0.6%)
	LOPERAMIDE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	MAGNESIUM HYDROXIDE	1 (1.3%)	0	1 (0.6%)
	METHYLCELLULOSE	0	1 (1.1%)	1 (0.6%)
	MINERALS NOS	1 (1.3%)	0	1 (0.6%)
	NEOMYCIN	0	1 (1.1%)	1 (0.6%)
	NICOTINAMIDE	1 (1.3%)	0	1 (0.6%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	PYRIDOXINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	RANITIDINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	RETINOL	1 (1.3%)	0	1 (0.6%)
	RIBOFLAVIN	1 (1.3%)	0	1 (0.6%)
	SENNA FRUIT	0	1 (1.1%)	1 (0.6%)
	THIAMINE MONONITRATE	1 (1.3%)	0	1 (0.6%)
	TOCOPHEROL	1 (1.3%)	0	1 (0.6%)
	TRIAMCINOLONE ACETONIDE	0	3 (3.4%)	3 (1.8%)
	VITAMINS NOS	6 (7.5%)	4 (4.5%)	10 (5.9%)
ANTIINFECTIVES,SYSTEMIC	Total	7 (8.8%)	7 (7.9%)	14 (8.3%)
	ACICLOVIR	1 (1.3%)	0	1 (0.6%)
	AMOXICILLIN	1 (1.3%)	2 (2.2%)	3 (1.8%)
	AMOXICILLIN TRIHYDRATE	1 (1.3%)	1 (1.1%)	2 (1.2%)
	CEFIXIME	1 (1.3%)	0	1 (0.6%)
	CEFPROZIL MONOHYDRATE	1 (1.3%)	0	1 (0.6%)
	CLAVULANIC ACID	0	1 (1.1%)	1 (0.6%)
	DOXYCYCLINE	1 (1.3%)	0	1 (0.6%)
	ERYTHROMYCIN	1 (1.3%)	0	1 (0.6%)
	ITRACONAZOLE	1 (1.3%)	0	1 (0.6%)
	MINOCYCLINE	0	1 (1.1%)	1 (0.6%)
	NEOMYCIN	0	1 (1.1%)	1 (0.6%)

The N’s in the denominator relate to patients entering Taper Phase or Follow-up Phase

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Table 13.12.3.5

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase

		Treatment Group		
ATC Code Level 1	Generic Term(s)	Paroxetine (N=80)	Placebo (N=89)	Total (N=169)
ANTIINFECTIVES,SYSTEMIC	RABIES VACCINE	0	1 (1.1%)	1 (0.6%)
	SULFAMETHOXAZOLE	0	1 (1.1%)	1 (0.6%)
ANTINEOPLASTIC & IMMUNOSUP	Total	1 (1.3%)	1 (1.1%)	2 (1.2%)
	TAMOXIFEN	0	1 (1.1%)	1 (0.6%)
	TRETINOIN	1 (1.3%)	0	1 (0.6%)
BLOOD/BLOOD FORM ORGANS	Total	1 (1.3%)	0	1 (0.6%)
	FISH OIL	1 (1.3%)	0	1 (0.6%)
CARDIOVASCULAR	Total	1 (1.3%)	0	1 (0.6%)
	GUANFACINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
CENTRAL NERVOUS SYSTEM	Total	22 (27.5%)	17 (19.1%)	39 (23.1%)
	ACETYLSALICYLIC ACID	2 (2.5%)	0	2 (1.2%)
	AMPHETAMINE ASPARTATE	2 (2.5%)	0	2 (1.2%)
	AMPHETAMINE SULFATE	2 (2.5%)	0	2 (1.2%)
	CAFFEINE	2 (2.5%)	0	2 (1.2%)
	CITALOPRAM	0	1 (1.1%)	1 (0.6%)
	DEXTROAMPHETAMINE SACCHARATE	2 (2.5%)	0	2 (1.2%)
	DEXTROAMPHETAMINE SULFATE	2 (2.5%)	0	2 (1.2%)
	FLUOXETINE	0	1 (1.1%)	1 (0.6%)
	FLUVOXAMINE MALEATE	2 (2.5%)	1 (1.1%)	3 (1.8%)
	GABAPENTIN	1 (1.3%)	0	1 (0.6%)
	IBUPROFEN	8 (10.0%)	5 (5.6%)	13 (7.7%)
	IMIPRAMINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	LORAZEPAM	0	1 (1.1%)	1 (0.6%)
	METHYLPHENIDATE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	PARACETAMOL	8 (10.0%)	6 (6.7%)	14 (8.3%)
	PAROXETINE	3 (3.8%)	4 (4.5%)	7 (4.1%)
	PHENAZONE	0	1 (1.1%)	1 (0.6%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (1.1%)	1 (0.6%)
	QUETIAPINE	1 (1.3%)	0	1 (0.6%)
	RISPERIDONE	0	1 (1.1%)	1 (0.6%)
	SERTRALINE HYDROCHLORIDE	0	1 (1.1%)	1 (0.6%)
	TRAZODONE	2 (2.5%)	0	2 (1.2%)
	VENLAFAXINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
DERMATOLOGICALS	Total	7 (8.8%)	14 (15.7%)	21 (12.4%)
	BENZOYL PEROXIDE	1 (1.3%)	0	1 (0.6%)
	BUDESONIDE	2 (2.5%)	2 (2.2%)	4 (2.4%)
	CHLOROXYLENOL	0	1 (1.1%)	1 (0.6%)
	CORTISONE	0	1 (1.1%)	1 (0.6%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase

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Table 13.12.3.5

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=80)	Placebo (N=89)	Total (N=169)
DERMATOLOGICALS	DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.3%)	2 (2.2%)	3 (1.8%)
	ERYTHROMYCIN	1 (1.3%)	0	1 (0.6%)
	FLUTICASONE PROPIONATE	1 (1.3%)	3 (3.4%)	4 (2.4%)
	MOMETASONE FUROATE	0	1 (1.1%)	1 (0.6%)
	NEOMYCIN	0	1 (1.1%)	1 (0.6%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	SALICYLIC ACID	1 (1.3%)	0	1 (0.6%)
	TOCOPHEROL	1 (1.3%)	0	1 (0.6%)
	TRETINOIN	1 (1.3%)	0	1 (0.6%)
	TRIAMCINOLONE ACETONIDE	0	3 (3.4%)	3 (1.8%)
GU SYSTEM/SEX HORMONES	Total	1 (1.3%)	2 (2.2%)	3 (1.8%)
	ETHINYLESTRADIOL	1 (1.3%)	1 (1.1%)	2 (1.2%)
	LEVONORGESTREL	1 (1.3%)	0	1 (0.6%)
	NORGESTREL	0	1 (1.1%)	1 (0.6%)
	ORAL CONTRACEPTIVE	0	1 (1.1%)	1 (0.6%)
MUSCULO-SKELETAL	Total	9 (11.3%)	7 (7.9%)	16 (9.5%)
	DICLOFENAC SODIUM	0	1 (1.1%)	1 (0.6%)
	IBUPROFEN	8 (10.0%)	5 (5.6%)	13 (7.7%)
	NAPROXEN SODIUM	1 (1.3%)	1 (1.1%)	2 (1.2%)
	SALICYLIC ACID	1 (1.3%)	0	1 (0.6%)
RESPIRATORY	Total	19 (23.8%)	24 (27.0%)	43 (25.4%)
	AZELASTINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	BECLOMETASONE DIPROPIONATE	1 (1.3%)	1 (1.1%)	2 (1.2%)
	BROMPHENIRAMINE MALEATE	0	1 (1.1%)	1 (0.6%)
	BUDESONIDE	2 (2.5%)	2 (2.2%)	4 (2.4%)
	CETIRIZINE HYDROCHLORIDE	1 (1.3%)	4 (4.5%)	5 (3.0%)
	CHLORPHENAMINE MALEATE	1 (1.3%)	1 (1.1%)	2 (1.2%)
	CHLORPHENAMINE TANNATE	0	1 (1.1%)	1 (0.6%)
	CLEMASTINE FUMARATE	0	1 (1.1%)	1 (0.6%)
	DEXTROMETHORPHAN HYDROBROMIDE	1 (1.3%)	0	1 (0.6%)
	DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.3%)	2 (2.2%)	3 (1.8%)
	ETHANOL	1 (1.3%)	0	1 (0.6%)
	FEXOFENADINE HYDROCHLORIDE	4 (5.0%)	1 (1.1%)	5 (3.0%)
	FLUTICASONE PROPIONATE	1 (1.3%)	3 (3.4%)	4 (2.4%)
	GUAIFENESIN	1 (1.3%)	1 (1.1%)	2 (1.2%)
	LORATADINE	5 (6.3%)	7 (7.9%)	12 (7.1%)
	MEPYRAMINE MALEATE	0	1 (1.1%)	1 (0.6%)
	MEPYRAMINE TANNATE	0	1 (1.1%)	1 (0.6%)
	MOMETASONE FUROATE	0	1 (1.1%)	1 (0.6%)
	MONTELUKAST SODIUM	0	1 (1.1%)	1 (0.6%)
	PARACETAMOL	0	1 (1.1%)	1 (0.6%)

The N's in the denominator relate to patients entering Taper Phase or Follow-up Phase

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Table 13.12.3.5

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase

		Treatment Group		
ATC Code Level 1	Generic Term(s)	Paroxetine (N=80)	Placebo (N=89)	Total (N=169)
RESPIRATORY	PHENIRAMINE MALEATE	0	1 (1.1%)	1 (0.6%)
	PHENYLEPHRINE HYDROCHLORIDE	0	1 (1.1%)	1 (0.6%)
	PHENYLEPHRINE TANNATE	0	1 (1.1%)	1 (0.6%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	0	3 (3.4%)	3 (1.8%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	2 (2.5%)	3 (3.4%)	5 (3.0%)
	SALBUTAMOL	4 (5.0%)	5 (5.6%)	9 (5.3%)
	TRIAMCINOLONE ACETONIDE	0	3 (3.4%)	3 (1.8%)
	TRIPROLIDINE HYDROCHLORIDE	0	1 (1.1%)	1 (0.6%)
SENSORY ORGANS	Total	2 (2.5%)	7 (7.9%)	9 (5.3%)
	CORTISONE	0	1 (1.1%)	1 (0.6%)
	DEXTRAN	1 (1.3%)	0	1 (0.6%)
	DICLOFENAC SODIUM	0	1 (1.1%)	1 (0.6%)
	ERYTHROMYCIN	1 (1.3%)	0	1 (0.6%)
	HYPROMELLOSE	1 (1.3%)	0	1 (0.6%)
	METHYLCELLULOSE	0	1 (1.1%)	1 (0.6%)
	NEOMYCIN	0	1 (1.1%)	1 (0.6%)
	TRIAMCINOLONE ACETONIDE	0	3 (3.4%)	3 (1.8%)
SYSTEMIC HORMONAL	Total	2 (2.5%)	8 (9.0%)	10 (5.9%)
	CORTISONE	0	1 (1.1%)	1 (0.6%)
	DESMOPRESSIN	1 (1.3%)	2 (2.2%)	3 (1.8%)
	LEVOTHYROXINE SODIUM	1 (1.3%)	2 (2.2%)	3 (1.8%)
	TRIAMCINOLONE ACETONIDE	0	3 (3.4%)	3 (1.8%)
UNCLASSIFIABLE	Total	0	1 (1.1%)	1 (0.6%)
	UNKNOWN MEDICATION	0	1 (1.1%)	1 (0.6%)
VARIOUS	Total	1 (1.3%)	1 (1.1%)	2 (1.2%)
	GARLIC	0	1 (1.1%)	1 (0.6%)
	GLYCEROL	0	1 (1.1%)	1 (0.6%)
	HERBAL MEDICATION	0	1 (1.1%)	1 (0.6%)
	SOYA OIL	0	1 (1.1%)	1 (0.6%)
	SPIRULINA	1 (1.3%)	0	1 (0.6%)
	WATER	0	1 (1.1%)	1 (0.6%)

The N’s in the denominator relate to patients entering Taper Phase or Follow-up Phase

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Table 13.12.3.6

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase or Follow-up Phase
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase

Generic Term	Treatment Group: Paroxetine (N=80)	Placebo (N=89)	Total (N=169)
Total number of patients with at least one concomitant medication during taper or follow-up	42 (52.5%)	48 (53.9%)	90 (53.3%)
PARACETAMOL	8 (10.0%)	6 (6.7%)	14 (8.3%)
IBUPROFEN	8 (10.0%)	5 (5.6%)	13 (7.7%)
VITAMINS NOS	6 (7.5%)	4 (4.5%)	10 (5.9%)
LORATADINE	5 (6.3%)	7 (7.9%)	12 (7.1%)
SALBUTAMOL	4 (5.0%)	5 (5.6%)	9 (5.3%)
FEXOFENADINE HYDROCHLORIDE	4 (5.0%)	1 (1.1%)	5 (3.0%)
PAROXETINE	3 (3.8%)	4 (4.5%)	7 (4.1%)
ASCORBIC ACID	3 (3.8%)	0	3 (1.8%)
PSEUDOEPHEDRINE HYDROCHLORIDE	2 (2.5%)	3 (3.4%)	5 (3.0%)
BUDESONIDE	2 (2.5%)	2 (2.2%)	4 (2.4%)
FLUVOXAMINE MALEATE	2 (2.5%)	1 (1.1%)	3 (1.8%)
ACETYLSALICYLIC ACID	2 (2.5%)	0	2 (1.2%)
AMPHETAMINE ASPARTATE	2 (2.5%)	0	2 (1.2%)
AMPHETAMINE SULFATE	2 (2.5%)	0	2 (1.2%)
BISMUTH SUBSALICYLATE	2 (2.5%)	0	2 (1.2%)
CAFFEINE	2 (2.5%)	0	2 (1.2%)
DEXTROAMPHETAMINE SACCHARATE	2 (2.5%)	0	2 (1.2%)
DEXTROAMPHETAMINE SULFATE	2 (2.5%)	0	2 (1.2%)
DIMETICONE, ACTIVATED	2 (2.5%)	0	2 (1.2%)
TRAZODONE	2 (2.5%)	0	2 (1.2%)
CETIRIZINE HYDROCHLORIDE	1 (1.3%)	4 (4.5%)	5 (3.0%)
FLUTICASONE PROPIONATE	1 (1.3%)	3 (3.4%)	4 (2.4%)
AMOXICILLIN	1 (1.3%)	2 (2.2%)	3 (1.8%)
CALCIUM CARBONATE	1 (1.3%)	2 (2.2%)	3 (1.8%)
DESMOPRESSIN	1 (1.3%)	2 (2.2%)	3 (1.8%)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.3%)	2 (2.2%)	3 (1.8%)
LEVOTHYROXINE SODIUM	1 (1.3%)	2 (2.2%)	3 (1.8%)
AMOXICILLIN TRIHYDRATE	1 (1.3%)	1 (1.1%)	2 (1.2%)
BECLOMETASONE DIPROPIONATE	1 (1.3%)	1 (1.1%)	2 (1.2%)
CHLORPHENAMINE MALEATE	1 (1.3%)	1 (1.1%)	2 (1.2%)
ETHINYLESTRADIOL	1 (1.3%)	1 (1.1%)	2 (1.2%)
GUAIFENESIN	1 (1.3%)	1 (1.1%)	2 (1.2%)
NAPROXEN SODIUM	1 (1.3%)	1 (1.1%)	2 (1.2%)
ACICLOVIR	1 (1.3%)	0	1 (0.6%)
ALUMINIUM HYDROXIDE	1 (1.3%)	0	1 (0.6%)
AZELASTINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
BENZOYL PEROXIDE	1 (1.3%)	0	1 (0.6%)
CALCIUM	1 (1.3%)	0	1 (0.6%)
CEFIXIME	1 (1.3%)	0	1 (0.6%)
CEFPROZIL MONOHYDRATE	1 (1.3%)	0	1 (0.6%)
CYANOCOBALAMIN	1 (1.3%)	0	1 (0.6%)

The N’s in the denominator relate to patients entering Taper Phase or Follow-up Phase

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Table 13.12.3.6

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase or Follow-up Phase
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase

Generic Term	Treatment Group: Paroxetine (N=80)	Placebo (N=89)	Total (N=169)
DEXTRAN	1 (1.3%)	0	1 (0.6%)
DEXTROMETHORPHAN HYDROBROMIDE	1 (1.3%)	0	1 (0.6%)
DOXYCYCLINE	1 (1.3%)	0	1 (0.6%)
ERGOCALCIFEROL	1 (1.3%)	0	1 (0.6%)
ERYTHROMYCIN	1 (1.3%)	0	1 (0.6%)
ETHANOL	1 (1.3%)	0	1 (0.6%)
FERROUS FUMARATE	1 (1.3%)	0	1 (0.6%)
FISH OIL	1 (1.3%)	0	1 (0.6%)
FLUORIDE NOS	1 (1.3%)	0	1 (0.6%)
GABAPENTIN	1 (1.3%)	0	1 (0.6%)
GUANFACINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
HYPROMELLOSE	1 (1.3%)	0	1 (0.6%)
IMIPRAMINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
ITRACONAZOLE	1 (1.3%)	0	1 (0.6%)
LEVONORGESTREL	1 (1.3%)	0	1 (0.6%)
LOPERAMIDE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
MAGNESIUM HYDROXIDE	1 (1.3%)	0	1 (0.6%)
METHYLPHENIDATE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
MINERALS NOS	1 (1.3%)	0	1 (0.6%)
NICOTINAMIDE	1 (1.3%)	0	1 (0.6%)
PROMETHAZINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
PYRIDOXINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
QUETIAPINE	1 (1.3%)	0	1 (0.6%)
RANITIDINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
RETINOL	1 (1.3%)	0	1 (0.6%)
RIBOFLAVIN	1 (1.3%)	0	1 (0.6%)
SALICYLIC ACID	1 (1.3%)	0	1 (0.6%)
SPIRULINA	1 (1.3%)	0	1 (0.6%)
THIAMINE MONONITRATE	1 (1.3%)	0	1 (0.6%)
TOCOPHEROL	1 (1.3%)	0	1 (0.6%)
TRETINOIN	1 (1.3%)	0	1 (0.6%)
VENLAFAXINE HYDROCHLORIDE	1 (1.3%)	0	1 (0.6%)
PHENYLPROPANOLAMINE HYDROCHLORIDE	0	3 (3.4%)	3 (1.8%)
TRIAMCINOLONE ACETONIDE	0	3 (3.4%)	3 (1.8%)
BROMPHENIRAMINE MALEATE	0	1 (1.1%)	1 (0.6%)
CHLOROXYLENOL	0	1 (1.1%)	1 (0.6%)
CHLORPHENAMINE TANNATE	0	1 (1.1%)	1 (0.6%)
CITALOPRAM	0	1 (1.1%)	1 (0.6%)
CLAVULANIC ACID	0	1 (1.1%)	1 (0.6%)
CLEMASTINE FUMARATE	0	1 (1.1%)	1 (0.6%)
CORTISONE	0	1 (1.1%)	1 (0.6%)
DICLOFENAC SODIUM	0	1 (1.1%)	1 (0.6%)
FLUOXETINE	0	1 (1.1%)	1 (0.6%)
GARLIC	0	1 (1.1%)	1 (0.6%)

The N’s in the denominator relate to patients entering Taper Phase or Follow-up Phase

Table 13.12.3.6

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase or Follow-up Phase
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase

	Treatment Group		
Generic Term	Paroxetine (N=80)	Placebo (N=89)	Total (N=169)
GLYCEROL	0	1 (1.1%)	1 (0.6%)
HERBAL MEDICATION	0	1 (1.1%)	1 (0.6%)
LORAZEPAM	0	1 (1.1%)	1 (0.6%)
MEPYRAMINE MALEATE	0	1 (1.1%)	1 (0.6%)
MEPYRAMINE TANNATE	0	1 (1.1%)	1 (0.6%)
METHYLCELLULOSE	0	1 (1.1%)	1 (0.6%)
MINOCYCLINE	0	1 (1.1%)	1 (0.6%)
MOMETASONE FUROATE	0	1 (1.1%)	1 (0.6%)
MONTELUKAST SODIUM	0	1 (1.1%)	1 (0.6%)
NEOMYCIN	0	1 (1.1%)	1 (0.6%)
NORGESTREL	0	1 (1.1%)	1 (0.6%)
ORAL CONTRACEPTIVE	0	1 (1.1%)	1 (0.6%)
PHENAZONE	0	1 (1.1%)	1 (0.6%)
PHENIRAMINE MALEATE	0	1 (1.1%)	1 (0.6%)
PHENYLEPHRINE HYDROCHLORIDE	0	1 (1.1%)	1 (0.6%)
PHENYLEPHRINE TANNATE	0	1 (1.1%)	1 (0.6%)
RABIES VACCINE	0	1 (1.1%)	1 (0.6%)
RISPERIDONE	0	1 (1.1%)	1 (0.6%)
SENNA FRUIT	0	1 (1.1%)	1 (0.6%)
SERTRALINE HYDROCHLORIDE	0	1 (1.1%)	1 (0.6%)
SOYA OIL	0	1 (1.1%)	1 (0.6%)
SULFAMETHOXAZOLE	0	1 (1.1%)	1 (0.6%)
TAMOXIFEN	0	1 (1.1%)	1 (0.6%)
TRIPROLIDINE HYDROCHLORIDE	0	1 (1.1%)	1 (0.6%)
UNKNOWN MEDICATION	0	1 (1.1%)	1 (0.6%)
WATER	0	1 (1.1%)	1 (0.6%)

The N’s in the denominator relate to patients entering Taper Phase or Follow-up Phase

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Table 13.13.1

Number (%) of Patients who missed more than 3 consecutive days of Study Medication by Visit and Overall

Intention-To-Treat Population

Age Group : Children

	Treatment Group					
	Paroxetine (N = 58)		Placebo (N = 57)		Total (N = 115)	
Visit	Missed > 3 Consecutive Days No	Yes	Missed > 3 Consecutive Days No	Yes	Missed > 3 Consecutive Days No	Yes
Week 1	56 (98.2%)	1 (1.8%)	57 (100.0%)	0	113(99.1%)	1 (0.9%)
Week 2	53 (98.1%)	1 (1.9%)	54 (100.0%)	0	107(99.1%)	1 (0.9%)
Week 3	52 (100.0%)	0	51 (92.7%)	4 (7.3%)	103(96.3%)	4 (3.7%)
Week 4	50 (98.0%)	1 (2.0%)	51 (96.2%)	2 (3.8%)	101(97.1%)	3 (2.9%)
Week 6	44 (91.7%)	4 (8.3%)	51 (98.1%)	1 (1.9%)	95 (95.0%)	5 (5.0%)
Week 8	40 (97.6%)	1 (2.4%)	47 (92.2%)	4 (7.8%)	87 (94.6%)	5 (5.4%)
Week 10	36 (94.7%)	2 (5.3%)	47 (97.9%)	1 (2.1%)	83 (96.5%)	3 (3.5%)
Overall*	48 (84.2%)	9 (15.8%)	46 (80.7%)	11 (19.3%)	94 (82.5%)	20 (17.5%)

Note: Percentages are out of number of patients in each treatment group who have this study medication information on the relevant CRF page, patients with unknown compliance and a duration of study medication of > 3 days at that visit are considered non-compliant

* Overall = Number of patients who miss >3 consecutive days at any point in the study. Patients who miss >3 consecutive days on more than one occasion are only counted once.

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Table 13.13.1

Number (%) of Patients who missed more than 3 consecutive days of Study Medication by Visit and Overall

Intention-To-Treat Population

Age Group : Adolescents

	Treatment Group					
	Paroxetine (N = 40)		Placebo (N = 48)		Total (N = 88)	
	Missed > 3 Consecutive Days		Missed > 3 Consecutive Days		Missed > 3 Consecutive Days	
Visit	No	Yes	No	Yes	No	Yes
Week 1	40 (100.0%)	0	48 (100.0%)	0	88 (100.0%)	0
Week 2	40 (100.0%)	0	46 (97.9%)	1 (2.1%)	86 (98.9%)	1 (1.1%)
Week 3	39 (100.0%)	0	44 (100.0%)	0	83 (100.0%)	0
Week 4	35 (94.6%)	2 (5.4%)	41 (100.0%)	0	76 (97.4%)	2 (2.6%)
Week 6	32 (91.4%)	3 (8.6%)	41 (100.0%)	0	73 (96.1%)	3 (3.9%)
Week 8	29 (90.6%)	3 (9.4%)	34 (91.9%)	3 (8.1%)	63 (91.3%)	6 (8.7%)
Week 10	28 (96.6%)	1 (3.4%)	29 (87.9%)	4 (12.1%)	57 (91.9%)	5 (8.1%)
Overall*	32 (80.0%)	8 (20.0%)	40 (83.3%)	8 (16.7%)	72 (81.8%)	16 (18.2%)

Note: Percentages are out of number of patients in each treatment group who have this study medication information on the relevant CRF page, patients with unknown compliance and a duration of study medication of > 3 days at that visit are considered non-compliant

* Overall = Number of patients who miss >3 consecutive days at any point in the study. Patients who miss >3 consecutive days on more than one occasion are only counted once.

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Table 13.13.1

Number (%) of Patients who missed more than 3 consecutive days of Study Medication by Visit and Overall

Intention-To-Treat Population

Age Group : Total

	Treatment Group					
	Paroxetine (N = 98)		Placebo (N = 105)		Total (N = 203)	
Visit	Missed > 3 Consecutive Days No	Yes	Missed > 3 Consecutive Days No	Yes	Missed > 3 Consecutive Days No	Yes
Week 1	96 (99.0%)	1 (1.0%)	105(100.0%)	0	201(99.5%)	1 (0.5%)
Week 2	93 (98.9%)	1 (1.1%)	100(99.0%)	1 (1.0%)	193(99.0%)	2 (1.0%)
Week 3	91 (100.0%)	0	95 (96.0%)	4 (4.0%)	186(97.9%)	4 (2.1%)
Week 4	85 (96.6%)	3 (3.4%)	92 (97.9%)	2 (2.1%)	177(97.3%)	5 (2.7%)
Week 6	76 (91.6%)	7 (8.4%)	92 (98.9%)	1 (1.1%)	168(95.5%)	8 (4.5%)
Week 8	69 (94.5%)	4 (5.5%)	81 (92.0%)	7 (8.0%)	150(93.2%)	11 (6.8%)
Week 10	64 (95.5%)	3 (4.5%)	76 (93.8%)	5 (6.2%)	140(94.6%)	8 (5.4%)
Overall*	80 (82.5%)	17 (17.5%)	86 (81.9%)	19 (18.1%)	166(82.2%)	36 (17.8%)

Note: Percentages are out of number of patients in each treatment group who have this study medication information on the relevant CRF page, patients with unknown compliance and a duration of study medication of > 3 days at that visit are considered non-compliant

* Overall = Number of patients who miss >3 consecutive days at any point in the study. Patients who miss >3 consecutive days on more than one occasion are only counted once.

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Table 13.13.2

Tablet Accountability (number (%) of patients) at Each Visit and Overall

Intention-To-Treat Population

Age Group : Children

	Paroxetine (N=58)		Placebo (N=57)		Total (N=115)	
	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)
Week 1	45 (88.2%)	6 (11.8%)	49 (92.5%)	4 (7.5%)	94 (90.4%)	10 (9.6%)
Week 2	43 (81.1%)	10 (18.9%)	51 (94.4%)	3 (5.6%)	94 (87.9%)	13 (12.1%)
Week 3	42 (87.5%)	6 (12.5%)	46 (86.8%)	7 (13.2%)	88 (87.1%)	13 (12.9%)
Week 4	45 (90.0%)	5 (10.0%)	41 (83.7%)	8 (16.3%)	86 (86.9%)	13 (13.1%)
Week 6	33 (76.7%)	10 (23.3%)	45 (86.5%)	7 (13.5%)	78 (82.1%)	17 (17.9%)
Week 8	32 (80.0%)	8 (20.0%)	42 (85.7%)	7 (14.3%)	74 (83.1%)	15 (16.9%)
Week 10	29 (80.6%)	7 (19.4%)	35 (77.8%)	10 (22.2%)	64 (79.0%)	17 (21.0%)
Overall**	39 (88.6%)	5 (11.4%)	38 (86.4%)	6 (13.6%)	77 (87.5%)	11 (12.5%)

Note: Percentages are out of number of patients in each treatment group who have this study medication information on the relevant CRF page.

* 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 * No. of Capsules Per Day)] * 100

** Accountability overall is defined as the result of the following calculation falling within the 80%-120% band:
[(Total No. of Caps Disp - Total No. of Caps Ret) / {Sum for each visit (No. of Days * No. of Caps per Day)}] * 100

Note: No. of Days = Stop Date - Start Date + 1

Note: Accountability and Overall Accountability are only calculated if all data needed is present

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Table 13.13.2

Tablet Accountability (number (%) of patients) at Each Visit and Overall

Intention-To-Treat Population

Age Group : Adolescents

	Paroxetine (N=40)		Placebo (N=48)		Total (N=88)	
	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)
Week 1	35 (92.1%)	3 (7.9%)	44 (93.6%)	3 (6.4%)	79 (92.9%)	6 (7.1%)
Week 2	33 (84.6%)	6 (15.4%)	38 (82.6%)	8 (17.4%)	71 (83.5%)	14 (16.5%)
Week 3	28 (82.4%)	6 (17.6%)	37 (92.5%)	3 (7.5%)	65 (87.8%)	9 (12.2%)
Week 4	28 (82.4%)	6 (17.6%)	35 (87.5%)	5 (12.5%)	63 (85.1%)	11 (14.9%)
Week 6	31 (93.9%)	2 (6.1%)	34 (85.0%)	6 (15.0%)	65 (89.0%)	8 (11.0%)
Week 8	27 (90.0%)	3 (10.0%)	30 (88.2%)	4 (11.8%)	57 (89.1%)	7 (10.9%)
Week 10	18 (66.7%)	9 (33.3%)	26 (81.3%)	6 (18.8%)	44 (74.6%)	15 (25.4%)
Overall**	31 (93.9%)	2 (6.1%)	32 (94.1%)	2 (5.9%)	63 (94.0%)	4 (6.0%)

Note: Percentages are out of number of patients in each treatment group who have this study medication information on the relevant CRF page.

* 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 * No. of Capsules Per Day)] * 100

** Accountability overall is defined as the result of the following calculation falling within the 80%-120% band:
[(Total No. of Caps Disp - Total No. of Caps Ret) / {Sum for each visit (No. of Days * No. of Caps per Day)}] * 100

Note: No. of Days = Stop Date - Start Date + 1

Note: Accountability and Overall Accountability are only calculated if all data needed is present

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Table 13.13.2

Tablet Accountability (number (%) of patients) at Each Visit and Overall

Intention-To-Treat Population

Age Group : Total

	Paroxetine (N=98)		Placebo (N=105)		Total (N=203)	
	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)	Account* n(%)	Non-Account n(%)
Week 1	80 (89.9%)	9 (10.1%)	93 (93.0%)	7 (7.0%)	173 (91.5%)	16 (8.5%)
Week 2	76 (82.6%)	16 (17.4%)	89 (89.0%)	11 (11.0%)	165 (85.9%)	27 (14.1%)
Week 3	70 (85.4%)	12 (14.6%)	83 (89.2%)	10 (10.8%)	153 (87.4%)	22 (12.6%)
Week 4	73 (86.9%)	11 (13.1%)	76 (85.4%)	13 (14.6%)	149 (86.1%)	24 (13.9%)
Week 6	64 (84.2%)	12 (15.8%)	79 (85.9%)	13 (14.1%)	143 (85.1%)	25 (14.9%)
Week 8	59 (84.3%)	11 (15.7%)	72 (86.7%)	11 (13.3%)	131 (85.6%)	22 (14.4%)
Week 10	47 (74.6%)	16 (25.4%)	61 (79.2%)	16 (20.8%)	108 (77.1%)	32 (22.9%)
Overall**	70 (90.9%)	7 (9.1%)	70 (89.7%)	8 (10.3%)	140 (90.3%)	15 (9.7%)

Note: Percentages are out of number of patients in each treatment group who have this study medication information on the relevant CRF page.

* 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 * No. of Capsules Per Day)] * 100

** Accountability overall is defined as the result of the following calculation falling within the 80%-120% band:
[(Total No. of Caps Disp - Total No. of Caps Ret) / {Sum for each visit (No. of Days * No. of Caps per Day)}] * 100

Note: No. of Days = Stop Date - Start Date + 1

Note: Accountability and Overall Accountability are only calculated if all data needed is present

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Table 13.13.3

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	58	100.0	0	0.0	0	0.0	0	0.0	0	0.0	58	100.0
Week 2	22	39.3	34	60.7	0	0.0	0	0.0	0	0.0	56	100.0
Week 3	12	23.1	22	42.3	18	34.6	0	0.0	0	0.0	52	100.0
Week 4	8	15.7	23	45.1	11	21.6	9	17.6	0	0.0	51	100.0
Week 6	7	14.3	22	44.9	7	14.3	7	14.3	6	12.2	49	100.0
Week 8	6	14.6	16	39.0	5	12.2	5	12.2	9	22.0	41	100.0
Week 10	5	12.8	15	38.5	6	15.4	6	15.4	7	17.9	39	100.0

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Table 13.13.3

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	40	100.0	0	0.0	0	0.0	0	0.0	0	0.0	40	100.0
Week 2	8	20.0	32	80.0	0	0.0	0	0.0	0	0.0	40	100.0
Week 3	5	12.8	10	25.6	24	61.5	0	0.0	0	0.0	39	100.0
Week 4	4	10.8	6	16.2	7	18.9	20	54.1	0	0.0	37	100.0
Week 6	1	2.9	6	17.1	6	17.1	12	34.3	10	28.6	35	100.0
Week 8	1	3.1	3	9.4	7	21.9	7	21.9	14	43.8	32	100.0
Week 10	1	3.4	3	10.3	2	6.9	12	41.4	11	37.9	29	100.0

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Table 13.13.3

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	98	100.0	0	0.0	0	0.0	0	0.0	0	0.0	98	100.0
Week 2	30	31.3	66	68.8	0	0.0	0	0.0	0	0.0	96	100.0
Week 3	17	18.7	32	35.2	42	46.2	0	0.0	0	0.0	91	100.0
Week 4	12	13.6	29	33.0	18	20.5	29	33.0	0	0.0	88	100.0
Week 6	8	9.5	28	33.3	13	15.5	19	22.6	16	19.0	84	100.0
Week 8	7	9.6	19	26.0	12	16.4	12	16.4	23	31.5	73	100.0
Week 10	6	8.8	18	26.5	8	11.8	18	26.5	18	26.5	68	100.0

Table 13.13.3

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	57	100.0	0	0.0	0	0.0	0	0.0	0	0.0	57	100.0
Week 2	17	30.9	38	69.1	0	0.0	0	0.0	0	0.0	55	100.0
Week 3	9	16.4	19	34.5	27	49.1	0	0.0	0	0.0	55	100.0
Week 4	4	7.5	16	30.2	12	22.6	21	39.6	0	0.0	53	100.0
Week 6	4	7.5	10	18.9	12	22.6	12	22.6	15	28.3	53	100.0
Week 8	3	5.9	8	15.7	10	19.6	12	23.5	18	35.3	51	100.0
Week 10	3	6.3	9	18.8	6	12.5	11	22.9	19	39.6	48	100.0

Table 13.13.3

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	48	100.0	0	0.0	0	0.0	0	0.0	0	0.0	48	100.0
Week 2	9	18.8	39	81.3	0	0.0	0	0.0	0	0.0	48	100.0
Week 3	4	8.9	11	24.4	30	66.7	0	0.0	0	0.0	45	100.0
Week 4	2	4.8	6	14.3	10	23.8	24	57.1	0	0.0	42	100.0
Week 6	2	4.9	4	9.8	6	14.6	9	22.0	20	48.8	41	100.0
Week 8	1	2.7	2	5.4	6	16.2	5	13.5	23	62.2	37	100.0
Week 10	0	0.0	2	6.1	6	18.2	4	12.1	21	63.6	33	100.0

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Table 13.13.3

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	105	100.0	0	0.0	0	0.0	0	0.0	0	0.0	105	100.0
Week 2	26	25.2	77	74.8	0	0.0	0	0.0	0	0.0	103	100.0
Week 3	13	13.0	30	30.0	57	57.0	0	0.0	0	0.0	100	100.0
Week 4	6	6.3	22	23.2	22	23.2	45	47.4	0	0.0	95	100.0
Week 6	6	6.4	14	14.9	18	19.1	21	22.3	35	37.2	94	100.0
Week 8	4	4.5	10	11.4	16	18.2	17	19.3	41	46.6	88	100.0
Week 10	3	3.7	11	13.6	12	14.8	15	18.5	40	49.4	81	100.0

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Table 13.13.4

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
7 (12.1%)	22 (37.9%)	13 (22.4%)	5 (8.6%)	11 (19.0%)	58 (100.0%)

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Table 13.13.4

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
1 (2.5%)	5 (12.5%)	6 (15.0%)	13 (32.5%)	15 (37.5%)	40 (100.0%)

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Table 13.13.4

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
8 (8.2%)	27 (27.6%)	19 (19.4%)	18 (18.4%)	26 (26.5%)	98 (100.0%)

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Table 13.13.4

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 (5.3%)	8 (14.0%)	11 (19.3%)	12 (21.1%)	23 (40.4%)	57 (100.0%)

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Table 13.13.4

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
2 (4.2%)	5 (10.4%)	9 (18.8%)	5 (10.4%)	27 (56.3%)	48 (100.0%)

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Table 13.13.4

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
5 (4.8%)	13 (12.4%)	20 (19.0%)	17 (16.2%)	50 (47.6%)	105 (100.0%)

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Table 13.13.5.1

Overall duration of Exposure to Study Medication(Excluding Taper Medication)

Intention-To-Treat Population

Age Group: Children

Days	Paroxetine (N=58)	Placebo (N=57)	Total (N=115)
	----------Treatment Group----------		
>= 1	58 (100.0%)	57 (100.0%)	115 (100.0%)
> 7	56 (96.6%)	57 (100.0%)	113 (98.3%)
> 14	53 (91.4%)	55 (96.5%)	108 (93.9%)
> 21	51 (87.9%)	54 (94.7%)	105 (91.3%)
> 28	51 (87.9%)	53 (93.0%)	104 (90.4%)
> 42	44 (75.9%)	51 (89.5%)	95 (82.6%)
> 56	41 (70.7%)	49 (86.0%)	90 (78.3%)
> 70	20 (34.5%)	29 (50.9%)	49 (42.6%)
> 84	1 (1.7%)	0	1 (0.9%)
Overall Mean	58.5	66.2	62.4
Minimum	1	8	1
Maximum	90	81	90

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Table 13.13.5.1

Overall duration of Exposure to Study Medication(Excluding Taper Medication)

Intention-To-Treat Population

Age Group: Adolescents

Days	Paroxetine (N=40)	Placebo (N=48)	Total (N=88)
		Treatment Group	
>= 1	40 (100.0%)	48 (100.0%)	88 (100.0%)
> 7	40 (100.0%)	46 (95.8%)	86 (97.7%)
> 14	39 (97.5%)	45 (93.8%)	84 (95.5%)
> 21	39 (97.5%)	43 (89.6%)	82 (93.2%)
> 28	36 (90.0%)	42 (87.5%)	78 (88.6%)
> 42	33 (82.5%)	39 (81.3%)	72 (81.8%)
> 56	31 (77.5%)	35 (72.9%)	66 (75.0%)
> 70	14 (35.0%)	21 (43.8%)	35 (39.8%)
> 84	0	2 (4.2%)	2 (2.3%)
Overall Mean	62.2	60.7	61.4
Minimum	14	6	6
Maximum	81	92	92

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Table 13.13.5.1

Overall duration of Exposure to Study Medication(Excluding Taper Medication)

Intention-To-Treat Population

Age Group: Total

Days	Treatment Group: Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
>= 1	98 (100.0%)	105 (100.0%)	203 (100.0%)
> 7	96 (98.0%)	103 (98.1%)	199 (98.0%)
> 14	92 (93.9%)	100 (95.2%)	192 (94.6%)
> 21	90 (91.8%)	97 (92.4%)	187 (92.1%)
> 28	87 (88.8%)	95 (90.5%)	182 (89.7%)
> 42	77 (78.6%)	90 (85.7%)	167 (82.3%)
> 56	72 (73.5%)	84 (80.0%)	156 (76.8%)
> 70	34 (34.7%)	50 (47.6%)	84 (41.4%)
> 84	1 (1.0%)	2 (1.9%)	3 (1.5%)
Overall Mean	60.0	63.7	61.9
Minimum	1	6	1
Maximum	90	92	92

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Table 13.13.5.2

Overall duration of Exposure to Study Medication(Including Taper Medication)

Intention-To-Treat Population

Age Group: Children

Days	Paroxetine (N=58)	Placebo (N=57)	Total (N=115)
		Treatment Group	
>= 1	58 (100.0%)	57 (100.0%)	115 (100.0%)
> 7	56 (96.6%)	57 (100.0%)	113 (98.3%)
> 14	53 (91.4%)	55 (96.5%)	108 (93.9%)
> 21	51 (87.9%)	54 (94.7%)	105 (91.3%)
> 28	51 (87.9%)	53 (93.0%)	104 (90.4%)
> 42	45 (77.6%)	51 (89.5%)	96 (83.5%)
> 56	41 (70.7%)	49 (86.0%)	90 (78.3%)
> 70	34 (58.6%)	43 (75.4%)	77 (67.0%)
> 84	15 (25.9%)	28 (49.1%)	43 (37.4%)
> 98	3 (5.2%)	8 (14.0%)	11 (9.6%)
> 112	0	0	0
Overall Mean	65.8	78.9	72.3
Minimum	1	8	1
Maximum	101	111	111

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Table 13.13.5.2

Overall duration of Exposure to Study Medication(Including Taper Medication)

Intention-To-Treat Population

Age Group: Adolescents

Days	Paroxetine (N=40)	Placebo (N=48)	Total (N=88)
		Treatment Group	
>= 1	40 (100.0%)	48 (100.0%)	88 (100.0%)
> 7	40 (100.0%)	46 (95.8%)	86 (97.7%)
> 14	39 (97.5%)	45 (93.8%)	84 (95.5%)
> 21	39 (97.5%)	43 (89.6%)	82 (93.2%)
> 28	37 (92.5%)	42 (87.5%)	79 (89.8%)
> 42	33 (82.5%)	39 (81.3%)	72 (81.8%)
> 56	32 (80.0%)	36 (75.0%)	68 (77.3%)
> 70	28 (70.0%)	33 (68.8%)	61 (69.3%)
> 84	21 (52.5%)	22 (45.8%)	43 (48.9%)
> 98	2 (5.0%)	11 (22.9%)	13 (14.8%)
> 112	1 (2.5%)	0	1 (1.1%)
Overall Mean	75.2	73.9	74.5
Minimum	14	6	6
Maximum	114	108	114

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Table 13.13.5.2

Overall duration of Exposure to Study Medication(Including Taper Medication)

Intention-To-Treat Population

Age Group: Total

Days	Paroxetine (N=98)	Placebo (N=105)	Total (N=203)
	----------Treatment Group----------		
>= 1	98 (100.0%)	105 (100.0%)	203 (100.0%)
> 7	96 (98.0%)	103 (98.1%)	199 (98.0%)
> 14	92 (93.9%)	100 (95.2%)	192 (94.6%)
> 21	90 (91.8%)	97 (92.4%)	187 (92.1%)
> 28	88 (89.8%)	95 (90.5%)	183 (90.1%)
> 42	78 (79.6%)	90 (85.7%)	168 (82.8%)
> 56	73 (74.5%)	85 (81.0%)	158 (77.8%)
> 70	62 (63.3%)	76 (72.4%)	138 (68.0%)
> 84	36 (36.7%)	50 (47.6%)	86 (42.4%)
> 98	5 (5.1%)	19 (18.1%)	24 (11.8%)
> 112	1 (1.0%)	0	1 (0.5%)
Overall Mean	69.6	76.6	73.2
Minimum	1	6	1
Maximum	114	111	114

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Table 13.13.6

Mean Daily Dosage (mg) of Paroxetine / Dosage level of Placebo by Visit and Overall

Intention-To-Treat Population
Age Group : Children
Mean Daily Dosage of Paroxetine

Visit	N	Mean	Std Dev
Week 1	58	10.0	0.00
Week 2	56	16.1	4.93
Week 3	52	21.2	7.58
Week 4	51	24.1	9.63
Week 6	49	26.5	12.51
Week 8	41	28.8	14.18
Week 10	39	28.7	13.41
Patient Mean	58	20.3	7.92

Table 13.13.6

Mean Daily Dosage (mg) of Paroxetine / Dosage level of Placebo by Visit and Overall

Intention-To-Treat Population
Age Group : Adolescents
Mean Daily Dosage of Paroxetine

Visit	N	Mean	Std Dev
Week 1	40	10.0	0.00
Week 2	40	18.0	4.05
Week 3	39	24.9	7.21
Week 4	37	31.6	10.68
Week 6	35	36.9	11.57
Week 8	32	39.4	11.62
Week 10	29	40.0	11.02
Patient Mean	40	26.8	7.84

Table 13.13.6

Mean Daily Dosage (mg) of Paroxetine / Dosage level of Placebo by Visit and Overall

Intention-To-Treat Population
Age Group : Total
Mean Daily Dosage of Paroxetine

Visit	N	Mean	Std Dev
Week 1	98	10.0	0.00
Week 2	96	16.9	4.66
Week 3	91	22.7	7.61
Week 4	88	27.3	10.69
Week 6	84	30.8	13.10
Week 8	73	33.4	14.07
Week 10	68	33.5	13.58
Patient Mean	98	23.0	8.48

Table 13.13.6

Mean Daily Dosage (mg) of Paroxetine / Dosage 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	57	1.0	0.00
Week 2	55	1.7	0.47
Week 3	55	2.3	0.75
Week 4	53	2.9	1.01
Week 6	53	3.5	1.29
Week 8	51	3.7	1.28
Week 10	48	3.7	1.34
Patient Mean	57	2.6	0.80

Table 13.13.6

Mean Daily Dosage (mg) of Paroxetine / Dosage 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	48	1.0	0.00
Week 2	48	1.8	0.39
Week 3	45	2.6	0.66
Week 4	42	3.3	0.90
Week 6	41	4.0	1.22
Week 8	37	4.3	1.10
Week 10	33	4.3	0.99
Patient Mean	48	2.8	0.81

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Table 13.13.6

Mean Daily Dosage (mg) of Paroxetine / Dosage 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	105	1.0	0.00
Week 2	103	1.7	0.44
Week 3	100	2.4	0.72
Week 4	95	3.1	0.98
Week 6	94	3.7	1.29
Week 8	88	3.9	1.23
Week 10	81	4.0	1.24
Patient Mean	105	2.7	0.81

Table 13.13.7

Mean Daily Dosage (mg) of Paroxetine / Dose Level of Placebo at Week 10 LOCF Endpoint for CY-BOCS Total Score

Intention-To-Treat Population

Treatment Group:Paroxetine

Week 10 LOCF Endpoint	N	Mean	Std Dev
Children	54	25.4	13.28
Adolescents	40	36.5	10.99
Total	94	30.1	13.48

Summary statistics for the visit making up each patients LOCF assessment for CY-BOCS Total Score

Table 13.13.7

Mean Daily Dosage (mg) of Paroxetine / Dose Level of Placebo at Week 10 LOCF Endpoint for CY-BOCS Total Score

Intention-To-Treat Population

Treatment Group:Placebo

Week 10 LOCF Endpoint	N	Mean	Std Dev
Children	56	3.5	1.33
Adolescents	46	3.8	1.20
Total	102	3.6	1.28

Summary statistics for the visit making up each patients LOCF assessment for CY-BOCS Total Score

12 Source Tables: Efficacy Results

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Table 14.1.1b

Summary Statistics for CY-BOCS Total Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Screening	N	58	40	98	56	47	103
	MEAN	23.5	25.4	24.3	25.3	24.8	25.1
	MEDIAN	23.0	25.0	24.0	25.0	25.0	25.0
	STDDEV	4.65	4.96	4.85	4.84	4.57	4.70
	MINIMUM	16	16	16	16	16	16
	MAXIMUM	36	35	36	37	35	37
	MISSING	0	0	0	1	1	2
Baseline	N	58	40	98	57	48	105
	MEAN	23.8	25.2	24.4	25.3	25.3	25.3
	MEDIAN	23.0	24.5	23.5	25.0	25.0	25.0
	STDDEV	5.00	4.82	4.95	5.31	4.79	5.05
	MINIMUM	16	18	16	16	16	16
	MAXIMUM	36	36	36	37	37	37
	MISSING	0	0	0	0	0	0
Week 2	N	49	38	87	48	39	87
	MEAN	19.3	22.1	20.5	22.7	23.3	23.0
	MEDIAN	19.0	21.0	20.0	22.0	24.0	23.0
	STDDEV	6.30	6.11	6.34	5.78	5.28	5.54
	MINIMUM	4	11	4	7	13	7
	MAXIMUM	36	34	36	37	36	37
	MISSING	6	2	8	8	7	15
Week 4	N	48	32	80	48	35	83
	MEAN	16.4	19.8	17.7	20.3	22.0	21.0
	MEDIAN	16.0	19.0	17.5	21.0	23.0	22.0
	STDDEV	7.07	7.91	7.56	6.12	5.39	5.85
	MINIMUM	0	3	0	4	12	4
	MAXIMUM	36	34	36	34	34	34
	MISSING	4	5	9	6	7	13
Week 6	N	45	34	79	51	39	90
	MEAN	14.2	18.3	16.0	18.7	21.3	19.8
	MEDIAN	14.0	19.0	15.0	19.0	22.0	20.0
	STDDEV	7.40	7.23	7.55	7.36	7.25	7.39
	MINIMUM	0	5	0	2	8	2
	MAXIMUM	36	34	36	37	38	38
	MISSING	4	1	5	1	1	2

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.

Table 14.1.1b

Summary Statistics for CY-BOCS Total Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 8	N	37	30	67	49	33	82
	MEAN	13.0	17.2	14.9	17.4	19.2	18.1
	MEDIAN	13.0	17.0	15.0	18.0	19.0	18.0
	STDDEV	8.43	7.19	8.12	8.07	6.49	7.48
	MINIMUM	0	8	0	0	5	0
	MAXIMUM	36	34	36	38	35	38
	MISSING	4	1	5	1	3	4
Week 10	N	37	30	67	45	33	78
	MEAN	12.4	16.6	14.3	16.2	18.7	17.3
	MEDIAN	13.0	16.5	14.0	16.0	19.0	17.5
	STDDEV	8.41	8.35	8.58	7.59	7.30	7.52
	MINIMUM	0	3	0	0	0	0
	MAXIMUM	34	35	35	33	36	36
	MISSING	1	0	1	2	0	2
Week 10 LOCF Endpoint	N	54	40	94	56	46	102
	MEAN	13.1	17.9	15.1	17.6	21.6	19.4
	MEDIAN	14.0	18.5	16.0	16.5	23.0	20.0
	STDDEV	8.38	8.24	8.62	7.91	8.13	8.21
	MINIMUM	0	3	0	0	0	0
	MAXIMUM	34	35	35	37	38	38
	MISSING	0	0	0	0	0	0

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.

Table 14.1.1c

Summary Statistics for CY-BOCS Total Score

Per-Protocol Population

		Paroxetine (N=73)			Placebo (N=82)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Screening	N	40	33	73	45	36	81
	MEAN	22.8	25.1	23.8	24.9	24.6	24.8
	MEDIAN	22.0	25.0	24.0	25.0	25.0	25.0
	STDDEV	4.29	4.70	4.60	4.34	4.48	4.38
	MINIMUM	16	16	16	16	16	16
	MAXIMUM	36	35	36	34	35	35
	MISSING	0	0	0	0	1	1
Baseline	N	40	33	73	45	37	82
	MEAN	23.2	25.1	24.0	24.6	25.2	24.9
	MEDIAN	22.5	24.0	23.0	24.0	26.0	25.0
	STDDEV	4.75	4.82	4.85	4.61	4.72	4.64
	MINIMUM	17	18	17	16	16	16
	MAXIMUM	36	36	36	37	37	37
	MISSING	0	0	0	0	0	0
Week 2	N	38	32	70	39	31	70
	MEAN	19.0	21.1	19.9	22.5	23.5	22.9
	MEDIAN	18.0	21.0	19.0	22.0	24.0	23.0
	STDDEV	6.35	5.68	6.10	5.85	4.98	5.47
	MINIMUM	4	11	4	7	13	7
	MAXIMUM	36	34	36	37	32	37
	MISSING	2	1	3	6	6	12
Week 4	N	37	27	64	42	26	68
	MEAN	16.0	18.7	17.1	20.2	21.6	20.7
	MEDIAN	15.0	18.0	16.0	21.0	22.5	21.5
	STDDEV	7.41	7.51	7.52	6.47	5.15	6.00
	MINIMUM	0	3	0	4	12	4
	MAXIMUM	36	34	36	34	34	34
	MISSING	2	3	5	3	7	10
Week 6	N	37	29	66	44	30	74
	MEAN	13.3	17.7	15.2	18.8	20.4	19.4
	MEDIAN	12.0	17.0	15.0	19.0	20.5	19.5
	STDDEV	7.03	7.16	7.36	6.60	6.87	6.71
	MINIMUM	0	5	0	2	8	2
	MAXIMUM	36	34	36	34	38	38
	MISSING	0	0	0	1	1	2

Note: 'MISSING' row indicates number of patients with either missing data at that visit (but still in the study or withdrawing that week), or insufficient data to calculate total.

Table 14.1.1c

Summary Statistics for CY-BOCS Total Score

Per-Protocol Population

		Paroxetine (N=73)			Placebo (N=82)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 8	N	29	27	56	42	28	70
	MEAN	11.8	16.6	14.1	17.3	18.8	17.9
	MEDIAN	10.0	17.0	13.0	18.0	18.5	18.0
	STDDEV	7.90	7.02	7.79	7.58	5.32	6.77
	MINIMUM	0	8	0	0	8	0
	MAXIMUM	36	34	36	34	34	34
	MISSING	4	1	5	1	1	2
Week 10	N	32	27	59	39	29	68
	MEAN	11.3	15.4	13.2	16.0	19.1	17.3
	MEDIAN	11.0	16.0	13.0	16.0	19.0	17.5
	STDDEV	7.96	7.42	7.93	7.39	6.58	7.18
	MINIMUM	0	3	0	0	6	0
	MAXIMUM	34	34	34	33	36	36
	MISSING	0	0	0	1	0	1
Week 10 LOCF Endpoint	N	40	33	73	45	37	82
	MEAN	11.6	16.4	13.8	17.0	20.9	18.8
	MEDIAN	11.0	17.0	14.0	16.0	21.0	19.0
	STDDEV	8.07	7.35	8.06	7.49	7.11	7.54
	MINIMUM	0	3	0	0	6	0
	MAXIMUM	34	34	34	33	38	38
	MISSING	0	0	0	0	0	0

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 14.1.2.1

Summary of Analysis for Change from Baseline in CY-BOCS Total score
Covariate Significance, Week 10 LOCF
Intention-To-Treat Population

	DF	Sum of Squares*	Mean Square	F-statistic	P-value
Terms in model					
Baseline Score	1	577.35	577.35	10.17	0.002
Age Group	1	779.63	779.63	13.74	<0.001
Gender	1	7.93	7.93	0.14	0.709
Comorbidity	1	66.22	66.22	1.17	0.281

*Type III Sums of Squares

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Table 14.1.2b

Summary of Analysis for Change from Baseline in CY-BOCS Total score
Adjusted for Baseline Score, Age Group, Gender and Comorbidity
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	24.36	4.95	98	25.29	5.05	105				
Change from Baseline to:										
Week 2	-3.67	0.50	87	-2.24	0.49	87				
Week 4	-6.55	0.69	80	-3.76	0.66	83				
Week 6	-8.08	0.81	79	-4.78	0.74	90				
Week 8	-9.30	0.88	67	-6.45	0.78	82				
Week 10	-9.82	0.92	67	-7.23	0.84	78	-2.59	-4.98	-0.20	0.034
Week 10 LOCF Endpoint	-8.78	0.82	94	-5.34	0.77	102	-3.45	-5.60	-1.29	0.002
70% LOCF Endpoint	-8.15	0.77	94	-4.96	0.73	102	-3.19	-5.21	-1.16	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 the first post-baseline visit as early withdrawal data at unscheduled visits is not tabulated but is carried forward for LOCF Endpoint
Note: 70% LOCF Endpoint was Week 8

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Table 14.1.2bZ

Summary of Analysis for Change from Baseline in CY-BOCS Total score (Excluding Centre 055)
Adjusted for Baseline Score, Age Group, Gender and Comorbidity
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	24.21	4.77	91	25.07	4.86	98				
Change from Baseline to:										
Week 10	-10.41	0.96	62	-7.06	0.85	73	-3.35	-5.81	-0.88	0.008
Week 10 LOCF Endpoint	-9.33	0.84	88	-5.45	0.78	95	-3.88	-6.08	-1.69	<0.001
70% LOCF Endpoint	-8.46	0.79	88	-5.26	0.74	95	-3.20	-5.26	-1.14	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 the first post-baseline visit as early withdrawal data at unscheduled visits is not tabulated but is carried forward for LOCF Endpoint
Note: 70% LOCF Endpoint was Week 8

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Table 14.1.2cZ

Summary of Analysis for Change from Baseline in CY-BOCS Total score (Excluding Centre 055)
Adjusted for Baseline Score, Age Group, Gender and Comorbidity
Per-Protocol 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	23.88	4.80	69	24.92	4.70	79				
Change from Baseline to:										
Week 10	-10.87	0.99	55	-6.80	0.87	65	-4.07	-6.61	-1.53	0.002
Week 10 LOCF Endpoint	-10.30	0.90	69	-5.62	0.81	79	-4.68	-6.99	-2.37	<0.001
70% LOCF Endpoint	-9.24	0.86	69	-5.37	0.77	79	-3.87	-6.06	-1.67	<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: 70% LOCF Endpoint was Week 8

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Table 14.1.2c

Summary of Analysis for Change from Baseline in CY-BOCS Total score
Adjusted for Baseline Score, Age Group, Gender and Comorbidity
Per-Protocol 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	24.04	4.85	73	24.91	4.64	82				
Change from Baseline to:										
Week 2	-4.07	0.54	70	-2.42	0.53	70				
Week 4	-7.24	0.81	64	-4.06	0.77	68				
Week 6	-8.49	0.82	66	-4.97	0.75	74				
Week 8	-9.68	0.91	56	-6.23	0.80	70				
Week 10	-10.45	0.94	59	-6.90	0.84	68	-3.55	-5.97	-1.12	0.005
Week 10 LOCF Endpoint	-10.01	0.86	73	-5.74	0.79	82	-4.27	-6.50	-2.04	<0.001
70% LOCF Endpoint	-9.09	0.81	73	-5.45	0.75	82	-3.63	-5.74	-1.53	<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: 70% LOCF Endpoint was Week 8

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Table 14.1.3b

Summary Statistics for Change from Baseline in CY-BOCS Total Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Baseline	N	58	40	98	57	48	105
	MEAN	23.8	25.2	24.4	25.3	25.3	25.3
	MEDIAN	23.0	24.5	23.5	25.0	25.0	25.0
	STDDEV	5.00	4.82	4.95	5.31	4.79	5.05
	MINIMUM	16	18	16	16	16	16
	MAXIMUM	36	36	36	37	37	37
	MISSING	0	0	0	0	0	0
Week 2	N	49	38	87	48	39	87
	MEAN	-4.2	-3.4	-3.9	-2.2	-2.5	-2.3
	MEDIAN	-4.0	-2.5	-3.0	-1.0	-2.0	-1.0
	STDDEV	4.63	5.24	4.89	4.57	3.55	4.12
	MINIMUM	-16	-19	-19	-15	-10	-15
	MAXIMUM	6	4	6	10	3	10
	MISSING	6	2	8	8	7	15
Week 4	N	48	32	80	48	35	83
	MEAN	-7.2	-6.2	-6.8	-4.4	-3.3	-4.0
	MEDIAN	-7.0	-5.0	-6.5	-3.0	-3.0	-3.0
	STDDEV	6.34	6.87	6.53	6.30	4.64	5.66
	MINIMUM	-26	-30	-30	-24	-15	-24
	MAXIMUM	8	5	8	7	6	7
	MISSING	4	5	9	6	7	13
Week 6	N	45	34	79	51	39	90
	MEAN	-9.2	-7.2	-8.3	-6.5	-3.6	-5.2
	MEDIAN	-9.0	-7.0	-8.0	-5.0	-3.0	-4.5
	STDDEV	6.76	6.77	6.79	7.83	6.42	7.35
	MINIMUM	-21	-24	-24	-30	-15	-30
	MAXIMUM	8	6	8	10	17	17
	MISSING	4	1	5	1	1	2
Week 8	N	37	30	67	49	33	82
	MEAN	-11.0	-8.3	-9.8	-7.6	-5.4	-6.7
	MEDIAN	-10.0	-8.5	-9.0	-8.0	-5.0	-6.0
	STDDEV	7.27	5.95	6.80	8.03	5.33	7.12
	MINIMUM	-25	-20	-25	-25	-18	-25
	MAXIMUM	3	6	6	7	4	7
	MISSING	4	1	5	1	3	4
Week 10	N	37	30	67	45	33	78
	MEAN	-11.5	-9.0	-10.4	-8.4	-5.7	-7.3
	MEDIAN	-11.0	-10.5	-11.0	-8.0	-5.0	-6.0
	STDDEV	6.78	7.48	7.16	7.81	7.01	7.56

Table 14.1.3b

Summary Statistics for Change from Baseline in CY-BOCS Total Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 10	MINIMUM	-27	-23	-27	-25	-23	-25
	MAXIMUM	0	10	10	6	5	6
	MISSING	1	0	1	2	0	2
Week 10 LOCF Endpoint	N	54	40	94	56	46	102
	MEAN	-10.6	-7.3	-9.2	-7.6	-3.5	-5.7
	MEDIAN	-9.5	-6.0	-9.0	-5.5	-2.0	-4.5
	STDDEV	7.55	7.38	7.61	8.14	7.67	8.15
	MINIMUM	-27	-23	-27	-25	-23	-25
	MAXIMUM	5	10	10	10	17	17
	MISSING	0	0	0	0	0	0

Table 14.1.3c

Summary Statistics for Change from Baseline in CY-BOCS Total Score

Per-Protocol Population

		Paroxetine (N=73)			Placebo (N=82)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Baseline	N	40	33	73	45	37	82
	MEAN	23.2	25.1	24.0	24.6	25.2	24.9
	MEDIAN	22.5	24.0	23.0	24.0	26.0	25.0
	STDDEV	4.75	4.82	4.85	4.61	4.72	4.64
	MINIMUM	17	18	17	16	16	16
	MAXIMUM	36	36	36	37	37	37
	MISSING	0	0	0	0	0	0
Week 2	N	38	32	70	39	31	70
	MEAN	-4.2	-4.2	-4.2	-2.3	-2.6	-2.4
	MEDIAN	-4.0	-3.0	-4.0	-1.0	-2.0	-1.5
	STDDEV	4.44	5.26	4.80	4.08	3.57	3.84
	MINIMUM	-16	-19	-19	-13	-10	-13
	MAXIMUM	6	4	6	10	3	10
	MISSING	2	1	3	6	6	12
Week 4	N	37	27	64	42	26	68
	MEAN	-7.3	-7.3	-7.3	-4.3	-4.0	-4.2
	MEDIAN	-7.0	-5.0	-7.0	-3.0	-4.0	-3.0
	STDDEV	6.74	6.73	6.68	6.36	4.59	5.72
	MINIMUM	-26	-30	-30	-24	-15	-24
	MAXIMUM	8	1	8	7	6	7
	MISSING	2	3	5	3	7	10
Week 6	N	37	29	66	44	30	74
	MEAN	-9.5	-8.0	-8.8	-6.0	-4.7	-5.5
	MEDIAN	-9.0	-7.0	-8.5	-5.0	-4.0	-5.0
	STDDEV	6.43	6.77	6.57	6.73	4.81	6.02
	MINIMUM	-21	-24	-24	-20	-15	-20
	MAXIMUM	8	6	8	10	5	10
	MISSING	0	0	0	1	1	2
Week 8	N	29	27	56	42	28	70
	MEAN	-11.3	-9.1	-10.2	-7.4	-5.6	-6.7
	MEDIAN	-11.0	-10.0	-10.5	-8.0	-5.5	-6.0
	STDDEV	7.33	5.38	6.51	7.63	4.69	6.63
	MINIMUM	-23	-20	-23	-24	-15	-24
	MAXIMUM	3	0	3	7	4	7
	MISSING	4	1	5	1	1	2
Week 10	N	32	27	59	39	29	68
	MEAN	-12.0	-10.2	-11.2	-8.4	-5.3	-7.1
	MEDIAN	-11.0	-11.0	-11.0	-8.0	-5.0	-6.0
	STDDEV	6.96	6.52	6.77	7.33	6.38	7.06

Table 14.1.3c

Summary Statistics for Change from Baseline in CY-BOCS Total Score

Per-Protocol Population

		Paroxetine (N=73)			Placebo (N=82)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 10	MINIMUM	-27	-23	-27	-25	-18	-25
	MAXIMUM	0	0	0	6	5	6
	MISSING	0	0	0	1	0	1
Week 10 LOCF Endpoint	N	40	33	73	45	37	82
	MEAN	-11.6	-8.8	-10.3	-7.7	-4.3	-6.2
	MEDIAN	-11.0	-9.0	-10.0	-6.0	-2.0	-5.0
	STDDEV	7.38	6.88	7.24	7.35	6.31	7.06
	MINIMUM	-27	-23	-27	-25	-18	-25
	MAXIMUM	2	5	5	6	5	6
	MISSING	0	0	0	0	0	0

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Table 14.2.1

Number and Percentage of Responders for CY-BOCS Total Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N=98)						Placebo (N=105)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
Week 2	>= 25% reduction	17	34.7	9	23.7	26	29.9	8	16.7	6	15.4	14	16.1
	< 25% reduction	32	65.3	29	76.3	61	70.1	40	83.3	33	84.6	73	83.9
	Total	49	100.0	38	100.0	87	100.0	48	100.0	39	100.0	87	100.0
Week 4	>= 25% reduction	29	60.4	13	40.6	42	52.5	13	27.1	8	22.9	21	25.3
	< 25% reduction	19	39.6	19	59.4	38	47.5	35	72.9	27	77.1	62	74.7
	Total	48	100.0	32	100.0	80	100.0	48	100.0	35	100.0	83	100.0
Week 6	>= 25% reduction	32	71.1	18	52.9	50	63.3	24	47.1	15	38.5	39	43.3
	< 25% reduction	13	28.9	16	47.1	29	36.7	27	52.9	24	61.5	51	56.7
	Total	45	100.0	34	100.0	79	100.0	51	100.0	39	100.0	90	100.0
Week 8	>= 25% reduction	30	81.1	19	63.3	49	73.1	26	53.1	14	42.4	40	48.8
	< 25% reduction	7	18.9	11	36.7	18	26.9	23	46.9	19	57.6	42	51.2
	Total	37	100.0	30	100.0	67	100.0	49	100.0	33	100.0	82	100.0
Week 10	>= 25% reduction	31	83.8	19	63.3	50	74.6	24	53.3	14	42.4	38	48.7
	< 25% reduction	6	16.2	11	36.7	17	25.4	21	46.7	19	57.6	40	51.3
	Total	37	100.0	30	100.0	67	100.0	45	100.0	33	100.0	78	100.0
Week 10 LOCF Endpoint	>= 25% reduction	40	74.1	21	52.5	61	64.9	27	48.2	15	32.6	42	41.2
	< 25% reduction	14	25.9	19	47.5	33	35.1	29	51.8	31	67.4	60	58.8
	Total	54	100.0	40	100.0	94	100.0	56	100.0	46	100.0	102	100.0

Responder defined as >=25% reduction in CY-BOCS total score from baseline

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Table 14.2.2

Summary of Analysis for CY-BOCS - Proportion of Responders
Adjusted for Baseline Score, Age Group, Gender and Comorbidity
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 2	26	29.9	87	14	16.1	87	.	.	.	.
Week 4	42	52.5	80	21	25.3	83	.	.	.	.
Week 6	50	63.3	79	39	43.3	90	.	.	.	.
Week 8	49	73.1	67	40	48.8	82	.	.	.	.
Week 10	50	74.6	67	38	48.7	78	2.78	1.32	5.85	0.007
Week 10 LOCF Endpoint	61	64.9	94	42	41.2	102	2.66	1.45	4.87	0.002
70% LOCF Endpoint	59	62.8	94	43	42.2	102	2.30	1.27	4.17	0.006

* The odds ratios represent the odds of improving with paroxetine relative to that with placebo.
Note: Percentage of responders is unadjusted, whilst the odds ratio is adjusted for the terms in the model.
Responder defined as >=25% reduction in CY-BOCS total score from baseline
Note: 70% LOCF Endpoint was Week 8

Table 14.3.1

Number and Percentage of Patients in Each Category Of CGI Global Improvement

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 98)						Placebo (N = 105)					
		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)	2	3.7	1	2.6	3	3.2	2	3.8	0	0.0	2	2.0
	Minimally improved (3)	20	37.0	5	12.8	25	26.9	6	11.5	10	21.3	16	16.2
	No change (4)	31	57.4	31	79.5	62	66.7	41	78.8	35	74.5	76	76.8
	Minimally worse (5)	0	0.0	2	5.1	2	2.2	3	5.8	2	4.3	5	5.1
	Much worse (6)	1	1.9	0	0.0	1	1.1	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	54	100.0	39	100.0	93	100.0	52	100.0	47	100.0	99	100.0
Week 2	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Very much improved (1)	2	3.9	0	0.0	2	2.2	1	1.9	0	0.0	1	1.1
	Much Improved (2)	9	17.6	5	13.2	14	15.7	2	3.8	3	7.5	5	5.4
	Minimally improved (3)	23	45.1	10	26.3	33	37.1	18	34.6	14	35.0	32	34.8
	No change (4)	14	27.5	21	55.3	35	39.3	29	55.8	21	52.5	50	54.3
	Minimally worse (5)	2	3.9	1	2.6	3	3.4	1	1.9	2	5.0	3	3.3
	Much worse (6)	1	2.0	1	2.6	2	2.2	0	0.0	0	0.0	0	0.0
	Very much worse (7)	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	1	1.1
	Total	51	100.0	38	100.0	89	100.0	52	100.0	40	100.0	92	100.0

(CONTINUED)

Responders are patients who have a score of 1 or 2

Table 14.3.1

Number and Percentage of Patients in Each Category Of CGI Global Improvement

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 98)						Placebo (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
Week 3	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	7.5	0	0.0	4	4.5	0	0.0	1	2.8	1	1.2
	Much Improved (2)	16	30.2	8	22.2	24	27.0	6	12.5	6	16.7	12	14.3
	Minimally improved (3)	18	34.0	13	36.1	31	34.8	24	50.0	12	33.3	36	42.9
	No change (4)	14	26.4	14	38.9	28	31.5	16	33.3	17	47.2	33	39.3
	Minimally worse (5)	1	1.9	1	2.8	2	2.2	1	2.1	0	0.0	1	1.2
	Much worse (6)	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	1	1.2
	Very much worse (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	53	100.0	36	100.0	89	100.0	48	100.0	36	100.0	84	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)	6	12.0	2	5.9	8	9.5	4	7.8	0	0.0	4	4.3
	Much Improved (2)	13	26.0	6	17.6	19	22.6	5	9.8	6	14.6	11	12.0
	Minimally improved (3)	21	42.0	16	47.1	37	44.0	23	45.1	19	46.3	42	45.7
	No change (4)	7	14.0	9	26.5	16	19.0	16	31.4	16	39.0	32	34.8
	Minimally worse (5)	1	2.0	1	2.9	2	2.4	3	5.9	0	0.0	3	3.3
	Much worse (6)	1	2.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0
	Very much worse (7)	1	2.0	0	0.0	1	1.2	0	0.0	0	0.0	0	0.0
	Total	50	100.0	34	100.0	84	100.0	51	100.0	41	100.0	92	100.0

(CONTINUED)

Responders are patients who have a score of 1 or 2

Table 14.3.1

Number and Percentage of Patients in Each Category Of CGI Global Improvement

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 98)						Placebo (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
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)	12	26.7	2	5.9	14	17.7	5	9.8	3	7.7	8	8.9
	Much Improved (2)	13	28.9	13	38.2	26	32.9	11	21.6	5	12.8	16	17.8
	Minimally improved (3)	11	24.4	8	23.5	19	24.1	18	35.3	14	35.9	32	35.6
	No change (4)	7	15.6	9	26.5	16	20.3	14	27.5	14	35.9	28	31.1
	Minimally worse (5)	0	0.0	1	2.9	1	1.3	2	3.9	0	0.0	2	2.2
	Much worse (6)	2	4.4	1	2.9	3	3.8	1	2.0	3	7.7	4	4.4
	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	34	100.0	79	100.0	51	100.0	39	100.0	90	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)	12	32.4	3	10.0	15	22.4	9	18.4	1	3.0	10	12.2
	Much Improved (2)	12	32.4	8	26.7	20	29.9	11	22.4	9	27.3	20	24.4
	Minimally improved (3)	9	24.3	9	30.0	18	26.9	15	30.6	9	27.3	24	29.3
	No change (4)	3	8.1	9	30.0	12	17.9	10	20.4	12	36.4	22	26.8
	Minimally worse (5)	1	2.7	0	0.0	1	1.5	4	8.2	2	6.1	6	7.3
	Much worse (6)	0	0.0	1	3.3	1	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	37	100.0	30	100.0	67	100.0	49	100.0	33	100.0	82	100.0

(CONTINUED)

Responders are patients who have a score of 1 or 2

Table 14.3.1

Number and Percentage of Patients in Each Category Of CGI Global Improvement

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 98)						Placebo (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
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)	10	27.0	7	23.3	17	25.4	6	13.3	3	9.1	9	11.5
	Much Improved (2)	13	35.1	8	26.7	21	31.3	18	40.0	6	18.2	24	30.8
	Minimally improved (3)	8	21.6	6	20.0	14	20.9	7	15.6	11	33.3	18	23.1
	No change (4)	3	8.1	7	23.3	10	14.9	12	26.7	13	39.4	25	32.1
	Minimally worse (5)	2	5.4	1	3.3	3	4.5	2	4.4	0	0.0	2	2.6
	Much worse (6)	1	2.7	1	3.3	2	3.0	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	37	100.0	30	100.0	67	100.0	45	100.0	33	100.0	78	100.0
Week 10 LOCF Endpoint	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)	13	23.2	7	17.5	20	20.8	6	10.5	3	6.3	9	8.6
	Much Improved (2)	16	28.6	9	22.5	25	26.0	20	35.1	6	12.5	26	24.8
	Minimally improved (3)	14	25.0	9	22.5	23	24.0	8	14.0	12	25.0	20	19.0
	No change (4)	7	12.5	11	27.5	18	18.8	17	29.8	22	45.8	39	37.1
	Minimally worse (5)	2	3.6	2	5.0	4	4.2	5	8.8	2	4.2	7	6.7
	Much worse (6)	4	7.1	2	5.0	6	6.3	0	0.0	3	6.3	3	2.9
	Very much worse (7)	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	1	1.0
	Total	56	100.0	40	100.0	96	100.0	57	100.0	48	100.0	105	100.0

Responders are patients who have a score of 1 or 2

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Table 14.3.2

Summary of Analysis for CGI Global Improvement - Proportion of Responders
Adjusted for Baseline Score (CGI Severity of Illness), Age Group, Gender and Comorbidity
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	3	3.2	93	2	2.0	99	.	.	.	.
Week 2	16	18.0	89	6	6.5	92	.	.	.	.
Week 3	28	31.5	89	13	15.5	84	.	.	.	.
Week 4	27	32.1	84	15	16.3	92	.	.	.	.
Week 6	40	50.6	79	24	26.7	90	.	.	.	.
Week 8	35	52.2	67	30	36.6	82	.	.	.	.
Week 10	38	56.7	67	33	42.3	78	1.65	0.82	3.33	0.162
Week 10 LOCF Endpoint	45	46.9	96	35	33.3	105	1.69	0.94	3.07	0.081
70% LOCF Endpoint	42	43.8	96	31	29.5	105	1.74	0.95	3.18	0.072

* The odds ratios represent the odds of improving with paroxetine relative to that with placebo.
Note: Percentage of responders is unadjusted, whilst the odds ratio is adjusted for the terms in the model.
Responders are patients who have a score of 1 or 2
Note: Due to inadequate number of patients in some categories of CGI Severity of Illness,
Mildly ill was merged with Moderately ill; and Among the most Extremely ill was merged with Severely ill
Note: 70% LOCF Endpoint was Week 8

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Table 14.4.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 98)						Placebo (N = 105)					
		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	0	0.0	0	0.0
	Normal, not at all ill (1)	0	0.0	0	0.0	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	0	0.0	0	0.0
	Mildly ill (3)	0	0.0	0	0.0	0	0.0	3	5.3	1	2.1	4	3.8
	Moderately ill (4)	39	67.2	18	45.0	57	58.2	28	49.1	21	43.8	49	46.7
	Markedly ill (5)	15	25.9	18	45.0	33	33.7	16	28.1	20	41.7	36	34.3
	Severely ill (6)	3	5.2	3	7.5	6	6.1	10	17.5	6	12.5	16	15.2
	Among the most extremely ill patients (7)	1	1.7	1	2.5	2	2.0	0	0.0	0	0.0	0	0.0
	Total	58	100.0	40	100.0	98	100.0	57	100.0	48	100.0	105	100.0
Week 1	Severity												
	Not assessed (0)	0	0.0	0	0.0	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	0	0.0	0	0.0
	Borderline mentally ill (2)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Mildly ill (3)	0	0.0	1	2.6	1	1.1	5	9.6	1	2.1	6	6.1
	Moderately ill (4)	38	70.4	19	48.7	57	61.3	25	48.1	22	46.8	47	47.5
	Markedly ill (5)	14	25.9	14	35.9	28	30.1	17	32.7	18	38.3	35	35.4
	Severely ill (6)	1	1.9	5	12.8	6	6.5	5	9.6	6	12.8	11	11.1
	Among the most extremely ill patients (7)	1	1.9	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0

(CONTINUED)

Table 14.4.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 98)						Placebo (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit	Total												
Week 1		54	100.0	39	100.0	93	100.0	52	100.0	47	100.0	99	100.0
Week 2	Severity												
	Not assessed (0)	0	0.0	0	0.0	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	0	0.0	0	0.0
	Borderline mentally ill (2)	2	3.9	0	0.0	2	2.2	1	1.9	0	0.0	1	1.1
	Mildly ill (3)	11	21.6	3	7.9	14	15.7	6	11.5	5	12.5	11	12.0
	Moderately ill (4)	28	54.9	17	44.7	45	50.6	24	46.2	16	40.0	40	43.5
	Markedly ill (5)	8	15.7	15	39.5	23	25.8	14	26.9	15	37.5	29	31.5
	Severely ill (6)	2	3.9	3	7.9	5	5.6	7	13.5	4	10.0	11	12.0
	Among the most extremely ill patients (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	51	100.0	38	100.0	89	100.0	52	100.0	40	100.0	92	100.0
Week 3	Severity												
	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Normal, not at all ill (1)	3	5.7	0	0.0	3	3.4	0	0.0	0	0.0	0	0.0
	Borderline mentally ill (2)	1	1.9	1	2.8	2	2.2	0	0.0	3	8.3	3	3.6
	Mildly ill (3)	18	34.0	5	13.9	23	25.8	7	14.6	5	13.9	12	14.3
	Moderately ill (4)	24	45.3	14	38.9	38	42.7	27	56.3	14	38.9	41	48.8
	Markedly ill (5)	4	7.5	14	38.9	18	20.2	13	27.1	10	27.8	23	27.4

(CONTINUED)

Table 14.4.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 98)						Placebo (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit	Severity												
Week 3	Severely ill (6)	3	5.7	2	5.6	5	5.6	1	2.1	4	11.1	5	6.0
	Among the most extremely ill patients (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	53	100.0	36	100.0	89	100.0	48	100.0	36	100.0	84	100.0
Week 4	Severity												
	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Normal, not at all ill (1)	3	6.0	0	0.0	3	3.6	0	0.0	0	0.0	0	0.0
	Borderline mentally ill (2)	4	8.0	2	5.9	6	7.1	5	9.8	2	4.9	7	7.6
	Mildly ill (3)	12	24.0	6	17.6	18	21.4	4	7.8	3	7.3	7	7.6
	Moderately ill (4)	26	52.0	16	47.1	42	50.0	30	58.8	23	56.1	53	57.6
	Markedly ill (5)	2	4.0	9	26.5	11	13.1	12	23.5	12	29.3	24	26.1
	Severely ill (6)	3	6.0	1	2.9	4	4.8	0	0.0	1	2.4	1	1.1
	Among the most extremely ill patients (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	50	100.0	34	100.0	84	100.0	51	100.0	41	100.0	92	100.0
Week 6	Severity												
	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Normal, not at all ill (1)	5	11.1	0	0.0	5	6.3	0	0.0	0	0.0	0	0.0
	Borderline mentally ill (2)	6	13.3	1	2.9	7	8.9	6	11.8	3	7.7	9	10.0
	Mildly ill (3)	15	33.3	11	32.4	26	32.9	9	17.6	5	12.8	14	15.6

(CONTINUED)

Table 14.4.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 98)						Placebo (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit	Severity												
Week 6	Moderately ill (4)	13	28.9	11	32.4	24	30.4	26	51.0	20	51.3	46	51.1
	Markedly ill (5)	4	8.9	9	26.5	13	16.5	9	17.6	9	23.1	18	20.0
	Severely ill (6)	2	4.4	2	5.9	4	5.1	1	2.0	2	5.1	3	3.3
	Among the most extremely ill patients (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	45	100.0	34	100.0	79	100.0	51	100.0	39	100.0	90	100.0
Week 8	Severity												
	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Normal, not at all ill (1)	3	8.1	0	0.0	3	4.5	1	2.0	0	0.0	1	1.2
	Borderline mentally ill (2)	14	37.8	4	13.3	18	26.9	9	18.4	3	9.1	12	14.6
	Mildly ill (3)	7	18.9	7	23.3	14	20.9	12	24.5	5	15.2	17	20.7
	Moderately ill (4)	11	29.7	11	36.7	22	32.8	19	38.8	19	57.6	38	46.3
	Markedly ill (5)	1	2.7	8	26.7	9	13.4	8	16.3	4	12.1	12	14.6
	Severely ill (6)	1	2.7	0	0.0	1	1.5	0	0.0	2	6.1	2	2.4
	Among the most extremely ill patients (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	37	100.0	30	100.0	67	100.0	49	100.0	33	100.0	82	100.0
Week 10	Severity												
	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Normal, not at all ill (1)	5	13.5	0	0.0	5	7.5	3	6.7	1	3.0	4	5.1

(CONTINUED)

Table 14.4.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 98)						Placebo (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit	Severity												
Week 10	Borderline mentally ill (2)	10	27.0	6	20.0	16	23.9	8	17.8	3	9.1	11	14.1
	Mildly ill (3)	9	24.3	8	26.7	17	25.4	12	26.7	5	15.2	17	21.8
	Moderately ill (4)	11	29.7	8	26.7	19	28.4	16	35.6	18	54.5	34	43.6
	Markedly ill (5)	1	2.7	8	26.7	9	13.4	6	13.3	5	15.2	11	14.1
	Severely ill (6)	1	2.7	0	0.0	1	1.5	0	0.0	1	3.0	1	1.3
	Among the most extremely ill patients (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	37	100.0	30	100.0	67	100.0	45	100.0	33	100.0	78	100.0
Week 10 LOCF Endpoint	Severity												
	Not assessed (0)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Normal, not at all ill (1)	7	12.5	0	0.0	7	7.3	3	5.3	1	2.1	4	3.8
	Borderline mentally ill (2)	13	23.2	6	15.0	19	19.8	8	14.0	3	6.3	11	10.5
	Mildly ill (3)	10	17.9	9	22.5	19	19.8	15	26.3	5	10.4	20	19.0
	Moderately ill (4)	20	35.7	11	27.5	31	32.3	20	35.1	23	47.9	43	41.0
	Markedly ill (5)	2	3.6	12	30.0	14	14.6	11	19.3	11	22.9	22	21.0
	Severely ill (6)	4	7.1	2	5.0	6	6.3	0	0.0	5	10.4	5	4.8
	Among the most extremely ill patients (7)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	56	100.0	40	100.0	96	100.0	57	100.0	48	100.0	105	100.0

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Table 14.4.2

Number and Percentage of Patients by Change in CGI Severity of Illness from Baseline

Intention-To-Treat Population

		Paroxetine (N = 98)						Placebo (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Change from Baseline to:	Change in Severity												
Week 1	-4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	-3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	-2	1	1.9	0	0.0	1	1.1	2	3.8	0	0.0	2	2.0
	-1	3	5.6	4	10.3	7	7.5	4	7.7	3	6.4	7	7.1
	0	48	88.9	34	87.2	82	88.2	44	84.6	43	91.5	87	87.9
	1	2	3.7	1	2.6	3	3.2	2	3.8	1	2.1	3	3.0
	2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	54	100.0	39	100.0	93	100.0	52	100.0	47	100.0	99	100.0
Week 2	Change in Severity												
	-4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	-3	1	2.0	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0
	-2	6	11.8	1	2.6	7	7.9	2	3.8	1	2.5	3	3.3
	-1	12	23.5	8	21.1	20	22.5	6	11.5	9	22.5	15	16.3
	0	30	58.8	28	73.7	58	65.2	43	82.7	28	70.0	71	77.2
	1	2	3.9	1	2.6	3	3.4	1	1.9	2	5.0	3	3.3
	2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	51	100.0	38	100.0	89	100.0	52	100.0	40	100.0	92	100.0

(CONTINUED)

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Table 14.4.2

Number and Percentage of Patients by Change in CGI Severity of Illness from Baseline

Intention-To-Treat Population

		Paroxetine (N = 98)						Placebo (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Change from Baseline to:	Change in Severity												
Week 3	-4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	-3	4	7.5	0	0.0	4	4.5	1	2.1	1	2.8	2	2.4
	-2	6	11.3	4	11.1	10	11.2	4	8.3	4	11.1	8	9.5
	-1	21	39.6	7	19.4	28	31.5	10	20.8	7	19.4	17	20.2
	0	20	37.7	25	69.4	45	50.6	32	66.7	24	66.7	56	66.7
	1	1	1.9	0	0.0	1	1.1	1	2.1	0	0.0	1	1.2
	2	1	1.9	0	0.0	1	1.1	0	0.0	0	0.0	0	0.0
	Total	53	100.0	36	100.0	89	100.0	48	100.0	36	100.0	84	100.0
Week 4	Change in Severity												
	-4	1	2.0	0	0.0	1	1.2	1	2.0	0	0.0	1	1.1
	-3	3	6.0	1	2.9	4	4.8	1	2.0	1	2.4	2	2.2
	-2	7	14.0	4	11.8	11	13.1	10	19.6	3	7.3	13	14.1
	-1	20	40.0	11	32.4	31	36.9	8	15.7	10	24.4	18	19.6
	0	16	32.0	17	50.0	33	39.3	30	58.8	26	63.4	56	60.9
	1	1	2.0	1	2.9	2	2.4	1	2.0	1	2.4	2	2.2
	2	2	4.0	0	0.0	2	2.4	0	0.0	0	0.0	0	0.0
	Total	50	100.0	34	100.0	84	100.0	51	100.0	41	100.0	92	100.0

(CONTINUED)

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Table 14.4.2

Number and Percentage of Patients by Change in CGI Severity of Illness from Baseline

Intention-To-Treat Population

		Paroxetine (N = 98)						Placebo (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Change from Baseline to:	Change in Severity												
Week 6	-4	2	4.4	0	0.0	2	2.5	1	2.0	1	2.6	2	2.2
	-3	5	11.1	0	0.0	5	6.3	3	5.9	3	7.7	6	6.7
	-2	10	22.2	5	14.7	15	19.0	8	15.7	0	0.0	8	8.9
	-1	14	31.1	16	47.1	30	38.0	13	25.5	13	33.3	26	28.9
	0	11	24.4	10	29.4	21	26.6	25	49.0	20	51.3	45	50.0
	1	2	4.4	3	8.8	5	6.3	1	2.0	1	2.6	2	2.2
	2	1	2.2	0	0.0	1	1.3	0	0.0	1	2.6	1	1.1
	Total	45	100.0	34	100.0	79	100.0	51	100.0	39	100.0	90	100.0
Week 8	Change in Severity												
	-4	2	5.4	0	0.0	2	3.0	1	2.0	0	0.0	1	1.2
	-3	3	8.1	1	3.3	4	6.0	6	12.2	3	9.1	9	11.0
	-2	15	40.5	5	16.7	20	29.9	9	18.4	3	9.1	12	14.6
	-1	10	27.0	12	40.0	22	32.8	15	30.6	10	30.3	25	30.5
	0	7	18.9	12	40.0	19	28.4	17	34.7	17	51.5	34	41.5
	1	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	1.2
	2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	37	100.0	30	100.0	67	100.0	49	100.0	33	100.0	82	100.0

(CONTINUED)

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Table 14.4.2

Number and Percentage of Patients by Change in CGI Severity of Illness from Baseline

Intention-To-Treat Population

		Paroxetine (N = 98)						Placebo (N = 105)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Change from Baseline to:	Change in Severity												
Week 10	-4	1	2.7	0	0.0	1	1.5	2	4.4	1	3.0	3	3.8
	-3	6	16.2	1	3.3	7	10.4	3	6.7	4	12.1	7	9.0
	-2	11	29.7	10	33.3	21	31.3	12	26.7	1	3.0	13	16.7
	-1	12	32.4	8	26.7	20	29.9	10	22.2	10	30.3	20	25.6
	0	7	18.9	11	36.7	18	26.9	17	37.8	17	51.5	34	43.6
	1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	37	100.0	30	100.0	67	100.0	44	97.8	33	100.0	77	98.7
Week 10 LOCF Endpoint	Change in Severity												
	-4	1	1.8	0	0.0	1	1.0	2	3.5	1	2.1	3	2.9
	-3	9	16.1	1	2.5	10	10.4	4	7.0	4	8.3	8	7.6
	-2	14	25.0	11	27.5	25	26.0	13	22.8	1	2.1	14	13.3
	-1	16	28.6	9	22.5	25	26.0	13	22.8	11	22.9	24	22.9
	0	13	23.2	17	42.5	30	31.3	22	38.6	27	56.3	49	46.7
	1	1	1.8	2	5.0	3	3.1	2	3.5	3	6.3	5	4.8
	2	2	3.6	0	0.0	2	2.1	0	0.0	1	2.1	1	1.0
	Total	56	100.0	40	100.0	96	100.0	56	98.2	48	100.0	104	99.0

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Table 14.4.3

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	4.4	4.0	4	7	58	4.6	4.0	3	6	57		
Change from baseline to:												
Week 1	-0.1	0.0	-2	1	54	-0.1	0.0	-2	1	52		
Week 2	-0.5	0.0	-3	1	51	-0.2	0.0	-2	1	52		
Week 3	-0.8	-1.0	-3	2	53	-0.4	0.0	-3	1	48		
Week 4	-0.8	-1.0	-4	2	50	-0.7	0.0	-4	1	51		
Week 6	-1.2	-1.0	-4	2	45	-0.8	0.0	-4	1	51		
Week 8	-1.5	-2.0	-4	0	37	-1.1	-1.0	-4	1	49		
Week 10	-1.5	-1.0	-4	0	37	-1.2	-1.0	-5	0	45	0	0.178
Week 10 LOCF Endpoint	-1.3	-1.0	-4	2	56	-1.1	-1.0	-5	1	57	0	0.251
70% LOCF Endpoint	-1.2	-1.0	-4	2	56	-1.0	-1.0	-4	1	57	0	0.260

* P-value from Wilcoxon Rank Sum Test
Note: 70% LOCF Endpoint was Week 8

Table 14.4.3

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	4	7	40	4.6	5.0	3	6	48		
Change from baseline to:												
Week 1	-0.1	0.0	-1	1	39	-0.0	0.0	-1	1	47		
Week 2	-0.2	0.0	-2	1	38	-0.2	0.0	-2	1	40		
Week 3	-0.4	0.0	-2	0	36	-0.5	0.0	-3	0	36		
Week 4	-0.6	0.0	-3	1	34	-0.4	0.0	-3	1	41		
Week 6	-0.7	-1.0	-2	1	34	-0.6	0.0	-4	2	39		
Week 8	-0.8	-1.0	-3	0	30	-0.8	0.0	-3	0	33		
Week 10	-1.0	-1.0	-3	0	30	-0.8	0.0	-4	0	33	0	0.247
Week 10 LOCF Endpoint	-0.8	-1.0	-3	1	40	-0.5	0.0	-4	2	48	0	0.098
70% LOCF Endpoint	-0.7	-1.0	-3	1	40	-0.4	0.0	-3	2	48	0	0.129

* P-value from Wilcoxon Rank Sum Test
Note: 70% LOCF Endpoint was Week 8

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Table 14.5.1

Summary Statistics for GAF Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Baseline	N	58	40	98	57	48	105
	MEAN	53.2	53.8	53.4	52.3	50.8	51.6
	MEDIAN	52.5	52.5	52.5	51.0	50.0	50.0
	STDDEV	6.89	6.19	6.59	7.57	6.67	7.18
	MINIMUM	40	44	40	32	35	32
	MAXIMUM	70	70	70	78	68	78
	MISSING	0	0	0	0	0	0
Week 2	N	49	38	87	48	40	88
	MEAN	58.9	56.7	58.0	54.6	54.3	54.5
	MEDIAN	59.0	55.0	58.0	55.0	54.5	55.0
	STDDEV	9.18	6.79	8.25	7.96	7.10	7.54
	MINIMUM	35	44	35	31	36	31
	MAXIMUM	78	70	78	78	70	78
	MISSING	6	2	8	8	6	14
Week 4	N	48	32	80	48	35	83
	MEAN	61.0	60.1	60.7	58.9	56.9	58.0
	MEDIAN	60.0	59.0	60.0	58.5	55.0	58.0
	STDDEV	11.94	10.71	11.40	8.69	8.10	8.45
	MINIMUM	30	38	30	40	37	37
	MAXIMUM	90	90	90	81	72	81
	MISSING	4	5	9	6	7	13
Week 6	N	45	34	79	51	39	90
	MEAN	64.7	61.1	63.1	58.6	57.4	58.1
	MEDIAN	65.0	61.5	63.0	59.0	58.0	59.0
	STDDEV	13.08	10.90	12.25	9.57	9.18	9.37
	MINIMUM	32	28	28	36	40	36
	MAXIMUM	93	80	93	81	82	82
	MISSING	4	1	5	1	1	2
Week 8	N	37	30	67	49	33	82
	MEAN	67.0	62.3	64.9	60.8	58.9	60.0
	MEDIAN	65.0	60.0	65.0	60.0	58.0	60.0
	STDDEV	11.94	11.16	11.75	11.78	9.54	10.91
	MINIMUM	45	42	42	35	40	35
	MAXIMUM	91	88	91	85	82	85
	MISSING	4	1	5	1	3	4

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)

Table 14.5.1

Summary Statistics for GAF Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 10	N	37	30	67	45	33	78
	MEAN	68.7	63.6	66.4	63.2	60.1	61.9
	MEDIAN	65.0	62.5	65.0	61.0	58.0	60.0
	STDDEV	13.49	11.75	12.90	10.71	10.53	10.67
	MINIMUM	45	34	34	40	44	40
	MAXIMUM	91	89	91	90	90	90
	MISSING	1	0	1	2	0	2
Week 10 LOCF Endpoint	N	54	40	94	56	46	102
	MEAN	65.1	61.1	63.4	61.6	57.3	59.6
	MEDIAN	63.0	60.0	61.0	60.0	55.5	58.0
	STDDEV	14.54	11.57	13.44	11.40	10.51	11.16
	MINIMUM	30	34	30	31	42	31
	MAXIMUM	91	89	91	90	90	90
	MISSING	0	0	0	0	0	0

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 14.5.2

Summary of Analysis for Change from Baseline in GAF score
Adjusted for Baseline Score, Age Group, Gender and Comorbidity
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	53.44	6.59	98	51.59	7.18	105				
Change from Baseline to:										
Week 2	4.09	0.68	87	2.33	0.66	88				
Week 4	6.38	1.06	80	5.41	1.02	83				
Week 6	9.16	1.19	79	6.07	1.07	90				
Week 8	10.43	1.33	67	7.71	1.18	82				
Week 10	11.93	1.40	67	9.58	1.28	78	2.35	-1.29	5.99	0.205
Week 10 LOCF Endpoint	8.93	1.23	94	7.02	1.16	102	1.91	-1.33	5.15	0.247
70% LOCF Endpoint	7.72	1.15	94	5.86	1.08	102	1.86	-1.17	4.88	0.227

* 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: 70% LOCF Endpoint was Week 8

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Table 14.5.3

Summary Statistics for Change from Baseline in GAF Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Baseline	N	58	40	98	57	48	105
	MEAN	53.2	53.8	53.4	52.3	50.8	51.6
	MEDIAN	52.5	52.5	52.5	51.0	50.0	50.0
	STDDEV	6.89	6.19	6.59	7.57	6.67	7.18
	MINIMUM	40	44	40	32	35	32
	MAXIMUM	70	70	70	78	68	78
	MISSING	0	0	0	0	0	0
Week 2	N	49	38	87	48	40	88
	MEAN	5.4	2.9	4.3	2.3	3.2	2.7
	MEDIAN	3.0	0.0	2.0	0.0	2.0	1.5
	STDDEV	7.68	6.30	7.18	4.87	5.52	5.17
	MINIMUM	-13	-5	-13	-14	-8	-14
	MAXIMUM	29	19	29	16	15	16
	MISSING	6	2	8	8	6	14
Week 4	N	48	32	80	48	35	83
	MEAN	7.0	6.2	6.7	6.0	5.7	5.8
	MEDIAN	5.0	5.0	5.0	5.0	5.0	5.0
	STDDEV	10.68	10.95	10.73	8.74	6.58	7.86
	MINIMUM	-25	-10	-25	-12	-2	-12
	MAXIMUM	39	45	45	32	26	32
	MISSING	4	5	9	6	7	13
Week 6	N	45	34	79	51	39	90
	MEAN	11.5	7.3	9.7	7.1	6.4	6.8
	MEDIAN	8.0	5.5	7.0	5.0	5.0	5.0
	STDDEV	12.27	9.90	11.43	7.84	9.87	8.73
	MINIMUM	-19	-20	-20	-6	-16	-16
	MAXIMUM	43	25	43	32	40	40
	MISSING	4	1	5	1	1	2
Week 8	N	37	30	67	49	33	82
	MEAN	13.6	8.4	11.3	8.8	8.0	8.5
	MEDIAN	12.0	5.0	10.0	7.0	6.0	7.0
	STDDEV	12.18	10.67	11.74	10.69	9.31	10.11
	MINIMUM	-5	-6	-6	-16	-6	-16
	MAXIMUM	41	37	41	35	36	36
	MISSING	4	1	5	1	3	4
Week 10	N	37	30	67	45	33	78
	MEAN	15.4	9.7	12.8	10.9	9.0	10.1
	MEDIAN	15.0	7.0	9.0	9.0	5.0	6.5
	STDDEV	13.83	12.14	13.31	9.99	11.01	10.41

Table 14.5.3

Summary Statistics for Change from Baseline in GAF Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 10	MINIMUM	-8	-14	-14	-3	-4	-4
	MAXIMUM	47	38	47	31	45	45
	MISSING	1	0	1	2	0	2
Week 10 LOCF Endpoint	N	54	40	94	56	46	102
	MEAN	11.7	7.3	9.9	9.3	6.3	7.9
	MEDIAN	8.0	4.5	6.0	6.5	5.0	5.0
	STDDEV	14.29	11.41	13.26	10.08	11.02	10.56
	MINIMUM	-25	-14	-25	-14	-16	-16
	MAXIMUM	47	38	47	31	45	45
	MISSING	0	0	0	0	0	0

Table 14.6.1

Summary Statistics for CY-BOCS Obsession Subscale Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Screening	N	58	40	98	56	47	103
	MEAN	11.1	12.1	11.5	12.0	12.0	12.0
	MEDIAN	11.0	12.0	12.0	12.0	12.0	12.0
	STDDEV	3.22	2.93	3.13	2.67	2.55	2.60
	MINIMUM	0	5	0	5	8	5
	MAXIMUM	18	18	18	18	18	18
	MISSING	0	0	0	1	1	2
Baseline	N	58	40	98	57	48	105
	MEAN	11.2	12.0	11.5	12.1	12.5	12.2
	MEDIAN	11.0	12.0	11.0	12.0	12.0	12.0
	STDDEV	3.41	2.59	3.11	3.19	2.74	2.99
	MINIMUM	0	8	0	5	7	5
	MAXIMUM	18	19	19	20	19	20
	MISSING	0	0	0	0	0	0
Week 2	N	49	38	87	48	39	87
	MEAN	9.0	10.7	9.8	11.0	11.1	11.1
	MEDIAN	10.0	10.0	10.0	11.0	11.0	11.0
	STDDEV	3.83	3.17	3.64	3.12	2.90	3.01
	MINIMUM	0	5	0	3	5	3
	MAXIMUM	18	17	18	19	17	19
	MISSING	6	2	8	8	7	15
Week 4	N	48	32	80	48	35	83
	MEAN	7.4	9.6	8.2	9.8	10.8	10.3
	MEDIAN	7.0	9.0	8.0	10.0	11.0	10.0
	STDDEV	4.04	4.02	4.16	3.17	2.73	3.02
	MINIMUM	0	1	0	3	5	3
	MAXIMUM	18	17	18	17	17	17
	MISSING	4	5	9	6	7	13
Week 6	N	45	34	79	51	39	90
	MEAN	6.5	8.8	7.5	9.3	10.4	9.7
	MEDIAN	6.0	8.5	7.0	9.0	11.0	10.0
	STDDEV	4.15	3.50	4.03	4.16	3.87	4.05
	MINIMUM	0	2	0	0	2	0
	MAXIMUM	18	17	18	19	19	19
	MISSING	4	1	5	1	1	2
Week 8	N	37	30	67	49	33	82

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 14.6.1

Summary Statistics for CY-BOCS Obsession Subscale Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 8	MEAN	5.9	8.3	7.0	8.7	9.0	8.8
	MEDIAN	6.0	8.5	7.0	9.0	9.0	9.0
	STDDEV	4.25	3.90	4.23	4.23	3.40	3.90
	MINIMUM	0	0	0	0	2	0
	MAXIMUM	18	17	18	20	17	20
	MISSING	4	1	5	1	3	4
Week 10	N	37	30	67	45	33	78
	MEAN	5.7	8.1	6.8	7.8	9.0	8.3
	MEDIAN	5.0	8.5	6.0	8.0	10.0	9.0
	STDDEV	4.18	4.44	4.43	3.91	3.92	3.93
	MINIMUM	0	0	0	0	0	0
	MAXIMUM	17	18	18	16	18	18
	MISSING	1	0	1	2	0	2
Week 10 LOCF Endpoint	N	54	40	94	56	46	102
	MEAN	6.0	8.8	7.2	8.6	10.5	9.4
	MEDIAN	6.0	9.0	7.5	8.5	10.5	9.5
	STDDEV	4.43	4.29	4.55	4.04	4.34	4.27
	MINIMUM	0	0	0	0	0	0
	MAXIMUM	17	18	18	17	19	19
	MISSING	0	0	0	0	0	0

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 14.6.2

Summary of Analysis for Change from Baseline in CY-BOCS Obsessions Subscale Score
Adjusted for Baseline Score, Age Group, Gender and Comorbidity
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	11.53	3.11	98	12.24	2.99	105				
Change from Baseline to:										
Week 2	-1.69	0.28	87	-1.04	0.28	87				
Week 4	-3.31	0.35	80	-1.69	0.34	83				
Week 6	-4.00	0.45	79	-2.03	0.41	90				
Week 8	-4.62	0.47	67	-2.99	0.42	82				
Week 10	-4.73	0.48	67	-3.36	0.44	78	-1.37	-2.62	-0.11	0.033
Week 10 LOCF Endpoint	-4.22	0.43	94	-2.42	0.41	102	-1.80	-2.94	-0.67	0.002
70% LOCF Endpoint	-3.93	0.41	94	-2.18	0.39	102	-1.75	-2.83	-0.66	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 the first post-baseline visit as early withdrawal data
at unscheduled visits is not tabulated but is carried forward for LOCF Endpoint
Note: 70% LOCF Endpoint was Week 8

Table 14.6.3

Summary Statistics for Change from Baseline in CY-BOCS Obsession Subscale Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Baseline	N	58	40	98	57	48	105
	MEAN	11.2	12.0	11.5	12.1	12.5	12.2
	MEDIAN	11.0	12.0	11.0	12.0	12.0	12.0
	STDDEV	3.41	2.59	3.11	3.19	2.74	2.99
	MINIMUM	0	8	0	5	7	5
	MAXIMUM	18	19	19	20	19	20
	MISSING	0	0	0	0	0	0
Week 2	N	49	38	87	48	39	87
	MEAN	-2.1	-1.3	-1.7	-0.9	-1.5	-1.2
	MEDIAN	-1.0	-1.0	-1.0	0.0	-1.0	-1.0
	STDDEV	2.82	2.64	2.75	2.70	2.16	2.47
	MINIMUM	-8	-10	-10	-8	-6	-8
	MAXIMUM	5	4	5	7	3	7
	MISSING	6	2	8	8	7	15
Week 4	N	48	32	80	48	35	83
	MEAN	-3.8	-2.8	-3.4	-2.1	-1.6	-1.9
	MEDIAN	-3.5	-2.5	-3.0	-2.0	-1.0	-2.0
	STDDEV	3.29	3.57	3.42	3.27	2.65	3.02
	MINIMUM	-12	-14	-14	-10	-9	-10
	MAXIMUM	2	5	5	4	3	4
	MISSING	4	5	9	6	7	13
Week 6	N	45	34	79	51	39	90
	MEAN	-4.6	-3.3	-4.0	-2.7	-1.8	-2.4
	MEDIAN	-4.0	-3.0	-4.0	-2.0	-2.0	-2.0
	STDDEV	3.91	3.57	3.79	4.75	3.59	4.29
	MINIMUM	-13	-13	-13	-20	-8	-20
	MAXIMUM	4	5	5	8	9	9
	MISSING	4	1	5	1	1	2
Week 8	N	37	30	67	49	33	82
	MEAN	-5.6	-3.8	-4.8	-3.2	-3.0	-3.2
	MEDIAN	-5.0	-4.0	-4.0	-3.0	-3.0	-3.0
	STDDEV	4.02	3.33	3.81	4.37	2.71	3.77
	MINIMUM	-12	-10	-12	-13	-8	-13
	MAXIMUM	4	5	5	7	1	7
	MISSING	4	1	5	1	3	4
Week 10	N	37	30	67	45	33	78
	MEAN	-5.8	-4.0	-5.0	-3.8	-2.9	-3.4
	MEDIAN	-5.0	-3.5	-4.0	-3.0	-2.0	-2.5
	STDDEV	3.73	4.23	4.03	4.05	3.63	3.88

Table 14.6.3

Summary Statistics for Change from Baseline in CY-BOCS Obsession Subscale Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 10	MINIMUM	-14	-11	-14	-13	-11	-13
	MAXIMUM	1	8	8	3	3	3
	MISSING	1	0	1	2	0	2
Week 10 LOCF Endpoint	N	54	40	94	56	46	102
	MEAN	-5.1	-3.2	-4.3	-3.4	-1.8	-2.7
	MEDIAN	-4.0	-3.0	-3.5	-2.0	-1.0	-2.0
	STDDEV	4.28	4.04	4.27	4.26	4.10	4.24
	MINIMUM	-14	-11	-14	-13	-11	-13
	MAXIMUM	4	8	8	7	9	9
	MISSING	0	0	0	0	0	0

Table 14.7.1

Summary Statistics for CY-BOCS Compulsions Subscale Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Screening	N	58	40	98	56	47	103
	MEAN	12.4	13.3	12.8	13.3	12.8	13.0
	MEDIAN	12.0	13.0	12.5	13.0	13.0	13.0
	STDDEV	2.73	2.55	2.69	2.71	2.75	2.72
	MINIMUM	6	9	6	8	7	7
	MAXIMUM	18	20	20	20	19	20
	MISSING	0	0	0	1	1	2
Baseline	N	58	40	98	57	48	105
	MEAN	12.5	13.3	12.8	13.2	12.8	13.0
	MEDIAN	12.0	13.0	12.0	13.0	13.0	13.0
	STDDEV	2.78	2.68	2.75	2.67	2.69	2.67
	MINIMUM	7	10	7	8	7	7
	MAXIMUM	18	20	20	20	19	20
	MISSING	0	0	0	0	0	0
Week 2	N	49	37	86	48	39	87
	MEAN	10.2	11.2	10.7	11.7	12.2	11.9
	MEDIAN	10.0	11.0	10.0	12.0	12.0	12.0
	STDDEV	3.61	3.35	3.52	3.03	2.97	3.00
	MINIMUM	1	5	1	4	7	4
	MAXIMUM	18	18	18	18	19	19
	MISSING	6	3	9	8	7	15
Week 4	N	48	32	80	48	35	83
	MEAN	9.0	10.2	9.5	10.5	11.2	10.8
	MEDIAN	9.0	10.0	9.0	11.0	11.0	11.0
	STDDEV	4.11	4.08	4.11	3.41	3.09	3.28
	MINIMUM	0	2	0	0	5	0
	MAXIMUM	18	18	18	17	18	18
	MISSING	4	5	9	6	7	13
Week 6	N	45	34	79	51	39	90
	MEAN	7.8	9.5	8.5	9.4	11.0	10.1
	MEDIAN	8.0	9.0	8.0	10.0	11.0	10.0
	STDDEV	4.23	3.94	4.18	3.60	3.69	3.70
	MINIMUM	0	3	0	2	5	2
	MAXIMUM	18	17	18	18	19	19
	MISSING	4	1	5	1	1	2
Week 8	N	37	30	67	49	33	82

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 14.7.1

Summary Statistics for CY-BOCS Compulsions Subscale Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 8	MEAN	7.1	8.9	7.9	8.7	10.2	9.3
	MEDIAN	6.0	9.0	8.0	9.0	10.0	10.0
	STDDEV	4.56	3.62	4.24	4.08	3.50	3.90
	MINIMUM	0	3	0	0	2	0
	MAXIMUM	19	17	19	18	18	18
	MISSING	4	1	5	1	3	4
Week 10	N	37	30	67	45	33	78
	MEAN	6.7	8.5	7.5	8.4	9.7	8.9
	MEDIAN	7.0	9.0	7.0	9.0	10.0	9.0
	STDDEV	4.77	4.25	4.59	4.01	3.69	3.90
	MINIMUM	0	0	0	0	0	0
	MAXIMUM	18	17	18	17	18	18
	MISSING	1	0	1	2	0	2
Week 10 LOCF Endpoint	N	54	40	94	56	46	102
	MEAN	7.1	9.2	8.0	9.0	11.1	10.0
	MEDIAN	7.0	9.0	8.5	9.0	11.0	10.0
	STDDEV	4.52	4.25	4.50	4.16	4.03	4.21
	MINIMUM	0	0	0	0	0	0
	MAXIMUM	18	17	18	20	19	20
	MISSING	0	0	0	0	0	0

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 14.7.2

Summary of Analysis for Change from Baseline in CY-BOCS Compulsions Subscale Score
Adjusted for Baseline Score, Age Group, Gender and Comorbidity
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	12.83	2.75	98	13.05	2.67	105				
Change from Baseline to:										
Week 2	-2.06	0.28	86	-1.16	0.27	87				
Week 4	-3.25	0.39	80	-2.06	0.37	83				
Week 6	-4.11	0.42	79	-2.70	0.38	90				
Week 8	-4.68	0.47	67	-3.44	0.42	82				
Week 10	-5.07	0.49	67	-3.86	0.45	78	-1.21	-2.48	0.06	0.062
Week 10 LOCF Endpoint	-4.59	0.43	94	-2.87	0.40	102	-1.72	-2.85	-0.60	0.003
70% LOCF Endpoint	-4.26	0.41	94	-2.72	0.38	102	-1.54	-2.61	-0.47	0.005

* 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: 70% LOCF Endpoint was Week 8

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Table 14.7.3

Summary Statistics for Change from Baseline in CY-BOCS Compulsions Subscale Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Baseline	N	58	40	98	57	48	105
	MEAN	12.5	13.3	12.8	13.2	12.8	13.0
	MEDIAN	12.0	13.0	12.0	13.0	13.0	13.0
	STDDEV	2.78	2.68	2.75	2.67	2.69	2.67
	MINIMUM	7	10	7	8	7	7
	MAXIMUM	18	20	20	20	19	20
	MISSING	0	0	0	0	0	0
Week 2	N	49	37	86	48	39	87
	MEAN	-2.2	-2.2	-2.2	-1.2	-1.1	-1.2
	MEDIAN	-2.0	-1.0	-1.0	-1.0	0.0	0.0
	STDDEV	2.66	3.10	2.84	2.31	2.11	2.21
	MINIMUM	-9	-11	-11	-9	-7	-9
	MAXIMUM	6	3	6	3	3	3
	MISSING	6	3	9	8	7	15
Week 4	N	48	32	80	48	35	83
	MEAN	-3.4	-3.5	-3.5	-2.4	-1.7	-2.1
	MEDIAN	-3.0	-3.0	-3.0	-1.5	-2.0	-2.0
	STDDEV	3.57	3.65	3.58	3.62	2.60	3.22
	MINIMUM	-14	-16	-16	-14	-7	-14
	MAXIMUM	7	1	7	4	3	4
	MISSING	4	5	9	6	7	13
Week 6	N	45	34	79	51	39	90
	MEAN	-4.6	-3.9	-4.3	-3.7	-1.8	-2.9
	MEDIAN	-4.0	-4.0	-4.0	-3.0	-2.0	-3.0
	STDDEV	3.90	3.56	3.75	3.75	3.32	3.68
	MINIMUM	-13	-11	-13	-11	-7	-11
	MAXIMUM	7	4	7	4	8	8
	MISSING	4	1	5	1	1	2
Week 8	N	37	30	67	49	33	82
	MEAN	-5.3	-4.5	-4.9	-4.4	-2.4	-3.6
	MEDIAN	-5.0	-4.0	-5.0	-4.0	-3.0	-4.0
	STDDEV	3.76	3.31	3.56	4.35	3.42	4.10
	MINIMUM	-13	-10	-13	-13	-10	-13
	MAXIMUM	1	1	1	4	5	5
	MISSING	4	1	5	1	3	4
Week 10	N	37	30	67	45	33	78
	MEAN	-5.7	-5.0	-5.4	-4.7	-2.8	-3.9
	MEDIAN	-5.0	-6.0	-5.0	-4.0	-3.0	-4.0
	STDDEV	3.52	3.90	3.68	4.31	3.91	4.23

Table 14.7.3

Summary Statistics for Change from Baseline in CY-BOCS Compulsions Subscale Score

Intention-To-Treat Population

		Paroxetine (N=98)			Placebo (N=105)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 10	MINIMUM	-14	-12	-14	-15	-12	-15
	MAXIMUM	2	2	2	3	3	3
	MISSING	1	0	1	2	0	2
Week 10 LOCF Endpoint	N	54	40	94	56	46	102
	MEAN	-5.4	-4.1	-4.9	-4.1	-1.7	-3.0
	MEDIAN	-5.0	-3.5	-4.0	-4.0	0.0	-2.5
	STDDEV	3.87	3.89	3.92	4.44	4.02	4.41
	MINIMUM	-14	-12	-14	-15	-12	-15
	MAXIMUM	2	3	3	4	8	8
	MISSING	0	0	0	0	0	0

13 Source Tables: Safety Results

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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=98)	Placebo (N=105)
TOTAL	TOTAL	24 (24.5%)	20 (19.0%)
Body as a Whole	TOTAL	16 (16.3%)	8 (7.6%)
	HEADACHE	10 (10.2%)	6 (5.7%)
	ABDOMINAL PAIN	3 (3.1%)	2 (1.9%)
	FEVER	3 (3.1%)	1 (1.0%)
	TRAUMA	2 (2.0%)	1 (1.0%)
	INFECTION	1 (1.0%)	1 (1.0%)
	ASTHENIA	1 (1.0%)	0
	BACK PAIN	1 (1.0%)	0
Respiratory System	TOTAL	8 (8.2%)	6 (5.7%)
	RHINITIS	5 (5.1%)	2 (1.9%)
	PHARYNGITIS	2 (2.0%)	1 (1.0%)
	RESPIRATORY DISORDER	1 (1.0%)	0
	SINUSITIS	0	2 (1.9%)
	ASTHMA	0	1 (1.0%)
Digestive System	TOTAL	2 (2.0%)	2 (1.9%)
	VOMITING	1 (1.0%)	1 (1.0%)
	DIARRHEA	1 (1.0%)	0
	NAUSEA	0	2 (1.9%)
Hemic and Lymphatic System	TOTAL	1 (1.0%)	1 (1.0%)
	PURPURA	1 (1.0%)	0
	LYMPHADENOPATHY	0	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (1.0%)	3 (2.9%)
	WEIGHT GAIN	1 (1.0%)	2 (1.9%)
	WEIGHT LOSS	0	1 (1.0%)
Cardiovascular System	TOTAL	0	1 (1.0%)
	CARDIOVASCULAR DISORDER	0	1 (1.0%)
Endocrine System	TOTAL	0	1 (1.0%)
	THYROID DISORDER	0	1 (1.0%)
Nervous System	TOTAL	0	1 (1.0%)
	ANXIETY	0	1 (1.0%)
Special Senses	TOTAL	0	1 (1.0%)
	EAR PAIN	0	1 (1.0%)

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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
Gender Non Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=98)	Placebo (N=105)
Body System	Preferred Term		
Urogenital System	TOTAL	0	2 (1.9%)
	URINARY INCONTINENCE	0	1 (1.0%)
	URINE ABNORMALITY	0	1 (1.0%)

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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
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=64)
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=45)	Placebo (N=41)
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=58)	Placebo (N=57)
TOTAL	TOTAL	49 (84.5%)	42 (73.7%)
Body as a Whole	TOTAL	32 (55.2%)	24 (42.1%)
	HEADACHE	13 (22.4%)	11 (19.3%)
	ABDOMINAL PAIN	13 (22.4%)	9 (15.8%)
	TRAUMA	7 (12.1%)	1 (1.8%)
	FEVER	4 (6.9%)	4 (7.0%)
	INFECTION	3 (5.2%)	9 (15.8%)
	ALLERGIC REACTION	3 (5.2%)	3 (5.3%)
	PAIN	3 (5.2%)	3 (5.3%)
	ASTHENIA	3 (5.2%)	1 (1.8%)
	CHEST PAIN	3 (5.2%)	0
	BACK PAIN	1 (1.7%)	0
Nervous System	TOTAL	27 (46.6%)	18 (31.6%)
	HYPERKINESIA	10 (17.2%)	4 (7.0%)
	INSOMNIA	7 (12.1%)	2 (3.5%)
	HOSTILITY	7 (12.1%)	1 (1.8%)
	SOMNOLENCE	5 (8.6%)	3 (5.3%)
	NEUROSIS	5 (8.6%)	1 (1.8%)
	NERVOUSNESS	4 (6.9%)	2 (3.5%)
	AGITATION	3 (5.2%)	0
	PERSONALITY DISORDER	3 (5.2%)	0
	CONCENTRATION IMPAIRED	2 (3.4%)	1 (1.8%)
	SPEECH DISORDER	2 (3.4%)	0
	TREMOR	2 (3.4%)	0
	DIZZINESS	1 (1.7%)	4 (7.0%)
	ANXIETY	1 (1.7%)	0
	DEPERSONALIZATION	1 (1.7%)	0
	DIPLOPIA	1 (1.7%)	0
	EMOTIONAL LABILITY	1 (1.7%)	0
	INCOORDINATION	1 (1.7%)	0
	MYOCLONUS	0	2 (3.5%)
	NYSTAGMUS	0	1 (1.8%)
Digestive System	TOTAL	23 (39.7%)	19 (33.3%)
	NAUSEA	6 (10.3%)	9 (15.8%)
	DECREASED APPETITE	6 (10.3%)	1 (1.8%)
	DIARRHEA	5 (8.6%)	2 (3.5%)
	VOMITING	5 (8.6%)	2 (3.5%)
	DYSPEPSIA	2 (3.4%)	2 (3.5%)
	CONSTIPATION	1 (1.7%)	3 (5.3%)
	DRY MOUTH	1 (1.7%)	3 (5.3%)
	GASTROINTESTINAL DISORDER	1 (1.7%)	2 (3.5%)

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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=58)	Placebo (N=57)
Digestive System	COLITIS	1 (1.7%)	0
	FLATULENCE	1 (1.7%)	0
	INCREASED APPETITE	1 (1.7%)	0
	STOMATITIS	1 (1.7%)	0
	TOOTH CARIES	1 (1.7%)	0
	TOOTH DISORDER	1 (1.7%)	0
	ULCERATIVE STOMATITIS	1 (1.7%)	0
	GASTROENTERITIS	0	1 (1.8%)
	GINGIVITIS	0	1 (1.8%)
Respiratory System	TOTAL	15 (25.9%)	18 (31.6%)
	RESPIRATORY DISORDER	7 (12.1%)	6 (10.5%)
	PHARYNGITIS	4 (6.9%)	4 (7.0%)
	SINUSITIS	4 (6.9%)	2 (3.5%)
	RHINITIS	2 (3.4%)	6 (10.5%)
	EPISTAXIS	2 (3.4%)	0
	COUGH INCREASED	1 (1.7%)	5 (8.8%)
	STRIDOR	1 (1.7%)	0
Skin and Appendages	TOTAL	4 (6.9%)	3 (5.3%)
	SWEATING	2 (3.4%)	0
	PHOTOSENSITIVITY	1 (1.7%)	0
	PUSTULAR RASH	1 (1.7%)	0
	FUNGAL DERMATITIS	0	1 (1.8%)
	RASH	0	1 (1.8%)
	SKIN BENIGN NEOPLASM	0	1 (1.8%)
Urogenital System	TOTAL	4 (6.9%)	3 (5.3%)
	URINARY INCONTINENCE	2 (3.4%)	2 (3.5%)
	ALBUMINURIA	1 (1.7%)	0
	URINARY RETENTION	1 (1.7%)	0
	URINARY TRACT INFECTION	0	1 (1.8%)
Special Senses	TOTAL	3 (5.2%)	3 (5.3%)
	CONJUNCTIVITIS	2 (3.4%)	0
	KERATOCONJUNCTIVITIS	1 (1.7%)	0
	OTITIS MEDIA	0	2 (3.5%)
	EAR DISORDER	0	1 (1.8%)
	EAR PAIN	0	1 (1.8%)
Musculoskeletal System	TOTAL	2 (3.4%)	0
	MYALGIA	2 (3.4%)	0
Cardiovascular System	TOTAL	1 (1.7%)	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=58)	 Placebo (N=57)
Cardiovascular System	VASODILATATION	1 (1.7%)	0
Hemic and Lymphatic System	TOTAL	1 (1.7%)	0
	ANEMIA	1 (1.7%)	0
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.8%)
	THIRST	0	1 (1.8%)

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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=31)	Placebo (N=35)
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=27)	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=40)	Placebo (N=48)
TOTAL	TOTAL	34 (85.0%)	35 (72.9%)
Body as a Whole	TOTAL	18 (45.0%)	18 (37.5%)
	HEADACHE	11 (27.5%)	11 (22.9%)
	ASTHENIA	5 (12.5%)	0
	ABDOMINAL PAIN	4 (10.0%)	3 (6.3%)
	TRAUMA	3 (7.5%)	2 (4.2%)
	INFECTION	2 (5.0%)	3 (6.3%)
	PAIN	2 (5.0%)	0
	ALLERGIC REACTION	1 (2.5%)	1 (2.1%)
	FEVER	0	3 (6.3%)
	BACK PAIN	0	1 (2.1%)
Digestive System	TOTAL	16 (40.0%)	4 (8.3%)
	NAUSEA	10 (25.0%)	1 (2.1%)
	DRY MOUTH	3 (7.5%)	2 (4.2%)
	DECREASED APPETITE	3 (7.5%)	0
	DIARRHEA	3 (7.5%)	0
	BRUXISM	1 (2.5%)	0
	CONSTIPATION	1 (2.5%)	0
	FLATULENCE	1 (2.5%)	0
	GASTROINTESTINAL DISORDER	1 (2.5%)	0
	VOMITING	1 (2.5%)	0
	DYSPEPSIA	0	1 (2.1%)
Nervous System	TOTAL	16 (40.0%)	11 (22.9%)
	SOMNOLENCE	7 (17.5%)	4 (8.3%)
	DIZZINESS	4 (10.0%)	3 (6.3%)
	INSOMNIA	2 (5.0%)	3 (6.3%)
	AGITATION	2 (5.0%)	2 (4.2%)
	HYPERKINESIA	2 (5.0%)	2 (4.2%)
	EMOTIONAL LABILITY	2 (5.0%)	0
	HOSTILITY	2 (5.0%)	0
	NERVOUSNESS	1 (2.5%)	4 (8.3%)
	ABNORMAL DREAMS	1 (2.5%)	1 (2.1%)
	ANXIETY	1 (2.5%)	1 (2.1%)
	DEPRESSION	1 (2.5%)	0
	DEPERSONALIZATION	0	1 (2.1%)
Respiratory System	TOTAL	13 (32.5%)	14 (29.2%)
	RESPIRATORY DISORDER	5 (12.5%)	9 (18.8%)
	PHARYNGITIS	4 (10.0%)	2 (4.2%)
	RHINITIS	2 (5.0%)	4 (8.3%)
	ASTHMA	2 (5.0%)	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=40)	 Placebo (N=48)
Respiratory System	SINUSITIS	1 (2.5%)	3 (6.3%)
	COUGH INCREASED	1 (2.5%)	1 (2.1%)
	EPISTAXIS	1 (2.5%)	0
	YAWN	1 (2.5%)	0
Special Senses	TOTAL	3 (7.5%)	3 (6.3%)
	OTITIS EXTERNA	1 (2.5%)	1 (2.1%)
	OTITIS MEDIA	1 (2.5%)	1 (2.1%)
	EAR PAIN	1 (2.5%)	0
	MYDRIASIS	1 (2.5%)	0
	ABNORMAL VISION	0	1 (2.1%)
Urogenital System	TOTAL	3 (7.5%)	2 (4.2%)
	HAEMATURIA	1 (2.5%)	1 (2.1%)
	CYSTITIS	1 (2.5%)	0
	URINARY FREQUENCY	1 (2.5%)	0
	URINARY TRACT INFECTION	0	1 (2.1%)
Cardiovascular System	TOTAL	2 (5.0%)	1 (2.1%)
	VASODILATATION	1 (2.5%)	1 (2.1%)
	HYPERTENSION	1 (2.5%)	0
Metabolic and Nutritional Disorders	TOTAL	2 (5.0%)	0
	PERIPHERAL EDEMA	1 (2.5%)	0
	WEIGHT LOSS	1 (2.5%)	0
Endocrine System	TOTAL	1 (2.5%)	0
	THYROID DISORDER	1 (2.5%)	0
Musculoskeletal System	TOTAL	1 (2.5%)	3 (6.3%)
	ARTHRALGIA	1 (2.5%)	1 (2.1%)
	MYALGIA	0	2 (4.2%)
Skin and Appendages	TOTAL	1 (2.5%)	2 (4.2%)
	ACNE	1 (2.5%)	0
	DRY SKIN	0	1 (2.1%)
	HERPES SIMPLEX	0	1 (2.1%)
Hemic and Lymphatic System	TOTAL	0	1 (2.1%)
	LEUKOPENIA	0	1 (2.1%)

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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

		Treatment Group	
		Paroxetine (N=22)	Placebo (N=29)
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, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=18)	 Placebo (N=19)
TOTAL	TOTAL	3 (16.7%)	1 (5.3%)
Urogenital System	TOTAL	3 (16.7%)	1 (5.3%)
	DYSMENORRHEA	3 (16.7%)	1 (5.3%)

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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=98)	Treatment Group Placebo (N=105)
TOTAL	TOTAL	83 (84.7%)	77 (73.3%)
Body as a Whole	TOTAL	50 (51.0%)	42 (40.0%)
	HEADACHE	24 (24.5%)	22 (21.0%)
	ABDOMINAL PAIN	17 (17.3%)	12 (11.4%)
	TRAUMA	10 (10.2%)	3 (2.9%)
	ASTHENIA	8 (8.2%)	1 (1.0%)
	INFECTION	5 (5.1%)	12 (11.4%)
	PAIN	5 (5.1%)	3 (2.9%)
	FEVER	4 (4.1%)	7 (6.7%)
	ALLERGIC REACTION	4 (4.1%)	4 (3.8%)
	CHEST PAIN	3 (3.1%)	0
	BACK PAIN	1 (1.0%)	1 (1.0%)
Nervous System	TOTAL	43 (43.9%)	29 (27.6%)
	SOMNOLENCE	12 (12.2%)	7 (6.7%)
	HYPERKINESIA	12 (12.2%)	6 (5.7%)
	INSOMNIA	9 (9.2%)	5 (4.8%)
	HOSTILITY	9 (9.2%)	1 (1.0%)
	DIZZINESS	5 (5.1%)	7 (6.7%)
	NERVOUSNESS	5 (5.1%)	6 (5.7%)
	AGITATION	5 (5.1%)	2 (1.9%)
	NEUROSIS	5 (5.1%)	1 (1.0%)
	EMOTIONAL LABILITY	3 (3.1%)	0
	PERSONALITY DISORDER	3 (3.1%)	0
	ANXIETY	2 (2.0%)	1 (1.0%)
	CONCENTRATION IMPAIRED	2 (2.0%)	1 (1.0%)
	SPEECH DISORDER	2 (2.0%)	0
	TREMOR	2 (2.0%)	0
	ABNORMAL DREAMS	1 (1.0%)	1 (1.0%)
	DEPERSONALIZATION	1 (1.0%)	1 (1.0%)
	DEPRESSION	1 (1.0%)	0
	DIPLOPIA	1 (1.0%)	0
	INCOORDINATION	1 (1.0%)	0
	MYOCLONUS	0	2 (1.9%)
	NYSTAGMUS	0	1 (1.0%)
Digestive System	TOTAL	39 (39.8%)	23 (21.9%)
	NAUSEA	16 (16.3%)	10 (9.5%)
	DECREASED APPETITE	9 (9.2%)	1 (1.0%)
	DIARRHEA	8 (8.2%)	2 (1.9%)
	VOMITING	6 (6.1%)	2 (1.9%)
	DRY MOUTH	4 (4.1%)	5 (4.8%)
	CONSTIPATION	2 (2.0%)	3 (2.9%)

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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 : Total, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=98)	Treatment Group Placebo (N=105)
Digestive System	DYSPEPSIA	2 (2.0%)	3 (2.9%)
	GASTROINTESTINAL DISORDER	2 (2.0%)	2 (1.9%)
	FLATULENCE	2 (2.0%)	0
	BRUXISM	1 (1.0%)	0
	COLITIS	1 (1.0%)	0
	INCREASED APPETITE	1 (1.0%)	0
	STOMATITIS	1 (1.0%)	0
	TOOTH CARIES	1 (1.0%)	0
	TOOTH DISORDER	1 (1.0%)	0
	ULCERATIVE STOMATITIS	1 (1.0%)	0
	GASTROENTERITIS	0	1 (1.0%)
	GINGIVITIS	0	1 (1.0%)
Respiratory System	TOTAL	28 (28.6%)	32 (30.5%)
	RESPIRATORY DISORDER	12 (12.2%)	15 (14.3%)
	PHARYNGITIS	8 (8.2%)	6 (5.7%)
	SINUSITIS	5 (5.1%)	5 (4.8%)
	RHINITIS	4 (4.1%)	10 (9.5%)
	EPISTAXIS	3 (3.1%)	0
	COUGH INCREASED	2 (2.0%)	6 (5.7%)
	ASTHMA	2 (2.0%)	0
	STRIDOR	1 (1.0%)	0
	YAWN	1 (1.0%)	0
Urogenital System	TOTAL	7 (7.1%)	5 (4.8%)
	URINARY INCONTINENCE	2 (2.0%)	2 (1.9%)
	HAEMATURIA	1 (1.0%)	1 (1.0%)
	ALBUMINURIA	1 (1.0%)	0
	CYSTITIS	1 (1.0%)	0
	URINARY FREQUENCY	1 (1.0%)	0
	URINARY RETENTION	1 (1.0%)	0
	URINARY TRACT INFECTION	0	2 (1.9%)
Special Senses	TOTAL	6 (6.1%)	6 (5.7%)
	CONJUNCTIVITIS	2 (2.0%)	0
	OTITIS MEDIA	1 (1.0%)	3 (2.9%)
	EAR PAIN	1 (1.0%)	1 (1.0%)
	OTITIS EXTERNA	1 (1.0%)	1 (1.0%)
	KERATOCONJUNCTIVITIS	1 (1.0%)	0
	MYDRIASIS	1 (1.0%)	0
	ABNORMAL VISION	0	1 (1.0%)
	EAR DISORDER	0	1 (1.0%)
Skin and Appendages	TOTAL	5 (5.1%)	5 (4.8%)

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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=98)	 Placebo (N=105)
Skin and Appendages	SWEATING	2 (2.0%)	0
	ACNE	1 (1.0%)	0
	PHOTOSENSITIVITY	1 (1.0%)	0
	PUSTULAR RASH	1 (1.0%)	0
	DRY SKIN	0	1 (1.0%)
	FUNGAL DERMATITIS	0	1 (1.0%)
	HERPES SIMPLEX	0	1 (1.0%)
	RASH	0	1 (1.0%)
	SKIN BENIGN NEOPLASM	0	1 (1.0%)
Cardiovascular System	TOTAL	3 (3.1%)	1 (1.0%)
	VASODILATATION	2 (2.0%)	1 (1.0%)
	HYPERTENSION	1 (1.0%)	0
Musculoskeletal System	TOTAL	3 (3.1%)	3 (2.9%)
	MYALGIA	2 (2.0%)	2 (1.9%)
	ARTHRALGIA	1 (1.0%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	2 (2.0%)	1 (1.0%)
	PERIPHERAL EDEMA	1 (1.0%)	0
	WEIGHT LOSS	1 (1.0%)	0
	THIRST	0	1 (1.0%)
Endocrine System	TOTAL	1 (1.0%)	0
	THYROID DISORDER	1 (1.0%)	0
Hemic and Lymphatic System	TOTAL	1 (1.0%)	1 (1.0%)
	ANEMIA	1 (1.0%)	0
	LEUKOPENIA	0	1 (1.0%)

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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, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=64)
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 : Total, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=45)	 Placebo (N=41)
TOTAL	TOTAL	3 (6.7%)	1 (2.4%)
Urogenital System	TOTAL	3 (6.7%)	1 (2.4%)
	DYSMENORRHEA	3 (6.7%)	1 (2.4%)

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Table 15.1.1.1X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase
by Descending Order
Intention-To-Treat Population
Age Group : Children, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=58)	 Placebo (N=57)
TOTAL	49 (84.5%)	42 (73.7%)
HEADACHE	13 (22.4%)	11 (19.3%)
ABDOMINAL PAIN	13 (22.4%)	9 (15.8%)
HYPERKINESIA	10 (17.2%)	4 (7.0%)
RESPIRATORY DISORDER	7 (12.1%)	6 (10.5%)
INSOMNIA	7 (12.1%)	2 (3.5%)
HOSTILITY	7 (12.1%)	1 (1.8%)
TRAUMA	7 (12.1%)	1 (1.8%)
NAUSEA	6 (10.3%)	9 (15.8%)
DECREASED APPETITE	6 (10.3%)	1 (1.8%)
SOMNOLENCE	5 (8.6%)	3 (5.3%)
DIARRHEA	5 (8.6%)	2 (3.5%)
VOMITING	5 (8.6%)	2 (3.5%)
NEUROSIS	5 (8.6%)	1 (1.8%)
FEVER	4 (6.9%)	4 (7.0%)
PHARYNGITIS	4 (6.9%)	4 (7.0%)
NERVOUSNESS	4 (6.9%)	2 (3.5%)
SINUSITIS	4 (6.9%)	2 (3.5%)
INFECTION	3 (5.2%)	9 (15.8%)
ALLERGIC REACTION	3 (5.2%)	3 (5.3%)
PAIN	3 (5.2%)	3 (5.3%)
ASTHENIA	3 (5.2%)	1 (1.8%)
AGITATION	3 (5.2%)	0
CHEST PAIN	3 (5.2%)	0
PERSONALITY DISORDER	3 (5.2%)	0
RHINITIS	2 (3.4%)	6 (10.5%)
DYSPEPSIA	2 (3.4%)	2 (3.5%)
URINARY INCONTINENCE	2 (3.4%)	2 (3.5%)
CONCENTRATION IMPAIRED	2 (3.4%)	1 (1.8%)
CONJUNCTIVITIS	2 (3.4%)	0
EPISTAXIS	2 (3.4%)	0
MYALGIA	2 (3.4%)	0
SPEECH DISORDER	2 (3.4%)	0
SWEATING	2 (3.4%)	0
TREMOR	2 (3.4%)	0
COUGH INCREASED	1 (1.7%)	5 (8.8%)
DIZZINESS	1 (1.7%)	4 (7.0%)
CONSTIPATION	1 (1.7%)	3 (5.3%)
DRY MOUTH	1 (1.7%)	3 (5.3%)
GASTROINTESTINAL DISORDER	1 (1.7%)	2 (3.5%)
ALBUMINURIA	1 (1.7%)	0
ANEMIA	1 (1.7%)	0
ANXIETY	1 (1.7%)	0
BACK PAIN	1 (1.7%)	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=58)	 Placebo (N=57)
COLITIS	1 (1.7%)	0
DEPERSONALIZATION	1 (1.7%)	0
DIPLOPIA	1 (1.7%)	0
EMOTIONAL LABILITY	1 (1.7%)	0
FLATULENCE	1 (1.7%)	0
INCOORDINATION	1 (1.7%)	0
INCREASED APPETITE	1 (1.7%)	0
KERATOCONJUNCTIVITIS	1 (1.7%)	0
PHOTOSENSITIVITY	1 (1.7%)	0
PUSTULAR RASH	1 (1.7%)	0
STOMATITIS	1 (1.7%)	0
STRIDOR	1 (1.7%)	0
TOOTH CARIES	1 (1.7%)	0
TOOTH DISORDER	1 (1.7%)	0
ULCERATIVE STOMATITIS	1 (1.7%)	0
URINARY RETENTION	1 (1.7%)	0
VASODILATATION	1 (1.7%)	0
MYOCLONUS	0	2 (3.5%)
OTITIS MEDIA	0	2 (3.5%)
EAR DISORDER	0	1 (1.8%)
EAR PAIN	0	1 (1.8%)
FUNGAL DERMATITIS	0	1 (1.8%)
GASTROENTERITIS	0	1 (1.8%)
GINGIVITIS	0	1 (1.8%)
NYSTAGMUS	0	1 (1.8%)
RASH	0	1 (1.8%)
SKIN BENIGN NEOPLASM	0	1 (1.8%)
THIRST	0	1 (1.8%)
URINARY TRACT INFECTION	0	1 (1.8%)

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Table 15.1.1.1X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase
by Descending Order
Intention-To-Treat Population
Age Group : Children, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=31)	 Placebo (N=35)
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=27)	 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=40)	 Placebo (N=48)
TOTAL	34 (85.0%)	35 (72.9%)
HEADACHE	11 (27.5%)	11 (22.9%)
NAUSEA	10 (25.0%)	1 (2.1%)
SOMNOLENCE	7 (17.5%)	4 (8.3%)
RESPIRATORY DISORDER	5 (12.5%)	9 (18.8%)
ASTHENIA	5 (12.5%)	0
ABDOMINAL PAIN	4 (10.0%)	3 (6.3%)
DIZZINESS	4 (10.0%)	3 (6.3%)
PHARYNGITIS	4 (10.0%)	2 (4.2%)
DRY MOUTH	3 (7.5%)	2 (4.2%)
TRAUMA	3 (7.5%)	2 (4.2%)
DECREASED APPETITE	3 (7.5%)	0
DIARRHEA	3 (7.5%)	0
RHINITIS	2 (5.0%)	4 (8.3%)
INFECTION	2 (5.0%)	3 (6.3%)
INSOMNIA	2 (5.0%)	3 (6.3%)
AGITATION	2 (5.0%)	2 (4.2%)
HYPERKINESIA	2 (5.0%)	2 (4.2%)
ASTHMA	2 (5.0%)	0
EMOTIONAL LABILITY	2 (5.0%)	0
HOSTILITY	2 (5.0%)	0
PAIN	2 (5.0%)	0
NERVOUSNESS	1 (2.5%)	4 (8.3%)
SINUSITIS	1 (2.5%)	3 (6.3%)
ABNORMAL DREAMS	1 (2.5%)	1 (2.1%)
ALLERGIC REACTION	1 (2.5%)	1 (2.1%)
ANXIETY	1 (2.5%)	1 (2.1%)
ARTHRALGIA	1 (2.5%)	1 (2.1%)
COUGH INCREASED	1 (2.5%)	1 (2.1%)
HAEMATURIA	1 (2.5%)	1 (2.1%)
OTITIS EXTERNA	1 (2.5%)	1 (2.1%)
OTITIS MEDIA	1 (2.5%)	1 (2.1%)
VASODILATATION	1 (2.5%)	1 (2.1%)
ACNE	1 (2.5%)	0
BRUXISM	1 (2.5%)	0
CONSTIPATION	1 (2.5%)	0
CYSTITIS	1 (2.5%)	0
DEPRESSION	1 (2.5%)	0
EAR PAIN	1 (2.5%)	0
EPISTAXIS	1 (2.5%)	0
FLATULENCE	1 (2.5%)	0
GASTROINTESTINAL DISORDER	1 (2.5%)	0
HYPERTENSION	1 (2.5%)	0
MYDRIASIS	1 (2.5%)	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=40)	 Placebo (N=48)
PERIPHERAL EDEMA	1 (2.5%)	0
THYROID DISORDER	1 (2.5%)	0
URINARY FREQUENCY	1 (2.5%)	0
VOMITING	1 (2.5%)	0
WEIGHT LOSS	1 (2.5%)	0
YAWN	1 (2.5%)	0
FEVER	0	3 (6.3%)
MYALGIA	0	2 (4.2%)
ABNORMAL VISION	0	1 (2.1%)
BACK PAIN	0	1 (2.1%)
DEPERSONALIZATION	0	1 (2.1%)
DRY SKIN	0	1 (2.1%)
DYSPEPSIA	0	1 (2.1%)
HERPES SIMPLEX	0	1 (2.1%)
LEUKOPENIA	0	1 (2.1%)
URINARY TRACT INFECTION	0	1 (2.1%)

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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=22)	 Placebo (N=29)
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=18)	 Placebo (N=19)
TOTAL	3 (16.7%)	1 (5.3%)
DYSMENORRHEA	3 (16.7%)	1 (5.3%)

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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, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=98)	 Placebo (N=105)
TOTAL	83 (84.7%)	77 (73.3%)
HEADACHE	24 (24.5%)	22 (21.0%)
ABDOMINAL PAIN	17 (17.3%)	12 (11.4%)
NAUSEA	16 (16.3%)	10 (9.5%)
RESPIRATORY DISORDER	12 (12.2%)	15 (14.3%)
SOMNOLENCE	12 (12.2%)	7 (6.7%)
HYPERKINESIA	12 (12.2%)	6 (5.7%)
TRAUMA	10 (10.2%)	3 (2.9%)
INSOMNIA	9 (9.2%)	5 (4.8%)
DECREASED APPETITE	9 (9.2%)	1 (1.0%)
HOSTILITY	9 (9.2%)	1 (1.0%)
PHARYNGITIS	8 (8.2%)	6 (5.7%)
DIARRHEA	8 (8.2%)	2 (1.9%)
ASTHENIA	8 (8.2%)	1 (1.0%)
VOMITING	6 (6.1%)	2 (1.9%)
INFECTION	5 (5.1%)	12 (11.4%)
DIZZINESS	5 (5.1%)	7 (6.7%)
NERVOUSNESS	5 (5.1%)	6 (5.7%)
SINUSITIS	5 (5.1%)	5 (4.8%)
PAIN	5 (5.1%)	3 (2.9%)
AGITATION	5 (5.1%)	2 (1.9%)
NEUROSIS	5 (5.1%)	1 (1.0%)
RHINITIS	4 (4.1%)	10 (9.5%)
FEVER	4 (4.1%)	7 (6.7%)
DRY MOUTH	4 (4.1%)	5 (4.8%)
ALLERGIC REACTION	4 (4.1%)	4 (3.8%)
CHEST PAIN	3 (3.1%)	0
EMOTIONAL LABILITY	3 (3.1%)	0
EPISTAXIS	3 (3.1%)	0
PERSONALITY DISORDER	3 (3.1%)	0
COUGH INCREASED	2 (2.0%)	6 (5.7%)
CONSTIPATION	2 (2.0%)	3 (2.9%)
DYSPEPSIA	2 (2.0%)	3 (2.9%)
GASTROINTESTINAL DISORDER	2 (2.0%)	2 (1.9%)
MYALGIA	2 (2.0%)	2 (1.9%)
URINARY INCONTINENCE	2 (2.0%)	2 (1.9%)
ANXIETY	2 (2.0%)	1 (1.0%)
CONCENTRATION IMPAIRED	2 (2.0%)	1 (1.0%)
VASODILATATION	2 (2.0%)	1 (1.0%)
ASTHMA	2 (2.0%)	0
CONJUNCTIVITIS	2 (2.0%)	0
FLATULENCE	2 (2.0%)	0
SPEECH DISORDER	2 (2.0%)	0
SWEATING	2 (2.0%)	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, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=98)	 Placebo (N=105)
TREMOR	2 (2.0%)	0
OTITIS MEDIA	1 (1.0%)	3 (2.9%)
ABNORMAL DREAMS	1 (1.0%)	1 (1.0%)
ARTHRALGIA	1 (1.0%)	1 (1.0%)
BACK PAIN	1 (1.0%)	1 (1.0%)
DEPERSONALIZATION	1 (1.0%)	1 (1.0%)
EAR PAIN	1 (1.0%)	1 (1.0%)
HAEMATURIA	1 (1.0%)	1 (1.0%)
OTITIS EXTERNA	1 (1.0%)	1 (1.0%)
ACNE	1 (1.0%)	0
ALBUMINURIA	1 (1.0%)	0
ANEMIA	1 (1.0%)	0
BRUXISM	1 (1.0%)	0
COLITIS	1 (1.0%)	0
CYSTITIS	1 (1.0%)	0
DEPRESSION	1 (1.0%)	0
DIPLOPIA	1 (1.0%)	0
HYPERTENSION	1 (1.0%)	0
INCOORDINATION	1 (1.0%)	0
INCREASED APPETITE	1 (1.0%)	0
KERATOCONJUNCTIVITIS	1 (1.0%)	0
MYDRIASIS	1 (1.0%)	0
PERIPHERAL EDEMA	1 (1.0%)	0
PHOTOSENSITIVITY	1 (1.0%)	0
PUSTULAR RASH	1 (1.0%)	0
STOMATITIS	1 (1.0%)	0
STRIDOR	1 (1.0%)	0
THYROID DISORDER	1 (1.0%)	0
TOOTH CARIES	1 (1.0%)	0
TOOTH DISORDER	1 (1.0%)	0
ULCERATIVE STOMATITIS	1 (1.0%)	0
URINARY FREQUENCY	1 (1.0%)	0
URINARY RETENTION	1 (1.0%)	0
WEIGHT LOSS	1 (1.0%)	0
YAWN	1 (1.0%)	0
MYOCLONUS	0	2 (1.9%)
URINARY TRACT INFECTION	0	2 (1.9%)
ABNORMAL VISION	0	1 (1.0%)
DRY SKIN	0	1 (1.0%)
EAR DISORDER	0	1 (1.0%)
FUNGAL DERMATITIS	0	1 (1.0%)
GASTROENTERITIS	0	1 (1.0%)
GINGIVITIS	0	1 (1.0%)
HERPES SIMPLEX	0	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 : Total, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=98)	 Placebo (N=105)
LEUKOPENIA	0	1 (1.0%)
NYSTAGMUS	0	1 (1.0%)
RASH	0	1 (1.0%)
SKIN BENIGN NEOPLASM	0	1 (1.0%)
THIRST	0	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 : Total, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=53)	 Placebo (N=64)
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=45)	 Placebo (N=41)
TOTAL	3 (6.7%)	1 (2.4%)
DYSMENORRHEA	3 (6.7%)	1 (2.4%)

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
By Body System
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=31)	Placebo (N=41)
TOTAL	TOTAL	3 (9.7%)	8 (19.5%)
Body as a Whole	TOTAL	3 (9.7%)	5 (12.2%)
	HEADACHE	2 (6.5%)	3 (7.3%)
	INFECTION	1 (3.2%)	2 (4.9%)
	ALLERGIC REACTION	1 (3.2%)	0
	ABDOMINAL PAIN	0	1 (2.4%)
Digestive System	TOTAL	1 (3.2%)	0
	ULCERATIVE STOMATITIS	1 (3.2%)	0
Nervous System	TOTAL	1 (3.2%)	3 (7.3%)
	DIZZINESS	1 (3.2%)	0
	NEUROSIS	0	3 (7.3%)
Respiratory System	TOTAL	1 (3.2%)	1 (2.4%)
	RHINITIS	1 (3.2%)	1 (2.4%)
Special Senses	TOTAL	0	3 (7.3%)
	CONJUNCTIVITIS	0	1 (2.4%)
	EAR PAIN	0	1 (2.4%)
	OTITIS MEDIA	0	1 (2.4%)

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Table 15.1.1.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase
By Body System
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=15)	Placebo (N=26)
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=16)	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 : Adolescents, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=29)	Placebo (N=33)
TOTAL	TOTAL	6 (20.7%)	4 (12.1%)
Nervous System	TOTAL	3 (10.3%)	2 (6.1%)
	NERVOUSNESS	1 (3.4%)	2 (6.1%)
	ANXIETY	1 (3.4%)	0
	PARESTHESIA	1 (3.4%)	0
Musculoskeletal System	TOTAL	2 (6.9%)	0
	ARTHRALGIA	1 (3.4%)	0
	MYALGIA	1 (3.4%)	0
Digestive System	TOTAL	1 (3.4%)	1 (3.0%)
	DIARRHEA	1 (3.4%)	0
	DECREASED APPETITE	0	1 (3.0%)
	NAUSEA	0	1 (3.0%)
Respiratory System	TOTAL	1 (3.4%)	1 (3.0%)
	SINUSITIS	1 (3.4%)	0
	RHINITIS	0	1 (3.0%)
Body as a Whole	TOTAL	0	3 (9.1%)
	ASTHENIA	0	2 (6.1%)
	HEADACHE	0	1 (3.0%)
Cardiovascular System	TOTAL	0	1 (3.0%)
	VASODILATATION	0	1 (3.0%)

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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=16)	Placebo (N=21)
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=13)	Placebo (N=12)
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=60)	Placebo (N=74)
TOTAL	TOTAL	9 (15.0%)	12 (16.2%)
Nervous System	TOTAL	4 (6.7%)	5 (6.8%)
	NERVOUSNESS	1 (1.7%)	2 (2.7%)
	ANXIETY	1 (1.7%)	0
	DIZZINESS	1 (1.7%)	0
	PARESTHESIA	1 (1.7%)	0
	NEUROSIS	0	3 (4.1%)
Body as a Whole	TOTAL	3 (5.0%)	8 (10.8%)
	HEADACHE	2 (3.3%)	4 (5.4%)
	INFECTION	1 (1.7%)	2 (2.7%)
	ALLERGIC REACTION	1 (1.7%)	0
	ASTHENIA	0	2 (2.7%)
	ABDOMINAL PAIN	0	1 (1.4%)
Digestive System	TOTAL	2 (3.3%)	1 (1.4%)
	DIARRHEA	1 (1.7%)	0
	ULCERATIVE STOMATITIS	1 (1.7%)	0
	DECREASED APPETITE	0	1 (1.4%)
	NAUSEA	0	1 (1.4%)
Musculoskeletal System	TOTAL	2 (3.3%)	0
	ARTHRALGIA	1 (1.7%)	0
	MYALGIA	1 (1.7%)	0
Respiratory System	TOTAL	2 (3.3%)	2 (2.7%)
	RHINITIS	1 (1.7%)	2 (2.7%)
	SINUSITIS	1 (1.7%)	0
Cardiovascular System	TOTAL	0	1 (1.4%)
	VASODILATATION	0	1 (1.4%)
Special Senses	TOTAL	0	3 (4.1%)
	CONJUNCTIVITIS	0	1 (1.4%)
	EAR PAIN	0	1 (1.4%)
	OTITIS MEDIA	0	1 (1.4%)

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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 : Total, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=31)	Placebo (N=47)
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=29)	Placebo (N=27)
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=31)	 Placebo (N=41)
TOTAL	3 (9.7%)	8 (19.5%)
HEADACHE	2 (6.5%)	3 (7.3%)
INFECTION	1 (3.2%)	2 (4.9%)
RHINITIS	1 (3.2%)	1 (2.4%)
ALLERGIC REACTION	1 (3.2%)	0
DIZZINESS	1 (3.2%)	0
ULCERATIVE STOMATITIS	1 (3.2%)	0
NEUROSIS	0	3 (7.3%)
ABDOMINAL PAIN	0	1 (2.4%)
CONJUNCTIVITIS	0	1 (2.4%)
EAR PAIN	0	1 (2.4%)
OTITIS MEDIA	0	1 (2.4%)

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Table 15.1.1.2.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase
by Descending Order
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=15)	Treatment Group: Placebo (N=26)
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=16)	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 : Adolescents, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=29)	 Placebo (N=33)
TOTAL	6 (20.7%)	4 (12.1%)
NERVOUSNESS	1 (3.4%)	2 (6.1%)
ANXIETY	1 (3.4%)	0
ARTHRALGIA	1 (3.4%)	0
DIARRHEA	1 (3.4%)	0
MYALGIA	1 (3.4%)	0
PARESTHESIA	1 (3.4%)	0
SINUSITIS	1 (3.4%)	0
ASTHENIA	0	2 (6.1%)
DECREASED APPETITE	0	1 (3.0%)
HEADACHE	0	1 (3.0%)
NAUSEA	0	1 (3.0%)
RHINITIS	0	1 (3.0%)
VASODILATATION	0	1 (3.0%)

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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, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=16)	Treatment Group: Placebo (N=21)
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=13)	Treatment Group: Placebo (N=12)
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=60)	 Placebo (N=74)
TOTAL	9 (15.0%)	12 (16.2%)
HEADACHE	2 (3.3%)	4 (5.4%)
INFECTION	1 (1.7%)	2 (2.7%)
NERVOUSNESS	1 (1.7%)	2 (2.7%)
RHINITIS	1 (1.7%)	2 (2.7%)
ALLERGIC REACTION	1 (1.7%)	0
ANXIETY	1 (1.7%)	0
ARTHRALGIA	1 (1.7%)	0
DIARRHEA	1 (1.7%)	0
DIZZINESS	1 (1.7%)	0
MYALGIA	1 (1.7%)	0
PARESTHESIA	1 (1.7%)	0
SINUSITIS	1 (1.7%)	0
ULCERATIVE STOMATITIS	1 (1.7%)	0
NEUROSIS	0	3 (4.1%)
ASTHENIA	0	2 (2.7%)
ABDOMINAL PAIN	0	1 (1.4%)
CONJUNCTIVITIS	0	1 (1.4%)
DECREASED APPETITE	0	1 (1.4%)
EAR PAIN	0	1 (1.4%)
NAUSEA	0	1 (1.4%)
OTITIS MEDIA	0	1 (1.4%)
VASODILATATION	0	1 (1.4%)

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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 : Total, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=31)	Treatment Group: Placebo (N=47)
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=29)	Treatment Group: Placebo (N=27)
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=98)	Placebo (N=105)
TOTAL	TOTAL	83 (84.7%)	80 (76.2%)
Body as a Whole	TOTAL	51 (52.0%)	45 (42.9%)
	HEADACHE	25 (25.5%)	24 (22.9%)
	ABDOMINAL PAIN	17 (17.3%)	13 (12.4%)
	TRAUMA	10 (10.2%)	3 (2.9%)
	ASTHENIA	8 (8.2%)	3 (2.9%)
	INFECTION	6 (6.1%)	13 (12.4%)
	ALLERGIC REACTION	5 (5.1%)	4 (3.8%)
	PAIN	5 (5.1%)	3 (2.9%)
	FEVER	4 (4.1%)	7 (6.7%)
	CHEST PAIN	3 (3.1%)	0
	BACK PAIN	1 (1.0%)	1 (1.0%)
Nervous System	TOTAL	44 (44.9%)	32 (30.5%)
	SOMNOLENCE	12 (12.2%)	7 (6.7%)
	HYPERKINESIA	12 (12.2%)	6 (5.7%)
	INSOMNIA	9 (9.2%)	5 (4.8%)
	HOSTILITY	9 (9.2%)	1 (1.0%)
	DIZZINESS	6 (6.1%)	7 (6.7%)
	NERVOUSNESS	5 (5.1%)	8 (7.6%)
	NEUROSIS	5 (5.1%)	4 (3.8%)
	AGITATION	5 (5.1%)	2 (1.9%)
	ANXIETY	3 (3.1%)	1 (1.0%)
	EMOTIONAL LABILITY	3 (3.1%)	0
	PERSONALITY DISORDER	3 (3.1%)	0
	CONCENTRATION IMPAIRED	2 (2.0%)	1 (1.0%)
	SPEECH DISORDER	2 (2.0%)	0
	TREMOR	2 (2.0%)	0
	ABNORMAL DREAMS	1 (1.0%)	1 (1.0%)
	DEPERSONALIZATION	1 (1.0%)	1 (1.0%)
	DEPRESSION	1 (1.0%)	0
	DIPLOPIA	1 (1.0%)	0
	INCOORDINATION	1 (1.0%)	0
	PARESTHESIA	1 (1.0%)	0
	MYOCLONUS	0	2 (1.9%)
	NYSTAGMUS	0	1 (1.0%)
Digestive System	TOTAL	40 (40.8%)	24 (22.9%)
	NAUSEA	16 (16.3%)	11 (10.5%)
	DECREASED APPETITE	9 (9.2%)	2 (1.9%)
	DIARRHEA	9 (9.2%)	2 (1.9%)
	VOMITING	6 (6.1%)	2 (1.9%)
	DRY MOUTH	4 (4.1%)	5 (4.8%)

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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=98)	Treatment Group Placebo (N=105)
Digestive System	CONSTIPATION	2 (2.0%)	3 (2.9%)
	DYSPEPSIA	2 (2.0%)	3 (2.9%)
	GASTROINTESTINAL DISORDER	2 (2.0%)	2 (1.9%)
	FLATULENCE	2 (2.0%)	0
	ULCERATIVE STOMATITIS	2 (2.0%)	0
	BRUXISM	1 (1.0%)	0
	COLITIS	1 (1.0%)	0
	INCREASED APPETITE	1 (1.0%)	0
	STOMATITIS	1 (1.0%)	0
	TOOTH CARIES	1 (1.0%)	0
	TOOTH DISORDER	1 (1.0%)	0
	GASTROENTERITIS	0	1 (1.0%)
	GINGIVITIS	0	1 (1.0%)
Respiratory System	TOTAL	29 (29.6%)	32 (30.5%)
	RESPIRATORY DISORDER	12 (12.2%)	15 (14.3%)
	PHARYNGITIS	8 (8.2%)	6 (5.7%)
	SINUSITIS	6 (6.1%)	5 (4.8%)
	RHINITIS	5 (5.1%)	10 (9.5%)
	EPISTAXIS	3 (3.1%)	0
	COUGH INCREASED	2 (2.0%)	6 (5.7%)
	ASTHMA	2 (2.0%)	0
	STRIDOR	1 (1.0%)	0
	YAWN	1 (1.0%)	0
Urogenital System	TOTAL	7 (7.1%)	5 (4.8%)
	URINARY INCONTINENCE	2 (2.0%)	2 (1.9%)
	HAEMATURIA	1 (1.0%)	1 (1.0%)
	ALBUMINURIA	1 (1.0%)	0
	CYSTITIS	1 (1.0%)	0
	URINARY FREQUENCY	1 (1.0%)	0
	URINARY RETENTION	1 (1.0%)	0
	URINARY TRACT INFECTION	0	2 (1.9%)
Special Senses	TOTAL	6 (6.1%)	9 (8.6%)
	CONJUNCTIVITIS	2 (2.0%)	1 (1.0%)
	OTITIS MEDIA	1 (1.0%)	4 (3.8%)
	EAR PAIN	1 (1.0%)	2 (1.9%)
	OTITIS EXTERNA	1 (1.0%)	1 (1.0%)
	KERATOCONJUNCTIVITIS	1 (1.0%)	0
	MYDRIASIS	1 (1.0%)	0
	ABNORMAL VISION	0	1 (1.0%)
	EAR DISORDER	0	1 (1.0%)

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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=98)	Treatment Group Placebo (N=105)
Musculoskeletal System	TOTAL	5 (5.1%)	3 (2.9%)
	MYALGIA	3 (3.1%)	2 (1.9%)
	ARTHRALGIA	2 (2.0%)	1 (1.0%)
Skin and Appendages	TOTAL	5 (5.1%)	5 (4.8%)
	SWEATING	2 (2.0%)	0
	ACNE	1 (1.0%)	0
	PHOTOSENSITIVITY	1 (1.0%)	0
	PUSTULAR RASH	1 (1.0%)	0
	DRY SKIN	0	1 (1.0%)
	FUNGAL DERMATITIS	0	1 (1.0%)
	HERPES SIMPLEX	0	1 (1.0%)
	RASH	0	1 (1.0%)
	SKIN BENIGN NEOPLASM	0	1 (1.0%)
Cardiovascular System	TOTAL	3 (3.1%)	2 (1.9%)
	VASODILATATION	2 (2.0%)	2 (1.9%)
	HYPERTENSION	1 (1.0%)	0
Metabolic and Nutritional Disorders	TOTAL	2 (2.0%)	1 (1.0%)
	PERIPHERAL EDEMA	1 (1.0%)	0
	WEIGHT LOSS	1 (1.0%)	0
	THIRST	0	1 (1.0%)
Endocrine System	TOTAL	1 (1.0%)	0
	THYROID DISORDER	1 (1.0%)	0
Hemic and Lymphatic System	TOTAL	1 (1.0%)	1 (1.0%)
	ANEMIA	1 (1.0%)	0
	LEUKOPENIA	0	1 (1.0%)

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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
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=64)
Body System	Preferred Term		
TOTAL	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
Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=45)	Treatment Group: Placebo (N=41)
TOTAL	TOTAL	3 (6.7%)	1 (2.4%)
Urogenital System	TOTAL	3 (6.7%)	1 (2.4%)
	DYSMENORRHEA	3 (6.7%)	1 (2.4%)

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Table 15.1.1.3.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase or Taper Phase by Descending Order
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=98)	Treatment Group: Placebo (N=105)
TOTAL	83 (84.7%)	80 (76.2%)
HEADACHE	25 (25.5%)	24 (22.9%)
ABDOMINAL PAIN	17 (17.3%)	13 (12.4%)
NAUSEA	16 (16.3%)	11 (10.5%)
RESPIRATORY DISORDER	12 (12.2%)	15 (14.3%)
SOMNOLENCE	12 (12.2%)	7 (6.7%)
HYPERKINESIA	12 (12.2%)	6 (5.7%)
TRAUMA	10 (10.2%)	3 (2.9%)
INSOMNIA	9 (9.2%)	5 (4.8%)
DECREASED APPETITE	9 (9.2%)	2 (1.9%)
DIARRHEA	9 (9.2%)	2 (1.9%)
HOSTILITY	9 (9.2%)	1 (1.0%)
PHARYNGITIS	8 (8.2%)	6 (5.7%)
ASTHENIA	8 (8.2%)	3 (2.9%)
INFECTION	6 (6.1%)	13 (12.4%)
DIZZINESS	6 (6.1%)	7 (6.7%)
SINUSITIS	6 (6.1%)	5 (4.8%)
VOMITING	6 (6.1%)	2 (1.9%)
RHINITIS	5 (5.1%)	10 (9.5%)
NERVOUSNESS	5 (5.1%)	8 (7.6%)
ALLERGIC REACTION	5 (5.1%)	4 (3.8%)
NEUROSIS	5 (5.1%)	4 (3.8%)
PAIN	5 (5.1%)	3 (2.9%)
AGITATION	5 (5.1%)	2 (1.9%)
FEVER	4 (4.1%)	7 (6.7%)
DRY MOUTH	4 (4.1%)	5 (4.8%)
MYALGIA	3 (3.1%)	2 (1.9%)
ANXIETY	3 (3.1%)	1 (1.0%)
CHEST PAIN	3 (3.1%)	0
EMOTIONAL LABILITY	3 (3.1%)	0
EPISTAXIS	3 (3.1%)	0
PERSONALITY DISORDER	3 (3.1%)	0
COUGH INCREASED	2 (2.0%)	6 (5.7%)
CONSTIPATION	2 (2.0%)	3 (2.9%)
DYSPEPSIA	2 (2.0%)	3 (2.9%)
GASTROINTESTINAL DISORDER	2 (2.0%)	2 (1.9%)
URINARY INCONTINENCE	2 (2.0%)	2 (1.9%)
VASODILATATION	2 (2.0%)	2 (1.9%)
ARTHRALGIA	2 (2.0%)	1 (1.0%)
CONCENTRATION IMPAIRED	2 (2.0%)	1 (1.0%)
CONJUNCTIVITIS	2 (2.0%)	1 (1.0%)
ASTHMA	2 (2.0%)	0
FLATULENCE	2 (2.0%)	0
SPEECH DISORDER	2 (2.0%)	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
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=98)	Treatment Group: Placebo (N=105)
SWEATING	2 (2.0%)	0
TREMOR	2 (2.0%)	0
ULCERATIVE STOMATITIS	2 (2.0%)	0
OTITIS MEDIA	1 (1.0%)	4 (3.8%)
EAR PAIN	1 (1.0%)	2 (1.9%)
ABNORMAL DREAMS	1 (1.0%)	1 (1.0%)
BACK PAIN	1 (1.0%)	1 (1.0%)
DEPERSONALIZATION	1 (1.0%)	1 (1.0%)
HAEMATURIA	1 (1.0%)	1 (1.0%)
OTITIS EXTERNA	1 (1.0%)	1 (1.0%)
ACNE	1 (1.0%)	0
ALBUMINURIA	1 (1.0%)	0
ANEMIA	1 (1.0%)	0
BRUXISM	1 (1.0%)	0
COLITIS	1 (1.0%)	0
CYSTITIS	1 (1.0%)	0
DEPRESSION	1 (1.0%)	0
DIPLOPIA	1 (1.0%)	0
HYPERTENSION	1 (1.0%)	0
INCOORDINATION	1 (1.0%)	0
INCREASED APPETITE	1 (1.0%)	0
KERATOCONJUNCTIVITIS	1 (1.0%)	0
MYDRIASIS	1 (1.0%)	0
PARESTHESIA	1 (1.0%)	0
PERIPHERAL EDEMA	1 (1.0%)	0
PHOTOSENSITIVITY	1 (1.0%)	0
PUSTULAR RASH	1 (1.0%)	0
STOMATITIS	1 (1.0%)	0
STRIDOR	1 (1.0%)	0
THYROID DISORDER	1 (1.0%)	0
TOOTH CARIES	1 (1.0%)	0
TOOTH DISORDER	1 (1.0%)	0
URINARY FREQUENCY	1 (1.0%)	0
URINARY RETENTION	1 (1.0%)	0
WEIGHT LOSS	1 (1.0%)	0
YAWN	1 (1.0%)	0
MYOCLONUS	0	2 (1.9%)
URINARY TRACT INFECTION	0	2 (1.9%)
ABNORMAL VISION	0	1 (1.0%)
DRY SKIN	0	1 (1.0%)
EAR DISORDER	0	1 (1.0%)
FUNGAL DERMATITIS	0	1 (1.0%)
GASTROENTERITIS	0	1 (1.0%)
GINGIVITIS	0	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=98)	 Placebo (N=105)
HERPES SIMPLEX	0	1 (1.0%)
LEUKOPENIA	0	1 (1.0%)
NYSTAGMUS	0	1 (1.0%)
RASH	0	1 (1.0%)
SKIN BENIGN NEOPLASM	0	1 (1.0%)
THIRST	0	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
Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=53)	Treatment Group: Placebo (N=64)
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=45)	Treatment Group: Placebo (N=41)
TOTAL	3 (6.7%)	1 (2.4%)
DYSMENORRHEA	3 (6.7%)	1 (2.4%)

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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=37)	Treatment Group Placebo (N=39)
TOTAL	TOTAL	7 (18.9%)	3 (7.7%)
Digestive System	TOTAL	4 (10.8%)	1 (2.6%)
	VOMITING	3 (8.1%)	0
	NAUSEA	2 (5.4%)	0
	DRY MOUTH	0	1 (2.6%)
Body as a Whole	TOTAL	2 (5.4%)	0
	HEADACHE	2 (5.4%)	0
Nervous System	TOTAL	2 (5.4%)	1 (2.6%)
	HOSTILITY	1 (2.7%)	0
	NERVOUSNESS	1 (2.7%)	0
	INSOMNIA	0	1 (2.6%)
Respiratory System	TOTAL	1 (2.7%)	0
	RESPIRATORY DISORDER	1 (2.7%)	0
Urogenital System	TOTAL	0	1 (2.6%)
	ALBUMINURIA	0	1 (2.6%)
	HAEMATURIA	0	1 (2.6%)

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-up Phase
By Body System
Intention-To-Treat Population Entering The Follow-Up Phase
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=20)	Placebo (N=22)
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=17)	Placebo (N=17)
Body System	Preferred Term		
TOTAL	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
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=37)	Placebo (N=39)
TOTAL	7 (18.9%)	3 (7.7%)
VOMITING	3 (8.1%)	0
HEADACHE	2 (5.4%)	0
NAUSEA	2 (5.4%)	0
HOSTILITY	1 (2.7%)	0
NERVOUSNESS	1 (2.7%)	0
RESPIRATORY DISORDER	1 (2.7%)	0
ALBUMINURIA	0	1 (2.6%)
DRY MOUTH	0	1 (2.6%)
HAEMATURIA	0	1 (2.6%)
INSOMNIA	0	1 (2.6%)

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-up Phase
by Descending Order
Intention-To-Treat Population Entering The Follow-Up Phase
Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=20)	 Placebo (N=22)
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=17)	 Placebo (N=17)
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
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=80)	Treatment Group: Placebo (N=89)
TOTAL	TOTAL	15 (18.8%)	15 (16.9%)
Digestive System	TOTAL	6 (7.5%)	2 (2.2%)
	VOMITING	3 (3.8%)	0
	NAUSEA	2 (2.5%)	1 (1.1%)
	DIARRHEA	1 (1.3%)	0
	ULCERATIVE STOMATITIS	1 (1.3%)	0
	DECREASED APPETITE	0	1 (1.1%)
	DRY MOUTH	0	1 (1.1%)
Nervous System	TOTAL	6 (7.5%)	6 (6.7%)
	NERVOUSNESS	2 (2.5%)	2 (2.2%)
	ANXIETY	1 (1.3%)	0
	DIZZINESS	1 (1.3%)	0
	HOSTILITY	1 (1.3%)	0
	PARESTHESIA	1 (1.3%)	0
	NEUROSIS	0	3 (3.4%)
	INSOMNIA	0	1 (1.1%)
Body as a Whole	TOTAL	5 (6.3%)	8 (9.0%)
	HEADACHE	4 (5.0%)	4 (4.5%)
	INFECTION	1 (1.3%)	2 (2.2%)
	ALLERGIC REACTION	1 (1.3%)	0
	ASTHENIA	0	2 (2.2%)
	ABDOMINAL PAIN	0	1 (1.1%)
Respiratory System	TOTAL	3 (3.8%)	2 (2.2%)
	RHINITIS	1 (1.3%)	2 (2.2%)
	RESPIRATORY DISORDER	1 (1.3%)	0
	SINUSITIS	1 (1.3%)	0
Musculoskeletal System	TOTAL	2 (2.5%)	0
	ARTHRALGIA	1 (1.3%)	0
	MYALGIA	1 (1.3%)	0
Cardiovascular System	TOTAL	0	1 (1.1%)
	VASODILATATION	0	1 (1.1%)
Special Senses	TOTAL	0	3 (3.4%)
	CONJUNCTIVITIS	0	1 (1.1%)
	EAR PAIN	0	1 (1.1%)
	OTITIS MEDIA	0	1 (1.1%)
Urogenital System	TOTAL	0	1 (1.1%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
By Body System
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Gender Non Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=80)	Placebo (N=89)
Body System	Preferred Term		
Urogenital System	ALBUMINURIA	0	1 (1.1%)
	HAEMATURIA	0	1 (1.1%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
By Body System
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=43)	Placebo (N=54)
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=37)	Placebo (N=35)
Body System	Preferred Term		
TOTAL	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
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=80)	Treatment Group: Placebo (N=89)
TOTAL	15 (18.8%)	15 (16.9%)
HEADACHE	4 (5.0%)	4 (4.5%)
VOMITING	3 (3.8%)	0
NERVOUSNESS	2 (2.5%)	2 (2.2%)
NAUSEA	2 (2.5%)	1 (1.1%)
INFECTION	1 (1.3%)	2 (2.2%)
RHINITIS	1 (1.3%)	2 (2.2%)
ALLERGIC REACTION	1 (1.3%)	0
ANXIETY	1 (1.3%)	0
ARTHRALGIA	1 (1.3%)	0
DIARRHEA	1 (1.3%)	0
DIZZINESS	1 (1.3%)	0
HOSTILITY	1 (1.3%)	0
MYALGIA	1 (1.3%)	0
PARESTHESIA	1 (1.3%)	0
RESPIRATORY DISORDER	1 (1.3%)	0
SINUSITIS	1 (1.3%)	0
ULCERATIVE STOMATITIS	1 (1.3%)	0
NEUROSIS	0	3 (3.4%)
ASTHENIA	0	2 (2.2%)
ABDOMINAL PAIN	0	1 (1.1%)
ALBUMINURIA	0	1 (1.1%)
CONJUNCTIVITIS	0	1 (1.1%)
DECREASED APPETITE	0	1 (1.1%)
DRY MOUTH	0	1 (1.1%)
EAR PAIN	0	1 (1.1%)
HAEMATURIA	0	1 (1.1%)
INSOMNIA	0	1 (1.1%)
OTITIS MEDIA	0	1 (1.1%)
VASODILATATION	0	1 (1.1%)

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Table 15.1.1.5.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase Or Follow-Up Phase By Descending Order
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=43)	Treatment Group: Placebo (N=54)
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=37)	Treatment Group: Placebo (N=35)
TOTAL	0	0

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Table 15.1.1.6

Number (%) of Patients With Emergent Adverse Experiences During the Treatment, Taper or Follow-Up Phase
By Body System
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=98)	Treatment Group: Placebo (N=105)
TOTAL	TOTAL	83 (84.7%)	80 (76.2%)
Body as a Whole	TOTAL	52 (53.1%)	45 (42.9%)
	HEADACHE	26 (26.5%)	24 (22.9%)
	ABDOMINAL PAIN	17 (17.3%)	13 (12.4%)
	TRAUMA	10 (10.2%)	3 (2.9%)
	ASTHENIA	8 (8.2%)	3 (2.9%)
	INFECTION	6 (6.1%)	13 (12.4%)
	ALLERGIC REACTION	5 (5.1%)	4 (3.8%)
	PAIN	5 (5.1%)	3 (2.9%)
	FEVER	4 (4.1%)	7 (6.7%)
	CHEST PAIN	3 (3.1%)	0
	BACK PAIN	1 (1.0%)	1 (1.0%)
Nervous System	TOTAL	44 (44.9%)	33 (31.4%)
	SOMNOLENCE	12 (12.2%)	7 (6.7%)
	HYPERKINESIA	12 (12.2%)	6 (5.7%)
	INSOMNIA	9 (9.2%)	6 (5.7%)
	HOSTILITY	9 (9.2%)	1 (1.0%)
	NERVOUSNESS	6 (6.1%)	8 (7.6%)
	DIZZINESS	6 (6.1%)	7 (6.7%)
	NEUROSIS	5 (5.1%)	4 (3.8%)
	AGITATION	5 (5.1%)	2 (1.9%)
	ANXIETY	3 (3.1%)	1 (1.0%)
	EMOTIONAL LABILITY	3 (3.1%)	0
	PERSONALITY DISORDER	3 (3.1%)	0
	CONCENTRATION IMPAIRED	2 (2.0%)	1 (1.0%)
	SPEECH DISORDER	2 (2.0%)	0
	TREMOR	2 (2.0%)	0
	ABNORMAL DREAMS	1 (1.0%)	1 (1.0%)
	DEPERSONALIZATION	1 (1.0%)	1 (1.0%)
	DEPRESSION	1 (1.0%)	0
	DIPLOPIA	1 (1.0%)	0
	INCOORDINATION	1 (1.0%)	0
	PARESTHESIA	1 (1.0%)	0
	MYOCLONUS	0	2 (1.9%)
	NYSTAGMUS	0	1 (1.0%)
Digestive System	TOTAL	42 (42.9%)	24 (22.9%)
	NAUSEA	18 (18.4%)	11 (10.5%)
	DECREASED APPETITE	9 (9.2%)	2 (1.9%)
	DIARRHEA	9 (9.2%)	2 (1.9%)
	VOMITING	8 (8.2%)	2 (1.9%)
	DRY MOUTH	4 (4.1%)	5 (4.8%)

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Table 15.1.1.6

Number (%) of Patients With Emergent Adverse Experiences During the Treatment, Taper or Follow-Up Phase
By Body System
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=98)	Placebo (N=105)
Digestive System	CONSTIPATION	2 (2.0%)	3 (2.9%)
	DYSPEPSIA	2 (2.0%)	3 (2.9%)
	GASTROINTESTINAL DISORDER	2 (2.0%)	2 (1.9%)
	FLATULENCE	2 (2.0%)	0
	ULCERATIVE STOMATITIS	2 (2.0%)	0
	BRUXISM	1 (1.0%)	0
	COLITIS	1 (1.0%)	0
	INCREASED APPETITE	1 (1.0%)	0
	STOMATITIS	1 (1.0%)	0
	TOOTH CARIES	1 (1.0%)	0
	TOOTH DISORDER	1 (1.0%)	0
	GASTROENTERITIS	0	1 (1.0%)
	GINGIVITIS	0	1 (1.0%)
Respiratory System	TOTAL	30 (30.6%)	32 (30.5%)
	RESPIRATORY DISORDER	13 (13.3%)	15 (14.3%)
	PHARYNGITIS	8 (8.2%)	6 (5.7%)
	SINUSITIS	6 (6.1%)	5 (4.8%)
	RHINITIS	5 (5.1%)	10 (9.5%)
	EPISTAXIS	3 (3.1%)	0
	COUGH INCREASED	2 (2.0%)	6 (5.7%)
	ASTHMA	2 (2.0%)	0
	STRIDOR	1 (1.0%)	0
	YAWN	1 (1.0%)	0
Urogenital System	TOTAL	7 (7.1%)	6 (5.7%)
	URINARY INCONTINENCE	2 (2.0%)	2 (1.9%)
	HAEMATURIA	1 (1.0%)	2 (1.9%)
	ALBUMINURIA	1 (1.0%)	1 (1.0%)
	CYSTITIS	1 (1.0%)	0
	URINARY FREQUENCY	1 (1.0%)	0
	URINARY RETENTION	1 (1.0%)	0
	URINARY TRACT INFECTION	0	2 (1.9%)
Special Senses	TOTAL	6 (6.1%)	9 (8.6%)
	CONJUNCTIVITIS	2 (2.0%)	1 (1.0%)
	OTITIS MEDIA	1 (1.0%)	4 (3.8%)
	EAR PAIN	1 (1.0%)	2 (1.9%)
	OTITIS EXTERNA	1 (1.0%)	1 (1.0%)
	KERATOCONJUNCTIVITIS	1 (1.0%)	0
	MYDRIASIS	1 (1.0%)	0
	ABNORMAL VISION	0	1 (1.0%)
	EAR DISORDER	0	1 (1.0%)

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Table 15.1.1.6

Number (%) of Patients With Emergent Adverse Experiences During the Treatment, Taper or Follow-Up Phase
By Body System
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=98)	Placebo (N=105)
Musculoskeletal System	TOTAL	5 (5.1%)	3 (2.9%)
	MYALGIA	3 (3.1%)	2 (1.9%)
	ARTHRALGIA	2 (2.0%)	1 (1.0%)
Skin and Appendages	TOTAL	5 (5.1%)	5 (4.8%)
	SWEATING	2 (2.0%)	0
	ACNE	1 (1.0%)	0
	PHOTOSENSITIVITY	1 (1.0%)	0
	PUSTULAR RASH	1 (1.0%)	0
	DRY SKIN	0	1 (1.0%)
	FUNGAL DERMATITIS	0	1 (1.0%)
	HERPES SIMPLEX	0	1 (1.0%)
	RASH	0	1 (1.0%)
	SKIN BENIGN NEOPLASM	0	1 (1.0%)
Cardiovascular System	TOTAL	3 (3.1%)	2 (1.9%)
	VASODILATATION	2 (2.0%)	2 (1.9%)
	HYPERTENSION	1 (1.0%)	0
Metabolic and Nutritional Disorders	TOTAL	2 (2.0%)	1 (1.0%)
	PERIPHERAL EDEMA	1 (1.0%)	0
	WEIGHT LOSS	1 (1.0%)	0
	THIRST	0	1 (1.0%)
Endocrine System	TOTAL	1 (1.0%)	0
	THYROID DISORDER	1 (1.0%)	0
Hemic and Lymphatic System	TOTAL	1 (1.0%)	1 (1.0%)
	ANEMIA	1 (1.0%)	0
	LEUKOPENIA	0	1 (1.0%)

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Table 15.1.1.6

Number (%) of Patients With Emergent Adverse Experiences During the Treatment, Taper or Follow-Up Phase
By Body System
Intention-To-Treat Population
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=64)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.1.6

Number (%) of Patients With Emergent Adverse Experiences During the Treatment, Taper or Follow-Up Phase
By Body System
Intention-To-Treat Population
Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=45)	Placebo (N=41)
Body System	Preferred Term		
TOTAL	TOTAL	3 (6.7%)	1 (2.4%)
Urogenital System	TOTAL	3 (6.7%)	1 (2.4%)
	DYSMENORRHEA	3 (6.7%)	1 (2.4%)

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Table 15.1.1.6.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment, Taper Or Follow-Up Phase By Descending Order
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=98)	Treatment Group: Placebo (N=105)
TOTAL	83 (84.7%)	80 (76.2%)
HEADACHE	26 (26.5%)	24 (22.9%)
NAUSEA	18 (18.4%)	11 (10.5%)
ABDOMINAL PAIN	17 (17.3%)	13 (12.4%)
RESPIRATORY DISORDER	13 (13.3%)	15 (14.3%)
SOMNOLENCE	12 (12.2%)	7 (6.7%)
HYPERKINESIA	12 (12.2%)	6 (5.7%)
TRAUMA	10 (10.2%)	3 (2.9%)
INSOMNIA	9 (9.2%)	6 (5.7%)
DECREASED APPETITE	9 (9.2%)	2 (1.9%)
DIARRHEA	9 (9.2%)	2 (1.9%)
HOSTILITY	9 (9.2%)	1 (1.0%)
PHARYNGITIS	8 (8.2%)	6 (5.7%)
ASTHENIA	8 (8.2%)	3 (2.9%)
VOMITING	8 (8.2%)	2 (1.9%)
INFECTION	6 (6.1%)	13 (12.4%)
NERVOUSNESS	6 (6.1%)	8 (7.6%)
DIZZINESS	6 (6.1%)	7 (6.7%)
SINUSITIS	6 (6.1%)	5 (4.8%)
RHINITIS	5 (5.1%)	10 (9.5%)
ALLERGIC REACTION	5 (5.1%)	4 (3.8%)
NEUROSIS	5 (5.1%)	4 (3.8%)
PAIN	5 (5.1%)	3 (2.9%)
AGITATION	5 (5.1%)	2 (1.9%)
FEVER	4 (4.1%)	7 (6.7%)
DRY MOUTH	4 (4.1%)	5 (4.8%)
MYALGIA	3 (3.1%)	2 (1.9%)
ANXIETY	3 (3.1%)	1 (1.0%)
CHEST PAIN	3 (3.1%)	0
EMOTIONAL LABILITY	3 (3.1%)	0
EPISTAXIS	3 (3.1%)	0
PERSONALITY DISORDER	3 (3.1%)	0
COUGH INCREASED	2 (2.0%)	6 (5.7%)
CONSTIPATION	2 (2.0%)	3 (2.9%)
DYSPEPSIA	2 (2.0%)	3 (2.9%)
GASTROINTESTINAL DISORDER	2 (2.0%)	2 (1.9%)
URINARY INCONTINENCE	2 (2.0%)	2 (1.9%)
VASODILATATION	2 (2.0%)	2 (1.9%)
ARTHRALGIA	2 (2.0%)	1 (1.0%)
CONCENTRATION IMPAIRED	2 (2.0%)	1 (1.0%)
CONJUNCTIVITIS	2 (2.0%)	1 (1.0%)
ASTHMA	2 (2.0%)	0
FLATULENCE	2 (2.0%)	0
SPEECH DISORDER	2 (2.0%)	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, Taper Or Follow-Up Phase By Descending Order
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=98)	Treatment Group: Placebo (N=105)
SWEATING	2 (2.0%)	0
TREMOR	2 (2.0%)	0
ULCERATIVE STOMATITIS	2 (2.0%)	0
OTITIS MEDIA	1 (1.0%)	4 (3.8%)
EAR PAIN	1 (1.0%)	2 (1.9%)
HAEMATURIA	1 (1.0%)	2 (1.9%)
ABNORMAL DREAMS	1 (1.0%)	1 (1.0%)
ALBUMINURIA	1 (1.0%)	1 (1.0%)
BACK PAIN	1 (1.0%)	1 (1.0%)
DEPERSONALIZATION	1 (1.0%)	1 (1.0%)
OTITIS EXTERNA	1 (1.0%)	1 (1.0%)
ACNE	1 (1.0%)	0
ANEMIA	1 (1.0%)	0
BRUXISM	1 (1.0%)	0
COLITIS	1 (1.0%)	0
CYSTITIS	1 (1.0%)	0
DEPRESSION	1 (1.0%)	0
DIPLOPIA	1 (1.0%)	0
HYPERTENSION	1 (1.0%)	0
INCOORDINATION	1 (1.0%)	0
INCREASED APPETITE	1 (1.0%)	0
KERATOCONJUNCTIVITIS	1 (1.0%)	0
MYDRIASIS	1 (1.0%)	0
PARESTHESIA	1 (1.0%)	0
PERIPHERAL EDEMA	1 (1.0%)	0
PHOTOSENSITIVITY	1 (1.0%)	0
PUSTULAR RASH	1 (1.0%)	0
STOMATITIS	1 (1.0%)	0
STRIDOR	1 (1.0%)	0
THYROID DISORDER	1 (1.0%)	0
TOOTH CARIES	1 (1.0%)	0
TOOTH DISORDER	1 (1.0%)	0
URINARY FREQUENCY	1 (1.0%)	0
URINARY RETENTION	1 (1.0%)	0
WEIGHT LOSS	1 (1.0%)	0
YAWN	1 (1.0%)	0
MYOCLONUS	0	2 (1.9%)
URINARY TRACT INFECTION	0	2 (1.9%)
ABNORMAL VISION	0	1 (1.0%)
DRY SKIN	0	1 (1.0%)
EAR DISORDER	0	1 (1.0%)
FUNGAL DERMATITIS	0	1 (1.0%)
GASTROENTERITIS	0	1 (1.0%)
GINGIVITIS	0	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, Taper Or Follow-Up Phase By Descending Order
Intention-To-Treat Population
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=98)	Treatment Group: Placebo (N=105)
HERPES SIMPLEX	0	1 (1.0%)
LEUKOPENIA	0	1 (1.0%)
NYSTAGMUS	0	1 (1.0%)
RASH	0	1 (1.0%)
SKIN BENIGN NEOPLASM	0	1 (1.0%)
THIRST	0	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, Taper Or Follow-Up Phase By Descending Order
Intention-To-Treat Population
Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=53)	Placebo (N=64)
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, Taper Or Follow-Up Phase By Descending Order
Intention-To-Treat Population
Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=45)	Treatment Group: Placebo (N=41)
TOTAL	3 (6.7%)	1 (2.4%)
DYSMENORRHEA	3 (6.7%)	1 (2.4%)

Confidential

Table 15.1.2, Narratives of Patients with Serious Adverse Event(s)

SB Document Number: BRL-029060/RSD-101C1D/1

Patients With Serious Adverse Event(s)
Patients With Serious Adverse Event(s) Leading to Withdrawal

1 Patient Identification Number: 704.033.25513

Protocol: 29060 704
AEGIS number: 2000034498-1
Study medication: PAROXETINE

Verbatim[preferred term]: SUICIDAL THOUGHTS [SUICIDE ATTEMPT] (coded as Emotional Lability)

Case reference number 2000034498-1 is a clinical trial report from double-blind study 29060/704 for obsessive-compulsive disorder (OCD). This report refers to a 15-year-old male (patient identification number 704.033.25513).

The patient's medical history was not provided. The patient acknowledges using cannabis (Marijuana) on 01-Nov-2000. The patient had no other concomitant medications to report.

On 23-Oct-2000, the patient began treatment with study medication. On 16-Nov-2000, 24 days after the first dose, the patient began to have suicidal thoughts while staying at a youth shelter. The staff at the youth shelter took the patient to the emergency room, and the patient was admitted for further evaluation. Due to the event, treatment with study medication was stopped on 16-Nov-2000. No new medications were started. On 23-Nov-2000, the event was reported as resolved.

The investigator reported the suicidal thoughts to be probably unrelated to treatment with study medication, and associated with the patient's depression.

Additional clarifying information, available at study end, is provided below.
The patient's psychiatric history (measured by K-SADS-PL interview) includes a past and current history of OCD with onset January 1994. No other psychiatric conditions were reported.

The patient began treatment with active study medication on 23 October 2000 at a dose of 10 mg/day. The patient was titrated up, in 10 mg/week increments, to the highest dose of 40 mg/day on 15 November 2000.

The serious adverse event (suicidal thoughts) was considered to be severe in intensity. No other serious or non-serious events were reported.

Patients With Serious Adverse Event(s)

2 Patient Identification Number: 704.048.27175

Protocol: 29060 704
AEGIS number: 2001013708-1
Study medication: PAROXETINE

Verbatim[preferred term]: IRRITABLE/HOSTILE/AGGRESSIVE BEHAVIOR WORSENED {OPPOSITIONAL DEFIANT} [AGGRESSIVE REACTION] (coded as Hostility)

Case reference number 2001013708-1 is a clinical trial report from double-blind study 29060/704 for obsessive-compulsive disorder (OCD). This report refers to an 11-year-old female (patient identification number 704.048.27175).

The patient medical history included headaches, sleeping difficulty, temper tantrums, auditory and visual hallucinations, suicidal thoughts, back pain, and gastric problems. The patient had no concomitant medication usage reported at this time.

The patient completed the treatment phase of the study receiving study medication from 22-Mar-2001 to 28-May-2001. On 29-May-2001, Week 11, the patient began the taper phase of the study.

During visit nine (date not specified), the site was notified that the patient began to experience irritability, hostile and aggressive behavior. The behavior began on 15-May-2001, due to the patient's grandmother coming to live with patient's family. The patient indicated her grandmother's presence was upsetting her. On 29-May-2001, the patient's grandmother reported the patient could not control her temper. On 31-May-2001, three days after receiving the last dose of study medication during the treatment phase, and two days after entering the taper phase of the study, the patient became "out of control" and was taken to the emergency room and admitted to the hospital for worsening irritable, hostile, and aggressive behavior. The patient had been working on anger management prior to this event. It was also reported that the patient was having problems with violent behavior at school with destruction of property. The patient stated that she was having hallucinations (not reported as a serious event), but was hesitant to tell people stating, "because I was afraid they would not believe me". Study medication during the taper phase was stopped on 30-May-2001 and the events

abated on 01-Jun-2001. The patient was discharged from the hospital on 07-Jun-2001.

Screening laboratory values from 13-Mar-2001 included SGOT (serum glutamic oxaloacetic transaminase) 24 U/L (reference range 0-42), SGPT (serum glutamate pyruvate transaminase) 14 U/L (reference range 0-45), alkaline phosphatase 273 U/L (reference range 60-415), and creatinine 0.6 mg/dL (reference range 0.3-1).

Laboratory results from 29-May-2001 included SGOT 28 U/L (reference range 0-42), SGPT 14 U/L (reference range 0-45), alkaline phosphatase 265 U/L (reference range 60-415), and creatinine 0.6 mg/dL (reference range 0.3-1).

Laboratory results for 01-Jun-2001 included SGOT 162 IU/L (reference range 10-45), SGPT 275 IU/L (reference range 26-65), alkaline phosphatase 374 U/L (reference range 51-363), creatinine 0.6 mg/dL (reference range 0.7-1.4), urine culture 9000 CFU/ML mixed gram positive flora (unknown), and urine drug screen: positive opiates confirmed by thin layer chromatography.

The investigator reported the irritable, hostile, aggressive behavior {oppositional defiant} to be probably unrelated to treatment with study medication, but due to the patient's grandmother coming to live with the family.

It was reported that the information obtained from the hospital was totally different from what the patient and her care takers reported to the investigator, in spite of a careful interviewing process. Every visit included detailed questions about over-the-counter medications, side effects and changes in the patient's mental status. The investigator questions the reliability of the information given at the hospital.

Additional clarifying information, available at study end, is provided below. The patient's psychiatric history (measured by K-SADS-PL interview) includes a current history of OCD with onset June 1994. No other psychiatric conditions were reported.

The patient had no significant medical or surgical history reported. Concomitant medications included Midol® (acetylsalicylic acid, caffeine, cinnamedrine HCl) for abdominal pain, Excedrin PM® (diphenhydramine citrate, paracetamol) for mouth pain and Novocain® (procaine HCl) for tooth cavity repair. No concomitant psychotropic medication was reported. Post-treatment medications included Luvox® (fluvoxamine maleate) for depression, Neurontin® (gabapetin)

for aggression and Trazadone® for OCD, all of which were started on 8 June 2001, 9 days after the last dose of taper medication.

The patient began treatment with active study medication on 22 March 2001 at a dose of 10 mg/day. The patient was titrated up, in 10 mg/week increments, to the highest dose of 50 mg/day on 30 April 2001. The patient completed the treatment phase of the study on 28 May 2001 and took their last dose of taper medication on 30 May 2001.

The following additional non-serious adverse events were reported during the study. On 28 March 2001 (Day 7), the patient reported moderately severe nausea and vomiting that resolved in two days without corrective therapy. Moderately severe tooth caries (tooth cavity) were reported on 16 April 2001 (Day 26) and corrective treatment was given. On 17 April 2001 (Day 27) , the patient reported moderately severe mouth pain (stomatitis) that cleared with treatment in one day. On 29 April 2001(Day 39), the patient reported mild abdominal pain that resolved with treatment in three days. All of these events were considered to be unrelated to treatment with study medication.

Patients With Serious Adverse Event(s)

3 Patient Identification Number: 704.055.28171

Protocol: 29060 704
AEGIS number: 2001003479-1
Study medication: PLACEBO

Verbatim[preferred term]: HOSPITALIZED FOR TIMEOUT {AGGRESSIVE BEHAVIOR)
[AGGRESSIVE REACTION] (coded as Hostility)

Case reference number 2001003479-1 is a clinical trial report from double-blind study 29060/704 for obsessive-compulsive disorder (OCD). This report refers to a nine-year-old male (patient identification number 704.055.28171).

The patient has no significant medical history and concomitant medication use.

On 27-Dec-2000, the patient began therapy with study medication. On 24-Jan-2001, the patient was up-titrated to dose level five. On 06-Feb-2001, 41 days after the first dose of study medication and 13 days after up-titration, the patient was hospitalized for a "timeout" (aggressive behavior) due to a conflict with his mother. No physical abnormalities were found and all laboratory data was clinically insignificant. The patient's medications (unspecified) were regulated, and after various therapy sessions, the patient returned to baseline behavior at the time of discharge. No action was taken with respect to study medication due to the event. The event was reported as resolved on 20-Feb-2001.

The investigator reported the aggressive behavior to be unrelated to treatment with study medication, and associated with another condition (not specified).

The patient completed the study and received the last dose of study medication on 06-Mar-2001.

Additional clarifying information, available at study end, is provided below.
The patient has a previous surgical history of a bone and joint reconstruction to correct leg alignment, and a current medical history that includes a congenital left hip dislocation, and pigeon-toe. There are no concomitant medications, including psychotropic medications, reported. Psychiatric history (measured by K-SADS-PL interview) includes previous and current OCD with onset November 1997.

The investigator reported that the aggressive behavior was moderately severe in intensity.

Two non-serious adverse events were also reported during the study. On 7 January 2001 (Day 12), the patient reported mild abdominal pain and mild nausea. No treatment was given for these events which resolved in 4 days, and 2 days, respectively.

Patients With Serious Adverse Event (s)

4 Patient Identification Number: 704.055.28174

Protocol: 29060 704
AEGIS number: 2001005981-1
Study medication: PAROXETINE

Verbatim[preferred term]: AGGRESSIVE BEHAVIOR [AGGRESSIVE REACTION] (coded as Hostility)

AGGRESSIVE BEHAVIOR (SECOND EPISODE) [AGGRESSIVE REACTION] (coded as Hostility)

Case reference number 2001005981-1 is a clinical trial report from double-blind study 29060/704 for obsessive-compulsive disorder (OCD). This report refers to a 14-year-old male (patient identification number 704.055.28174).

The patient's medical history included frequent headaches. The patient had no concomitant medications reported.

On 26-Jan-2001, the patient began treatment with study medication. On 05-Mar-2001, 38 days after the first dose, the patient and his mother got into a "bad altercation", and the police were called to "break it up". The patient was taken to the hospital for a "time-out" due to his aggressive behavior. All laboratory tests were clinically insignificant. During the course of the hospitalization, the patient's medications were regulated, treatment with Thorazine (chlorpromazine HCl) was prescribed, and he attended various therapy sessions. The patient's behavior returned to baseline at the time of discharge. On 24-Mar-2001, the event was reported as resolved. Treatment with study medication was not interrupted due to this event.

The investigator reported the aggressive behavior to be unrelated to treatment with study medication and associated with the patient's dysfunctional family.

On 29 March 2001, the patient completed the study and received the last dose of study medication. Also on 29 March 2001, 62 days after the first dose, the patient and his mother got into another altercation and he threatened her. The patient was hospitalized for aggressive behavior. The patient was discharged from the hospital on 30 March 2001 in stable condition. The event resolved in 26 days.

The investigator reported the aggressive behavior (second episode) to be unrelated to treatment with study medication, and associated with the patient's dysfunctional family.

Additional clarifying information, available at study end, is provided below. Concomitant medications included Thorazine® (chlorpromazine HCl) IM for agitation, topical Floxin® (ofloxacin), Amoxil® (amoxicillin trihydrate), topical Cipro HC® (ciprofloxacin HCl, hydrocortisone) for otitis media/externa, and Tylenol® (paracetamol) for headache. No other previous, current or follow-up medications, including psychotropic medications, were recorded. Psychiatric history (measured by K-SADS-PL interview) includes a previous and current history of OCD with onset December 1995. No other psychiatric history is indicated.

The patient began treatment with active study medication on 26 January, 2001 at dose level 1 (10mg/day), and was titrated up, in 10 mg/week increments, to the highest dose of 40 mg/day on 17 February 2001. On 29-Mar-2001, the patient completed the study and received the last dose of treatment with study medication; the last dose of taper medication was taken on 9 April 2001.

Both episodes of aggressive behavior (05 March 2001, 29 March 2001) were considered to be severe in intensity.

Several other non-serious adverse events were reported during the study. On 07 February 2001 (Day 13), the patient reported mild nausea which resolved without treatment in one day. On 06 March 2001 (Day 40), moderately severe agitation was reported, as was moderately severe otitis media/externa. These events were treated and resolved in 8 days and 10 days, respectively. On 30 March 2001 (Day 64), the patient had another episode of otitis media/externa and otitis media/externa with effusion. These were treated and resolved within 10 days. All non-serious events were considered to be unrelated to treatment with study medication.

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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=100)	Treatment Group: Placebo (N=107)
TOTAL	TOTAL	3 (3.0%)	1 (0.9%)
Nervous System	TOTAL	3 (3.0%)	1 (0.9%)
	HOSTILITY	2 (2.0%)	1 (0.9%)
	EMOTIONAL LABILITY	1 (1.0%)	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
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=66)
Body System	Preferred Term		
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

		Treatment Group	
		Paroxetine (N=47)	Placebo (N=41)
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, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=58)	Treatment Group: Placebo (N=57)
TOTAL	TOTAL	38 (65.5%)	40 (70.2%)
Body as a Whole	TOTAL	25 (43.1%)	22 (38.6%)
	ABDOMINAL PAIN	12 (20.7%)	8 (14.0%)
	HEADACHE	11 (19.0%)	10 (17.5%)
	FEVER	4 (6.9%)	3 (5.3%)
	ALLERGIC REACTION	3 (5.2%)	3 (5.3%)
	PAIN	3 (5.2%)	3 (5.3%)
	TRAUMA	3 (5.2%)	0
	CHEST PAIN	2 (3.4%)	0
	INFECTION	1 (1.7%)	5 (8.8%)
	ASTHENIA	1 (1.7%)	1 (1.8%)
	BACK PAIN	1 (1.7%)	0
Digestive System	TOTAL	17 (29.3%)	18 (31.6%)
	DIARRHEA	5 (8.6%)	2 (3.5%)
	DECREASED APPETITE	5 (8.6%)	1 (1.8%)
	NAUSEA	4 (6.9%)	8 (14.0%)
	VOMITING	4 (6.9%)	1 (1.8%)
	DRY MOUTH	1 (1.7%)	3 (5.3%)
	DYSPEPSIA	1 (1.7%)	2 (3.5%)
	COLITIS	1 (1.7%)	0
	INCREASED APPETITE	1 (1.7%)	0
	TOOTH DISORDER	1 (1.7%)	0
	ULCERATIVE STOMATITIS	1 (1.7%)	0
	CONSTIPATION	0	2 (3.5%)
	GASTROINTESTINAL DISORDER	0	2 (3.5%)
	GASTROENTERITIS	0	1 (1.8%)
	GINGIVITIS	0	1 (1.8%)
Nervous System	TOTAL	14 (24.1%)	12 (21.1%)
	HYPERKINESIA	4 (6.9%)	3 (5.3%)
	INSOMNIA	4 (6.9%)	2 (3.5%)
	SOMNOLENCE	4 (6.9%)	2 (3.5%)
	HOSTILITY	2 (3.4%)	0
	NEUROSIS	2 (3.4%)	0
	TREMOR	2 (3.4%)	0
	DIZZINESS	1 (1.7%)	4 (7.0%)
	ANXIETY	1 (1.7%)	0
	CONCENTRATION IMPAIRED	1 (1.7%)	0
	DIPLOPIA	1 (1.7%)	0
	NERVOUSNESS	1 (1.7%)	0
	PERSONALITY DISORDER	1 (1.7%)	0
	MYOCLONUS	0	2 (3.5%)

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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=58)	Treatment Group: Placebo (N=57)
Nervous System	NYSTAGMUS	0	1 (1.8%)
Respiratory System	TOTAL	12 (20.7%)	16 (28.1%)
	RESPIRATORY DISORDER	5 (8.6%)	4 (7.0%)
	PHARYNGITIS	4 (6.9%)	3 (5.3%)
	RHINITIS	2 (3.4%)	5 (8.8%)
	SINUSITIS	2 (3.4%)	2 (3.5%)
	EPISTAXIS	2 (3.4%)	0
	COUGH INCREASED	1 (1.7%)	5 (8.8%)
	STRIDOR	1 (1.7%)	0
Skin and Appendages	TOTAL	4 (6.9%)	3 (5.3%)
	SWEATING	2 (3.4%)	0
	PHOTOSENSITIVITY	1 (1.7%)	0
	PUSTULAR RASH	1 (1.7%)	0
	FUNGAL DERMATITIS	0	1 (1.8%)
	RASH	0	1 (1.8%)
	SKIN BENIGN NEOPLASM	0	1 (1.8%)
Special Senses	TOTAL	3 (5.2%)	2 (3.5%)
	CONJUNCTIVITIS	2 (3.4%)	0
	KERATOCONJUNCTIVITIS	1 (1.7%)	0
	OTITIS MEDIA	0	2 (3.5%)
Urogenital System	TOTAL	3 (5.2%)	2 (3.5%)
	URINARY INCONTINENCE	2 (3.4%)	1 (1.8%)
	ALBUMINURIA	1 (1.7%)	0
	URINARY TRACT INFECTION	0	1 (1.8%)
Hemic and Lymphatic System	TOTAL	1 (1.7%)	0
	ANEMIA	1 (1.7%)	0
Musculoskeletal System	TOTAL	1 (1.7%)	0
	MYALGIA	1 (1.7%)	0
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.8%)
	THIRST	0	1 (1.8%)

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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=58)	Treatment Group: Placebo (N=57)
TOTAL	TOTAL	28 (48.3%)	18 (31.6%)
Nervous System	TOTAL	17 (29.3%)	7 (12.3%)
	HYPERKINESIA	6 (10.3%)	2 (3.5%)
	HOSTILITY	4 (6.9%)	1 (1.8%)
	NERVOUSNESS	3 (5.2%)	2 (3.5%)
	INSOMNIA	3 (5.2%)	0
	NEUROSIS	3 (5.2%)	0
	AGITATION	2 (3.4%)	0
	PERSONALITY DISORDER	2 (3.4%)	0
	SPEECH DISORDER	2 (3.4%)	0
	CONCENTRATION IMPAIRED	1 (1.7%)	1 (1.8%)
	SOMNOLENCE	1 (1.7%)	1 (1.8%)
	DEPERSONALIZATION	1 (1.7%)	0
	EMOTIONAL LABILITY	1 (1.7%)	0
	INCOORDINATION	1 (1.7%)	0
	DIZZINESS	0	1 (1.8%)
Body as a Whole	TOTAL	10 (17.2%)	9 (15.8%)
	HEADACHE	3 (5.2%)	2 (3.5%)
	INFECTION	2 (3.4%)	5 (8.8%)
	ABDOMINAL PAIN	2 (3.4%)	1 (1.8%)
	TRAUMA	2 (3.4%)	1 (1.8%)
	ASTHENIA	2 (3.4%)	0
	CHEST PAIN	1 (1.7%)	0
	FEVER	0	1 (1.8%)
Digestive System	TOTAL	7 (12.1%)	3 (5.3%)
	NAUSEA	2 (3.4%)	1 (1.8%)
	DYSPEPSIA	2 (3.4%)	0
	CONSTIPATION	1 (1.7%)	1 (1.8%)
	VOMITING	1 (1.7%)	1 (1.8%)
	DECREASED APPETITE	1 (1.7%)	0
	FLATULENCE	1 (1.7%)	0
	GASTROINTESTINAL DISORDER	1 (1.7%)	0
	STOMATITIS	1 (1.7%)	0
	TOOTH CARIES	1 (1.7%)	0
	DRY MOUTH	0	1 (1.8%)
Respiratory System	TOTAL	5 (8.6%)	4 (7.0%)
	RESPIRATORY DISORDER	3 (5.2%)	2 (3.5%)
	SINUSITIS	2 (3.4%)	0
	RHINITIS	1 (1.7%)	1 (1.8%)
	COUGH INCREASED	1 (1.7%)	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=58)	 Placebo (N=57)
Respiratory System	EPISTAXIS	1 (1.7%)	0
	PHARYNGITIS	0	1 (1.8%)
Cardiovascular System	TOTAL	1 (1.7%)	0
	VASODILATATION	1 (1.7%)	0
Musculoskeletal System	TOTAL	1 (1.7%)	0
	MYALGIA	1 (1.7%)	0
Skin and Appendages	TOTAL	1 (1.7%)	0
	SWEATING	1 (1.7%)	0
Urogenital System	TOTAL	1 (1.7%)	1 (1.8%)
	URINARY RETENTION	1 (1.7%)	0
	URINARY INCONTINENCE	0	1 (1.8%)
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.8%)
	THIRST	0	1 (1.8%)
Special Senses	TOTAL	0	1 (1.8%)
	EAR DISORDER	0	1 (1.8%)
	EAR PAIN	0	1 (1.8%)

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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=58)	 Placebo (N=57)
TOTAL	TOTAL	5 (8.6%)	1 (1.8%)
Body as a Whole	TOTAL	3 (5.2%)	0
	TRAUMA	2 (3.4%)	0
	HEADACHE	1 (1.7%)	0
Nervous System	TOTAL	2 (3.4%)	1 (1.8%)
	AGITATION	1 (1.7%)	0
	HOSTILITY	1 (1.7%)	0
	HYPERKINESIA	1 (1.7%)	0
	NEUROSIS	0	1 (1.8%)

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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=31)	Placebo (N=35)
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=31)	Placebo (N=35)
Body System	Preferred Term		
TOTAL	TOTAL	0	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 : Children, Intensity : Severe, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=31)	Placebo (N=35)
Body System	Preferred Term		
TOTAL	TOTAL	0	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 : Children, Intensity : Mild, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=27)	Placebo (N=22)
Body System	Preferred Term		
TOTAL	TOTAL	0	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 : Children, Intensity : Moderate, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=27)	Placebo (N=22)
Body System	Preferred Term		
TOTAL	TOTAL	0	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 : Children, Intensity : Severe, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=27)	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=40)	Treatment Group: Placebo (N=48)
TOTAL	TOTAL	22 (55.0%)	28 (58.3%)
Body as a Whole	TOTAL	14 (35.0%)	12 (25.0%)
	HEADACHE	8 (20.0%)	7 (14.6%)
	ABDOMINAL PAIN	4 (10.0%)	1 (2.1%)
	ASTHENIA	4 (10.0%)	0
	TRAUMA	2 (5.0%)	2 (4.2%)
	INFECTION	1 (2.5%)	2 (4.2%)
	PAIN	1 (2.5%)	0
	ALLERGIC REACTION	0	1 (2.1%)
	BACK PAIN	0	1 (2.1%)
Digestive System	TOTAL	13 (32.5%)	3 (6.3%)
	NAUSEA	8 (20.0%)	0
	DECREASED APPETITE	3 (7.5%)	0
	DRY MOUTH	2 (5.0%)	2 (4.2%)
	DIARRHEA	2 (5.0%)	0
	FLATULENCE	1 (2.5%)	0
	GASTROINTESTINAL DISORDER	1 (2.5%)	0
	VOMITING	1 (2.5%)	0
	DYSPEPSIA	0	1 (2.1%)
Nervous System	TOTAL	8 (20.0%)	6 (12.5%)
	DIZZINESS	2 (5.0%)	2 (4.2%)
	INSOMNIA	2 (5.0%)	2 (4.2%)
	HYPERKINESIA	2 (5.0%)	0
	SOMNOLENCE	2 (5.0%)	0
	NERVOUSNESS	1 (2.5%)	2 (4.2%)
	ABNORMAL DREAMS	1 (2.5%)	1 (2.1%)
	AGITATION	1 (2.5%)	0
	ANXIETY	1 (2.5%)	0
Respiratory System	TOTAL	8 (20.0%)	11 (22.9%)
	RESPIRATORY DISORDER	3 (7.5%)	6 (12.5%)
	PHARYNGITIS	3 (7.5%)	1 (2.1%)
	RHINITIS	2 (5.0%)	3 (6.3%)
	SINUSITIS	1 (2.5%)	2 (4.2%)
	COUGH INCREASED	1 (2.5%)	1 (2.1%)
	YAWN	1 (2.5%)	0
Special Senses	TOTAL	2 (5.0%)	2 (4.2%)
	EAR PAIN	1 (2.5%)	0
	MYDRIASIS	1 (2.5%)	0
	ABNORMAL VISION	0	1 (2.1%)

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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=40)	 Placebo (N=48)
Special Senses	OTITIS EXTERNA	0	1 (2.1%)
Urogenital System	TOTAL	2 (5.0%)	2 (4.2%)
	HAEMATURIA	1 (2.5%)	1 (2.1%)
	URINARY FREQUENCY	1 (2.5%)	0
	URINARY TRACT INFECTION	0	1 (2.1%)
Cardiovascular System	TOTAL	1 (2.5%)	1 (2.1%)
	VASODILATATION	1 (2.5%)	1 (2.1%)
Metabolic and Nutritional Disorders	TOTAL	1 (2.5%)	0
	PERIPHERAL EDEMA	1 (2.5%)	0
Hemic and Lymphatic System	TOTAL	0	1 (2.1%)
	LEUKOPENIA	0	1 (2.1%)
Musculoskeletal System	TOTAL	0	2 (4.2%)
	ARTHRALGIA	0	1 (2.1%)
	MYALGIA	0	1 (2.1%)
Skin and Appendages	TOTAL	0	2 (4.2%)
	DRY SKIN	0	1 (2.1%)
	HERPES SIMPLEX	0	1 (2.1%)

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 : Adolescents, Intensity : Moderate, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=40)	 Placebo (N=48)
TOTAL	TOTAL	19 (47.5%)	18 (37.5%)
Nervous System	TOTAL	9 (22.5%)	7 (14.6%)
	SOMNOLENCE	5 (12.5%)	3 (6.3%)
	DIZZINESS	2 (5.0%)	1 (2.1%)
	AGITATION	1 (2.5%)	2 (4.2%)
	HYPERKINESIA	1 (2.5%)	2 (4.2%)
	EMOTIONAL LABILITY	1 (2.5%)	0
	HOSTILITY	1 (2.5%)	0
	NERVOUSNESS	0	3 (6.3%)
	INSOMNIA	0	2 (4.2%)
	DEPERSONALIZATION	0	1 (2.1%)
Body as a Whole	TOTAL	6 (15.0%)	9 (18.8%)
	HEADACHE	3 (7.5%)	4 (8.3%)
	INFECTION	1 (2.5%)	1 (2.1%)
	ALLERGIC REACTION	1 (2.5%)	0
	ASTHENIA	1 (2.5%)	0
	PAIN	1 (2.5%)	0
	TRAUMA	1 (2.5%)	0
	ABDOMINAL PAIN	0	3 (6.3%)
	FEVER	0	3 (6.3%)
Digestive System	TOTAL	5 (12.5%)	2 (4.2%)
	NAUSEA	2 (5.0%)	1 (2.1%)
	BRUXISM	1 (2.5%)	0
	CONSTIPATION	1 (2.5%)	0
	DIARRHEA	1 (2.5%)	0
	DRY MOUTH	1 (2.5%)	0
	DYSPEPSIA	0	1 (2.1%)
Respiratory System	TOTAL	5 (12.5%)	6 (12.5%)
	RESPIRATORY DISORDER	2 (5.0%)	3 (6.3%)
	ASTHMA	2 (5.0%)	0
	PHARYNGITIS	1 (2.5%)	1 (2.1%)
	EPISTAXIS	1 (2.5%)	0
	SINUSITIS	0	2 (4.2%)
	RHINITIS	0	1 (2.1%)
Cardiovascular System	TOTAL	1 (2.5%)	0
	HYPERTENSION	1 (2.5%)	0
Endocrine System	TOTAL	1 (2.5%)	0
	THYROID DISORDER	1 (2.5%)	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 : Moderate, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=40)	 Placebo (N=48)
Metabolic and Nutritional Disorders	TOTAL	1 (2.5%)	0
	WEIGHT LOSS	1 (2.5%)	0
Musculoskeletal System	TOTAL	1 (2.5%)	1 (2.1%)
	ARTHRALGIA	1 (2.5%)	0
	MYALGIA	0	1 (2.1%)
Skin and Appendages	TOTAL	1 (2.5%)	0
	ACNE	1 (2.5%)	0
Special Senses	TOTAL	1 (2.5%)	0
	OTITIS EXTERNA	1 (2.5%)	0
	OTITIS MEDIA	1 (2.5%)	0
Urogenital System	TOTAL	1 (2.5%)	0
	CYSTITIS	1 (2.5%)	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 : Severe, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=40)	 Placebo (N=48)
TOTAL	TOTAL	3 (7.5%)	4 (8.3%)
Nervous System	TOTAL	3 (7.5%)	3 (6.3%)
	DEPRESSION	1 (2.5%)	0
	EMOTIONAL LABILITY	1 (2.5%)	0
	HOSTILITY	1 (2.5%)	0
	ANXIETY	0	1 (2.1%)
	DIZZINESS	0	1 (2.1%)
	SOMNOLENCE	0	1 (2.1%)
Special Senses	TOTAL	0	1 (2.1%)
	OTITIS MEDIA	0	1 (2.1%)

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 : Adolescents, Intensity : Mild, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=22)	Placebo (N=29)
Body System	Preferred Term		
TOTAL	TOTAL	0	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 : Moderate, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=22)	Placebo (N=29)
Body System	Preferred Term		
TOTAL	TOTAL	0	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 : Severe, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=22)	Placebo (N=29)
Body System	Preferred Term		
TOTAL	TOTAL	0	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, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=18)	Placebo (N=19)
Body System	Preferred Term		
TOTAL	TOTAL	0	1 (5.3%)
Urogenital System	TOTAL	0	1 (5.3%)
	DYSMENORRHEA	0	1 (5.3%)

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

		Treatment Group	
		Paroxetine (N=18)	Placebo (N=19)
Body System	Preferred Term		
TOTAL	TOTAL	2 (11.1%)	0
Urogenital System	TOTAL	2 (11.1%)	0
	DYSMENORRHEA	2 (11.1%)	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 : Severe, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=18)	 Placebo (N=19)
TOTAL	TOTAL	1 (5.6%)	0
Urogenital System	TOTAL	1 (5.6%)	0
	DYSMENORRHEA	1 (5.6%)	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=98)	Treatment Group Placebo (N=105)
TOTAL	TOTAL	60 (61.2%)	68 (64.8%)
Body as a Whole	TOTAL	39 (39.8%)	34 (32.4%)
	HEADACHE	19 (19.4%)	17 (16.2%)
	ABDOMINAL PAIN	16 (16.3%)	9 (8.6%)
	TRAUMA	5 (5.1%)	2 (1.9%)
	ASTHENIA	5 (5.1%)	1 (1.0%)
	FEVER	4 (4.1%)	3 (2.9%)
	PAIN	4 (4.1%)	3 (2.9%)
	ALLERGIC REACTION	3 (3.1%)	4 (3.8%)
	INFECTION	2 (2.0%)	7 (6.7%)
	CHEST PAIN	2 (2.0%)	0
	BACK PAIN	1 (1.0%)	1 (1.0%)
Digestive System	TOTAL	30 (30.6%)	21 (20.0%)
	NAUSEA	12 (12.2%)	8 (7.6%)
	DECREASED APPETITE	8 (8.2%)	1 (1.0%)
	DIARRHEA	7 (7.1%)	2 (1.9%)
	VOMITING	5 (5.1%)	1 (1.0%)
	DRY MOUTH	3 (3.1%)	5 (4.8%)
	DYSPEPSIA	1 (1.0%)	3 (2.9%)
	GASTROINTESTINAL DISORDER	1 (1.0%)	2 (1.9%)
	COLITIS	1 (1.0%)	0
	FLATULENCE	1 (1.0%)	0
	INCREASED APPETITE	1 (1.0%)	0
	TOOTH DISORDER	1 (1.0%)	0
	ULCERATIVE STOMATITIS	1 (1.0%)	0
	CONSTIPATION	0	2 (1.9%)
	GASTROENTERITIS	0	1 (1.0%)
	GINGIVITIS	0	1 (1.0%)
Nervous System	TOTAL	22 (22.4%)	18 (17.1%)
	INSOMNIA	6 (6.1%)	4 (3.8%)
	HYPERKINESIA	6 (6.1%)	3 (2.9%)
	SOMNOLENCE	6 (6.1%)	2 (1.9%)
	DIZZINESS	3 (3.1%)	6 (5.7%)
	NERVOUSNESS	2 (2.0%)	2 (1.9%)
	ANXIETY	2 (2.0%)	0
	HOSTILITY	2 (2.0%)	0
	NEUROSIS	2 (2.0%)	0
	TREMOR	2 (2.0%)	0
	ABNORMAL DREAMS	1 (1.0%)	1 (1.0%)
	AGITATION	1 (1.0%)	0
	CONCENTRATION IMPAIRED	1 (1.0%)	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, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=98)	Treatment Group: Placebo (N=105)
Nervous System	DIPLOPIA	1 (1.0%)	0
	PERSONALITY DISORDER	1 (1.0%)	0
	MYOCLONUS	0	2 (1.9%)
	NYSTAGMUS	0	1 (1.0%)
Respiratory System	TOTAL	20 (20.4%)	27 (25.7%)
	RESPIRATORY DISORDER	8 (8.2%)	10 (9.5%)
	PHARYNGITIS	7 (7.1%)	4 (3.8%)
	RHINITIS	4 (4.1%)	8 (7.6%)
	SINUSITIS	3 (3.1%)	4 (3.8%)
	COUGH INCREASED	2 (2.0%)	6 (5.7%)
	EPISTAXIS	2 (2.0%)	0
	STRIDOR	1 (1.0%)	0
	YAWN	1 (1.0%)	0
Special Senses	TOTAL	5 (5.1%)	4 (3.8%)
	CONJUNCTIVITIS	2 (2.0%)	0
	EAR PAIN	1 (1.0%)	0
	KERATOCONJUNCTIVITIS	1 (1.0%)	0
	MYDRIASIS	1 (1.0%)	0
	OTITIS MEDIA	0	2 (1.9%)
	ABNORMAL VISION	0	1 (1.0%)
	OTITIS EXTERNA	0	1 (1.0%)
Urogenital System	TOTAL	5 (5.1%)	4 (3.8%)
	URINARY INCONTINENCE	2 (2.0%)	1 (1.0%)
	HAEMATURIA	1 (1.0%)	1 (1.0%)
	ALBUMINURIA	1 (1.0%)	0
	URINARY FREQUENCY	1 (1.0%)	0
	URINARY TRACT INFECTION	0	2 (1.9%)
Skin and Appendages	TOTAL	4 (4.1%)	5 (4.8%)
	SWEATING	2 (2.0%)	0
	PHOTOSENSITIVITY	1 (1.0%)	0
	PUSTULAR RASH	1 (1.0%)	0
	DRY SKIN	0	1 (1.0%)
	FUNGAL DERMATITIS	0	1 (1.0%)
	HERPES SIMPLEX	0	1 (1.0%)
	RASH	0	1 (1.0%)
	SKIN BENIGN NEOPLASM	0	1 (1.0%)
Cardiovascular System	TOTAL	1 (1.0%)	1 (1.0%)
	VASODILATATION	1 (1.0%)	1 (1.0%)

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=98)	 Placebo (N=105)
Hemic and Lymphatic System	TOTAL	1 (1.0%)	1 (1.0%)
	ANEMIA	1 (1.0%)	0
	LEUKOPENIA	0	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (1.0%)	1 (1.0%)
	PERIPHERAL EDEMA	1 (1.0%)	0
	THIRST	0	1 (1.0%)
Musculoskeletal System	TOTAL	1 (1.0%)	2 (1.9%)
	MYALGIA	1 (1.0%)	1 (1.0%)
	ARTHRALGIA	0	1 (1.0%)

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=98)	Treatment Group: Placebo (N=105)
TOTAL	TOTAL	47 (48.0%)	36 (34.3%)
Nervous System	TOTAL	26 (26.5%)	14 (13.3%)
	HYPERKINESIA	7 (7.1%)	4 (3.8%)
	SOMNOLENCE	6 (6.1%)	4 (3.8%)
	HOSTILITY	5 (5.1%)	1 (1.0%)
	NERVOUSNESS	3 (3.1%)	5 (4.8%)
	AGITATION	3 (3.1%)	2 (1.9%)
	INSOMNIA	3 (3.1%)	2 (1.9%)
	NEUROSIS	3 (3.1%)	0
	DIZZINESS	2 (2.0%)	2 (1.9%)
	EMOTIONAL LABILITY	2 (2.0%)	0
	PERSONALITY DISORDER	2 (2.0%)	0
	SPEECH DISORDER	2 (2.0%)	0
	CONCENTRATION IMPAIRED	1 (1.0%)	1 (1.0%)
	DEPERSONALIZATION	1 (1.0%)	1 (1.0%)
	INCOORDINATION	1 (1.0%)	0
Body as a Whole	TOTAL	16 (16.3%)	18 (17.1%)
	HEADACHE	6 (6.1%)	6 (5.7%)
	INFECTION	3 (3.1%)	6 (5.7%)
	TRAUMA	3 (3.1%)	1 (1.0%)
	ASTHENIA	3 (3.1%)	0
	ABDOMINAL PAIN	2 (2.0%)	4 (3.8%)
	ALLERGIC REACTION	1 (1.0%)	0
	CHEST PAIN	1 (1.0%)	0
	PAIN	1 (1.0%)	0
	FEVER	0	4 (3.8%)
Digestive System	TOTAL	12 (12.2%)	5 (4.8%)
	NAUSEA	4 (4.1%)	2 (1.9%)
	CONSTIPATION	2 (2.0%)	1 (1.0%)
	DYSPEPSIA	2 (2.0%)	1 (1.0%)
	DRY MOUTH	1 (1.0%)	1 (1.0%)
	VOMITING	1 (1.0%)	1 (1.0%)
	BRUXISM	1 (1.0%)	0
	DECREASED APPETITE	1 (1.0%)	0
	DIARRHEA	1 (1.0%)	0
	FLATULENCE	1 (1.0%)	0
	GASTROINTESTINAL DISORDER	1 (1.0%)	0
	STOMATITIS	1 (1.0%)	0
	TOOTH CARIES	1 (1.0%)	0
Respiratory System	TOTAL	10 (10.2%)	10 (9.5%)

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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=98)	Treatment Group: Placebo (N=105)
Respiratory System	RESPIRATORY DISORDER	5 (5.1%)	5 (4.8%)
	SINUSITIS	2 (2.0%)	2 (1.9%)
	ASTHMA	2 (2.0%)	0
	EPISTAXIS	2 (2.0%)	0
	PHARYNGITIS	1 (1.0%)	2 (1.9%)
	RHINITIS	1 (1.0%)	2 (1.9%)
	COUGH INCREASED	1 (1.0%)	0
Cardiovascular System	TOTAL	2 (2.0%)	0
	HYPERTENSION	1 (1.0%)	0
	VASODILATATION	1 (1.0%)	0
Musculoskeletal System	TOTAL	2 (2.0%)	1 (1.0%)
	MYALGIA	1 (1.0%)	1 (1.0%)
	ARTHRALGIA	1 (1.0%)	0
Skin and Appendages	TOTAL	2 (2.0%)	0
	ACNE	1 (1.0%)	0
	SWEATING	1 (1.0%)	0
Urogenital System	TOTAL	2 (2.0%)	1 (1.0%)
	CYSTITIS	1 (1.0%)	0
	URINARY RETENTION	1 (1.0%)	0
	URINARY INCONTINENCE	0	1 (1.0%)
Endocrine System	TOTAL	1 (1.0%)	0
	THYROID DISORDER	1 (1.0%)	0
Metabolic and Nutritional Disorders	TOTAL	1 (1.0%)	1 (1.0%)
	WEIGHT LOSS	1 (1.0%)	0
	THIRST	0	1 (1.0%)
Special Senses	TOTAL	1 (1.0%)	1 (1.0%)
	OTITIS EXTERNA	1 (1.0%)	0
	OTITIS MEDIA	1 (1.0%)	0
	EAR DISORDER	0	1 (1.0%)
	EAR PAIN	0	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 : Severe, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=98)	Placebo (N=105)
TOTAL	TOTAL	8 (8.2%)	5 (4.8%)
Nervous System	TOTAL	5 (5.1%)	4 (3.8%)
	HOSTILITY	2 (2.0%)	0
	AGITATION	1 (1.0%)	0
	DEPRESSION	1 (1.0%)	0
	EMOTIONAL LABILITY	1 (1.0%)	0
	HYPERKINESIA	1 (1.0%)	0
	ANXIETY	0	1 (1.0%)
	DIZZINESS	0	1 (1.0%)
	NEUROSIS	0	1 (1.0%)
	SOMNOLENCE	0	1 (1.0%)
Body as a Whole	TOTAL	3 (3.1%)	0
	TRAUMA	2 (2.0%)	0
	HEADACHE	1 (1.0%)	0
Special Senses	TOTAL	0	1 (1.0%)
	OTITIS MEDIA	0	1 (1.0%)

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, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=64)
Body System	Preferred Term		
TOTAL	TOTAL	0	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, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=64)
Body System	Preferred Term		
TOTAL	TOTAL	0	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 : Severe, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=64)
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=45)	Placebo (N=41)
Body System	Preferred Term		
TOTAL	TOTAL	0	1 (2.4%)
Urogenital System	TOTAL	0	1 (2.4%)
	DYSMENORRHEA	0	1 (2.4%)

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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 : Total, Intensity : Moderate, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=45)	 Placebo (N=41)
TOTAL	TOTAL	2 (4.4%)	0
Urogenital System	TOTAL	2 (4.4%)	0
	DYSMENORRHEA	2 (4.4%)	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 : Severe, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=45)	 Placebo (N=41)
TOTAL	TOTAL	1 (2.2%)	0
Urogenital System	TOTAL	1 (2.2%)	0
	DYSMENORRHEA	1 (2.2%)	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the 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=58)	Treatment Group: Placebo (N=57)
TOTAL	38 (65.5%)	40 (70.2%)
ABDOMINAL PAIN	12 (20.7%)	8 (14.0%)
HEADACHE	11 (19.0%)	10 (17.5%)
RESPIRATORY DISORDER	5 (8.6%)	4 (7.0%)
DIARRHEA	5 (8.6%)	2 (3.5%)
DECREASED APPETITE	5 (8.6%)	1 (1.8%)
NAUSEA	4 (6.9%)	8 (14.0%)
FEVER	4 (6.9%)	3 (5.3%)
HYPERKINESIA	4 (6.9%)	3 (5.3%)
PHARYNGITIS	4 (6.9%)	3 (5.3%)
INSOMNIA	4 (6.9%)	2 (3.5%)
SOMNOLENCE	4 (6.9%)	2 (3.5%)
VOMITING	4 (6.9%)	1 (1.8%)
ALLERGIC REACTION	3 (5.2%)	3 (5.3%)
PAIN	3 (5.2%)	3 (5.3%)
TRAUMA	3 (5.2%)	0
RHINITIS	2 (3.4%)	5 (8.8%)
SINUSITIS	2 (3.4%)	2 (3.5%)
URINARY INCONTINENCE	2 (3.4%)	1 (1.8%)
CHEST PAIN	2 (3.4%)	0
CONJUNCTIVITIS	2 (3.4%)	0
EPISTAXIS	2 (3.4%)	0
HOSTILITY	2 (3.4%)	0
NEUROSIS	2 (3.4%)	0
SWEATING	2 (3.4%)	0
TREMOR	2 (3.4%)	0
COUGH INCREASED	1 (1.7%)	5 (8.8%)
INFECTION	1 (1.7%)	5 (8.8%)
DIZZINESS	1 (1.7%)	4 (7.0%)
DRY MOUTH	1 (1.7%)	3 (5.3%)
DYSPEPSIA	1 (1.7%)	2 (3.5%)
ASTHENIA	1 (1.7%)	1 (1.8%)
ALBUMINURIA	1 (1.7%)	0
ANEMIA	1 (1.7%)	0
ANXIETY	1 (1.7%)	0
BACK PAIN	1 (1.7%)	0
COLITIS	1 (1.7%)	0
CONCENTRATION IMPAIRED	1 (1.7%)	0
DIPLOPIA	1 (1.7%)	0
INCREASED APPETITE	1 (1.7%)	0
KERATOCONJUNCTIVITIS	1 (1.7%)	0
MYALGIA	1 (1.7%)	0
NERVOUSNESS	1 (1.7%)	0
PERSONALITY DISORDER	1 (1.7%)	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=58)	Treatment Group: Placebo (N=57)
PHOTOSENSITIVITY	1 (1.7%)	0
PUSTULAR RASH	1 (1.7%)	0
STRIDOR	1 (1.7%)	0
TOOTH DISORDER	1 (1.7%)	0
ULCERATIVE STOMATITIS	1 (1.7%)	0
CONSTIPATION	0	2 (3.5%)
GASTROINTESTINAL DISORDER	0	2 (3.5%)
MYOCLONUS	0	2 (3.5%)
OTITIS MEDIA	0	2 (3.5%)
FUNGAL DERMATITIS	0	1 (1.8%)
GASTROENTERITIS	0	1 (1.8%)
GINGIVITIS	0	1 (1.8%)
NYSTAGMUS	0	1 (1.8%)
RASH	0	1 (1.8%)
SKIN BENIGN NEOPLASM	0	1 (1.8%)
THIRST	0	1 (1.8%)
URINARY TRACT INFECTION	0	1 (1.8%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the 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=58)	Treatment Group: Placebo (N=57)
TOTAL	28 (48.3%)	18 (31.6%)
HYPERKINESIA	6 (10.3%)	2 (3.5%)
HOSTILITY	4 (6.9%)	1 (1.8%)
HEADACHE	3 (5.2%)	2 (3.5%)
NERVOUSNESS	3 (5.2%)	2 (3.5%)
RESPIRATORY DISORDER	3 (5.2%)	2 (3.5%)
INSOMNIA	3 (5.2%)	0
NEUROSIS	3 (5.2%)	0
INFECTION	2 (3.4%)	5 (8.8%)
ABDOMINAL PAIN	2 (3.4%)	1 (1.8%)
NAUSEA	2 (3.4%)	1 (1.8%)
TRAUMA	2 (3.4%)	1 (1.8%)
AGITATION	2 (3.4%)	0
ASTHENIA	2 (3.4%)	0
DYSPEPSIA	2 (3.4%)	0
PERSONALITY DISORDER	2 (3.4%)	0
SINUSITIS	2 (3.4%)	0
SPEECH DISORDER	2 (3.4%)	0
CONCENTRATION IMPAIRED	1 (1.7%)	1 (1.8%)
CONSTIPATION	1 (1.7%)	1 (1.8%)
RHINITIS	1 (1.7%)	1 (1.8%)
SOMNOLENCE	1 (1.7%)	1 (1.8%)
VOMITING	1 (1.7%)	1 (1.8%)
CHEST PAIN	1 (1.7%)	0
COUGH INCREASED	1 (1.7%)	0
DECREASED APPETITE	1 (1.7%)	0
DEPERSONALIZATION	1 (1.7%)	0
EMOTIONAL LABILITY	1 (1.7%)	0
EPISTAXIS	1 (1.7%)	0
FLATULENCE	1 (1.7%)	0
GASTROINTESTINAL DISORDER	1 (1.7%)	0
INCOORDINATION	1 (1.7%)	0
MYALGIA	1 (1.7%)	0
STOMATITIS	1 (1.7%)	0
SWEATING	1 (1.7%)	0
TOOTH CARIES	1 (1.7%)	0
URINARY RETENTION	1 (1.7%)	0
VASODILATATION	1 (1.7%)	0
DIZZINESS	0	1 (1.8%)
DRY MOUTH	0	1 (1.8%)
EAR DISORDER	0	1 (1.8%)
EAR PAIN	0	1 (1.8%)
FEVER	0	1 (1.8%)
PHARYNGITIS	0	1 (1.8%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the 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=58)	Treatment Group: Placebo (N=57)
THIRST	0	1 (1.8%)
URINARY INCONTINENCE	0	1 (1.8%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the 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=58)	Treatment Group: Placebo (N=57)
TOTAL	5 (8.6%)	1 (1.8%)
TRAUMA	2 (3.4%)	0
AGITATION	1 (1.7%)	0
HEADACHE	1 (1.7%)	0
HOSTILITY	1 (1.7%)	0
HYPERKINESIA	1 (1.7%)	0
NEUROSIS	0	1 (1.8%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the 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=31)	Treatment Group: Placebo (N=35)
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=31)	Treatment Group: Placebo (N=35)
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=31)	Treatment Group: Placebo (N=35)
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=27)	Treatment Group: 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=27)	Treatment Group: 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=27)	Treatment Group: 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=40)	Treatment Group: Placebo (N=48)
TOTAL	22 (55.0%)	28 (58.3%)
HEADACHE	8 (20.0%)	7 (14.6%)
NAUSEA	8 (20.0%)	0
ABDOMINAL PAIN	4 (10.0%)	1 (2.1%)
ASTHENIA	4 (10.0%)	0
RESPIRATORY DISORDER	3 (7.5%)	6 (12.5%)
PHARYNGITIS	3 (7.5%)	1 (2.1%)
DECREASED APPETITE	3 (7.5%)	0
RHINITIS	2 (5.0%)	3 (6.3%)
DIZZINESS	2 (5.0%)	2 (4.2%)
DRY MOUTH	2 (5.0%)	2 (4.2%)
INSOMNIA	2 (5.0%)	2 (4.2%)
TRAUMA	2 (5.0%)	2 (4.2%)
DIARRHEA	2 (5.0%)	0
HYPERKINESIA	2 (5.0%)	0
SOMNOLENCE	2 (5.0%)	0
INFECTION	1 (2.5%)	2 (4.2%)
NERVOUSNESS	1 (2.5%)	2 (4.2%)
SINUSITIS	1 (2.5%)	2 (4.2%)
ABNORMAL DREAMS	1 (2.5%)	1 (2.1%)
COUGH INCREASED	1 (2.5%)	1 (2.1%)
HAEMATURIA	1 (2.5%)	1 (2.1%)
VASODILATATION	1 (2.5%)	1 (2.1%)
AGITATION	1 (2.5%)	0
ANXIETY	1 (2.5%)	0
EAR PAIN	1 (2.5%)	0
FLATULENCE	1 (2.5%)	0
GASTROINTESTINAL DISORDER	1 (2.5%)	0
MYDRIASIS	1 (2.5%)	0
PAIN	1 (2.5%)	0
PERIPHERAL EDEMA	1 (2.5%)	0
URINARY FREQUENCY	1 (2.5%)	0
VOMITING	1 (2.5%)	0
YAWN	1 (2.5%)	0
ABNORMAL VISION	0	1 (2.1%)
ALLERGIC REACTION	0	1 (2.1%)
ARTHRALGIA	0	1 (2.1%)
BACK PAIN	0	1 (2.1%)
DRY SKIN	0	1 (2.1%)
DYSPEPSIA	0	1 (2.1%)
HERPES SIMPLEX	0	1 (2.1%)
LEUKOPENIA	0	1 (2.1%)
MYALGIA	0	1 (2.1%)
OTITIS EXTERNA	0	1 (2.1%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the 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=40)	Treatment Group: Placebo (N=48)
URINARY TRACT INFECTION	0	1 (2.1%)

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=40)	Treatment Group: Placebo (N=48)
TOTAL	19 (47.5%)	18 (37.5%)
SOMNOLENCE	5 (12.5%)	3 (6.3%)
HEADACHE	3 (7.5%)	4 (8.3%)
RESPIRATORY DISORDER	2 (5.0%)	3 (6.3%)
DIZZINESS	2 (5.0%)	1 (2.1%)
NAUSEA	2 (5.0%)	1 (2.1%)
ASTHMA	2 (5.0%)	0
AGITATION	1 (2.5%)	2 (4.2%)
HYPERKINESIA	1 (2.5%)	2 (4.2%)
INFECTION	1 (2.5%)	1 (2.1%)
PHARYNGITIS	1 (2.5%)	1 (2.1%)
ACNE	1 (2.5%)	0
ALLERGIC REACTION	1 (2.5%)	0
ARTHRALGIA	1 (2.5%)	0
ASTHENIA	1 (2.5%)	0
BRUXISM	1 (2.5%)	0
CONSTIPATION	1 (2.5%)	0
CYSTITIS	1 (2.5%)	0
DIARRHEA	1 (2.5%)	0
DRY MOUTH	1 (2.5%)	0
EMOTIONAL LABILITY	1 (2.5%)	0
EPISTAXIS	1 (2.5%)	0
HOSTILITY	1 (2.5%)	0
HYPERTENSION	1 (2.5%)	0
OTITIS EXTERNA	1 (2.5%)	0
OTITIS MEDIA	1 (2.5%)	0
PAIN	1 (2.5%)	0
THYROID DISORDER	1 (2.5%)	0
TRAUMA	1 (2.5%)	0
WEIGHT LOSS	1 (2.5%)	0
ABDOMINAL PAIN	0	3 (6.3%)
FEVER	0	3 (6.3%)
NERVOUSNESS	0	3 (6.3%)
INSOMNIA	0	2 (4.2%)
SINUSITIS	0	2 (4.2%)
DEPERSONALIZATION	0	1 (2.1%)
DYSPEPSIA	0	1 (2.1%)
MYALGIA	0	1 (2.1%)
RHINITIS	0	1 (2.1%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the 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=40)	Treatment Group: Placebo (N=48)
TOTAL	3 (7.5%)	4 (8.3%)
DEPRESSION	1 (2.5%)	0
EMOTIONAL LABILITY	1 (2.5%)	0
HOSTILITY	1 (2.5%)	0
ANXIETY	0	1 (2.1%)
DIZZINESS	0	1 (2.1%)
OTITIS MEDIA	0	1 (2.1%)
SOMNOLENCE	0	1 (2.1%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the 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=22)	Treatment Group: Placebo (N=29)
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=22)	Treatment Group: Placebo (N=29)
TOTAL	0	0

Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the 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=22)	Treatment Group: Placebo (N=29)
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=18)	Treatment Group: Placebo (N=19)
TOTAL	0	1 (5.3%)
DYSMENORRHEA	0	1 (5.3%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the 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=18)	Treatment Group: Placebo (N=19)
TOTAL	2 (11.1%)	0
DYSMENORRHEA	2 (11.1%)	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 : Adolescents, Intensity : Severe, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=18)	Treatment Group: Placebo (N=19)
TOTAL	1 (5.6%)	0
DYSMENORRHEA	1 (5.6%)	0

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=98)	Treatment Group: Placebo (N=105)
TOTAL	60 (61.2%)	68 (64.8%)
HEADACHE	19 (19.4%)	17 (16.2%)
ABDOMINAL PAIN	16 (16.3%)	9 (8.6%)
NAUSEA	12 (12.2%)	8 (7.6%)
RESPIRATORY DISORDER	8 (8.2%)	10 (9.5%)
DECREASED APPETITE	8 (8.2%)	1 (1.0%)
PHARYNGITIS	7 (7.1%)	4 (3.8%)
DIARRHEA	7 (7.1%)	2 (1.9%)
INSOMNIA	6 (6.1%)	4 (3.8%)
HYPERKINESIA	6 (6.1%)	3 (2.9%)
SOMNOLENCE	6 (6.1%)	2 (1.9%)
TRAUMA	5 (5.1%)	2 (1.9%)
ASTHENIA	5 (5.1%)	1 (1.0%)
VOMITING	5 (5.1%)	1 (1.0%)
RHINITIS	4 (4.1%)	8 (7.6%)
FEVER	4 (4.1%)	3 (2.9%)
PAIN	4 (4.1%)	3 (2.9%)
DIZZINESS	3 (3.1%)	6 (5.7%)
DRY MOUTH	3 (3.1%)	5 (4.8%)
ALLERGIC REACTION	3 (3.1%)	4 (3.8%)
SINUSITIS	3 (3.1%)	4 (3.8%)
INFECTION	2 (2.0%)	7 (6.7%)
COUGH INCREASED	2 (2.0%)	6 (5.7%)
NERVOUSNESS	2 (2.0%)	2 (1.9%)
URINARY INCONTINENCE	2 (2.0%)	1 (1.0%)
ANXIETY	2 (2.0%)	0
CHEST PAIN	2 (2.0%)	0
CONJUNCTIVITIS	2 (2.0%)	0
EPISTAXIS	2 (2.0%)	0
HOSTILITY	2 (2.0%)	0
NEUROSIS	2 (2.0%)	0
SWEATING	2 (2.0%)	0
TREMOR	2 (2.0%)	0
DYSPEPSIA	1 (1.0%)	3 (2.9%)
GASTROINTESTINAL DISORDER	1 (1.0%)	2 (1.9%)
ABNORMAL DREAMS	1 (1.0%)	1 (1.0%)
BACK PAIN	1 (1.0%)	1 (1.0%)
HAEMATURIA	1 (1.0%)	1 (1.0%)
MYALGIA	1 (1.0%)	1 (1.0%)
VASODILATATION	1 (1.0%)	1 (1.0%)
AGITATION	1 (1.0%)	0
ALBUMINURIA	1 (1.0%)	0
ANEMIA	1 (1.0%)	0
COLITIS	1 (1.0%)	0

Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the 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=98)	Treatment Group: Placebo (N=105)
CONCENTRATION IMPAIRED	1 (1.0%)	0
DIPLOPIA	1 (1.0%)	0
EAR PAIN	1 (1.0%)	0
FLATULENCE	1 (1.0%)	0
INCREASED APPETITE	1 (1.0%)	0
KERATOCONJUNCTIVITIS	1 (1.0%)	0
MYDRIASIS	1 (1.0%)	0
PERIPHERAL EDEMA	1 (1.0%)	0
PERSONALITY DISORDER	1 (1.0%)	0
PHOTOSENSITIVITY	1 (1.0%)	0
PUSTULAR RASH	1 (1.0%)	0
STRIDOR	1 (1.0%)	0
TOOTH DISORDER	1 (1.0%)	0
ULCERATIVE STOMATITIS	1 (1.0%)	0
URINARY FREQUENCY	1 (1.0%)	0
YAWN	1 (1.0%)	0
CONSTIPATION	0	2 (1.9%)
MYOCLONUS	0	2 (1.9%)
OTITIS MEDIA	0	2 (1.9%)
URINARY TRACT INFECTION	0	2 (1.9%)
ABNORMAL VISION	0	1 (1.0%)
ARTHRALGIA	0	1 (1.0%)
DRY SKIN	0	1 (1.0%)
FUNGAL DERMATITIS	0	1 (1.0%)
GASTROENTERITIS	0	1 (1.0%)
GINGIVITIS	0	1 (1.0%)
HERPES SIMPLEX	0	1 (1.0%)
LEUKOPENIA	0	1 (1.0%)
NYSTAGMUS	0	1 (1.0%)
OTITIS EXTERNA	0	1 (1.0%)
RASH	0	1 (1.0%)
SKIN BENIGN NEOPLASM	0	1 (1.0%)
THIRST	0	1 (1.0%)

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=98)	Treatment Group: Placebo (N=105)
TOTAL	47 (48.0%)	36 (34.3%)
HYPERKINESIA	7 (7.1%)	4 (3.8%)
HEADACHE	6 (6.1%)	6 (5.7%)
SOMNOLENCE	6 (6.1%)	4 (3.8%)
RESPIRATORY DISORDER	5 (5.1%)	5 (4.8%)
HOSTILITY	5 (5.1%)	1 (1.0%)
NAUSEA	4 (4.1%)	2 (1.9%)
INFECTION	3 (3.1%)	6 (5.7%)
NERVOUSNESS	3 (3.1%)	5 (4.8%)
AGITATION	3 (3.1%)	2 (1.9%)
INSOMNIA	3 (3.1%)	2 (1.9%)
TRAUMA	3 (3.1%)	1 (1.0%)
ASTHENIA	3 (3.1%)	0
NEUROSIS	3 (3.1%)	0
ABDOMINAL PAIN	2 (2.0%)	4 (3.8%)
DIZZINESS	2 (2.0%)	2 (1.9%)
SINUSITIS	2 (2.0%)	2 (1.9%)
CONSTIPATION	2 (2.0%)	1 (1.0%)
DYSPEPSIA	2 (2.0%)	1 (1.0%)
ASTHMA	2 (2.0%)	0
EMOTIONAL LABILITY	2 (2.0%)	0
EPISTAXIS	2 (2.0%)	0
PERSONALITY DISORDER	2 (2.0%)	0
SPEECH DISORDER	2 (2.0%)	0
PHARYNGITIS	1 (1.0%)	2 (1.9%)
RHINITIS	1 (1.0%)	2 (1.9%)
CONCENTRATION IMPAIRED	1 (1.0%)	1 (1.0%)
DEPERSONALIZATION	1 (1.0%)	1 (1.0%)
DRY MOUTH	1 (1.0%)	1 (1.0%)
MYALGIA	1 (1.0%)	1 (1.0%)
VOMITING	1 (1.0%)	1 (1.0%)
ACNE	1 (1.0%)	0
ALLERGIC REACTION	1 (1.0%)	0
ARTHRALGIA	1 (1.0%)	0
BRUXISM	1 (1.0%)	0
CHEST PAIN	1 (1.0%)	0
COUGH INCREASED	1 (1.0%)	0
CYSTITIS	1 (1.0%)	0
DECREASED APPETITE	1 (1.0%)	0
DIARRHEA	1 (1.0%)	0
FLATULENCE	1 (1.0%)	0
GASTROINTESTINAL DISORDER	1 (1.0%)	0
HYPERTENSION	1 (1.0%)	0
INCOORDINATION	1 (1.0%)	0

Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the 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=98)	Treatment Group: Placebo (N=105)
OTITIS EXTERNA	1 (1.0%)	0
OTITIS MEDIA	1 (1.0%)	0
PAIN	1 (1.0%)	0
STOMATITIS	1 (1.0%)	0
SWEATING	1 (1.0%)	0
THYROID DISORDER	1 (1.0%)	0
TOOTH CARIES	1 (1.0%)	0
URINARY RETENTION	1 (1.0%)	0
VASODILATATION	1 (1.0%)	0
WEIGHT LOSS	1 (1.0%)	0
FEVER	0	4 (3.8%)
EAR DISORDER	0	1 (1.0%)
EAR PAIN	0	1 (1.0%)
THIRST	0	1 (1.0%)
URINARY INCONTINENCE	0	1 (1.0%)

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=98)	Treatment Group: Placebo (N=105)
TOTAL	8 (8.2%)	5 (4.8%)
HOSTILITY	2 (2.0%)	0
TRAUMA	2 (2.0%)	0
AGITATION	1 (1.0%)	0
DEPRESSION	1 (1.0%)	0
EMOTIONAL LABILITY	1 (1.0%)	0
HEADACHE	1 (1.0%)	0
HYPERKINESIA	1 (1.0%)	0
ANXIETY	0	1 (1.0%)
DIZZINESS	0	1 (1.0%)
NEUROSIS	0	1 (1.0%)
OTITIS MEDIA	0	1 (1.0%)
SOMNOLENCE	0	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 : Total, Intensity : Mild, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=53)	Treatment Group: Placebo (N=64)
TOTAL	0	0

Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the 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=53)	Treatment Group: Placebo (N=64)
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=53)	Treatment Group: Placebo (N=64)
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=45)	Treatment Group: Placebo (N=41)
TOTAL	0	1 (2.4%)
DYSMENORRHEA	0	1 (2.4%)

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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 : Total, Intensity : Moderate, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=45)	Treatment Group: Placebo (N=41)
TOTAL	2 (4.4%)	0
DYSMENORRHEA	2 (4.4%)	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 : Severe, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=45)	Treatment Group: Placebo (N=41)
TOTAL	1 (2.2%)	0
DYSMENORRHEA	1 (2.2%)	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 : Children, Intensity : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=31)	Placebo (N=41)
TOTAL	TOTAL	3 (9.7%)	6 (14.6%)
Body as a Whole	TOTAL	3 (9.7%)	4 (9.8%)
	HEADACHE	2 (6.5%)	1 (2.4%)
	INFECTION	1 (3.2%)	2 (4.9%)
	ALLERGIC REACTION	1 (3.2%)	0
	ABDOMINAL PAIN	0	1 (2.4%)
Digestive System	TOTAL	1 (3.2%)	0
	ULCERATIVE STOMATITIS	1 (3.2%)	0
Nervous System	TOTAL	1 (3.2%)	2 (4.9%)
	DIZZINESS	1 (3.2%)	0
	NEUROSIS	0	2 (4.9%)
Respiratory System	TOTAL	1 (3.2%)	1 (2.4%)
	RHINITIS	1 (3.2%)	1 (2.4%)
Special Senses	TOTAL	0	1 (2.4%)
	CONJUNCTIVITIS	0	1 (2.4%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System. Intention-To-Treat Population Entering The Taper Phase

Age Group : Children, Intensity : Moderate, Gender Non Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=31)	Placebo (N=41)
Body System	Preferred Term		
TOTAL	TOTAL	0	3 (7.3%)
Body as a Whole	TOTAL	0	2 (4.9%)
	HEADACHE	0	2 (4.9%)
Special Senses	TOTAL	0	2 (4.9%)
	EAR PAIN	0	1 (2.4%)
	OTITIS MEDIA	0	1 (2.4%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
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=31)	Placebo (N=41)
Body System	Preferred Term		
TOTAL	TOTAL	0	1 (2.4%)
Nervous System	TOTAL	0	1 (2.4%)
	NEUROSIS	0	1 (2.4%)

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System. Intention-To-Treat Population Entering The Taper Phase

Age Group : Children, Intensity : Mild, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=15)	Placebo (N=26)
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=15)	Placebo (N=26)
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=15)	Placebo (N=26)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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=16)	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, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=16)	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, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=16)	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 : Adolescents, Intensity : Mild, Gender Non Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=29)	Placebo (N=33)
Body System	Preferred Term		
TOTAL	TOTAL	3 (10.3%)	2 (6.1%)
Musculoskeletal System	TOTAL	2 (6.9%)	0
	ARTHRALGIA	1 (3.4%)	0
	MYALGIA	1 (3.4%)	0
Nervous System	TOTAL	1 (3.4%)	0
	PARESTHESIA	1 (3.4%)	0
Respiratory System	TOTAL	1 (3.4%)	1 (3.0%)
	SINUSITIS	1 (3.4%)	0
	RHINITIS	0	1 (3.0%)
Digestive System	TOTAL	0	1 (3.0%)
	NAUSEA	0	1 (3.0%)

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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=29)	Placebo (N=33)
Body System	Preferred Term		
TOTAL	TOTAL	2 (6.9%)	3 (9.1%)
Digestive System	TOTAL	1 (3.4%)	1 (3.0%)
	DIARRHEA	1 (3.4%)	0
	DECREASED APPETITE	0	1 (3.0%)
Nervous System	TOTAL	1 (3.4%)	2 (6.1%)
	NERVOUSNESS	1 (3.4%)	2 (6.1%)
Body as a Whole	TOTAL	0	3 (9.1%)
	ASTHENIA	0	2 (6.1%)
	HEADACHE	0	1 (3.0%)
Cardiovascular System	TOTAL	0	1 (3.0%)
	VASODILATATION	0	1 (3.0%)

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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, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=29)	Placebo (N=33)
TOTAL	TOTAL	1 (3.4%)	0
Nervous System	TOTAL	1 (3.4%)	0
	ANXIETY	1 (3.4%)	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=16)	Placebo (N=21)
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=16)	Placebo (N=21)
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=16)	Placebo (N=21)
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=13)	Placebo (N=12)
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=13)	Placebo (N=12)
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=13)	Placebo (N=12)
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=60)	Placebo (N=74)
TOTAL	TOTAL	6 (10.0%)	8 (10.8%)
Body as a Whole	TOTAL	3 (5.0%)	4 (5.4%)
	HEADACHE	2 (3.3%)	1 (1.4%)
	INFECTION	1 (1.7%)	2 (2.7%)
	ALLERGIC REACTION	1 (1.7%)	0
	ABDOMINAL PAIN	0	1 (1.4%)
Musculoskeletal System	TOTAL	2 (3.3%)	0
	ARTHRALGIA	1 (1.7%)	0
	MYALGIA	1 (1.7%)	0
Nervous System	TOTAL	2 (3.3%)	2 (2.7%)
	DIZZINESS	1 (1.7%)	0
	PARESTHESIA	1 (1.7%)	0
	NEUROSIS	0	2 (2.7%)
Respiratory System	TOTAL	2 (3.3%)	2 (2.7%)
	RHINITIS	1 (1.7%)	2 (2.7%)
	SINUSITIS	1 (1.7%)	0
Digestive System	TOTAL	1 (1.7%)	1 (1.4%)
	ULCERATIVE STOMATITIS	1 (1.7%)	0
	NAUSEA	0	1 (1.4%)
Special Senses	TOTAL	0	1 (1.4%)
	CONJUNCTIVITIS	0	1 (1.4%)

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=60)	Placebo (N=74)
TOTAL	TOTAL	2 (3.3%)	6 (8.1%)
Digestive System	TOTAL	1 (1.7%)	1 (1.4%)
	DIARRHEA	1 (1.7%)	0
	DECREASED APPETITE	0	1 (1.4%)
Nervous System	TOTAL	1 (1.7%)	2 (2.7%)
	NERVOUSNESS	1 (1.7%)	2 (2.7%)
Body as a Whole	TOTAL	0	5 (6.8%)
	HEADACHE	0	3 (4.1%)
	ASTHENIA	0	2 (2.7%)
Cardiovascular System	TOTAL	0	1 (1.4%)
	VASODILATATION	0	1 (1.4%)
Special Senses	TOTAL	0	2 (2.7%)
	EAR PAIN	0	1 (1.4%)
	OTITIS MEDIA	0	1 (1.4%)

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=60)	Placebo (N=74)
TOTAL	TOTAL	1 (1.7%)	1 (1.4%)
Nervous System	TOTAL	1 (1.7%)	1 (1.4%)
	ANXIETY	1 (1.7%)	0
	NEUROSIS	0	1 (1.4%)

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=31)	Placebo (N=47)
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=31)	Placebo (N=47)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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=31)	Placebo (N=47)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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=29)	Placebo (N=27)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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=29)	Placebo (N=27)
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=29)	Placebo (N=27)
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=31)	Treatment Group: Placebo (N=41)
TOTAL	3 (9.7%)	6 (14.6%)
HEADACHE	2 (6.5%)	1 (2.4%)
INFECTION	1 (3.2%)	2 (4.9%)
RHINITIS	1 (3.2%)	1 (2.4%)
ALLERGIC REACTION	1 (3.2%)	0
DIZZINESS	1 (3.2%)	0
ULCERATIVE STOMATITIS	1 (3.2%)	0
NEUROSIS	0	2 (4.9%)
ABDOMINAL PAIN	0	1 (2.4%)
CONJUNCTIVITIS	0	1 (2.4%)

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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=31)	Treatment Group: Placebo (N=41)
TOTAL	0	3 (7.3%)
HEADACHE	0	2 (4.9%)
EAR PAIN	0	1 (2.4%)
OTITIS MEDIA	0	1 (2.4%)

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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=31)	Treatment Group: Placebo (N=41)
TOTAL	0	1 (2.4%)
NEUROSIS	0	1 (2.4%)

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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 : Mild, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=15)	Treatment Group: Placebo (N=26)
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=15)	Treatment Group: Placebo (N=26)
TOTAL	0	0

BRL 29060 - 704

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=15)	Treatment Group: Placebo (N=26)
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=16)	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, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=16)	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, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=16)	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 : Adolescents, Intensity : Mild, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=29)	Treatment Group: Placebo (N=33)
TOTAL	3 (10.3%)	2 (6.1%)
ARTHRALGIA	1 (3.4%)	0
MYALGIA	1 (3.4%)	0
PARESTHESIA	1 (3.4%)	0
SINUSITIS	1 (3.4%)	0
NAUSEA	0	1 (3.0%)
RHINITIS	0	1 (3.0%)

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 : Adolescents, Intensity : Moderate, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=29)	Treatment Group: Placebo (N=33)
TOTAL	2 (6.9%)	3 (9.1%)
NERVOUSNESS	1 (3.4%)	2 (6.1%)
DIARRHEA	1 (3.4%)	0
ASTHENIA	0	2 (6.1%)
DECREASED APPETITE	0	1 (3.0%)
HEADACHE	0	1 (3.0%)
VASODILATATION	0	1 (3.0%)

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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, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=29)	Treatment Group: Placebo (N=33)
TOTAL	1 (3.4%)	0
ANXIETY	1 (3.4%)	0

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Table 15.1.3.2.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase by Intensity by Descending Order. Intention-To-Treat Population Entering The Taper Phase

Age Group : Adolescents, Intensity : Mild, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=16)	Treatment Group: Placebo (N=21)
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=16)	Treatment Group: Placebo (N=21)
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 : Adolescents, Intensity : Severe, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=16)	Treatment Group: Placebo (N=21)
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=13)	Treatment Group: Placebo (N=12)
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 : Adolescents, Intensity : Moderate, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=13)	Treatment Group: Placebo (N=12)
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=13)	Treatment Group: Placebo (N=12)
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 : Mild, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=60)	Treatment Group: Placebo (N=74)
TOTAL	6 (10.0%)	8 (10.8%)
HEADACHE	2 (3.3%)	1 (1.4%)
INFECTION	1 (1.7%)	2 (2.7%)
RHINITIS	1 (1.7%)	2 (2.7%)
ALLERGIC REACTION	1 (1.7%)	0
ARTHRALGIA	1 (1.7%)	0
DIZZINESS	1 (1.7%)	0
MYALGIA	1 (1.7%)	0
PARESTHESIA	1 (1.7%)	0
SINUSITIS	1 (1.7%)	0
ULCERATIVE STOMATITIS	1 (1.7%)	0
NEUROSIS	0	2 (2.7%)
ABDOMINAL PAIN	0	1 (1.4%)
CONJUNCTIVITIS	0	1 (1.4%)
NAUSEA	0	1 (1.4%)

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=60)	Treatment Group: Placebo (N=74)
TOTAL	2 (3.3%)	6 (8.1%)
NERVOUSNESS	1 (1.7%)	2 (2.7%)
DIARRHEA	1 (1.7%)	0
HEADACHE	0	3 (4.1%)
ASTHENIA	0	2 (2.7%)
DECREASED APPETITE	0	1 (1.4%)
EAR PAIN	0	1 (1.4%)
OTITIS MEDIA	0	1 (1.4%)
VASODILATATION	0	1 (1.4%)

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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 : Total, Intensity : Severe, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=60)	Treatment Group: Placebo (N=74)
TOTAL	1 (1.7%)	1 (1.4%)
ANXIETY	1 (1.7%)	0
NEUROSIS	0	1 (1.4%)

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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 : Total, Intensity : Mild, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=31)	Treatment Group: Placebo (N=47)
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=31)	Treatment Group: Placebo (N=47)
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=31)	Treatment Group: Placebo (N=47)
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 : Mild, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=29)	Treatment Group: Placebo (N=27)
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 : Moderate, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=29)	Treatment Group: Placebo (N=27)
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=29)	Treatment Group: Placebo (N=27)
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=98)	Treatment Group: Placebo (N=105)
TOTAL	TOTAL	60 (61.2%)	70 (66.7%)
Body as a Whole	TOTAL	40 (40.8%)	36 (34.3%)
	HEADACHE	20 (20.4%)	17 (16.2%)
	ABDOMINAL PAIN	16 (16.3%)	10 (9.5%)
	TRAUMA	5 (5.1%)	2 (1.9%)
	ASTHENIA	5 (5.1%)	1 (1.0%)
	ALLERGIC REACTION	4 (4.1%)	4 (3.8%)
	FEVER	4 (4.1%)	3 (2.9%)
	PAIN	4 (4.1%)	3 (2.9%)
	INFECTION	3 (3.1%)	9 (8.6%)
	CHEST PAIN	2 (2.0%)	0
	BACK PAIN	1 (1.0%)	1 (1.0%)
Digestive System	TOTAL	30 (30.6%)	22 (21.0%)
	NAUSEA	12 (12.2%)	9 (8.6%)
	DECREASED APPETITE	8 (8.2%)	1 (1.0%)
	DIARRHEA	7 (7.1%)	2 (1.9%)
	VOMITING	5 (5.1%)	1 (1.0%)
	DRY MOUTH	3 (3.1%)	5 (4.8%)
	ULCERATIVE STOMATITIS	2 (2.0%)	0
	DYSPEPSIA	1 (1.0%)	3 (2.9%)
	GASTROINTESTINAL DISORDER	1 (1.0%)	2 (1.9%)
	COLITIS	1 (1.0%)	0
	FLATULENCE	1 (1.0%)	0
	INCREASED APPETITE	1 (1.0%)	0
	TOOTH DISORDER	1 (1.0%)	0
	CONSTIPATION	0	2 (1.9%)
	GASTROENTERITIS	0	1 (1.0%)
	GINGIVITIS	0	1 (1.0%)
Nervous System	TOTAL	23 (23.5%)	20 (19.0%)
	INSOMNIA	6 (6.1%)	4 (3.8%)
	HYPERKINESIA	6 (6.1%)	3 (2.9%)
	SOMNOLENCE	6 (6.1%)	2 (1.9%)
	DIZZINESS	4 (4.1%)	6 (5.7%)
	NERVOUSNESS	2 (2.0%)	2 (1.9%)
	NEUROSIS	2 (2.0%)	2 (1.9%)
	ANXIETY	2 (2.0%)	0
	HOSTILITY	2 (2.0%)	0
	TREMOR	2 (2.0%)	0
	ABNORMAL DREAMS	1 (1.0%)	1 (1.0%)
	AGITATION	1 (1.0%)	0
	CONCENTRATION IMPAIRED	1 (1.0%)	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=98)	Treatment Group: Placebo (N=105)
Nervous System	DIPLOPIA	1 (1.0%)	0
	PARESTHESIA	1 (1.0%)	0
	PERSONALITY DISORDER	1 (1.0%)	0
	MYOCLONUS	0	2 (1.9%)
	NYSTAGMUS	0	1 (1.0%)
Respiratory System	TOTAL	21 (21.4%)	27 (25.7%)
	RESPIRATORY DISORDER	8 (8.2%)	10 (9.5%)
	PHARYNGITIS	7 (7.1%)	4 (3.8%)
	RHINITIS	5 (5.1%)	8 (7.6%)
	SINUSITIS	4 (4.1%)	4 (3.8%)
	COUGH INCREASED	2 (2.0%)	6 (5.7%)
	EPISTAXIS	2 (2.0%)	0
	STRIDOR	1 (1.0%)	0
	YAWN	1 (1.0%)	0
Special Senses	TOTAL	5 (5.1%)	5 (4.8%)
	CONJUNCTIVITIS	2 (2.0%)	1 (1.0%)
	EAR PAIN	1 (1.0%)	0
	KERATOCONJUNCTIVITIS	1 (1.0%)	0
	MYDRIASIS	1 (1.0%)	0
	OTITIS MEDIA	0	2 (1.9%)
	ABNORMAL VISION	0	1 (1.0%)
	OTITIS EXTERNA	0	1 (1.0%)
Urogenital System	TOTAL	5 (5.1%)	4 (3.8%)
	URINARY INCONTINENCE	2 (2.0%)	1 (1.0%)
	HAEMATURIA	1 (1.0%)	1 (1.0%)
	ALBUMINURIA	1 (1.0%)	0
	URINARY FREQUENCY	1 (1.0%)	0
	URINARY TRACT INFECTION	0	2 (1.9%)
Skin and Appendages	TOTAL	4 (4.1%)	5 (4.8%)
	SWEATING	2 (2.0%)	0
	PHOTOSENSITIVITY	1 (1.0%)	0
	PUSTULAR RASH	1 (1.0%)	0
	DRY SKIN	0	1 (1.0%)
	FUNGAL DERMATITIS	0	1 (1.0%)
	HERPES SIMPLEX	0	1 (1.0%)
	RASH	0	1 (1.0%)
	SKIN BENIGN NEOPLASM	0	1 (1.0%)
Musculoskeletal System	TOTAL	3 (3.1%)	2 (1.9%)
	MYALGIA	2 (2.0%)	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 : Mild, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=98)	Treatment Group: Placebo (N=105)
Musculoskeletal System	ARTHRALGIA	1 (1.0%)	1 (1.0%)
Cardiovascular System	TOTAL	1 (1.0%)	1 (1.0%)
	VASODILATATION	1 (1.0%)	1 (1.0%)
Hemic and Lymphatic System	TOTAL	1 (1.0%)	1 (1.0%)
	ANEMIA	1 (1.0%)	0
	LEUKOPENIA	0	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (1.0%)	1 (1.0%)
	PERIPHERAL EDEMA	1 (1.0%)	0
	THIRST	0	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, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=98)	Treatment Group: Placebo (N=105)
TOTAL	TOTAL	49 (50.0%)	40 (38.1%)
Nervous System	TOTAL	27 (27.6%)	15 (14.3%)
	HYPERKINESIA	7 (7.1%)	4 (3.8%)
	SOMNOLENCE	6 (6.1%)	4 (3.8%)
	HOSTILITY	5 (5.1%)	1 (1.0%)
	NERVOUSNESS	4 (4.1%)	7 (6.7%)
	AGITATION	3 (3.1%)	2 (1.9%)
	INSOMNIA	3 (3.1%)	2 (1.9%)
	NEUROSIS	3 (3.1%)	0
	DIZZINESS	2 (2.0%)	2 (1.9%)
	EMOTIONAL LABILITY	2 (2.0%)	0
	PERSONALITY DISORDER	2 (2.0%)	0
	SPEECH DISORDER	2 (2.0%)	0
	CONCENTRATION IMPAIRED	1 (1.0%)	1 (1.0%)
	DEPERSONALIZATION	1 (1.0%)	1 (1.0%)
	INCOORDINATION	1 (1.0%)	0
Body as a Whole	TOTAL	16 (16.3%)	23 (21.9%)
	HEADACHE	6 (6.1%)	9 (8.6%)
	INFECTION	3 (3.1%)	6 (5.7%)
	ASTHENIA	3 (3.1%)	2 (1.9%)
	TRAUMA	3 (3.1%)	1 (1.0%)
	ABDOMINAL PAIN	2 (2.0%)	4 (3.8%)
	ALLERGIC REACTION	1 (1.0%)	0
	CHEST PAIN	1 (1.0%)	0
	PAIN	1 (1.0%)	0
	FEVER	0	4 (3.8%)
Digestive System	TOTAL	13 (13.3%)	6 (5.7%)
	NAUSEA	4 (4.1%)	2 (1.9%)
	CONSTIPATION	2 (2.0%)	1 (1.0%)
	DYSPEPSIA	2 (2.0%)	1 (1.0%)
	DIARRHEA	2 (2.0%)	0
	DECREASED APPETITE	1 (1.0%)	1 (1.0%)
	DRY MOUTH	1 (1.0%)	1 (1.0%)
	VOMITING	1 (1.0%)	1 (1.0%)
	BRUXISM	1 (1.0%)	0
	FLATULENCE	1 (1.0%)	0
	GASTROINTESTINAL DISORDER	1 (1.0%)	0
	STOMATITIS	1 (1.0%)	0
	TOOTH CARIES	1 (1.0%)	0
Respiratory System	TOTAL	10 (10.2%)	10 (9.5%)

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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=98)	Treatment Group: Placebo (N=105)
Respiratory System	RESPIRATORY DISORDER	5 (5.1%)	5 (4.8%)
	SINUSITIS	2 (2.0%)	2 (1.9%)
	ASTHMA	2 (2.0%)	0
	EPISTAXIS	2 (2.0%)	0
	PHARYNGITIS	1 (1.0%)	2 (1.9%)
	RHINITIS	1 (1.0%)	2 (1.9%)
	COUGH INCREASED	1 (1.0%)	0
Cardiovascular System	TOTAL	2 (2.0%)	1 (1.0%)
	VASODILATATION	1 (1.0%)	1 (1.0%)
	HYPERTENSION	1 (1.0%)	0
Musculoskeletal System	TOTAL	2 (2.0%)	1 (1.0%)
	MYALGIA	1 (1.0%)	1 (1.0%)
	ARTHRALGIA	1 (1.0%)	0
Skin and Appendages	TOTAL	2 (2.0%)	0
	ACNE	1 (1.0%)	0
	SWEATING	1 (1.0%)	0
Urogenital System	TOTAL	2 (2.0%)	1 (1.0%)
	CYSTITIS	1 (1.0%)	0
	URINARY RETENTION	1 (1.0%)	0
	URINARY INCONTINENCE	0	1 (1.0%)
Endocrine System	TOTAL	1 (1.0%)	0
	THYROID DISORDER	1 (1.0%)	0
Metabolic and Nutritional Disorders	TOTAL	1 (1.0%)	1 (1.0%)
	WEIGHT LOSS	1 (1.0%)	0
	THIRST	0	1 (1.0%)
Special Senses	TOTAL	1 (1.0%)	3 (2.9%)
	OTITIS MEDIA	1 (1.0%)	1 (1.0%)
	OTITIS EXTERNA	1 (1.0%)	0
	EAR PAIN	0	2 (1.9%)
	EAR DISORDER	0	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 : Severe, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=98)	Placebo (N=105)
TOTAL	TOTAL	9 (9.2%)	6 (5.7%)
Nervous System	TOTAL	6 (6.1%)	5 (4.8%)
	HOSTILITY	2 (2.0%)	0
	ANXIETY	1 (1.0%)	1 (1.0%)
	AGITATION	1 (1.0%)	0
	DEPRESSION	1 (1.0%)	0
	EMOTIONAL LABILITY	1 (1.0%)	0
	HYPERKINESIA	1 (1.0%)	0
	NEUROSIS	0	2 (1.9%)
	DIZZINESS	0	1 (1.0%)
	SOMNOLENCE	0	1 (1.0%)
Body as a Whole	TOTAL	3 (3.1%)	0
	TRAUMA	2 (2.0%)	0
	HEADACHE	1 (1.0%)	0
Special Senses	TOTAL	0	1 (1.0%)
	OTITIS MEDIA	0	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 : Mild, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=64)
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

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=64)
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 : Severe, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=64)
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=45)	 Placebo (N=41)
TOTAL	TOTAL	0	1 (2.4%)
Urogenital System	TOTAL	0	1 (2.4%)
	DYSMENORRHEA	0	1 (2.4%)

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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=45)	 Placebo (N=41)
TOTAL	TOTAL	2 (4.4%)	0
Urogenital System	TOTAL	2 (4.4%)	0
	DYSMENORRHEA	2 (4.4%)	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, Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=45)	Treatment Group: Placebo (N=41)
TOTAL	TOTAL	1 (2.2%)	0
Urogenital System	TOTAL	1 (2.2%)	0
	DYSMENORRHEA	1 (2.2%)	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=37)	Placebo (N=39)
Body System	Preferred Term		
TOTAL	TOTAL	4 (10.8%)	2 (5.1%)
Body as a Whole	TOTAL	2 (5.4%)	0
	HEADACHE	2 (5.4%)	0
Digestive System	TOTAL	2 (5.4%)	1 (2.6%)
	NAUSEA	1 (2.7%)	0
	VOMITING	1 (2.7%)	0
	DRY MOUTH	0	1 (2.6%)
Nervous System	TOTAL	1 (2.7%)	0
	NERVOUSNESS	1 (2.7%)	0
Urogenital System	TOTAL	0	1 (2.6%)
	ALBUMINURIA	0	1 (2.6%)
	HAEMATURIA	0	1 (2.6%)

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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=37)	 Placebo (N=39)
TOTAL	TOTAL	3 (8.1%)	1 (2.6%)
Digestive System	TOTAL	2 (5.4%)	0
	VOMITING	2 (5.4%)	0
	NAUSEA	1 (2.7%)	0
Respiratory System	TOTAL	1 (2.7%)	0
	RESPIRATORY DISORDER	1 (2.7%)	0
Nervous System	TOTAL	0	1 (2.6%)
	INSOMNIA	0	1 (2.6%)

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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=37)	 Placebo (N=39)
TOTAL	TOTAL	2 (5.4%)	0
Digestive System	TOTAL	1 (2.7%)	0
	VOMITING	1 (2.7%)	0
Nervous System	TOTAL	1 (2.7%)	0
	HOSTILITY	1 (2.7%)	0

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=20)	Placebo (N=22)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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=20)	Placebo (N=22)
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=20)	Placebo (N=22)
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

Body System	Preferred Term	Treatment Group Paroxetine (N=17)	Placebo (N=17)
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, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=17)	Placebo (N=17)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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=17)	Placebo (N=17)
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=37)	 Placebo (N=39)
TOTAL	4 (10.8%)	2 (5.1%)
HEADACHE	2 (5.4%)	0
NAUSEA	1 (2.7%)	0
NERVOUSNESS	1 (2.7%)	0
VOMITING	1 (2.7%)	0
ALBUMINURIA	0	1 (2.6%)
DRY MOUTH	0	1 (2.6%)
HAEMATURIA	0	1 (2.6%)

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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=37)	Treatment Group: Placebo (N=39)
TOTAL	3 (8.1%)	1 (2.6%)
VOMITING	2 (5.4%)	0
NAUSEA	1 (2.7%)	0
RESPIRATORY DISORDER	1 (2.7%)	0
INSOMNIA	0	1 (2.6%)

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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=37)	Treatment Group: Placebo (N=39)
TOTAL	2 (5.4%)	0
HOSTILITY	1 (2.7%)	0
VOMITING	1 (2.7%)	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=20)	Treatment Group: Placebo (N=22)
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=20)	Treatment Group: Placebo (N=22)
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=20)	Treatment Group: Placebo (N=22)
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=17)	Treatment Group: Placebo (N=17)
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, Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=17)	Treatment Group: Placebo (N=17)
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=17)	Treatment Group: Placebo (N=17)
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=58)	Treatment Group: Placebo (N=57)
TOTAL	TOTAL	37 (63.8%)	27 (47.4%)
Nervous System	TOTAL	26 (44.8%)	14 (24.6%)
	HYPERKINESIA	9 (15.5%)	4 (7.0%)
	HOSTILITY	7 (12.1%)	0
	INSOMNIA	6 (10.3%)	2 (3.5%)
	SOMNOLENCE	5 (8.6%)	3 (5.3%)
	NERVOUSNESS	4 (6.9%)	2 (3.5%)
	NEUROSIS	4 (6.9%)	1 (1.8%)
	AGITATION	3 (5.2%)	0
	PERSONALITY DISORDER	3 (5.2%)	0
	CONCENTRATION IMPAIRED	2 (3.4%)	1 (1.8%)
	SPEECH DISORDER	2 (3.4%)	0
	TREMOR	2 (3.4%)	0
	DIZZINESS	1 (1.7%)	2 (3.5%)
	ANXIETY	1 (1.7%)	0
	DIPLOPIA	1 (1.7%)	0
	EMOTIONAL LABILITY	1 (1.7%)	0
	INCOORDINATION	1 (1.7%)	0
	MYOCLONUS	0	1 (1.8%)
Body as a Whole	TOTAL	15 (25.9%)	15 (26.3%)
	HEADACHE	10 (17.2%)	9 (15.8%)
	ABDOMINAL PAIN	7 (12.1%)	5 (8.8%)
	ASTHENIA	3 (5.2%)	1 (1.8%)
	CHEST PAIN	2 (3.4%)	0
	INFECTION	0	2 (3.5%)
	ALLERGIC REACTION	0	1 (1.8%)
	FEVER	0	1 (1.8%)
Digestive System	TOTAL	12 (20.7%)	10 (17.5%)
	DECREASED APPETITE	5 (8.6%)	1 (1.8%)
	NAUSEA	4 (6.9%)	4 (7.0%)
	DIARRHEA	2 (3.4%)	1 (1.8%)
	CONSTIPATION	1 (1.7%)	3 (5.3%)
	DRY MOUTH	1 (1.7%)	3 (5.3%)
	DYSPEPSIA	1 (1.7%)	1 (1.8%)
	GASTROINTESTINAL DISORDER	1 (1.7%)	1 (1.8%)
	VOMITING	0	1 (1.8%)
Skin and Appendages	TOTAL	3 (5.2%)	0
	SWEATING	2 (3.4%)	0
	PHOTOSENSITIVITY	1 (1.7%)	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=58)	 Placebo (N=57)
Urogenital System	TOTAL	3 (5.2%)	1 (1.8%)
	URINARY INCONTINENCE	2 (3.4%)	1 (1.8%)
	URINARY RETENTION	1 (1.7%)	0
Respiratory System	TOTAL	2 (3.4%)	3 (5.3%)
	EPISTAXIS	2 (3.4%)	0
	RHINITIS	0	3 (5.3%)
Cardiovascular System	TOTAL	1 (1.7%)	0
	VASODILATATION	1 (1.7%)	0
Musculoskeletal System	TOTAL	1 (1.7%)	0
	MYALGIA	1 (1.7%)	0
Metabolic and Nutritional Disorders	TOTAL	0	1 (1.8%)
	THIRST	0	1 (1.8%)

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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=31)	Placebo (N=35)
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=27)	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=40)	Treatment Group: Placebo (N=48)
TOTAL	TOTAL	23 (57.5%)	17 (35.4%)
Digestive System	TOTAL	13 (32.5%)	2 (4.2%)
	NAUSEA	6 (15.0%)	0
	DECREASED APPETITE	3 (7.5%)	0
	DRY MOUTH	2 (5.0%)	2 (4.2%)
	BRUXISM	1 (2.5%)	0
	CONSTIPATION	1 (2.5%)	0
	DIARRHEA	1 (2.5%)	0
	FLATULENCE	1 (2.5%)	0
	GASTROINTESTINAL DISORDER	1 (2.5%)	0
	VOMITING	1 (2.5%)	0
Body as a Whole	TOTAL	11 (27.5%)	8 (16.7%)
	HEADACHE	7 (17.5%)	7 (14.6%)
	ASTHENIA	5 (12.5%)	0
	ABDOMINAL PAIN	3 (7.5%)	1 (2.1%)
	PAIN	1 (2.5%)	0
	FEVER	0	1 (2.1%)
Nervous System	TOTAL	11 (27.5%)	11 (22.9%)
	SOMNOLENCE	7 (17.5%)	4 (8.3%)
	DIZZINESS	3 (7.5%)	3 (6.3%)
	INSOMNIA	2 (5.0%)	3 (6.3%)
	HYPERKINESIA	2 (5.0%)	2 (4.2%)
	NERVOUSNESS	1 (2.5%)	4 (8.3%)
	AGITATION	1 (2.5%)	2 (4.2%)
	ANXIETY	1 (2.5%)	1 (2.1%)
	ABNORMAL DREAMS	0	1 (2.1%)
Respiratory System	TOTAL	3 (7.5%)	2 (4.2%)
	EPISTAXIS	1 (2.5%)	0
	PHARYNGITIS	1 (2.5%)	0
	YAWN	1 (2.5%)	0
	RHINITIS	0	2 (4.2%)
	RESPIRATORY DISORDER	0	1 (2.1%)
Cardiovascular System	TOTAL	2 (5.0%)	1 (2.1%)
	VASODILATATION	1 (2.5%)	1 (2.1%)
	HYPERTENSION	1 (2.5%)	0
Metabolic and Nutritional Disorders	TOTAL	1 (2.5%)	0
	WEIGHT LOSS	1 (2.5%)	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=40)	Treatment Group: Placebo (N=48)
Special Senses	TOTAL	1 (2.5%)	0
	MYDRIASIS	1 (2.5%)	0
Urogenital System	TOTAL	1 (2.5%)	1 (2.1%)
	URINARY FREQUENCY	1 (2.5%)	0
	HAEMATURIA	0	1 (2.1%)
Hemic and Lymphatic System	TOTAL	0	1 (2.1%)
	LEUKOPENIA	0	1 (2.1%)
Musculoskeletal System	TOTAL	0	1 (2.1%)
	ARTHRALGIA	0	1 (2.1%)

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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=22)	Placebo (N=29)
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, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=18)	Placebo (N=19)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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=98)	Treatment Group: Placebo (N=105)
TOTAL	TOTAL	60 (61.2%)	44 (41.9%)
Nervous System	TOTAL	37 (37.8%)	25 (23.8%)
	SOMNOLENCE	12 (12.2%)	7 (6.7%)
	HYPERKINESIA	11 (11.2%)	6 (5.7%)
	INSOMNIA	8 (8.2%)	5 (4.8%)
	HOSTILITY	7 (7.1%)	0
	NERVOUSNESS	5 (5.1%)	6 (5.7%)
	DIZZINESS	4 (4.1%)	5 (4.8%)
	AGITATION	4 (4.1%)	2 (1.9%)
	NEUROSIS	4 (4.1%)	1 (1.0%)
	PERSONALITY DISORDER	3 (3.1%)	0
	ANXIETY	2 (2.0%)	1 (1.0%)
	CONCENTRATION IMPAIRED	2 (2.0%)	1 (1.0%)
	SPEECH DISORDER	2 (2.0%)	0
	TREMOR	2 (2.0%)	0
	DIPLOPIA	1 (1.0%)	0
	EMOTIONAL LABILITY	1 (1.0%)	0
	INCOORDINATION	1 (1.0%)	0
	ABNORMAL DREAMS	0	1 (1.0%)
	MYOCLONUS	0	1 (1.0%)
Body as a Whole	TOTAL	26 (26.5%)	23 (21.9%)
	HEADACHE	17 (17.3%)	16 (15.2%)
	ABDOMINAL PAIN	10 (10.2%)	6 (5.7%)
	ASTHENIA	8 (8.2%)	1 (1.0%)
	CHEST PAIN	2 (2.0%)	0
	PAIN	1 (1.0%)	0
	FEVER	0	2 (1.9%)
	INFECTION	0	2 (1.9%)
	ALLERGIC REACTION	0	1 (1.0%)
Digestive System	TOTAL	25 (25.5%)	12 (11.4%)
	NAUSEA	10 (10.2%)	4 (3.8%)
	DECREASED APPETITE	8 (8.2%)	1 (1.0%)
	DRY MOUTH	3 (3.1%)	5 (4.8%)
	DIARRHEA	3 (3.1%)	1 (1.0%)
	CONSTIPATION	2 (2.0%)	3 (2.9%)
	GASTROINTESTINAL DISORDER	2 (2.0%)	1 (1.0%)
	DYSPEPSIA	1 (1.0%)	1 (1.0%)
	VOMITING	1 (1.0%)	1 (1.0%)
	BRUXISM	1 (1.0%)	0
	FLATULENCE	1 (1.0%)	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 : Total, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=98)	Treatment Group: Placebo (N=105)
Respiratory System	TOTAL	5 (5.1%)	5 (4.8%)
	EPISTAXIS	3 (3.1%)	0
	PHARYNGITIS	1 (1.0%)	0
	YAWN	1 (1.0%)	0
	RHINITIS	0	5 (4.8%)
	RESPIRATORY DISORDER	0	1 (1.0%)
Urogenital System	TOTAL	4 (4.1%)	2 (1.9%)
	URINARY INCONTINENCE	2 (2.0%)	1 (1.0%)
	URINARY FREQUENCY	1 (1.0%)	0
	URINARY RETENTION	1 (1.0%)	0
	HAEMATURIA	0	1 (1.0%)
Cardiovascular System	TOTAL	3 (3.1%)	1 (1.0%)
	VASODILATATION	2 (2.0%)	1 (1.0%)
	HYPERTENSION	1 (1.0%)	0
Skin and Appendages	TOTAL	3 (3.1%)	0
	SWEATING	2 (2.0%)	0
	PHOTOSENSITIVITY	1 (1.0%)	0
Metabolic and Nutritional Disorders	TOTAL	1 (1.0%)	1 (1.0%)
	WEIGHT LOSS	1 (1.0%)	0
	THIRST	0	1 (1.0%)
Musculoskeletal System	TOTAL	1 (1.0%)	1 (1.0%)
	MYALGIA	1 (1.0%)	0
	ARTHRALGIA	0	1 (1.0%)
Special Senses	TOTAL	1 (1.0%)	0
	MYDRIASIS	1 (1.0%)	0
Hemic and Lymphatic System	TOTAL	0	1 (1.0%)
	LEUKOPENIA	0	1 (1.0%)

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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, Male Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=53)	Treatment Group: Placebo (N=64)
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 : Total, Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=45)	Placebo (N=41)
Body System	Preferred Term		
TOTAL	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, Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=58)	 Placebo (N=57)
TOTAL	37 (63.8%)	27 (47.4%)
HEADACHE	10 (17.2%)	9 (15.8%)
HYPERKINESIA	9 (15.5%)	4 (7.0%)
ABDOMINAL PAIN	7 (12.1%)	5 (8.8%)
HOSTILITY	7 (12.1%)	0
INSOMNIA	6 (10.3%)	2 (3.5%)
SOMNOLENCE	5 (8.6%)	3 (5.3%)
DECREASED APPETITE	5 (8.6%)	1 (1.8%)
NAUSEA	4 (6.9%)	4 (7.0%)
NERVOUSNESS	4 (6.9%)	2 (3.5%)
NEUROSIS	4 (6.9%)	1 (1.8%)
ASTHENIA	3 (5.2%)	1 (1.8%)
AGITATION	3 (5.2%)	0
PERSONALITY DISORDER	3 (5.2%)	0
CONCENTRATION IMPAIRED	2 (3.4%)	1 (1.8%)
DIARRHEA	2 (3.4%)	1 (1.8%)
URINARY INCONTINENCE	2 (3.4%)	1 (1.8%)
CHEST PAIN	2 (3.4%)	0
EPISTAXIS	2 (3.4%)	0
SPEECH DISORDER	2 (3.4%)	0
SWEATING	2 (3.4%)	0
TREMOR	2 (3.4%)	0
CONSTIPATION	1 (1.7%)	3 (5.3%)
DRY MOUTH	1 (1.7%)	3 (5.3%)
DIZZINESS	1 (1.7%)	2 (3.5%)
DYSPEPSIA	1 (1.7%)	1 (1.8%)
GASTROINTESTINAL DISORDER	1 (1.7%)	1 (1.8%)
ANXIETY	1 (1.7%)	0
DIPLOPIA	1 (1.7%)	0
EMOTIONAL LABILITY	1 (1.7%)	0
INCOORDINATION	1 (1.7%)	0
MYALGIA	1 (1.7%)	0
PHOTOSENSITIVITY	1 (1.7%)	0
URINARY RETENTION	1 (1.7%)	0
VASODILATATION	1 (1.7%)	0
RHINITIS	0	3 (5.3%)
INFECTION	0	2 (3.5%)
ALLERGIC REACTION	0	1 (1.8%)
FEVER	0	1 (1.8%)
MYOCLONUS	0	1 (1.8%)
THIRST	0	1 (1.8%)
VOMITING	0	1 (1.8%)

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Table 15.1.4.1.X

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Treatment Phase by Descending Order
Intention-To-Treat Population
Age Group : Children, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=31)	Treatment Group: Placebo (N=35)
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=27)	Treatment Group: 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=40)	Treatment Group: Placebo (N=48)
TOTAL	23 (57.5%)	17 (35.4%)
HEADACHE	7 (17.5%)	7 (14.6%)
SOMNOLENCE	7 (17.5%)	4 (8.3%)
NAUSEA	6 (15.0%)	0
ASTHENIA	5 (12.5%)	0
DIZZINESS	3 (7.5%)	3 (6.3%)
ABDOMINAL PAIN	3 (7.5%)	1 (2.1%)
DECREASED APPETITE	3 (7.5%)	0
INSOMNIA	2 (5.0%)	3 (6.3%)
DRY MOUTH	2 (5.0%)	2 (4.2%)
HYPERKINESIA	2 (5.0%)	2 (4.2%)
NERVOUSNESS	1 (2.5%)	4 (8.3%)
AGITATION	1 (2.5%)	2 (4.2%)
ANXIETY	1 (2.5%)	1 (2.1%)
VASODILATATION	1 (2.5%)	1 (2.1%)
BRUXISM	1 (2.5%)	0
CONSTIPATION	1 (2.5%)	0
DIARRHEA	1 (2.5%)	0
EPISTAXIS	1 (2.5%)	0
FLATULENCE	1 (2.5%)	0
GASTROINTESTINAL DISORDER	1 (2.5%)	0
HYPERTENSION	1 (2.5%)	0
MYDRIASIS	1 (2.5%)	0
PAIN	1 (2.5%)	0
PHARYNGITIS	1 (2.5%)	0
URINARY FREQUENCY	1 (2.5%)	0
VOMITING	1 (2.5%)	0
WEIGHT LOSS	1 (2.5%)	0
YAWN	1 (2.5%)	0
RHINITIS	0	2 (4.2%)
ABNORMAL DREAMS	0	1 (2.1%)
ARTHRALGIA	0	1 (2.1%)
FEVER	0	1 (2.1%)
HAEMATURIA	0	1 (2.1%)
LEUKOPENIA	0	1 (2.1%)
RESPIRATORY DISORDER	0	1 (2.1%)

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Table 15.1.4.1.X

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Treatment Phase by Descending Order
Intention-To-Treat Population
Age Group : Adolescents, Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=22)	Treatment Group: Placebo (N=29)
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=18)	Treatment Group: Placebo (N=19)
TOTAL	0	0

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=98)	 Placebo (N=105)
TOTAL	60 (61.2%)	44 (41.9%)
HEADACHE	17 (17.3%)	16 (15.2%)
SOMNOLENCE	12 (12.2%)	7 (6.7%)
HYPERKINESIA	11 (11.2%)	6 (5.7%)
ABDOMINAL PAIN	10 (10.2%)	6 (5.7%)
NAUSEA	10 (10.2%)	4 (3.8%)
INSOMNIA	8 (8.2%)	5 (4.8%)
ASTHENIA	8 (8.2%)	1 (1.0%)
DECREASED APPETITE	8 (8.2%)	1 (1.0%)
HOSTILITY	7 (7.1%)	0
NERVOUSNESS	5 (5.1%)	6 (5.7%)
DIZZINESS	4 (4.1%)	5 (4.8%)
AGITATION	4 (4.1%)	2 (1.9%)
NEUROSIS	4 (4.1%)	1 (1.0%)
DRY MOUTH	3 (3.1%)	5 (4.8%)
DIARRHEA	3 (3.1%)	1 (1.0%)
EPISTAXIS	3 (3.1%)	0
PERSONALITY DISORDER	3 (3.1%)	0
CONSTIPATION	2 (2.0%)	3 (2.9%)
ANXIETY	2 (2.0%)	1 (1.0%)
CONCENTRATION IMPAIRED	2 (2.0%)	1 (1.0%)
GASTROINTESTINAL DISORDER	2 (2.0%)	1 (1.0%)
URINARY INCONTINENCE	2 (2.0%)	1 (1.0%)
VASODILATATION	2 (2.0%)	1 (1.0%)
CHEST PAIN	2 (2.0%)	0
SPEECH DISORDER	2 (2.0%)	0
SWEATING	2 (2.0%)	0
TREMOR	2 (2.0%)	0
DYSPEPSIA	1 (1.0%)	1 (1.0%)
VOMITING	1 (1.0%)	1 (1.0%)
BRUXISM	1 (1.0%)	0
DIPLOPIA	1 (1.0%)	0
EMOTIONAL LABILITY	1 (1.0%)	0
FLATULENCE	1 (1.0%)	0
HYPERTENSION	1 (1.0%)	0
INCOORDINATION	1 (1.0%)	0
MYALGIA	1 (1.0%)	0
MYDRIASIS	1 (1.0%)	0
PAIN	1 (1.0%)	0
PHARYNGITIS	1 (1.0%)	0
PHOTOSENSITIVITY	1 (1.0%)	0
URINARY FREQUENCY	1 (1.0%)	0
URINARY RETENTION	1 (1.0%)	0
WEIGHT LOSS	1 (1.0%)	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=98)	 Placebo (N=105)
YAWN	1 (1.0%)	0
RHINITIS	0	5 (4.8%)
FEVER	0	2 (1.9%)
INFECTION	0	2 (1.9%)
ABNORMAL DREAMS	0	1 (1.0%)
ALLERGIC REACTION	0	1 (1.0%)
ARTHRALGIA	0	1 (1.0%)
HAEMATURIA	0	1 (1.0%)
LEUKOPENIA	0	1 (1.0%)
MYOCLONUS	0	1 (1.0%)
RESPIRATORY DISORDER	0	1 (1.0%)
THIRST	0	1 (1.0%)

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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=53)	 Placebo (N=64)
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=45)	 Placebo (N=41)
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

Body System	Preferred Term	Treatment Group Paroxetine (N=31)	 Placebo (N=41)
TOTAL	TOTAL	2 (6.5%)	5 (12.2%)
Body as a Whole	TOTAL	2 (6.5%)	2 (4.9%)
	HEADACHE	2 (6.5%)	2 (4.9%)
Nervous System	TOTAL	1 (3.2%)	3 (7.3%)
	DIZZINESS	1 (3.2%)	0
	NEUROSIS	0	3 (7.3%)
Respiratory System	TOTAL	0	1 (2.4%)
	RHINITIS	0	1 (2.4%)
Special Senses	TOTAL	0	1 (2.4%)
	CONJUNCTIVITIS	0	1 (2.4%)

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Table 15.1.4.2

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Taper Phase
By Body System
Intention-To-Treat Population Entering The Taper Phase
Age Group : Children, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=15)	Placebo (N=26)
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=16)	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 : Adolescents, Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=29)	Placebo (N=33)
TOTAL	TOTAL	3 (10.3%)	2 (6.1%)
Digestive System	TOTAL	1 (3.4%)	1 (3.0%)
	DIARRHEA	1 (3.4%)	0
	DECREASED APPETITE	0	1 (3.0%)
	NAUSEA	0	1 (3.0%)
Musculoskeletal System	TOTAL	1 (3.4%)	0
	MYALGIA	1 (3.4%)	0
Nervous System	TOTAL	1 (3.4%)	2 (6.1%)
	PARESTHESIA	1 (3.4%)	0
	NERVOUSNESS	0	2 (6.1%)
Body as a Whole	TOTAL	0	2 (6.1%)
	ASTHENIA	0	2 (6.1%)
Cardiovascular System	TOTAL	0	1 (3.0%)
	VASODILATATION	0	1 (3.0%)

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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=16)	Placebo (N=21)
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=13)	Placebo (N=12)
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=60)	Treatment Group: Placebo (N=74)
TOTAL	TOTAL	5 (8.3%)	7 (9.5%)
Body as a Whole	TOTAL	2 (3.3%)	4 (5.4%)
	HEADACHE	2 (3.3%)	2 (2.7%)
	ASTHENIA	0	2 (2.7%)
Nervous System	TOTAL	2 (3.3%)	5 (6.8%)
	DIZZINESS	1 (1.7%)	0
	PARESTHESIA	1 (1.7%)	0
	NEUROSIS	0	3 (4.1%)
	NERVOUSNESS	0	2 (2.7%)
Digestive System	TOTAL	1 (1.7%)	1 (1.4%)
	DIARRHEA	1 (1.7%)	0
	DECREASED APPETITE	0	1 (1.4%)
	NAUSEA	0	1 (1.4%)
Musculoskeletal System	TOTAL	1 (1.7%)	0
	MYALGIA	1 (1.7%)	0
Cardiovascular System	TOTAL	0	1 (1.4%)
	VASODILATATION	0	1 (1.4%)
Respiratory System	TOTAL	0	1 (1.4%)
	RHINITIS	0	1 (1.4%)
Special Senses	TOTAL	0	1 (1.4%)
	CONJUNCTIVITIS	0	1 (1.4%)

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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 : Total, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=31)	Placebo (N=47)
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=29)	Placebo (N=27)
Body System	Preferred Term		
TOTAL	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=98)	Treatment Group: Placebo (N=105)
TOTAL	TOTAL	60 (61.2%)	46 (43.8%)
Nervous System	TOTAL	38 (38.8%)	28 (26.7%)
	SOMNOLENCE	12 (12.2%)	7 (6.7%)
	HYPERKINESIA	11 (11.2%)	6 (5.7%)
	INSOMNIA	8 (8.2%)	5 (4.8%)
	HOSTILITY	7 (7.1%)	0
	NERVOUSNESS	5 (5.1%)	8 (7.6%)
	DIZZINESS	5 (5.1%)	5 (4.8%)
	NEUROSIS	4 (4.1%)	4 (3.8%)
	AGITATION	4 (4.1%)	2 (1.9%)
	PERSONALITY DISORDER	3 (3.1%)	0
	ANXIETY	2 (2.0%)	1 (1.0%)
	CONCENTRATION IMPAIRED	2 (2.0%)	1 (1.0%)
	SPEECH DISORDER	2 (2.0%)	0
	TREMOR	2 (2.0%)	0
	DIPLOPIA	1 (1.0%)	0
	EMOTIONAL LABILITY	1 (1.0%)	0
	INCOORDINATION	1 (1.0%)	0
	PARESTHESIA	1 (1.0%)	0
	ABNORMAL DREAMS	0	1 (1.0%)
	MYOCLONUS	0	1 (1.0%)
Body as a Whole	TOTAL	28 (28.6%)	24 (22.9%)
	HEADACHE	19 (19.4%)	17 (16.2%)
	ABDOMINAL PAIN	10 (10.2%)	6 (5.7%)
	ASTHENIA	8 (8.2%)	3 (2.9%)
	CHEST PAIN	2 (2.0%)	0
	PAIN	1 (1.0%)	0
	FEVER	0	2 (1.9%)
	INFECTION	0	2 (1.9%)
	ALLERGIC REACTION	0	1 (1.0%)
Digestive System	TOTAL	26 (26.5%)	13 (12.4%)
	NAUSEA	10 (10.2%)	5 (4.8%)
	DECREASED APPETITE	8 (8.2%)	2 (1.9%)
	DIARRHEA	4 (4.1%)	1 (1.0%)
	DRY MOUTH	3 (3.1%)	5 (4.8%)
	CONSTIPATION	2 (2.0%)	3 (2.9%)
	GASTROINTESTINAL DISORDER	2 (2.0%)	1 (1.0%)
	DYSPEPSIA	1 (1.0%)	1 (1.0%)
	VOMITING	1 (1.0%)	1 (1.0%)
	BRUXISM	1 (1.0%)	0
	FLATULENCE	1 (1.0%)	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=98)	Treatment Group: Placebo (N=105)
Respiratory System	TOTAL	5 (5.1%)	5 (4.8%)
	EPISTAXIS	3 (3.1%)	0
	PHARYNGITIS	1 (1.0%)	0
	YAWN	1 (1.0%)	0
	RHINITIS	0	5 (4.8%)
	RESPIRATORY DISORDER	0	1 (1.0%)
Urogenital System	TOTAL	4 (4.1%)	2 (1.9%)
	URINARY INCONTINENCE	2 (2.0%)	1 (1.0%)
	URINARY FREQUENCY	1 (1.0%)	0
	URINARY RETENTION	1 (1.0%)	0
	HAEMATURIA	0	1 (1.0%)
Cardiovascular System	TOTAL	3 (3.1%)	2 (1.9%)
	VASODILATATION	2 (2.0%)	2 (1.9%)
	HYPERTENSION	1 (1.0%)	0
Skin and Appendages	TOTAL	3 (3.1%)	0
	SWEATING	2 (2.0%)	0
	PHOTOSENSITIVITY	1 (1.0%)	0
Musculoskeletal System	TOTAL	2 (2.0%)	1 (1.0%)
	MYALGIA	2 (2.0%)	0
	ARTHRALGIA	0	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (1.0%)	1 (1.0%)
	WEIGHT LOSS	1 (1.0%)	0
	THIRST	0	1 (1.0%)
Special Senses	TOTAL	1 (1.0%)	1 (1.0%)
	MYDRIASIS	1 (1.0%)	0
	CONJUNCTIVITIS	0	1 (1.0%)
Hemic and Lymphatic System	TOTAL	0	1 (1.0%)
	LEUKOPENIA	0	1 (1.0%)

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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
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=64)
Body System	Preferred Term		
TOTAL	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
Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=45)	Placebo (N=41)
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
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=37)	Treatment Group: Placebo (N=39)
TOTAL	TOTAL	3 (8.1%)	0
Body as a Whole	TOTAL	2 (5.4%)	0
	HEADACHE	2 (5.4%)	0
Digestive System	TOTAL	2 (5.4%)	0
	NAUSEA	2 (5.4%)	0
	VOMITING	1 (2.7%)	0
Nervous System	TOTAL	1 (2.7%)	0
	NERVOUSNESS	1 (2.7%)	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=20)	Placebo (N=22)
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=17)	Placebo (N=17)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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Table 15.1.5, Narratives for Patients with Non-Serious Adverse Experiences Leading to Withdrawal

SB Document Number: BRL-029060/RSD-101C1B/1

Patients With Non-Serious Adverse Experiences Leading to Withdrawal

1 Patient Identification Number: 704.002.25442

Treatment Group: Paroxetine

Adverse Experience: Hyperkinesia, Neurosis (Increase in Hyperactive and Impulsive Behavior)

This 8-year-old white male was a participant in the trial of BRL-29060/704, which was conducted in children and adolescents with obsessive-compulsive disorder (OCD).

The patient entered the study with significant previous medical conditions of hand laceration, meconium aspiration, otitis media, and scalp laceration reported. Current medical history includes allergies to cats, grass, and trees, and mild to moderate asthma. Psychiatric history (measured by K-SADS-PL interview) includes a past and current history of OCD (onset February 1998), enuresis, and attention deficit disorder (ADD), and a current history of oppositional defiant disorder (ODD), onset April 1999.

Prior medications include Claritin® (loratadine) for allergies. Previous medication which continued concomitantly was Albuterol® (salbutamol) inhaler for asthma. The patient's prior OCD medications included BuSpar® (buspirone HCl), St. John's Wort® (hypericum extract), and Prozac® (fluoxetine).

The patient was randomized to the paroxetine regimen and received the first dose of study medication on 12 May 2000. The patient began treatment at a dose of 10 mg/day. On 12 May 2000 (Day 1), the patient experienced moderately severe hyperkinesia (increase in hyperactive and impulsive behavior) and neurosis (increase in hyperactive and impulsive behavior) that lasted for seven days. No treatment was given for these non-serious events, which the investigator considered to be probably unrelated to treatment with study medication. These events, however, resulted in the withdrawal of the patient from the study. The patient discontinued study medication on 15 May 2000 (Day 4).

No other non-serious adverse events were reported.

Patients With Non-Serious Adverse Experiences Leading to Withdrawal

2 Patient Identification Number: 704.006.25421

Treatment Group: Placebo

Adverse Experience: Agitation (Panic Attacks)

This 15-year-old white male was a participant in the trial of BRL-29060/704, which was conducted in children and adolescents with obsessive-compulsive disorder (OCD).

The patient entered the study with no significant previous medical or surgical history reported. Current medical history includes dyslexia, headaches, hearing disability, and urine positive for occult blood. Psychiatric history (measured by K-SADS-PL interview) includes current OCD with an onset of January 1995, and previous history of attention deficit disorder (ADD). No other psychiatric disorders were identified.

Prior psychotropic medication included Luvox® (fluvoxamine maleate) for OCD. Previous non-psychotropic medication included ibuprofen for headache. Concomitant medications include Allegra® (fexofenadine HCl) for nasal congestion, ibuprofen for headache, and Ativan® (lorazepam) for panic attack symptoms. Post-treatment medications include Paxil® (paroxetine), Risperdal® (risperidone), and Luvox® (fluvoxamine maleate) for OCD, and Ativan® (lorazepam) for anxiety.

The patient was randomized to the placebo regimen and received the first dose of study medication on 09 January 2001. On 19 February 2001 (Day 42), the patient experienced moderately severe agitation (panic attacks) that resolved with treatment (Ativan®) in 15 days. The patient did not take study medication on Day 42 or 43. This event was considered by the investigator to be possibly related to treatment with study medication. This event resulted in withdrawal of the patient from study. The patient discontinued study medication on 21 February 2001.

Several other non-serious adverse events were reported during the study. On 7 January 2001 (Day –1), and again on 14 January 2001 (Day 6), the patient reported mild headaches that resolved with treatment in one day. The investigator considered the headache on Day 6 to be possibly related to treatment with study medication. On 15 January 2001 (Day 7), the patient reported a mild dry skin

condition that continued throughout the study. This event was not treated and was considered to be unrelated to treatment with study medication. Mild nasal congestion was reported on Day 15. This continued throughout the study despite corrective treatment. This event was considered to be possibly related to treatment with study medication. On 02 February (Day 25), mild irritability was reported, and moderately severe irritability was reported again on 17 February 2001 (Day 40). No treatment was given. The first episode of irritability resolved in 15 days; the second continued throughout the study. Both events were considered to be possibly related to treatment with study medication. Mild right shoulder pain was reported on 06 February 2001 (Day 29). This resolved without treatment in one day and was considered to be possibly related to treatment with study medication. On 16 February 2001 (Day 39), severe anxiety was reported. This event was treated, but continued at the end of the study. Anxiety was considered to be possibly related to treatment with study medication. As a result of anxiety and the second occurrence of irritability, study medication was decreased from Dose Level 5 to Dose Level 3. Following cessation of study medication, on 26 February 2001 (Day 49), mild albuminuria and hematuria were reported. No treatment was given and these conditions, which were considered to be probably unrelated to treatment with study medication, resolved within 2 days. Mild anxiety was again reported on 14 March 2001 (Day 65). This was treated but continued and was considered to be probably unrelated to treatment with study medication.

Patients With Non-Serious Adverse Experiences Leading to Withdrawal

3 Patient Identification Number: 704.010.25367

Treatment Group: Paroxetine

Adverse Experience: Depression

This 12-year-old white male was a participant in the trial of BRL-29060/704, which was conducted in children and adolescents with obsessive-compulsive disorder (OCD).

The patient entered the study with a previous significant medical condition of sinusitis and a current medical condition of soft tissue disorder (seashells in right foot, were not removed). Psychiatric history (measured by K-SADS-PL interview) includes previous major depressive disorder (MDD) and current OCD with an onset of January 1996, and current attention deficit disorder (ADD) with an onset of January 1993.

Prior medications include Keflex® (cephalexin monohydrate) as prophylaxis for an unknown condition. Concomitant medications include Paxil® (paroxetine) for depression and OCD (beginning 18 February 2000 and continuing post-study), and Ritalin® (methylphenidate HCl) (beginning 18 February 2000 and continuing post-study) for depression and for attention deficit hyperactivity disorder (ADHD). Post-treatment medications include Anaplex® (pseudoephedrine HCl) for nasal congestion, and Adderall® (amphetamine aspartate, amphetamine sulfate, amphetamine saccharate) for ADHD.

The patient was randomized to the paroxetine regimen and received the first dose of study medication on 05 February 2000. The patient began treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 12 February 2000. On 17 February 2000, the patient experienced severe depression that resolved with treatment in 5 days. This non-serious event was considered by the investigator to be unrelated to treatment with study medication. The event resulted in withdrawal of the patient from the study. The patient discontinued study medication on 18 February 2000 (Day 14).

No other non-serious adverse events were reported during the study. One non-serious adverse event was reported post-treatment. On 05 March 2000 (Day 30) the patient reported mild rhinitis (nasal congestion) that resolved with treatment in

two days. This event was considered to be unrelated to treatment with study medication.

Patients With Non-Serious Adverse Experiences Leading to Withdrawal

4 Patient Identification Number: 704.010.25369

Treatment Group: Paroxetine

Adverse Experience: Urinary Retention (Urinary Retention)

This 7-year old white female was a participant in the trial of BRL-29060/704, which was conducted in children and adolescents with obsessive-compulsive disorder (OCD).

The patient entered the study with no significant previous or current medical or surgical history reported. Psychiatric history (measured by K-SADS-PL interview) includes current OCD with an onset of February 1995. No other psychiatric disorders were identified.

No previous medications were recorded. Concomitant medication included Mineral Oil® (paraffin liquid) for constipation. Follow-up medications included Robitussin® (dextromethorphan hydrobromide, ethanol, guaifenesin) and Children's Motrin® (ibuprofen) for upper respiratory infection, both of which were started 3 days after the last dose of study medication.

The patient was randomized to the paroxetine regimen and received the first dose of study medication on 15 February 2000. The patient began treatment at a dose of 10 mg/day. On 25 February 2000 (Day 11), while at a dose of 10 mg/day, the patient experienced a moderately severe urinary retention that resolved without treatment in 14 days. This non-serious event was considered by the investigator to be possibly related to treatment with study medication. This event resulted in withdrawal of the patient from the study. The patient discontinued study medication on 03 March 2000.

The patient also experienced moderately severe insomnia on 15 February 2000 (Day 1) that resolved without treatment in 31 days, moderately severe hyperactivity on 16 February 2000 (Day 2) that resolved without treatment in 20 days, and moderately severe hyperverbosity on 16 February (Day 2) that resolved without treatment in 30 days. These three non-serious events were considered by the investigator to be related to treatment with study medication. On 25 February 2000 (Day 11), the patient reported the onset of moderately severe constipation, which resolved with treatment in three days. This non-serious event was considered to be possibly related to treatment with study

medication. Three days after the study medication was discontinued (6 March 2000), the patient experienced the onset of a moderately severe upper respiratory infection. This resolved with treatment in 9 days and was considered to be unrelated to treatment with study medication.

Patients With Non-Serious Adverse Experiences Leading to Withdrawal

5 Patient Identification Number: 704.010.25372

Treatment Group: Paroxetine

Adverse Experience: Personality Disorder (Disinhibition)

This 9-year-old white female was a participant in the trial of BRL-29060/704, which was conducted in children and adolescents with obsessive-compulsive disorder (OCD).

The patient entered the study with no significant previous medical or surgical history reported. Psychiatric history (measured by K-SADS-PL interview) includes current OCD with an onset of May 1998. No other psychiatric disorders were identified.

There were no previous or concomitant medications reported. The patient received Children's Motrin® (ibuprofen) for nausea beginning on 9 August 2000, 10 days after the last dose of study medication.

The patient was randomized to the paroxetine regimen and received the first dose of study medication on 24 June 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to 30 mg/day on 8 July 2000. On 25 July 2000 (Day 32), while at a dose level of 30 mg, the patient experienced mild personality disorder (disinhibition). This event resolved without treatment in 15 days. The investigator considered this event to be possibly related to treatment with study medication. The patient was withdrawn from the study and discontinued study medication on 30 July 2000.

On 8 August 2000, 9 days after the last dose of study medication, the patient experienced mild nausea. The event was treated, but continued beyond the end of the study. The investigator considered the non-serious event to be possibly related to treatment with study medication.

Patients With Non-Serious Adverse Experiences Leading to Withdrawal

6 Patient Identification Number: 704.014.25357

Treatment Group: Paroxetine

Adverse Experience: Nervousness (Increase in ADHD Symptoms; "Fidgety", Inattentive, Distractable), Impaired Concentration (Increase in ADHD symptoms, "Fidgety", Inattentive, Distractable).

This 9-year-old white male was a participant in the trial of BRL-29060/704, which was conducted in children and adolescents with obsessive-compulsive disorder (OCD).

The patient entered the study with a previous and current medical history of hay fever, migraines and headaches. Psychiatric history (measured by K-SADS-PL interview) includes previous and current OCD and Tourette's syndrome with onset dates of January 1995. No other psychiatric disorders were identified.

Previous medication included Tylenol ES® (paracetamol) for headache. Concomitant medications included Tylenol Allergy Sinus Medication® (chlorpheniramine maleate, ibuprofen, paracetamol, pseudoephedrine HCl) for headache, and Astelin® (azelastine HCl) for hay fever, which continued post-treatment. Other post-treatment medications included Tenex® (guanfacine HCl) for ADHD.

The patient was randomized to the paroxetine regimen and took the first dose of study medication on 09 March 2001. The patient began receiving treatment at dose of 10 mg/day and was titrated up to 20 mg/day on 27 March 2001. On 8 May 2001 (Day 61), the patient experienced a moderately severe nervousness (increase in ADHD symptoms "fidgety", inattentive, and distractable) and impaired concentration (increase in ADHD symptoms "fidgety", inattentive, and distractable) that the investigator considered to be possibly related to treatment with study medication. The events were treated but continued beyond the end of the study. The patient's participation in the study was discontinued, and the patient received the last dose of study medication on 11 May 2001 (Day 64).

Several other non-serious events were reported. On 03 March 2001 (Day –5), the patient experienced moderately severe headache that resolved with treatment in 2 days. On 28 March 2001 (Day 20), the patient experienced mild asthenia (fatigue) that resolved without treatment in 2 days. Asthenia was considered to be

related to treatment with study medication by the investigator. On 17 April 2001 (Day 40), the patient experienced moderately severe agitation (increased agitation, hitting, kicking), emotional lability (mood fluctuations), and speech disorder (rapid speech). These conditions resolved without treatment in 4 days. The investigator considered all of these events to be possibly related to treatment with study medication. On 20 April 2001 (Day 43), moderately severe neurosis (increased anxiety and OCD symptoms) began. This event resolved without treatment in 23 days. On 02 May 2001 (Day 55), the patient experienced mild headache that resolved with treatment in one day. This event was considered by the investigator to be possibly related to treatment with study medication. No post-treatment events were reported.

Patients With Non-Serious Adverse Experiences Leading to Withdrawal

7 Patient Identification Number: 704.015.27044

Treatment Group: Paroxetine

Adverse Experience: Hostility (Oppositional Defiant Disorder)

This 7-year-old white male was a participant in the trial of BRL-29060/704, which was conducted in children and adolescents with obsessive-compulsive disorder (OCD).

The patient entered the study with previous refractory tonsillitis. Previous and current significant medical conditions included allergy to codeine, penicillin, and sulfa; epistaxis; and seasonal allergies. Psychiatric history (measured by K-SADS-PL interview) includes current OCD with an onset date of December 1999, and current simple phobia with an onset date of April 2000. No other psychiatric disorders were identified.

Previous and current medications included Claritin® (loratadine) for seasonal allergies. Concomitant medications included Claritin® (loratadine) and Cefzil® (cefprozil monohydrate) for sinus infection, which continued post-study; Children's Tylenol® (paracetamol) for multiple aches and myalgia; and Children's Motrin® (ibuprofen) for dog bite and myalgia. Post-treatment medications included Claritin® (loratadine) for allergies, and Children's Motrin® (ibuprofen) for oral ulcer, viral syndrome, and leg ache.

The patient was randomized to the paroxetine regimen and received the first dose of study medication on 26 September 2000. The patient began receiving treatment at a dose of 10 mg/day. On 09 October 2000 (Day 14), the patient experienced mild hostility (oppositional defiant disorder). The dose was titrated up, in 10 mg/week increments, to 30 mg/day on 23 October 2000 but the hostility continued. The event was considered related to treatment with study medication and resulted in withdrawal from the study. The last dose of treatment with study medication was 6 November 2000, and the last dose of taper medication was taken on 20 November 2000. The event resolved without treatment in 37 days, while the patient was taking taper medication.

On 27 September 2000 (Day 2), the patient experienced mild dry mouth, mild nausea, mild impaired concentration (distractible, inattentive), mild hyperkinesia (hyperactive), mild sweating (diaphoresis), and mild tremor (tremulous). No

treatment was given for these non-serious events, and all except sweating and tremor continued through the end of the study. Sweating resolved in 2 days and tremor resolved in 4 days. All were considered to be possibly related to treatment with study medication.

On 07 October 2000 (Day 12), the patient experienced mild myalgia in legs that recurred on 24 October 2000 (Day 29), and mild sinus infection. Corrective treatment was given for each and these events resolved in 2 days, 2 days, and 15 days, respectively. These events were considered to be unrelated to treatment with study medication.

On 18 October 2000 (Day 23), the patient experienced mild multiple aches (back pain, headache, pain, nausea) and mild enuresis. Multiple aches resolved with treatment in 2 days and were considered by the investigator to be unrelated to treatment with study medication. Enuresis was untreated and continued through the end of the study. This non-serious event was considered by the investigator to be possibly related to treatment with study medication.

On 29 October 2000 (Day 34), the patient reported trauma (a mild dog bite) to the upper lip, which was treated with ibuprofen and resolved in 2 days. The trauma was considered to be unrelated to treatment with study medication.

On 7 November 2000 (Day 43), one day after the last dose of study medication but while the patient was still taking taper medication, the patient experienced mild headache, viral syndrome, oral ulcer, and rhinitis. Viral syndrome, oral ulcer and rhinitis were considered to be unrelated to treatment with study medication. Allergic rhinitis resolved in 5 days with treatment; viral syndrome resolved in 10 days with treatment; and the oral ulcer continued with treatment through the end of the study. Headache continued through the end of the study, was untreated, and was considered to be possibly related to treatment with study medication. All of these events were non-serious.

Patients With Non-Serious Adverse Experiences Leading to Withdrawal

8 Patient Identification Number: 704.016.25452

Treatment Group: Paroxetine

Adverse Experience: Hyperkinesia (Hyperactive)

This 7-year old white male was a participant in the trial of BRL-29060/704, which was conducted in children and adolescents with obsessive-compulsive disorder (OCD).

The patient entered the study with no significant previous or current medical or surgical history recorded. Psychiatric history (measured by K-SADS-PL interview) includes previous and current OCD with an onset date of February 1995. No other psychiatric disorders were identified.

No previous or current medications were recorded.

The patient was randomized to the paroxetine regimen and received the first dose of study medication on 03 May 2000. The patient began receiving treatment at a 10 mg/day dose and was titrated up to 20 mg/day on 10 May 2000. The same day (Day 8), the patient experienced moderately severe hyperkinesia (hyperactive). The dose of study medication was decreased to 10 mg/day on 17 May 2000. The hyperkinesia resolved without corrective therapy in 8 days. This event was considered to be related to treatment with study medication. On 31 May 2000 the dose was again increased to 20 mg/day. The same day (Day 29), the patient experienced severe hyperkinesia (hyperactive). The condition resolved without treatment in 4 days. The investigator considered the event to be related to treatment with study medication and the patient was withdrawn from the study. The last dose of study medication was taken on 01 June 2000.

One other non-serious adverse event was reported during the study. On 09 May 2000 (Day 7), the patient experienced moderately severe trauma (sunburn) that resolved without treatment within 8 days. This event was considered to be unrelated to treatment with study medication. No other adverse experiences were reported.

Patients With Non-Serious Adverse Experiences Leading to Withdrawal

9 Patient Identification Number: 704.016.25453

Treatment Group: Placebo

Adverse Experience: Somnolence (Sedation)

This 17-year old white female was a participant in the trial of BRL-29060/704, which was conducted in children and adolescents with obsessive-compulsive disorder (OCD).

The patient entered the study with no significant previous or current medical or surgical history. Psychiatric history (measured by K-SADS-PL interview) includes previous and current OCD with an onset date of October 1986. No other psychiatric disorders were identified.

There were no previous or current medications recorded.

The patient was randomized to the placebo regimen and received the first dose of study medication on 19 May 2000. The last dose of study medication was taken on 25 May 2000 (Day 7). On 24 May 2000 (Day 6), the patient experienced severe somnolence (sedation) that resolved without treatment in 6 days. This event resulted in withdrawal from the study. The investigator considered this event to be related to treatment with study medication. No other adverse experiences were reported.

Patients With Non-Serious Adverse Experiences Leading to Withdrawal

10 Patient Identification Number: 704.016.27020

Treatment Group: Paroxetine

Adverse Experience: Dyspepsia (Heartburn, Acid Reflux), Gastrointestinal Disorder (Heartburn, Acid Reflux)

This 8-year-old white male was a participant in the trial of BRL-29060/704, which was conducted in children and adolescents with obsessive-compulsive disorder (OCD).

The patient entered the study with a significant current medical history of chapped lips (dry mouth), seasonal rhinitis (allergic rhinitis), and leukocytosis (slight elevation of white blood cells). Psychiatric history (measured by K-SADS-PL interview) includes previous and current OCD, and encopresis with onset dates of June 1995. No other psychiatric disorders were identified.

Previous medications included Triaminic® (phenylpropanolamine HCl, pheniramine maleate, mepyramine maleate) for seasonal rhinitis. Concomitant medications included Mylanta® (activated dimethicone, aluminum hydroxide, magnesium hydroxide) and Zantac® (ranitidine HCl) for heartburn, which continued post-treatment, and Rolaids® (calcium carbonate, magnesium hydroxide) also for heartburn, .

The patient was randomized to the paroxetine regimen and received the first dose of study medication on 29 November 2000. The patient began receiving treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 13 December 2000. The last dose of study medication was taken on 19 December 2000. On 6 December 2000 (Day 8), the patient experienced moderately severe dyspepsia and gastrointestinal disorder (heartburn, acid reflux). Corrective therapy was given for both events, but these events continued beyond the end of the study. These events resulted in withdrawal from the study. The investigator considered these events to be possibly related to treatment with study medication.

Several other non-serious events were reported. On 23 November 2000 (Day –5), and again on 28 November 2000 (Day 0), the patient experienced mild rhinitis (seasonal rhinitis). Each of these episodes resolved with treatment in 4 days. The second episode of rhinitis (Day 0) was considered to be probably unrelated to treatment with study medication. On 2 December 2000 (Day 4), the patient

experienced mild abdominal pain (stomach ache), which cleared without treatment in 2 days. On 5 December 2000 (Day 7), the patient experienced moderately severe chest pain (chest pain) that resolved without treatment in 4 days. Abdominal pain and chest pain were considered by the investigator to be possibly related to treatment with study medication.

Patients With Non-Serious Adverse Experiences Leading to Withdrawal

11 Patient Identification Number: 704.016.27022

Treatment Group: Paroxetine

Adverse Experience: Hyperkinesia (Hyperactivity)

This 7-year-old white male was a participant in the trial of BRL-29060/704, which was conducted in children and adolescents with obsessive-compulsive disorder (OCD).

No previous medical or surgical history was recorded. No significant current medical conditions were reported. Psychiatric history (measured by K-SADS-PL interview) includes prior and current OCD with an onset date of August 1999. No other psychiatric disorders were identified.

No previous or concomitant medications were recorded.

The patient was randomized to the paroxetine regimen and received the first dose of study medication on 28 November 2000. The patient began receiving treatment at a dose of 10 mg/day and was titrated up to 20 mg/day on 05 December 2000. The dose of study medication was decreased to 10 mg/day on 13 December 2000 and study medication was discontinued on 01 January 2001. On 22 December 2000 (Day 25), the patient experienced moderately severe hyperkinesia (hyperactivity) that resolved without treatment in 26 days. This event was considered to be related to treatment with study medication and the patient was withdrawn from the study.

Two other non-serious events were reported on 6 December 2000 (Day 9). Moderately severe hyperkinesia (hyperactivity) and insomnia (not sleeping) were reported. These resolved without treatment in 6 days and were considered by the investigator to be possibly related to treatment with study medication. No other adverse experiences were reported.

Patients With Non-Serious Adverse Experiences Leading to Withdrawal

12 Patient Identification Number: 704.025.27036

Treatment Group: Placebo

Adverse Experience: Neurosis (Increased Anxiety Due To OCD Symptoms)

This 6-year-old white male was a participant in the trial of BRL-29060/704, which was conducted in children and adolescents with obsessive-compulsive disorder (OCD).

The patient entered the study with no significant previous or current medical or surgical history recorded. Psychiatric history (measured by K-SADS-PL interview) includes previous and current OCD with an onset date of June 1997. No other psychiatric disorders were identified.

Previous medication included Paxil® (paroxetine) for OCD. No other previous or current medications were recorded.

The patient was randomized to the placebo regimen and received the first dose of study medication on 16 June 2000. The patient began receiving treatment at dose level 1 (equivalent to 10 mg/day of active medication), which was increased to Dose Level 2 (equivalent to 20 mg/day of active medication) on 24 June 2000. The last dose of study medication was taken on 24 June 2000. On 24 June 2000 (Day 9), the patient experienced severe neurosis (increased anxiety due to OCD symptoms) that resolved with treatment in 3 days. This condition was considered by the investigator to be related to treatment with study medication and the patient was withdrawn from the study.

No other adverse events were reported.

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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=58)	Placebo (N=57)
TOTAL	TOTAL	8 (13.8%)	1 (1.8%)
Nervous System	TOTAL	6 (10.3%)	1 (1.8%)
	HYPERKINESIA	3 (5.2%)	0
	NEUROSIS	1 (1.7%)	1 (1.8%)
	CONCENTRATION IMPAIRED	1 (1.7%)	0
	HOSTILITY	1 (1.7%)	0
	NERVOUSNESS	1 (1.7%)	0
	PERSONALITY DISORDER	1 (1.7%)	0
Digestive System	TOTAL	1 (1.7%)	0
	DYSPEPSIA	1 (1.7%)	0
	GASTROINTESTINAL DISORDER	1 (1.7%)	0
Urogenital System	TOTAL	1 (1.7%)	0
	URINARY RETENTION	1 (1.7%)	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, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=31)	Placebo (N=35)
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=27)	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

		Treatment Group	
		Paroxetine (N=40)	Placebo (N=48)
Body System	Preferred Term		
TOTAL	TOTAL	2 (5.0%)	2 (4.2%)
Nervous System	TOTAL	2 (5.0%)	2 (4.2%)
	DEPRESSION	1 (2.5%)	0
	EMOTIONAL LABILITY	1 (2.5%)	0
	AGITATION	0	1 (2.1%)
	SOMNOLENCE	0	1 (2.1%)

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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=22)	Placebo (N=29)
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

Body System	Preferred Term	Treatment Group Paroxetine (N=18)	Treatment Group Placebo (N=19)
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=98)	 Placebo (N=105)
TOTAL	TOTAL	10 (10.2%)	3 (2.9%)
Nervous System	TOTAL	8 (8.2%)	3 (2.9%)
	HYPERKINESIA	3 (3.1%)	0
	NEUROSIS	1 (1.0%)	1 (1.0%)
	CONCENTRATION IMPAIRED	1 (1.0%)	0
	DEPRESSION	1 (1.0%)	0
	EMOTIONAL LABILITY	1 (1.0%)	0
	HOSTILITY	1 (1.0%)	0
	NERVOUSNESS	1 (1.0%)	0
	PERSONALITY DISORDER	1 (1.0%)	0
	AGITATION	0	1 (1.0%)
	SOMNOLENCE	0	1 (1.0%)
Digestive System	TOTAL	1 (1.0%)	0
	DYSPEPSIA	1 (1.0%)	0
	GASTROINTESTINAL DISORDER	1 (1.0%)	0
Urogenital System	TOTAL	1 (1.0%)	0
	URINARY RETENTION	1 (1.0%)	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, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=64)
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=45)	Placebo (N=41)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

BRL 29060 - 704

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=58)	Treatment Group: Placebo (N=57)
TOTAL	8 (13.8%)	1 (1.8%)
HYPERKINESIA	3 (5.2%)	0
NEUROSIS	1 (1.7%)	1 (1.8%)
CONCENTRATION IMPAIRED	1 (1.7%)	0
DYSPEPSIA	1 (1.7%)	0
GASTROINTESTINAL DISORDER	1 (1.7%)	0
HOSTILITY	1 (1.7%)	0
NERVOUSNESS	1 (1.7%)	0
PERSONALITY DISORDER	1 (1.7%)	0
URINARY RETENTION	1 (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 : Children, Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=31)	 Placebo (N=35)
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=27)	 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=40)	Treatment Group: Placebo (N=48)
TOTAL	2 (5.0%)	2 (4.2%)
DEPRESSION	1 (2.5%)	0
EMOTIONAL LABILITY	1 (2.5%)	0
AGITATION	0	1 (2.1%)
SOMNOLENCE	0	1 (2.1%)

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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=22)	 Placebo (N=29)
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=18)	 Placebo (N=19)
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=98)	 Placebo (N=105)
TOTAL	10 (10.2%)	3 (2.9%)
HYPERKINESIA	3 (3.1%)	0
NEUROSIS	1 (1.0%)	1 (1.0%)
CONCENTRATION IMPAIRED	1 (1.0%)	0
DEPRESSION	1 (1.0%)	0
DYSPEPSIA	1 (1.0%)	0
EMOTIONAL LABILITY	1 (1.0%)	0
GASTROINTESTINAL DISORDER	1 (1.0%)	0
HOSTILITY	1 (1.0%)	0
NERVOUSNESS	1 (1.0%)	0
PERSONALITY DISORDER	1 (1.0%)	0
URINARY RETENTION	1 (1.0%)	0
AGITATION	0	1 (1.0%)
SOMNOLENCE	0	1 (1.0%)

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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=53)	 Placebo (N=64)
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=45)	Treatment Group: Placebo (N=41)
TOTAL	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, Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Post Week 10		Total	
Treatment Group	Preferred Term	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=58)	ABDOMINAL PAIN	5	8.6	4	6.9	1	1.7	1	1.7	1	1.7	1	1.7	0	0.0	0	0.0	13	22.4
	HEADACHE	3	5.2	3	5.2	2	3.4	0	0.0	1	1.7	3	5.2	1	1.7	0	0.0	13	22.4
	HYPERKINESIA	5	8.6	3	5.2	1	1.7	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	10	17.2
	HOSTILITY	0	0.0	2	3.4	1	1.7	1	1.7	1	1.7	1	1.7	1	1.7	0	0.0	7	12.1
	INSOMNIA	2	3.4	2	3.4	1	1.7	2	3.4	0	0.0	0	0.0	0	0.0	0	0.0	7	12.1
	RESPIRATORY DISORDER	1	1.7	1	1.7	1	1.7	1	1.7	2	3.4	1	1.7	0	0.0	0	0.0	7	12.1
	TRAUMA	1	1.7	0	0.0	0	0.0	2	3.4	2	3.4	0	0.0	2	3.4	0	0.0	7	12.1
	DECREASED APPETITE	3	5.2	1	1.7	0	0.0	2	3.4	0	0.0	0	0.0	0	0.0	0	0.0	6	10.3
	NAUSEA	3	5.2	0	0.0	2	3.4	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	6	10.3
	DIARRHEA	1	1.7	0	0.0	1	1.7	1	1.7	1	1.7	1	1.7	0	0.0	0	0.0	5	8.6
	NEUROSIS	2	3.4	1	1.7	0	0.0	1	1.7	1	1.7	0	0.0	0	0.0	0	0.0	5	8.6
	SOMNOLENCE	0	0.0	1	1.7	1	1.7	2	3.4	0	0.0	1	1.7	0	0.0	0	0.0	5	8.6
	VOMITING	1	1.7	0	0.0	1	1.7	1	1.7	0	0.0	2	3.4	0	0.0	0	0.0	5	8.6
	FEVER	2	3.4	0	0.0	0	0.0	1	1.7	0	0.0	1	1.7	0	0.0	0	0.0	4	6.9
	NERVOUSNESS	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	3	5.2	0	0.0	0	0.0	4	6.9
	PHARYNGITIS	3	5.2	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	6.9
	SINUSITIS	0	0.0	1	1.7	0	0.0	1	1.7	2	3.4	0	0.0	0	0.0	0	0.0	4	6.9
	AGITATION	0	0.0	0	0.0	2	3.4	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	3	5.2
	ALLERGIC REACTION	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7	1	1.7	0	0.0	0	0.0	3	5.2
	ASTHENIA	0	0.0	1	1.7	1	1.7	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	3	5.2

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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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Paroxetine (N=58)	CHEST PAIN	3	5.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	5.2
	INFECTION	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7	1	1.7	0	0.0	0	0.0	3	5.2
	PAIN	1	1.7	0	0.0	1	1.7	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	3	5.2
	PERSONALITY DISORDER	0	0.0	0	0.0	0	0.0	1	1.7	1	1.7	0	0.0	1	1.7	0	0.0	3	5.2
	CONCENTRATION IMPAIRED	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	2	3.4
	CONJUNCTIVITIS	0	0.0	0	0.0	0	0.0	1	1.7	1	1.7	0	0.0	0	0.0	0	0.0	2	3.4
	DYSPEPSIA	1	1.7	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.4
	EPISTAXIS	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	2	3.4
	MYALGIA	0	0.0	2	3.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.4
	RHINITIS	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	2	3.4
	SPEECH DISORDER	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	2	3.4
	SWEATING	2	3.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.4
	TREMOR	1	1.7	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.4
	URINARY INCONTINENCE	0	0.0	0	0.0	2	3.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.4
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	1	1.7
	ANEMIA	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	ANXIETY	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	BACK PAIN	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	COLITIS	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	CONSTIPATION	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7

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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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=58)	COUGH INCREASED	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	DEPERSONALIZATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	1	1.7
	DIPLOPIA	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	DIZZINESS	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	DRY MOUTH	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	EMOTIONAL LABILITY	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7
	FLATULENCE	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	GASTROINTESTINAL DISORDER	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	INCOORDINATION	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	INCREASED APPETITE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	1	1.7
	KERATOCONJUNCTIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	1	1.7
	PHOTOSENSITIVITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	1	1.7
	PUSTULAR RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	1	1.7
	STOMATITIS	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	STRIDOR	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	1	1.7
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	TOOTH DISORDER	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	ULCERATIVE STOMATITIS	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7
	URINARY RETENTION	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7

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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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Paroxetine (N=58)	VASODILATATION	0	0.0	1	1.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.7

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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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=57)	HEADACHE	5	8.8	2	3.5	3	5.3	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	11	19.3
	ABDOMINAL PAIN	2	3.5	5	8.8	2	3.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	9	15.8
	INFECTION	2	3.5	0	0.0	0	0.0	2	3.5	1	1.8	2	3.5	2	3.5	0	0.0	9	15.8
	NAUSEA	4	7.0	2	3.5	2	3.5	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	9	15.8
	RESPIRATORY DISORDER	1	1.8	1	1.8	0	0.0	2	3.5	1	1.8	0	0.0	1	1.8	0	0.0	6	10.5
	RHINITIS	0	0.0	0	0.0	1	1.8	2	3.5	0	0.0	2	3.5	1	1.8	0	0.0	6	10.5
	COUGH INCREASED	0	0.0	2	3.5	0	0.0	1	1.8	0	0.0	1	1.8	1	1.8	0	0.0	5	8.8
	DIZZINESS	0	0.0	2	3.5	2	3.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	7.0
	FEVER	1	1.8	0	0.0	0	0.0	1	1.8	1	1.8	0	0.0	1	1.8	0	0.0	4	7.0
	HYPERKINESIA	1	1.8	0	0.0	0	0.0	2	3.5	1	1.8	0	0.0	0	0.0	0	0.0	4	7.0
	PHARYNGITIS	1	1.8	2	3.5	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	7.0
	CONSTIPATION	0	0.0	1	1.8	1	1.8	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	3	5.3
	DRY MOUTH	2	3.5	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	5.3
	PAIN	0	0.0	1	1.8	0	0.0	1	1.8	0	0.0	1	1.8	0	0.0	0	0.0	3	5.3
	SOMNOLENCE	2	3.5	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	5.3
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	2	3.5	0	0.0	0	0.0	0	0.0	0	0.0	2	3.5
	DIARRHEA	0	0.0	0	0.0	1	1.8	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	2	3.5
	DYSPEPSIA	0	0.0	0	0.0	1	1.8	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	2	3.5
	GASTROINTESTINAL DISORDER	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	2	3.5

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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

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Placebo (N=57)	INSOMNIA	0	0.0	1	1.8	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.5
	MYOCLONUS	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	2	3.5
	NERVOUSNESS	0	0.0	0	0.0	0	0.0	2	3.5	0	0.0	0	0.0	0	0.0	0	0.0	2	3.5
	OTITIS MEDIA	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	2	3.5
	SINUSITIS	0	0.0	0	0.0	0	0.0	2	3.5	0	0.0	0	0.0	0	0.0	0	0.0	2	3.5
	URINARY INCONTINENCE	0	0.0	0	0.0	1	1.8	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	2	3.5
	VOMITING	1	1.8	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	2	3.5
	ASTHENIA	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	1	1.8
	DECREASED APPETITE	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	EAR DISORDER	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	EAR PAIN	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	FUNGAL DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	1	1.8
	GASTROENTERITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	1	1.8
	GINGIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	1	1.8
	HOSTILITY	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	1	1.8
	NEUROSIS	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	NYSTAGMUS	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	1	1.8
	SKIN BENIGN NEOPLASM	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8

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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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Placebo (N=57)	THIRST	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	TRAUMA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	1	1.8
	URINARY TRACT INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	1	1.8

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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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Paroxetine (N=31)	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

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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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Placebo (N=35)	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

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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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Paroxetine (N=27)	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

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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		Post Week 10		Total	
		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

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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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=40)	HEADACHE	2	5.0	3	7.5	1	2.5	1	2.5	2	5.0	0	0.0	2	5.0	0	0.0	11	27.5
	NAUSEA	4	10.0	2	5.0	1	2.5	2	5.0	0	0.0	0	0.0	1	2.5	0	0.0	10	25.0
	SOMNOLENCE	4	10.0	1	2.5	0	0.0	1	2.5	1	2.5	0	0.0	0	0.0	0	0.0	7	17.5
	ASTHENIA	4	10.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	5	12.5
	RESPIRATORY DISORDER	0	0.0	2	5.0	0	0.0	0	0.0	1	2.5	1	2.5	1	2.5	0	0.0	5	12.5
	ABDOMINAL PAIN	2	5.0	0	0.0	1	2.5	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	4	10.0
	DIZZINESS	2	5.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	4	10.0
	PHARYNGITIS	0	0.0	1	2.5	1	2.5	0	0.0	0	0.0	1	2.5	1	2.5	0	0.0	4	10.0
	DECREASED APPETITE	2	5.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	3	7.5
	DIARRHEA	1	2.5	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	3	7.5
	DRY MOUTH	3	7.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	7.5
	TRAUMA	0	0.0	2	5.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	3	7.5
	AGITATION	0	0.0	1	2.5	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	2	5.0
	ASTHMA	0	0.0	1	2.5	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	2	5.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	1	2.5	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	2	5.0
	HOSTILITY	0	0.0	0	0.0	1	2.5	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	2	5.0
	HYPERKINESIA	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	2	5.0
	INFECTION	0	0.0	0	0.0	0	0.0	1	2.5	1	2.5	0	0.0	0	0.0	0	0.0	2	5.0
	INSOMNIA	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	2	5.0
	PAIN	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	2	5.0

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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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=40)	RHINITIS	0	0.0	1	2.5	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	5.0
	ABNORMAL DREAMS	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	1	2.5
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	ANXIETY	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	ARTHRALGIA	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	BRUXISM	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	1	2.5
	CONSTIPATION	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	COUGH INCREASED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	1	2.5
	CYSTITIS	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	DEPRESSION	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	EAR PAIN	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	EPISTAXIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	1	2.5
	FLATULENCE	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	GASTROINTESTINAL DISORDER	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	1	2.5
	HYPERTENSION	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	MYDRIASIS	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	1	2.5
	NERVOUSNESS	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5

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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 : Adolescents, Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Paroxetine (N=40)	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	1	2.5
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	1	2.5
	PERIPHERAL EDEMA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	1	2.5
	SINUSITIS	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	THYROID DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5	0	0.0	1	2.5
	URINARY FREQUENCY	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	VASODILATATION	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	VOMITING	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	WEIGHT LOSS	0	0.0	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5
	YAWN	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.5

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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 : Adolescents, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=48)	HEADACHE	6	12.5	1	2.1	1	2.1	0	0.0	2	4.2	1	2.1	0	0.0	0	0.0	11	22.9
	RESPIRATORY DISORDER	3	6.3	1	2.1	1	2.1	1	2.1	1	2.1	1	2.1	1	2.1	0	0.0	9	18.8
	NERVOUSNESS	2	4.2	0	0.0	0	0.0	1	2.1	1	2.1	0	0.0	0	0.0	0	0.0	4	8.3
	RHINITIS	1	2.1	2	4.2	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	4	8.3
	SOMNOLENCE	1	2.1	2	4.2	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	8.3
	ABDOMINAL PAIN	1	2.1	1	2.1	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	3	6.3
	DIZZINESS	2	4.2	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.3
	FEVER	0	0.0	1	2.1	2	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.3
	INFECTION	2	4.2	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.3
	INSOMNIA	2	4.2	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	3	6.3
	SINUSITIS	1	2.1	0	0.0	1	2.1	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	3	6.3
	AGITATION	0	0.0	0	0.0	0	0.0	0	0.0	2	4.2	0	0.0	0	0.0	0	0.0	2	4.2
	DRY MOUTH	2	4.2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.2
	HYPERKINESIA	0	0.0	1	2.1	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	2	4.2
	MYALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	1	2.1	0	0.0	2	4.2
	PHARYNGITIS	0	0.0	1	2.1	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.2
	TRAUMA	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	2	4.2
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	ABNORMAL VISION	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	ALLERGIC REACTION	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1

(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

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Placebo (N=48)	ANXIETY	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	1	2.1
	ARTHRALGIA	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	BACK PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	1	2.1
	COUGH INCREASED	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	DEPERSONALIZATION	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	DRY SKIN	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	DYSPEPSIA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	1	2.1
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	1	2.1
	HERPES SIMPLEX	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	1	2.1
	NAUSEA	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	1	2.1
	URINARY TRACT INFECTION	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	VASODILATATION	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1

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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, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Paroxetine (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

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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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Placebo (N=29)	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

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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		Post Week 10		Total	
Treatment Group	Preferred Term	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=18)	DYSMENORRHEA	0	0.0	1	5.6	0	0.0	2	11.1	0	0.0	0	0.0	0	0.0	0	0.0	3	16.7

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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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Placebo (N=19)	DYSMENORRHEA	0	0.0	0	0.0	1	5.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.3

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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		Post Week 10		Total	
Treatment Group	Preferred Term	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=98)	HEADACHE	5	5.1	6	6.1	3	3.1	1	1.0	3	3.1	3	3.1	3	3.1	0	0.0	24	24.5
	ABDOMINAL PAIN	7	7.1	4	4.1	2	2.0	2	2.0	1	1.0	1	1.0	0	0.0	0	0.0	17	17.3
	NAUSEA	7	7.1	2	2.0	3	3.1	3	3.1	0	0.0	0	0.0	1	1.0	0	0.0	16	16.3
	HYPERKINESIA	6	6.1	3	3.1	1	1.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	12	12.2
	RESPIRATORY DISORDER	1	1.0	3	3.1	1	1.0	1	1.0	3	3.1	2	2.0	1	1.0	0	0.0	12	12.2
	SOMNOLENCE	4	4.1	2	2.0	1	1.0	3	3.1	1	1.0	1	1.0	0	0.0	0	0.0	12	12.2
	TRAUMA	1	1.0	2	2.0	0	0.0	2	2.0	3	3.1	0	0.0	2	2.0	0	0.0	10	10.2
	DECREASED APPETITE	5	5.1	1	1.0	0	0.0	3	3.1	0	0.0	0	0.0	0	0.0	0	0.0	9	9.2
	HOSTILITY	0	0.0	2	2.0	2	2.0	1	1.0	2	2.0	1	1.0	1	1.0	0	0.0	9	9.2
	INSOMNIA	3	3.1	2	2.0	1	1.0	2	2.0	0	0.0	1	1.0	0	0.0	0	0.0	9	9.2
	ASTHENIA	4	4.1	1	1.0	1	1.0	2	2.0	0	0.0	0	0.0	0	0.0	0	0.0	8	8.2
	DIARRHEA	2	2.0	0	0.0	2	2.0	1	1.0	1	1.0	1	1.0	1	1.0	0	0.0	8	8.2
	PHARYNGITIS	3	3.1	2	2.0	1	1.0	0	0.0	0	0.0	1	1.0	1	1.0	0	0.0	8	8.2
	VOMITING	2	2.0	0	0.0	1	1.0	1	1.0	0	0.0	2	2.0	0	0.0	0	0.0	6	6.1
	AGITATION	0	0.0	1	1.0	2	2.0	0	0.0	2	2.0	0	0.0	0	0.0	0	0.0	5	5.1
	DIZZINESS	3	3.1	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	5	5.1
	INFECTION	1	1.0	0	0.0	0	0.0	1	1.0	2	2.0	1	1.0	0	0.0	0	0.0	5	5.1
	NERVOUSNESS	0	0.0	0	0.0	1	1.0	1	1.0	0	0.0	3	3.1	0	0.0	0	0.0	5	5.1
	NEUROSIS	2	2.0	1	1.0	0	0.0	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	5	5.1
	PAIN	2	2.0	0	0.0	1	1.0	0	0.0	0	0.0	2	2.0	0	0.0	0	0.0	5	5.1

(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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=98)	SINUSITIS	1	1.0	1	1.0	0	0.0	1	1.0	2	2.0	0	0.0	0	0.0	0	0.0	5	5.1
	ALLERGIC REACTION	1	1.0	0	0.0	0	0.0	1	1.0	1	1.0	1	1.0	0	0.0	0	0.0	4	4.1
	DRY MOUTH	4	4.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	4.1
	FEVER	2	2.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	4	4.1
	RHINITIS	0	0.0	2	2.0	1	1.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	4	4.1
	CHEST PAIN	3	3.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3.1
	EMOTIONAL LABILITY	0	0.0	0	0.0	1	1.0	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	3	3.1
	EPISTAXIS	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	2	2.0	0	0.0	0	0.0	3	3.1
	PERSONALITY DISORDER	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0	0	0.0	1	1.0	0	0.0	3	3.1
	ANXIETY	0	0.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	ASTHMA	0	0.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	CONCENTRATION IMPAIRED	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	2	2.0
	CONJUNCTIVITIS	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	2	2.0
	CONSTIPATION	0	0.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	COUGH INCREASED	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	2	2.0
	DYSPEPSIA	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	FLATULENCE	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	GASTROINTESTINAL DISORDER	2	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	MYALGIA	0	0.0	2	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0

(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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=98)	SPEECH DISORDER	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	2	2.0
	SWEATING	2	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	TREMOR	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	URINARY INCONTINENCE	0	0.0	0	0.0	2	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	VASODILATATION	0	0.0	2	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	ABNORMAL DREAMS	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	ACNE	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	ANEMIA	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	ARTHRALGIA	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	BACK PAIN	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	BRUXISM	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	COLITIS	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	CYSTITIS	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	DEPERSONALIZATION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	DEPRESSION	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	DIPLOPIA	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	EAR PAIN	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	HYPERTENSION	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0

(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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=98)	INCOORDINATION	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	INCREASED APPETITE	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	KERATOCONJUNCTIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	MYDRIASIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	PERIPHERAL EDEMA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	PHOTOSENSITIVITY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	PUSTULAR RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	STOMATITIS	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	STRIDOR	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	THYROID DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	TOOTH CARIES	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	TOOTH DISORDER	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	ULCERATIVE STOMATITIS	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	URINARY FREQUENCY	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	URINARY RETENTION	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	WEIGHT LOSS	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	YAWN	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0

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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, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=105)	HEADACHE	11	10.5	3	2.9	4	3.8	0	0.0	2	1.9	1	1.0	1	1.0	0	0.0	22	21.0
	RESPIRATORY DISORDER	4	3.8	2	1.9	1	1.0	3	2.9	2	1.9	1	1.0	2	1.9	0	0.0	15	14.3
	ABDOMINAL PAIN	3	2.9	6	5.7	2	1.9	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	12	11.4
	INFECTION	4	3.8	1	1.0	0	0.0	2	1.9	1	1.0	2	1.9	2	1.9	0	0.0	12	11.4
	NAUSEA	4	3.8	3	2.9	2	1.9	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	10	9.5
	RHINITIS	1	1.0	2	1.9	1	1.0	3	2.9	0	0.0	2	1.9	1	1.0	0	0.0	10	9.5
	DIZZINESS	2	1.9	3	2.9	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	7	6.7
	FEVER	1	1.0	1	1.0	2	1.9	1	1.0	1	1.0	0	0.0	1	1.0	0	0.0	7	6.7
	SOMNOLENCE	3	2.9	2	1.9	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	7	6.7
	COUGH INCREASED	0	0.0	2	1.9	1	1.0	1	1.0	0	0.0	1	1.0	1	1.0	0	0.0	6	5.7
	HYPERKINESIA	1	1.0	1	1.0	0	0.0	2	1.9	2	1.9	0	0.0	0	0.0	0	0.0	6	5.7
	NERVOUSNESS	2	1.9	0	0.0	0	0.0	3	2.9	1	1.0	0	0.0	0	0.0	0	0.0	6	5.7
	PHARYNGITIS	1	1.0	3	2.9	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	6	5.7
	DRY MOUTH	4	3.8	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	5	4.8
	INSOMNIA	2	1.9	1	1.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	5	4.8
	SINUSITIS	1	1.0	0	0.0	1	1.0	2	1.9	1	1.0	0	0.0	0	0.0	0	0.0	5	4.8
	ALLERGIC REACTION	0	0.0	1	1.0	0	0.0	2	1.9	0	0.0	0	0.0	0	0.0	0	0.0	3	2.9
	CONSTIPATION	0	0.0	1	1.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	3	2.9
	DYSPEPSIA	0	0.0	0	0.0	1	1.0	0	0.0	2	1.9	0	0.0	0	0.0	0	0.0	3	2.9
	OTITIS MEDIA	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9	0	0.0	3	2.9

(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 : Total, Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=105)	PAIN	0	0.0	1	1.0	0	0.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	3	2.9
	TRAUMA	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0	0	0.0	3	2.9
	AGITATION	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9	0	0.0	0	0.0	0	0.0	2	1.9
	DIARRHEA	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	2	1.9
	GASTROINTESTINAL DISORDER	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	2	1.9
	MYALGIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0	0	0.0	2	1.9
	MYOCLONUS	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	2	1.9
	URINARY INCONTINENCE	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	2	1.9
	URINARY TRACT INFECTION	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	2	1.9
	VOMITING	1	1.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	2	1.9
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	ABNORMAL VISION	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	ANXIETY	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	ARTHRALGIA	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	ASTHENIA	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	BACK PAIN	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	CONCENTRATION IMPAIRED	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	DECREASED APPETITE	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	DEPERSONALIZATION	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0

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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, Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Placebo (N=105)	DRY SKIN	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	EAR DISORDER	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	EAR PAIN	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	FUNGAL DERMATITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	GASTROENTERITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	GINGIVITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	HERPES SIMPLEX	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	HOSTILITY	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	NEUROSIS	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	NYSTAGMUS	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	SKIN BENIGN NEOPLASM	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	THIRST	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	VASODILATATION	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0

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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, Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Week 10		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Paroxetine (N=53)	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

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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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Placebo (N=64)	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

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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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Paroxetine (N=45)	DYSMENORRHEA	0	0.0	1	2.2	0	0.0	2	4.4	0	0.0	0	0.0	0	0.0	0	0.0	3	6.7

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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		Post Week 10		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																		
Placebo (N=41)	DYSMENORRHEA	0	0.0	0	0.0	1	2.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4

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=98), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	58	59.2	47	48.0	8	8.2
Body as a Whole	TOTAL	38	38.8	16	16.3	3	3.1
	ABDOMINAL PAIN	15	15.3	2	2.0	0	0.0
	ALLERGIC REACTION	3	3.1	1	1.0	0	0.0
	ASTHENIA	5	5.1	3	3.1	0	0.0
	BACK PAIN	1	1.0	0	0.0	0	0.0
	CHEST PAIN	2	2.0	1	1.0	0	0.0
	FEVER	4	4.1	0	0.0	0	0.0
	HEADACHE	17	17.3	6	6.1	1	1.0
	INFECTION	2	2.0	3	3.1	0	0.0
	PAIN	4	4.1	1	1.0	0	0.0
	TRAUMA	5	5.1	3	3.1	2	2.0
Cardiovascular System	TOTAL	1	1.0	2	2.0	0	0.0
	HYPERTENSION	0	0.0	1	1.0	0	0.0
	VASODILATATION	1	1.0	1	1.0	0	0.0
Digestive System	TOTAL	30	30.6	12	12.2	0	0.0
	BRUXISM	0	0.0	1	1.0	0	0.0
	COLITIS	1	1.0	0	0.0	0	0.0
	CONSTIPATION	0	0.0	2	2.0	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=98), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DECREASED APPETITE	8	8.2	1	1.0	0	0.0
	DIARRHEA	7	7.1	1	1.0	0	0.0
	DRY MOUTH	3	3.1	1	1.0	0	0.0
	DYSPEPSIA	0	0.0	2	2.0	0	0.0
	FLATULENCE	1	1.0	1	1.0	0	0.0
	GASTROINTESTIN-AL DISORDER	1	1.0	1	1.0	0	0.0
	INCREASED APPETITE	1	1.0	0	0.0	0	0.0
	NAUSEA	12	12.2	4	4.1	0	0.0
	STOMATITIS	0	0.0	1	1.0	0	0.0
	TOOTH CARIES	0	0.0	1	1.0	0	0.0
	TOOTH DISORDER	1	1.0	0	0.0	0	0.0
	ULCERATIVE STOMATITIS	1	1.0	0	0.0	0	0.0
	VOMITING	5	5.1	1	1.0	0	0.0
Endocrine System	TOTAL	0	0.0	1	1.0	0	0.0
	THYROID DISORDER	0	0.0	1	1.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.0	0	0.0	0	0.0
	ANEMIA	1	1.0	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=98), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Metabolic and Nutritional Disorders	TOTAL	1	1.0	1	1.0	0	0.0
	PERIPHERAL EDEMA	1	1.0	0	0.0	0	0.0
	WEIGHT LOSS	0	0.0	1	1.0	0	0.0
Musculoskeletal System	TOTAL	1	1.0	2	2.0	0	0.0
	ARTHRALGIA	0	0.0	1	1.0	0	0.0
	MYALGIA	1	1.0	1	1.0	0	0.0
Nervous System	TOTAL	21	21.4	25	25.5	5	5.1
	ABNORMAL DREAMS	1	1.0	0	0.0	0	0.0
	AGITATION	1	1.0	3	3.1	1	1.0
	ANXIETY	2	2.0	0	0.0	0	0.0
	CONCENTRATION IMPAIRED	1	1.0	1	1.0	0	0.0
	DEPERSONALIZATION	0	0.0	1	1.0	0	0.0
	DEPRESSION	0	0.0	0	0.0	1	1.0
	DIPLOPIA	1	1.0	0	0.0	0	0.0
	DIZZINESS	3	3.1	2	2.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	2	2.0	1	1.0
	HOSTILITY	2	2.0	5	5.1	2	2.0

(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=98), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	HYPERKINESIA	5	5.1	6	6.1	1	1.0
	INCOORDINATION	0	0.0	1	1.0	0	0.0
	INSOMNIA	6	6.1	3	3.1	0	0.0
	NERVOUSNESS	2	2.0	3	3.1	0	0.0
	NEUROSIS	2	2.0	3	3.1	0	0.0
	PERSONALITY DISORDER	1	1.0	2	2.0	0	0.0
	SOMNOLENCE	6	6.1	6	6.1	0	0.0
	SPEECH DISORDER	0	0.0	2	2.0	0	0.0
	TREMOR	2	2.0	0	0.0	0	0.0
Respiratory System	TOTAL	19	19.4	10	10.2	0	0.0
	ASTHMA	0	0.0	2	2.0	0	0.0
	COUGH INCREASED	1	1.0	1	1.0	0	0.0
	EPISTAXIS	1	1.0	2	2.0	0	0.0
	PHARYNGITIS	7	7.1	1	1.0	0	0.0
	RESPIRATORY DISORDER	7	7.1	5	5.1	0	0.0
	RHINITIS	3	3.1	1	1.0	0	0.0
	SINUSITIS	3	3.1	2	2.0	0	0.0
	STRIDOR	1	1.0	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=98), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	YAWN	1	1.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	3	3.1	2	2.0	0	0.0
	ACNE	0	0.0	1	1.0	0	0.0
	PHOTOSENSITIVITY	1	1.0	0	0.0	0	0.0
	PUSTULAR RASH	1	1.0	0	0.0	0	0.0
	SWEATING	1	1.0	1	1.0	0	0.0
Special Senses	TOTAL	5	5.1	1	1.0	0	0.0
	CONJUNCTIVITIS	2	2.0	0	0.0	0	0.0
	EAR PAIN	1	1.0	0	0.0	0	0.0
	KERATOCONJUNCTIVITIS	1	1.0	0	0.0	0	0.0
	MYDRIASIS	1	1.0	0	0.0	0	0.0
	OTITIS EXTERNA	0	0.0	1	1.0	0	0.0
	OTITIS MEDIA	0	0.0	1	1.0	0	0.0
Urogenital System	TOTAL	5	5.1	2	2.0	0	0.0
	ALBUMINURIA	1	1.0	0	0.0	0	0.0
	CYSTITIS	0	0.0	1	1.0	0	0.0
	HAEMATURIA	1	1.0	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=98), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Urogenital System	URINARY FREQUENCY	1	1.0	0	0.0	0	0.0
	URINARY INCONTINENCE	2	2.0	0	0.0	0	0.0
	URINARY RETENTION	0	0.0	1	1.0	0	0.0

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=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 15.1.7.1

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=45), Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	2	4.4	1	2.2
Urogenital System	TOTAL	0	0.0	2	4.4	1	2.2
	DYSMENORRHEA	0	0.0	2	4.4	1	2.2

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=105), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	66	62.9	35	33.3	5	4.8
Body as a Whole	TOTAL	32	30.5	18	17.1	0	0.0
	ABDOMINAL PAIN	8	7.6	4	3.8	0	0.0
	ALLERGIC REACTION	4	3.8	0	0.0	0	0.0
	ASTHENIA	1	1.0	0	0.0	0	0.0
	BACK PAIN	1	1.0	0	0.0	0	0.0
	FEVER	3	2.9	4	3.8	0	0.0
	HEADACHE	16	15.2	6	5.7	0	0.0
	INFECTION	6	5.7	6	5.7	0	0.0
	PAIN	3	2.9	0	0.0	0	0.0
	TRAUMA	2	1.9	1	1.0	0	0.0
Cardiovascular System	TOTAL	1	1.0	0	0.0	0	0.0
	VASODILATATION	1	1.0	0	0.0	0	0.0
Digestive System	TOTAL	20	19.0	5	4.8	0	0.0
	CONSTIPATION	2	1.9	1	1.0	0	0.0
	DECREASED APPETITE	1	1.0	0	0.0	0	0.0
	DIARRHEA	2	1.9	0	0.0	0	0.0
	DRY MOUTH	4	3.8	1	1.0	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=105), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DYSPEPSIA	2	1.9	1	1.0	0	0.0
	GASTROENTERITIS	1	1.0	0	0.0	0	0.0
	GASTROINTESTINAL DISORDER	2	1.9	0	0.0	0	0.0
	GINGIVITIS	1	1.0	0	0.0	0	0.0
	NAUSEA	8	7.6	2	1.9	0	0.0
	VOMITING	1	1.0	1	1.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.0	0	0.0	0	0.0
	LEUKOPENIA	1	1.0	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	1	1.0	0	0.0
	THIRST	0	0.0	1	1.0	0	0.0
Musculoskeletal System	TOTAL	2	1.9	1	1.0	0	0.0
	ARTHRALGIA	1	1.0	0	0.0	0	0.0
	MYALGIA	1	1.0	1	1.0	0	0.0
Nervous System	TOTAL	14	13.3	13	12.4	4	3.8
	ABNORMAL DREAMS	1	1.0	0	0.0	0	0.0
	AGITATION	0	0.0	2	1.9	0	0.0
	ANXIETY	0	0.0	0	0.0	1	1.0
	CONCENTRATION IMPAIRED	0	0.0	1	1.0	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=105), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	DEPERSONALIZATION	0	0.0	1	1.0	0	0.0
	DIZZINESS	5	4.8	1	1.0	1	1.0
	HOSTILITY	0	0.0	1	1.0	0	0.0
	HYPERKINESIA	2	1.9	4	3.8	0	0.0
	INSOMNIA	3	2.9	2	1.9	0	0.0
	MYOCLONUS	2	1.9	0	0.0	0	0.0
	NERVOUSNESS	1	1.0	5	4.8	0	0.0
	NEUROSIS	0	0.0	0	0.0	1	1.0
	NYSTAGMUS	1	1.0	0	0.0	0	0.0
	SOMNOLENCE	2	1.9	4	3.8	1	1.0
Respiratory System	TOTAL	27	25.7	10	9.5	0	0.0
	COUGH INCREASED	6	5.7	0	0.0	0	0.0
	PHARYNGITIS	4	3.8	2	1.9	0	0.0
	RESPIRATORY DISORDER	10	9.5	5	4.8	0	0.0
	RHINITIS	8	7.6	2	1.9	0	0.0
	SINUSITIS	3	2.9	2	1.9	0	0.0
Skin and Appendages	TOTAL	5	4.8	0	0.0	0	0.0
	DRY SKIN	1	1.0	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=105), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	FUNGAL DERMATITIS	1	1.0	0	0.0	0	0.0
	HERPES SIMPLEX	1	1.0	0	0.0	0	0.0
	RASH	1	1.0	0	0.0	0	0.0
	SKIN BENIGN NEOPLASM	1	1.0	0	0.0	0	0.0
Special Senses	TOTAL	4	3.8	1	1.0	1	1.0
	ABNORMAL VISION	1	1.0	0	0.0	0	0.0
	EAR DISORDER	0	0.0	1	1.0	0	0.0
	EAR PAIN	0	0.0	1	1.0	0	0.0
	OTITIS EXTERNA	1	1.0	0	0.0	0	0.0
	OTITIS MEDIA	2	1.9	0	0.0	1	1.0
Urogenital System	TOTAL	4	3.8	1	1.0	0	0.0
	HAEMATURIA	1	1.0	0	0.0	0	0.0
	URINARY INCONTINENCE	1	1.0	1	1.0	0	0.0
	URINARY TRACT INFECTION	2	1.9	0	0.0	0	0.0

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=64), Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System. Intention-To-Treat Population

Treatment Group : Placebo (N=41), Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	2.4	0	0.0	0	0.0
Urogenital System	TOTAL	1	2.4	0	0.0	0	0.0
	DYSMENORRHEA	1	2.4	0	0.0	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Maximum Intensity
By Body System. Intention-To-Treat Population Entering The Taper Phase

Treatment Group : Paroxetine (N=60), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	6	10.0	2	3.3	1	1.7
Body as a Whole	TOTAL	3	5.0	0	0.0	0	0.0
	ALLERGIC REACTION	1	1.7	0	0.0	0	0.0
	HEADACHE	2	3.3	0	0.0	0	0.0
	INFECTION	1	1.7	0	0.0	0	0.0
Digestive System	TOTAL	1	1.7	1	1.7	0	0.0
	DIARRHEA	0	0.0	1	1.7	0	0.0
	ULCERATIVE STOMATITIS	1	1.7	0	0.0	0	0.0
Musculoskeletal System	TOTAL	2	3.3	0	0.0	0	0.0
	ARTHRALGIA	1	1.7	0	0.0	0	0.0
	MYALGIA	1	1.7	0	0.0	0	0.0
Nervous System	TOTAL	2	3.3	1	1.7	1	1.7
	ANXIETY	0	0.0	0	0.0	1	1.7
	DIZZINESS	1	1.7	0	0.0	0	0.0
	NERVOUSNESS	0	0.0	1	1.7	0	0.0
	PARESTHESIA	1	1.7	0	0.0	0	0.0
Respiratory System	TOTAL	2	3.3	0	0.0	0	0.0
	RHINITIS	1	1.7	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=60), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	SINUSITIS	1	1.7	0	0.0	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Maximum Intensity
By Body System. Intention-To-Treat Population Entering The Taper Phase

Treatment Group : Paroxetine (N=31), Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Maximum Intensity
By Body System. Intention-To-Treat Population Entering The Taper Phase

Treatment Group : Paroxetine (N=29), Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Maximum Intensity
By Body System. Intention-To-Treat Population Entering The Taper Phase

Treatment Group : Placebo (N=74), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	8	10.8	6	8.1	1	1.4
Body as a Whole	TOTAL	4	5.4	5	6.8	0	0.0
	ABDOMINAL PAIN	1	1.4	0	0.0	0	0.0
	ASTHENIA	0	0.0	2	2.7	0	0.0
	HEADACHE	1	1.4	3	4.1	0	0.0
	INFECTION	2	2.7	0	0.0	0	0.0
Cardiovascular System	TOTAL	0	0.0	1	1.4	0	0.0
	VASODILATATION	0	0.0	1	1.4	0	0.0
Digestive System	TOTAL	1	1.4	1	1.4	0	0.0
	DECREASED APPETITE	0	0.0	1	1.4	0	0.0
	NAUSEA	1	1.4	0	0.0	0	0.0
Nervous System	TOTAL	2	2.7	2	2.7	1	1.4
	NERVOUSNESS	0	0.0	2	2.7	0	0.0
	NEUROSIS	2	2.7	0	0.0	1	1.4
Respiratory System	TOTAL	2	2.7	0	0.0	0	0.0
	RHINITIS	2	2.7	0	0.0	0	0.0
Special Senses	TOTAL	1	1.4	2	2.7	0	0.0
	CONJUNCTIVITIS	1	1.4	0	0.0	0	0.0
	EAR PAIN	0	0.0	1	1.4	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 : Placebo (N=74), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Special Senses	OTITIS MEDIA	0	0.0	1	1.4	0	0.0

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=47), Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Maximum Intensity
By Body System. Intention-To-Treat Population Entering The Taper Phase

Treatment Group : Placebo (N=27), Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity
By Body System. Intention-To-Treat Population

Treatment Group : Paroxetine (N=98), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	59	60.2	49	50.0	9	9.2
Body as a Whole	TOTAL	39	39.8	16	16.3	3	3.1
	ABDOMINAL PAIN	15	15.3	2	2.0	0	0.0
	ALLERGIC REACTION	4	4.1	1	1.0	0	0.0
	ASTHENIA	5	5.1	3	3.1	0	0.0
	BACK PAIN	1	1.0	0	0.0	0	0.0
	CHEST PAIN	2	2.0	1	1.0	0	0.0
	FEVER	4	4.1	0	0.0	0	0.0
	HEADACHE	18	18.4	6	6.1	1	1.0
	INFECTION	3	3.1	3	3.1	0	0.0
	PAIN	4	4.1	1	1.0	0	0.0
	TRAUMA	5	5.1	3	3.1	2	2.0
Cardiovascular System	TOTAL	1	1.0	2	2.0	0	0.0
	HYPERTENSION	0	0.0	1	1.0	0	0.0
	VASODILATATION	1	1.0	1	1.0	0	0.0
Digestive System	TOTAL	30	30.6	13	13.3	0	0.0
	BRUXISM	0	0.0	1	1.0	0	0.0
	COLITIS	1	1.0	0	0.0	0	0.0
	CONSTIPATION	0	0.0	2	2.0	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=98), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DECREASED APPETITE	8	8.2	1	1.0	0	0.0
	DIARRHEA	7	7.1	2	2.0	0	0.0
	DRY MOUTH	3	3.1	1	1.0	0	0.0
	DYSPEPSIA	0	0.0	2	2.0	0	0.0
	FLATULENCE	1	1.0	1	1.0	0	0.0
	GASTROINTESTINAL DISORDER	1	1.0	1	1.0	0	0.0
	INCREASED APPETITE	1	1.0	0	0.0	0	0.0
	NAUSEA	12	12.2	4	4.1	0	0.0
	STOMATITIS	0	0.0	1	1.0	0	0.0
	TOOTH CARIES	0	0.0	1	1.0	0	0.0
	TOOTH DISORDER	1	1.0	0	0.0	0	0.0
	ULCERATIVE STOMATITIS	2	2.0	0	0.0	0	0.0
	VOMITING	5	5.1	1	1.0	0	0.0
Endocrine System	TOTAL	0	0.0	1	1.0	0	0.0
	THYROID DISORDER	0	0.0	1	1.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.0	0	0.0	0	0.0
	ANEMIA	1	1.0	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=98), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Metabolic and Nutritional Disorders	TOTAL	1	1.0	1	1.0	0	0.0
	PERIPHERAL EDEMA	1	1.0	0	0.0	0	0.0
	WEIGHT LOSS	0	0.0	1	1.0	0	0.0
Musculoskeletal System	TOTAL	3	3.1	2	2.0	0	0.0
	ARTHRALGIA	1	1.0	1	1.0	0	0.0
	MYALGIA	2	2.0	1	1.0	0	0.0
Nervous System	TOTAL	22	22.4	26	26.5	6	6.1
	ABNORMAL DREAMS	1	1.0	0	0.0	0	0.0
	AGITATION	1	1.0	3	3.1	1	1.0
	ANXIETY	2	2.0	0	0.0	1	1.0
	CONCENTRATION IMPAIRED	1	1.0	1	1.0	0	0.0
	DEPERSONALIZATION	0	0.0	1	1.0	0	0.0
	DEPRESSION	0	0.0	0	0.0	1	1.0
	DIPLOPIA	1	1.0	0	0.0	0	0.0
	DIZZINESS	4	4.1	2	2.0	0	0.0
	EMOTIONAL LABILITY	0	0.0	2	2.0	1	1.0
	HOSTILITY	2	2.0	5	5.1	2	2.0

(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=98), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	HYPERKINESIA	5	5.1	6	6.1	1	1.0
	INCOORDINATION	0	0.0	1	1.0	0	0.0
	INSOMNIA	6	6.1	3	3.1	0	0.0
	NERVOUSNESS	1	1.0	4	4.1	0	0.0
	NEUROSIS	2	2.0	3	3.1	0	0.0
	PARESTHESIA	1	1.0	0	0.0	0	0.0
	PERSONALITY DISORDER	1	1.0	2	2.0	0	0.0
	SOMNOLENCE	6	6.1	6	6.1	0	0.0
	SPEECH DISORDER	0	0.0	2	2.0	0	0.0
	TREMOR	2	2.0	0	0.0	0	0.0
Respiratory System	TOTAL	20	20.4	10	10.2	0	0.0
	ASTHMA	0	0.0	2	2.0	0	0.0
	COUGH INCREASED	1	1.0	1	1.0	0	0.0
	EPISTAXIS	1	1.0	2	2.0	0	0.0
	PHARYNGITIS	7	7.1	1	1.0	0	0.0
	RESPIRATORY DISORDER	7	7.1	5	5.1	0	0.0
	RHINITIS	4	4.1	1	1.0	0	0.0
	SINUSITIS	4	4.1	2	2.0	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=98), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	STRIDOR	1	1.0	0	0.0	0	0.0
	YAWN	1	1.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	3	3.1	2	2.0	0	0.0
	ACNE	0	0.0	1	1.0	0	0.0
	PHOTOSENSITIVITY	1	1.0	0	0.0	0	0.0
	PUSTULAR RASH	1	1.0	0	0.0	0	0.0
	SWEATING	1	1.0	1	1.0	0	0.0
Special Senses	TOTAL	5	5.1	1	1.0	0	0.0
	CONJUNCTIVITIS	2	2.0	0	0.0	0	0.0
	EAR PAIN	1	1.0	0	0.0	0	0.0
	KERATOCONJUNCTIVITIS	1	1.0	0	0.0	0	0.0
	MYDRIASIS	1	1.0	0	0.0	0	0.0
	OTITIS EXTERNA	0	0.0	1	1.0	0	0.0
	OTITIS MEDIA	0	0.0	1	1.0	0	0.0
Urogenital System	TOTAL	5	5.1	2	2.0	0	0.0
	ALBUMINURIA	1	1.0	0	0.0	0	0.0
	CYSTITIS	0	0.0	1	1.0	0	0.0
	HAEMATURIA	1	1.0	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=98), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
Urogenital System	URINARY FREQUENCY	1	1.0	0	0.0	0	0.0
	URINARY INCONTINENCE	2	2.0	0	0.0	0	0.0
	URINARY RETENTION	0	0.0	1	1.0	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 : 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 15.1.7.3

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=45), Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	2	4.4	1	2.2
Urogenital System	TOTAL	0	0.0	2	4.4	1	2.2
	DYSMENORRHEA	0	0.0	2	4.4	1	2.2

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=105), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	68	64.8	40	38.1	6	5.7
Body as a Whole	TOTAL	33	31.4	23	21.9	0	0.0
	ABDOMINAL PAIN	9	8.6	4	3.8	0	0.0
	ALLERGIC REACTION	4	3.8	0	0.0	0	0.0
	ASTHENIA	1	1.0	2	1.9	0	0.0
	BACK PAIN	1	1.0	0	0.0	0	0.0
	FEVER	3	2.9	4	3.8	0	0.0
	HEADACHE	15	14.3	9	8.6	0	0.0
	INFECTION	7	6.7	6	5.7	0	0.0
	PAIN	3	2.9	0	0.0	0	0.0
	TRAUMA	2	1.9	1	1.0	0	0.0
Cardiovascular System	TOTAL	1	1.0	1	1.0	0	0.0
	VASODILATATION	1	1.0	1	1.0	0	0.0
Digestive System	TOTAL	21	20.0	6	5.7	0	0.0
	CONSTIPATION	2	1.9	1	1.0	0	0.0
	DECREASED APPETITE	1	1.0	1	1.0	0	0.0
	DIARRHEA	2	1.9	0	0.0	0	0.0
	DRY MOUTH	4	3.8	1	1.0	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=105), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DYSPEPSIA	2	1.9	1	1.0	0	0.0
	GASTROENTERITIS	1	1.0	0	0.0	0	0.0
	GASTROINTESTINAL DISORDER	2	1.9	0	0.0	0	0.0
	GINGIVITIS	1	1.0	0	0.0	0	0.0
	NAUSEA	9	8.6	2	1.9	0	0.0
	VOMITING	1	1.0	1	1.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.0	0	0.0	0	0.0
	LEUKOPENIA	1	1.0	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	0	0.0	1	1.0	0	0.0
	THIRST	0	0.0	1	1.0	0	0.0
Musculoskeletal System	TOTAL	2	1.9	1	1.0	0	0.0
	ARTHRALGIA	1	1.0	0	0.0	0	0.0
	MYALGIA	1	1.0	1	1.0	0	0.0
Nervous System	TOTAL	16	15.2	15	14.3	5	4.8
	ABNORMAL DREAMS	1	1.0	0	0.0	0	0.0
	AGITATION	0	0.0	2	1.9	0	0.0
	ANXIETY	0	0.0	0	0.0	1	1.0
	CONCENTRATION IMPAIRED	0	0.0	1	1.0	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=105), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	DEPERSONALIZATION	0	0.0	1	1.0	0	0.0
	DIZZINESS	5	4.8	1	1.0	1	1.0
	HOSTILITY	0	0.0	1	1.0	0	0.0
	HYPERKINESIA	2	1.9	4	3.8	0	0.0
	INSOMNIA	3	2.9	2	1.9	0	0.0
	MYOCLONUS	2	1.9	0	0.0	0	0.0
	NERVOUSNESS	1	1.0	7	6.7	0	0.0
	NEUROSIS	2	1.9	0	0.0	2	1.9
	NYSTAGMUS	1	1.0	0	0.0	0	0.0
	SOMNOLENCE	2	1.9	4	3.8	1	1.0
Respiratory System	TOTAL	27	25.7	10	9.5	0	0.0
	COUGH INCREASED	6	5.7	0	0.0	0	0.0
	PHARYNGITIS	4	3.8	2	1.9	0	0.0
	RESPIRATORY DISORDER	10	9.5	5	4.8	0	0.0
	RHINITIS	8	7.6	2	1.9	0	0.0
	SINUSITIS	3	2.9	2	1.9	0	0.0
Skin and Appendages	TOTAL	5	4.8	0	0.0	0	0.0
	DRY SKIN	1	1.0	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=105), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	FUNGAL DERMATITIS	1	1.0	0	0.0	0	0.0
	HERPES SIMPLEX	1	1.0	0	0.0	0	0.0
	RASH	1	1.0	0	0.0	0	0.0
	SKIN BENIGN NEOPLASM	1	1.0	0	0.0	0	0.0
Special Senses	TOTAL	5	4.8	3	2.9	1	1.0
	ABNORMAL VISION	1	1.0	0	0.0	0	0.0
	CONJUNCTIVITIS	1	1.0	0	0.0	0	0.0
	EAR DISORDER	0	0.0	1	1.0	0	0.0
	EAR PAIN	0	0.0	2	1.9	0	0.0
	OTITIS EXTERNA	1	1.0	0	0.0	0	0.0
	OTITIS MEDIA	2	1.9	1	1.0	1	1.0
Urogenital System	TOTAL	4	3.8	1	1.0	0	0.0
	HAEMATURIA	1	1.0	0	0.0	0	0.0
	URINARY INCONTINENCE	1	1.0	1	1.0	0	0.0
	URINARY TRACT INFECTION	2	1.9	0	0.0	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=64), Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity
By Body System. Intention-To-Treat Population

Treatment Group : Placebo (N=41), Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	2.4	0	0.0	0	0.0
Urogenital System	TOTAL	1	2.4	0	0.0	0	0.0
	DYSMENORRHEA	1	2.4	0	0.0	0	0.0

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Maximum Intensity
By Body System. Intention-To-Treat Population Entering The Follow-Up Phase

Treatment Group : Paroxetine (N=37), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	4	10.8	2	5.4	2	5.4
Body as a Whole	TOTAL	2	5.4	0	0.0	0	0.0
	HEADACHE	2	5.4	0	0.0	0	0.0
Digestive System	TOTAL	2	5.4	1	2.7	1	2.7
	NAUSEA	1	2.7	1	2.7	0	0.0
	VOMITING	1	2.7	1	2.7	1	2.7
Nervous System	TOTAL	1	2.7	0	0.0	1	2.7
	HOSTILITY	0	0.0	0	0.0	1	2.7
	NERVOUSNESS	1	2.7	0	0.0	0	0.0
Respiratory System	TOTAL	0	0.0	1	2.7	0	0.0
	RESPIRATORY DISORDER	0	0.0	1	2.7	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=20), 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=17), 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=39), Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	2	5.1	1	2.6	0	0.0
Digestive System	TOTAL	1	2.6	0	0.0	0	0.0
	DRY MOUTH	1	2.6	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	1	2.6	0	0.0
	INSOMNIA	0	0.0	1	2.6	0	0.0
Urogenital System	TOTAL	1	2.6	0	0.0	0	0.0
	ALBUMINURIA	1	2.6	0	0.0	0	0.0
	HAEMATURIA	1	2.6	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=22), 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 : Placebo (N=17), 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 15.1.8

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=58)	Treatment Group: Placebo (N=57)
TOTAL	TOTAL	16 (27.6%)	5 (8.8%)
Nervous System	TOTAL	14 (24.1%)	4 (7.0%)
	HYPERKINESIA	6 (10.3%)	2 (3.5%)
	HOSTILITY	3 (5.2%)	0
	INSOMNIA	2 (3.4%)	0
	NEUROSIS	2 (3.4%)	0
	SOMNOLENCE	2 (3.4%)	0
	NERVOUSNESS	1 (1.7%)	1 (1.8%)
	AGITATION	1 (1.7%)	0
	ANXIETY	1 (1.7%)	0
	PERSONALITY DISORDER	1 (1.7%)	0
	CONCENTRATION IMPAIRED	0	1 (1.8%)
Body as a Whole	TOTAL	2 (3.4%)	1 (1.8%)
	ASTHENIA	1 (1.7%)	0
	TRAUMA	1 (1.7%)	0
	HEADACHE	0	1 (1.8%)
Digestive System	TOTAL	1 (1.7%)	1 (1.8%)
	INCREASED APPETITE	1 (1.7%)	0
	NAUSEA	0	1 (1.8%)
	VOMITING	0	1 (1.8%)

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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

Body System	Preferred Term	Treatment Group: Paroxetine (N=31)	Treatment Group: Placebo (N=35)
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=27)	Placebo (N=22)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

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=40)	 Placebo (N=48)
TOTAL	TOTAL	4 (10.0%)	3 (6.3%)
Nervous System	TOTAL	4 (10.0%)	3 (6.3%)
	SOMNOLENCE	2 (5.0%)	0
	NERVOUSNESS	1 (2.5%)	3 (6.3%)
	ANXIETY	1 (2.5%)	1 (2.1%)
	HYPERKINESIA	1 (2.5%)	1 (2.1%)
	INSOMNIA	0	2 (4.2%)
	AGITATION	0	1 (2.1%)
Digestive System	TOTAL	1 (2.5%)	0
	BRUXISM	1 (2.5%)	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, Male Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=22)	Placebo (N=29)
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

Body System	Preferred Term	Treatment Group: Paroxetine (N=18)	Treatment Group: Placebo (N=19)
TOTAL	TOTAL	0	0

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=98)	Treatment Group: Placebo (N=105)
TOTAL	TOTAL	20 (20.4%)	8 (7.6%)
Nervous System	TOTAL	18 (18.4%)	7 (6.7%)
	HYPERKINESIA	7 (7.1%)	3 (2.9%)
	SOMNOLENCE	4 (4.1%)	0
	HOSTILITY	3 (3.1%)	0
	NERVOUSNESS	2 (2.0%)	4 (3.8%)
	INSOMNIA	2 (2.0%)	2 (1.9%)
	ANXIETY	2 (2.0%)	1 (1.0%)
	NEUROSIS	2 (2.0%)	0
	AGITATION	1 (1.0%)	1 (1.0%)
	PERSONALITY DISORDER	1 (1.0%)	0
	CONCENTRATION IMPAIRED	0	1 (1.0%)
Body as a Whole	TOTAL	2 (2.0%)	1 (1.0%)
	ASTHENIA	1 (1.0%)	0
	TRAUMA	1 (1.0%)	0
	HEADACHE	0	1 (1.0%)
Digestive System	TOTAL	2 (2.0%)	1 (1.0%)
	BRUXISM	1 (1.0%)	0
	INCREASED APPETITE	1 (1.0%)	0
	NAUSEA	0	1 (1.0%)
	VOMITING	0	1 (1.0%)

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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, Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=64)
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=45)	Placebo (N=41)
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 and Treatment Phase
Intention-To-Treat Population

Vital Signs Variable : Systolic Blood Pressure / mmHg

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Minimum	Maximum	N	Mean	Median	Std Dev	Minimum	Maximum
Baseline	98	106.5	106.0	11.32	79	138	105	108.1	108.0	12.33	74	142
Change from baseline to:												
Week 1	93	1.6	2.0	7.99	-16	21	99	-1.3	0.0	10.65	-36	24
Week 2	88	1.1	1.0	11.83	-26	38	88	-1.5	0.0	11.34	-32	31
Week 3	88	-0.0	0.0	9.50	-23	27	84	-0.4	0.0	12.96	-34	36
Week 4	83	1.7	2.0	11.95	-30	39	92	-2.9	-2.0	12.04	-38	31
Week 6	75	2.5	1.0	10.91	-25	27	88	-3.0	-2.0	11.44	-36	20
Week 8	67	0.8	0.0	10.37	-23	28	82	-0.6	-1.5	10.81	-27	35
Week 10	56	1.0	2.0	9.94	-22	29	66	1.4	0.5	13.00	-25	40
Post Week 10	0	.	.	.	.	.	1	6.0	6.0	.	6	6

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 and Treatment Phase
Intention-To-Treat Population

Vital Signs Variable : Diastolic Blood Pressure / mmHg

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Minimum	Maximum	N	Mean	Median	Std Dev	Minimum	Maximum
Baseline	98	66.2	66.0	8.97	40	87	105	66.5	68.0	8.65	44	86
Change from baseline to:												
Week 1	93	-0.1	0.0	11.68	-39	43	99	-0.7	0.0	9.89	-40	28
Week 2	88	-0.6	-1.5	13.11	-36	47	88	0.1	0.0	9.20	-20	38
Week 3	88	1.2	2.0	9.78	-23	28	84	-0.0	0.0	9.57	-35	32
Week 4	83	0.7	0.0	11.47	-42	30	92	-0.6	0.0	9.98	-27	21
Week 6	75	0.5	0.0	10.58	-23	38	88	0.4	0.0	9.38	-24	24
Week 8	67	1.6	2.0	10.73	-25	38	82	-0.9	0.0	9.53	-34	23
Week 10	56	2.0	2.0	10.79	-27	29	66	1.2	0.0	10.92	-26	23
Post Week 10	0	.	.	.	.	.	1	-13.0	-13.0	.	-13	-13

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 and Treatment Phase
Intention-To-Treat Population

Vital Signs Variable : Heart Rate / BPM

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Minimum	Maximum	N	Mean	Median	Std Dev	Minimum	Maximum
Baseline	98	82.1	80.0	11.86	51	114	105	79.4	80.0	11.29	52	118
Change from baseline to:												
Week 1	93	-1.5	0.0	10.34	-24	32	99	1.1	0.0	11.68	-34	41
Week 2	88	-2.7	-2.5	11.70	-42	24	88	1.2	0.0	12.53	-39	43
Week 3	88	-0.4	-2.0	13.33	-44	40	84	-0.2	0.0	11.86	-24	35
Week 4	83	0.6	1.0	13.14	-42	48	92	1.0	0.0	11.20	-23	41
Week 6	75	1.0	1.0	11.86	-32	28	89	1.5	0.0	10.76	-24	33
Week 8	67	-0.5	0.0	10.83	-26	26	82	1.7	1.5	10.41	-22	29
Week 10	56	2.7	3.5	9.59	-31	25	66	1.1	2.0	10.84	-22	24
Post Week 10	0	.	.	.	.	.	1	-2.0	-2.0	.	-2	-2

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 and Treatment Phase
Intention-To-Treat Population

Vital Signs Variable : Height / cm

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Minimum	Maximum	N	Mean	Median	Std Dev	Minimum	Maximum
Baseline	98	147.95	148.60	18.737	106.6	188.0	104	150.52	149.90	17.470	106.6	192.0
Change from baseline to: Week 10	53	1.54	1.00	3.626	-2.5	25.5	59	1.19	0.80	1.565	-0.7	6.0

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline

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Table 15.2.1.1

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
Pre-Treatment and Treatment Phase
Intention-To-Treat Population

Vital Signs Variable : Weight / kg

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Minimum	Maximum	N	Mean	Median	Std Dev	Minimum	Maximum
Baseline	98	46.33	42.00	20.520	18.6	110.9	104	48.94	43.80	19.512	19.0	104.0
Change from baseline to: Week 10	53	1.01	0.80	1.953	-3.7	5.9	60	0.82	0.90	2.712	-12.3	6.3

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 and Treatment Phase
Intention-To-Treat Population

Vital Signs Variable : Body Mass Index / kg/m2

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Minimum	Maximum	N	Mean	Median	Std Dev	Minimum	Maximum
Baseline	98	20.15	19.35	5.294	13.0	41.9	104	20.85	19.65	5.321	13.7	40.1
Change from baseline to: Week 10	53	-0.01	0.10	1.639	-9.8	2.9	59	0.10	0.30	1.140	-4.3	2.1

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, 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	Minimum	Maximum	N	Mean	Median	Std Dev	Minimum	Maximum
Baseline	98	106.5	106.0	11.32	79	138	105	108.1	108.0	12.33	74	142
Change from baseline to:												
Week 1	0	.	.	.	.	.	0	.	.	.	.	.
Week 2	2	-6.0	-6.0	2.83	-8	-4	2	13.5	13.5	0.71	13	14
Week 3	1	-17.0	-17.0	.	-17	-17	2	12.0	12.0	16.97	0	24
Week 4	2	-8.0	-8.0	14.14	-18	2	0	.	.	.	.	.
Week 6	6	3.5	1.0	13.47	-16	24	3	5.7	10.0	10.21	-6	13
Week 8	5	-7.4	-5.0	8.14	-21	0	2	-3.0	-3.0	12.73	-12	6
Week 10	52	0.4	0.0	10.34	-22	22	48	-2.0	-2.0	12.48	-30	36
Post Week 10	17	1.8	2.0	11.20	-31	20	36	0.5	1.0	14.11	-26	38

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 10')
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, 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	Minimum	Maximum	N	Mean	Median	Std Dev	Minimum	Maximum
Baseline	98	66.2	66.0	8.97	40	87	105	66.5	68.0	8.65	44	86
Change from baseline to:												
Week 1	0	.	.	.	.	.	0	.	.	.	.	.
Week 2	2	-17.5	-17.5	0.71	-18	-17	2	1.5	1.5	4.95	-2	5
Week 3	1	-30.0	-30.0	.	-30	-30	2	8.0	8.0	14.14	-2	18
Week 4	2	1.0	1.0	4.24	-2	4	0	.	.	.	.	.
Week 6	6	1.7	0.0	8.98	-8	16	3	10.3	14.0	10.02	-1	18
Week 8	5	0.2	0.0	4.44	-5	6	2	-1.5	-1.5	12.02	-10	7
Week 10	52	1.5	0.0	11.40	-28	28	48	-2.8	-1.0	8.59	-31	13
Post Week 10	17	2.7	0.0	8.90	-13	26	36	0.3	1.0	8.41	-16	16

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 10')
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, 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	Minimum	Maximum	N	Mean	Median	Std Dev	Minimum	Maximum
Baseline	98	82.1	80.0	11.86	51	114	105	79.4	80.0	11.29	52	118
Change from baseline to:												
Week 1	0	.	.	.	.	.	0	.	.	.	.	.
Week 2	2	2.0	2.0	15.56	-9	13	2	8.5	8.5	20.51	-6	23
Week 3	1	17.0	17.0	.	17	17	2	6.0	6.0	8.49	0	12
Week 4	2	7.0	7.0	21.21	-8	22	0	.	.	.	.	.
Week 6	6	3.7	2.0	13.17	-14	24	3	-10.3	-16.0	11.59	-18	3
Week 8	5	-4.6	-4.0	9.10	-17	4	2	1.5	1.5	2.12	0	3
Week 10	52	-1.8	0.0	12.05	-29	21	48	0.4	0.0	11.76	-20	33
Post Week 10	17	-0.9	-2.0	13.74	-32	26	36	0.6	1.0	12.44	-23	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 10')
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, Taper Phase and Follow-Up Phase
Intention-To-Treat Population

Vital Signs Variable : Height / cm

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Minimum	Maximum	N	Mean	Median	Std Dev	Minimum	Maximum
Baseline	98	147.95	148.60	18.737	106.6	188.0	104	150.52	149.90	17.470	106.6	192.0
Change from baseline to:												
Week 10	13	1.01	0.60	1.124	0.0	3.0	16	1.14	1.20	1.602	-2.6	4.0

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 10')
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, Taper Phase and Follow-Up Phase
Intention-To-Treat Population

Vital Signs Variable : Weight / kg

	Treatment Group											
	Paroxetine						Placebo					
	N	Mean	Median	Std Dev	Minimum	Maximum	N	Mean	Median	Std Dev	Minimum	Maximum
Baseline	98	46.33	42.00	20.520	18.6	110.9	104	48.94	43.80	19.512	19.0	104.0
Change from baseline to: Week 10	13	1.19	1.10	1.369	-2.0	3.7	16	1.23	0.70	2.505	-3.7	5.0

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 10')
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, 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	Minimum	Maximum	N	Mean	Median	Std Dev	Minimum	Maximum
Baseline	98	20.15	19.35	5.294	13.0	41.9	104	20.85	19.65	5.321	13.7	40.1
Change from baseline to:												
Week 10	13	0.40	0.20	0.736	-0.7	1.8	16	0.26	-0.05	1.215	-1.6	2.9

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 10')
have both assessments in the summary statistics, but N represents the number of subjects at that week.

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Table 15.2.2.1

Number (%) of Patients with Vital Signs of Potential Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population

Vital Signs Variable : Systolic Blood Pressure / mmHg

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	96	N/A	105	N/A
Number with Baseline and Post-Baseline Assessment	96	100.0	105	100.0
Low	29	30.2	38	36.2
Significant Decrease	2	2.1	6	5.7
Low & Significant Decrease	0	0.0	3	2.9
Low & Significant Increase	0	0.0	0	0.0
High	2	2.1	1	1.0
Significant Increase	0	0.0	1	1.0
High & Significant Increase	0	0.0	1	1.0
High & Significant Decrease	0	0.0	0	0.0

Number 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 limits used for weight
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, Treatment Phase (including Taper)

Intention-To-Treat Population

Vital Signs Variable : Diastolic Blood Pressure / mmHg

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	96	N/A	105	N/A
Number with Baseline and Post-Baseline Assessment	96	100.0	105	100.0
Low	9	9.4	12	11.4
Significant Decrease	13	13.5	8	7.6
Low & Significant Decrease	4	4.2	1	1.0
Low & Significant Increase	0	0.0	1	1.0
High	10	10.4	5	4.8
Significant Increase	3	3.1	2	1.9
High & Significant Increase	2	2.1	1	1.0
High & Significant Decrease	3	3.1	0	0.0

Number 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 limits used for weight
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, Treatment Phase (including Taper)

Intention-To-Treat Population

Vital Signs Variable : Heart Rate / BPM

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	96	N/A	105	N/A
Number with Baseline and Post-Baseline Assessment	96	100.0	105	100.0
Low	13	13.5	15	14.3
Significant Decrease	3	3.1	2	1.9
Low & Significant Decrease	0	0.0	2	1.9
Low & Significant Increase	1	1.0	0	0.0
High	6	6.3	1	1.0
Significant Increase	5	5.2	4	3.8
High & Significant Increase	3	3.1	0	0.0
High & Significant Decrease	0	0.0	0	0.0

Number 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 limits used for weight
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, Treatment Phase (including Taper)

Intention-To-Treat Population

Vital Signs Variable : Weight / kg

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	72	N/A	82	N/A
Number with Baseline and Post-Baseline Assessment	72	100.0	81	100.0
Low	0	0.0	0	0.0
Significant Decrease	0	0.0	3	3.7
Low & Significant Decrease	0	0.0	0	0.0
Low & Significant Increase	0	0.0	0	0.0
High	14	19.4	22	27.2
Significant Increase	8	11.1	15	18.5
High & Significant Increase	0	0.0	3	3.7
High & Significant Decrease	0	0.0	0	0.0

Number 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 limits used for weight
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, 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	97	N/A	105	N/A
Number with Baseline and Post-Baseline Assessment	97	100.0	105	100.0
Low	34	35.1	39	37.1
Significant Decrease	2	2.1	6	5.7
Low & Significant Decrease	0	0.0	3	2.9
Low & Significant Increase	0	0.0	0	0.0
High	2	2.1	1	1.0
Significant Increase	0	0.0	1	1.0
High & Significant Increase	0	0.0	1	1.0
High & Significant Decrease	0	0.0	0	0.0

Number 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 limits used for weight
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, 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	97	N/A	105	N/A
Number with Baseline and Post-Baseline Assessment	97	100.0	105	100.0
Low	10	10.3	12	11.4
Significant Decrease	14	14.4	8	7.6
Low & Significant Decrease	5	5.2	1	1.0
Low & Significant Increase	0	0.0	1	1.0
High	10	10.3	5	4.8
Significant Increase	3	3.1	2	1.9
High & Significant Increase	2	2.1	1	1.0
High & Significant Decrease	3	3.1	0	0.0

Number 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 limits used for weight
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, 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	97	N/A	105	N/A
Number with Baseline and Post-Baseline Assessment	97	100.0	105	100.0
Low	13	13.4	16	15.2
Significant Decrease	3	3.1	2	1.9
Low & Significant Decrease	0	0.0	2	1.9
Low & Significant Increase	1	1.0	0	0.0
High	6	6.2	3	2.9
Significant Increase	5	5.2	5	4.8
High & Significant Increase	3	3.1	1	1.0
High & Significant Decrease	0	0.0	0	0.0

Number 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 limits used for weight
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, 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	82	N/A	91	N/A
Number with Baseline and Post-Baseline Assessment	82	100.0	90	100.0
Low	0	0.0	0	0.0
Significant Decrease	0	0.0	3	3.3
Low & Significant Decrease	0	0.0	0	0.0
Low & Significant Increase	0	0.0	0	0.0
High	15	18.3	22	24.4
Significant Increase	8	9.8	17	18.9
High & Significant Increase	0	0.0	3	3.3
High & Significant Decrease	0	0.0	0	0.0

Number 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 limits used for weight
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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of 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 .	0 .	1 (1.7%)
Number of Patients with Assessment	14 (100.0%)	59 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Hematocrit, Unit:%

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Low (Extended)	0 .	5 (8.5%)	3 (5.2%)
Number of Patients with Assessment	14 (100.0%)	59 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	14 (100.0%)	59 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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		Treatment Group: Paroxetine		Treatment Group: Placebo	
High (Extended)	0	.	1	(1.7%)	0	.
Low (Extended)	0	.	1	(1.7%)	0	.
Number of Patients with Assessment	14	(100.0%)	59	(100.0%)	58	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	14 (100.0%)	59 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	14 (100.0%)	59 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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)	1 (7.1%)	1 (1.7%)	2 (3.4%)
Number of Patients with Assessment	14 (100.0%)	59 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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)	0 .	2 (3.4%)	0 .
Number of Patients with Assessment	14 (100.0%)	59 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	14 (100.0%)	59 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Neutrophils Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
High (Extended)	0 .	1 (1.7%)	1 (1.7%)
Low (Extended)	2 (14.3%)	2 (3.4%)	4 (6.9%)
Number of Patients with Assessment	14 (100.0%)	59 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	14 (100.0%)	60 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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 (7.1%)	0 .	0 .
Number of Patients with Assessment	14 (100.0%)	60 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	14 (100.0%)	60 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	14 (100.0%)	60 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Alkaline Phosphatase, Unit:IU/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	14 (100.0%)	60 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	14 (100.0%)	60 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	14 (100.0%)	60 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	14 (100.0%)	60 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	14 (100.0%)	60 (100.0%)	56 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Free T3, Unit:PMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	14 (100.0%)	57 (100.0%)	57 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Children
Parameter:Total Free Thyroxine, Unit:PMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	14 (100.0%)	57 (100.0%)	58 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Hemoglobin, Unit:G/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Hematocrit, Unit:%

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Low (Extended)	1 (10.0%)	3 (7.5%)	3 (6.1%)
Number of Patients with Assessment	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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
Number of Patients with Assessment	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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)	1 (10.0%)	1 (2.5%)	0 .
Number of Patients with Assessment	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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
High (Extended)	0 .	0 .	1 (2.0%)
Number of Patients with Assessment	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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 .	0 .	1 (2.0%)
Number of Patients with Assessment	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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 .	1 (2.5%)	2 (4.1%)
Number of Patients with Assessment	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Alkaline Phosphatase, Unit:IU/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Aspartate Aminotransferase, Unit:IU/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Total Bilirubin, Unit:UMOL/L

Flag	Treatment Group: No Therapy Dispensed	Treatment Group: Paroxetine	Treatment Group: Placebo
High (Extended)	0 .	1 (2.5%)	0 .
Number of Patients with Assessment	10 (100.0%)	40 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 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 .	1 (2.5%)	0 .
Number of Patients with Assessment	10 (100.0%)	40 (100.0%)	48 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any 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 Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Free T3, Unit:PMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	10 (100.0%)	40 (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 Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Adolescents
Parameter:Total Free Thyroxine, Unit:PMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	10 (100.0%)	38 (100.0%)	46 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Hemoglobin, Unit:G/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Low (Extended)	0 .	0 .	1 (0.9%)
Number of Patients with Assessment	24 (100.0%)	99 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Hematocrit, Unit:%

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Low (Extended)	1 (4.2%)	8 (8.1%)	6 (5.6%)
Number of Patients with Assessment	24 (100.0%)	99 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of 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	24 (100.0%)	99 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of 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	.	1	(1.0%)	0	.
Low (Extended)	0	.	1	(1.0%)	0	.
Number of Patients with Assessment	24	(100.0%)	99	(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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of 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	24 (100.0%)	99 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Basophils Absolute, Unit:10^9/L

	Treatment Group		
Flag	No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	24 (100.0%)	99 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of 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 (8.3%)	2 (2.0%)	2 (1.9%)
Number of Patients with Assessment	24 (100.0%)	99 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of 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)	0 .	2 (2.0%)	1 (0.9%)
Number of Patients with Assessment	24 (100.0%)	99 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of 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 .	0 .	1 (0.9%)
Number of Patients with Assessment	24 (100.0%)	99 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of 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 .	1 (1.0%)	1 (0.9%)
Low (Extended)	2 (8.3%)	3 (3.0%)	6 (5.6%)
Number of Patients with Assessment	24 (100.0%)	99 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of 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	24 (100.0%)	100 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of 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 (4.2%)	0 .	0 .
Number of Patients with Assessment	24 (100.0%)	100 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of 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	24 (100.0%)	100 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of 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	24 (100.0%)	100 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Alkaline Phosphatase, Unit:IU/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	24 (100.0%)	100 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Aspartate Aminotransferase, Unit:IU/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	24 (100.0%)	100 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of 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	24 (100.0%)	100 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of 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 .	1 (1.0%)	0 .
Number of Patients with Assessment	24 (100.0%)	100 (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 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of 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 .	1 (1.0%)	0 .
Number of Patients with Assessment	24 (100.0%)	100 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Free T3, Unit:PMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	24 (100.0%)	97 (100.0%)	102 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.1

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Pre-Treatment Phase

All Patients
Age Group:Total
Parameter:Total Free Thyroxine, Unit:PMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	24 (100.0%)	95 (100.0%)	104 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Hemoglobin Unit : G/L

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	3 (7.9%)	1 (2.3%)
Number of Patients with Assessment	38 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Hematocrit Unit : %

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Low (Extended)	6 (15.8%)	4 (9.1%)
Number of Patients with Assessment	38 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	38 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : White Blood Cell Count Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	1 (2.6%)	0 .
Number of Patients with Assessment	38 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Platelets Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	38 (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 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of 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	38 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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)	0	.	2	(4.5%)
Number of Patients with Assessment	38	(100.0%)	44	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Lymphocytes Absolute Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	38 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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
Number of Patients with Assessment	38 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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
Low (Extended)	2 (5.3%)	1 (2.3%)
Number of Patients with Assessment	38 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	41 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Potassium Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	41 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Blood Urea Nitrogen Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	41 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	41 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Alkaline Phosphatase Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	41 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Aspartate Aminotransferase Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	41 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Alanine Aminotransferase Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	41 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	41 (100.0%)	44 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Thyroid Stimulating Hormone Unit : MU/L

Flag	Treatment Group Placebo
Number of Patients with Assessment	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 Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Free T3 Unit : PMOL/L

Flag	Treatment Group Placebo
Number of Patients with Assessment	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 Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Total Free Thyroxine Unit : PMOL/L

Flag	Treatment Group Placebo
Number of Patients with Assessment	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 Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Hemoglobin Unit : G/L

Flag	Treatment Group: Paroxetine		Treatment Group: Placebo	
Low (Extended)	0	.	1	(2.7%)
Number of Patients with Assessment	33	(100.0%)	37	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Hematocrit Unit : %

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	5 (15.2%)	3 (8.1%)
Number of Patients with Assessment	33 (100.0%)	37 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	33 (100.0%)	37 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : White Blood Cell Count Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	33 (100.0%)	37 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Platelets Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	33 (100.0%)	37 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	33 (100.0%)	37 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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
Number of Patients with Assessment	33 (100.0%)	37 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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
High (Extended)	1 (3.0%)	1 (2.7%)
Number of Patients with Assessment	33 (100.0%)	37 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	33 (100.0%)	37 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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
Number of Patients with Assessment	33 (100.0%)	37 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Sodium Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	31 (100.0%)	36 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Potassium Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	31 (100.0%)	36 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Blood Urea Nitrogen Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	31 (100.0%)	36 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	31 (100.0%)	36 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Alkaline Phosphatase Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	31 (100.0%)	36 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	31 (100.0%)	36 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	31 (100.0%)	36 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Total Bilirubin Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	31 (100.0%)	36 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	1 (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 Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Free T3 Unit : PMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	1 (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 Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Adolescents
Parameter : Total Free Thyroxine Unit : PMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	1 (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 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)	3 (4.2%)	2 (2.5%)
Number of Patients with Assessment	71 (100.0%)	81 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Hematocrit Unit : %

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Low (Extended)	11 (15.5%)	7 (8.6%)
Number of Patients with Assessment	71 (100.0%)	81 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	71 (100.0%)	81 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : White Blood Cell Count Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	1 (1.4%)	0 .
Number of Patients with Assessment	71 (100.0%)	81 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Platelets Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	71 (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 Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Basophils Absolute Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	71 (100.0%)	81 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Eosinophils Absolute Unit : 10^9/L

Flag	Treatment Group: Paroxetine		Treatment Group: Placebo	
High (Extended)	0	.	2	(2.5%)
Number of Patients with Assessment	71	(100.0%)	81	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Lymphocytes Absolute Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
High (Extended)	1 (1.4%)	1 (1.2%)
Number of Patients with Assessment	71 (100.0%)	81 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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
Number of Patients with Assessment	71 (100.0%)	81 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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
Low (Extended)	2 (2.8%)	1 (1.2%)
Number of Patients with Assessment	71 (100.0%)	81 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Sodium Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	72 (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 Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Potassium Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	72 (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 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	72 (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 Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Creatinine Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	72 (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 Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Alkaline Phosphatase Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	72 (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 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	72 (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 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	72 (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 Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Total Bilirubin Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	72 (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 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	1 (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 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Free T3 Unit : PMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	1 (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 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Total
Parameter : Total Free Thyroxine Unit : PMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	1 (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 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	Treatment Group: Placebo
Number of Patients with Assessment	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Hematocrit, Unit : %

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	Treatment Group: Placebo
Number of Patients with Assessment	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	Treatment Group: Placebo
Number of Patients with Assessment	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	Treatment Group: Placebo
Number of Patients with Assessment	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	Placebo
High (Extended)	1 (10.0%)	0 .
Number of Patients with Assessment	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Sodium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Potassium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	Treatment Group: Placebo
Number of Patients with Assessment	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Alkaline Phosphatase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	Treatment Group: Placebo
Number of Patients with Assessment	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	10 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Thyroid Stimulating Hormone, Unit : MU/L

Flag	Treatment Group Paroxetine
Number of Patients with Assessment	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 Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Free T3, Unit : PMOL/L

Flag	Treatment Group Paroxetine
Number of Patients with Assessment	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 Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Total Free Thyroxine, Unit : PMOL/L

Flag	Treatment Group Paroxetine
Number of Patients with Assessment	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 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	2 (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 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	2	(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 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	2 (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 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

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	2 (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 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	2 (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 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	2 (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 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	2 (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 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	2 (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 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	2 (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 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	Treatment Group: Placebo
Number of Patients with Assessment	2 (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 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	2 (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 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	2 (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 Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	2 (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 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	2 (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 Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Alkaline Phosphatase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	2 (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 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	2 (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 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	2 (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 Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Total Bilirubin, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	2 (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 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 Placebo
Number of Patients with Assessment	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 Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Free T3, Unit : PMOL/L

Flag	Treatment Group Placebo
Number of Patients with Assessment	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 Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Adolescents
Parameter : Total Free Thyroxine, Unit : PMOL/L

Flag	Treatment Group Placebo
Number of Patients with Assessment	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 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	Treatment Group: Placebo
Number of Patients with Assessment	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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)	0 .	1 (8.3%)
Number of Patients with Assessment	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	Placebo
High (Extended)	1 (8.3%)	0 .
Number of Patients with Assessment	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Sodium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Potassium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Alkaline Phosphatase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	Treatment Group: Placebo
Number of Patients with Assessment	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	Treatment Group: Placebo
Number of Patients with Assessment	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	12 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	1 (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 Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Free T3, Unit : PMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	1 (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 Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Total Free Thyroxine, Unit : PMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	1 (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 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	Treatment Group: Placebo
Low (Extended)	3 (6.3%)	1 (2.0%)
Number of Patients with Assessment	48 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Hematocrit, Unit : %

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Low (Extended)	6 (12.5%)	4 (8.2%)
Number of Patients with Assessment	48 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
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	48 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : White Blood Cell Count, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
Low (Extended)	1 (2.1%)	0 .
Number of Patients with Assessment	48 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
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	48 (100.0%)	48 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Basophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	48 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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)	0	.	2	(4.1%)
Number of Patients with Assessment	48	(100.0%)	49	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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
Number of Patients with Assessment	48 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Monocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	48 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	Treatment Group: Placebo
High (Extended)	1 (2.1%)	0 .
Low (Extended)	2 (4.2%)	1 (2.0%)
Number of Patients with Assessment	48 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Sodium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	50 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Potassium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	50 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	50 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Creatinine, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	50 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Alkaline Phosphatase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	50 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	50 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	50 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
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	50 (100.0%)	49 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	1 (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 Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Free T3, Unit : PMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	1 (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 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Children
Parameter : Total Free Thyroxine, Unit : PMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	1 (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 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of 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	
Low (Extended)	0	.	1	(2.5%)
Number of Patients with Assessment	34	(100.0%)	40	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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)	5 (14.7%)	3 (7.5%)
Number of Patients with Assessment	34 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
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	34 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : White Blood Cell Count, Unit : 10^9/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	34 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
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	34 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
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	34 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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		
Number of Patients with Assessment	34 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
High (Extended)	1 (2.9%)	1 (2.5%)
Number of Patients with Assessment	34 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
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	34 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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
Number of Patients with Assessment	34 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Sodium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	32 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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
Number of Patients with Assessment	32 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
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	32 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Creatinine, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	32 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Alkaline Phosphatase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	32 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Aspartate Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	32 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	32 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Total Bilirubin, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	32 (100.0%)	40 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	1 (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 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Free T3, Unit : PMOL/L

	Treatment Group	
	Paroxetine	Placebo
Flag		
Number of Patients with Assessment	1 (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 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Adolescents
Parameter : Total Free Thyroxine, Unit : PMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	1 (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 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	Treatment Group: Placebo
Low (Extended)	3 (3.7%)	2 (2.2%)
Number of Patients with Assessment	82 (100.0%)	89 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Hematocrit, Unit : %

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Low (Extended)	11 (13.4%)	7 (7.9%)
Number of Patients with Assessment	82 (100.0%)	89 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Red Blood Cell Count, Unit : 10^12/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	82 (100.0%)	89 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	Placebo
Low (Extended)	1 (1.2%)	0 .
Number of Patients with Assessment	82 (100.0%)	89 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Platelets, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	82 (100.0%)	88 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Basophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	82 (100.0%)	89 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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		Treatment Group: Placebo	
High (Extended)	0	.	2	(2.2%)
Number of Patients with Assessment	82	(100.0%)	89	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	Treatment Group: Placebo
High (Extended)	1 (1.2%)	1 (1.1%)
Number of Patients with Assessment	82 (100.0%)	89 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Monocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine		Treatment Group: Placebo	
Number of Patients with Assessment	82	(100.0%)	89	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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)	1 (1.2%)	0 .
Low (Extended)	2 (2.4%)	1 (1.1%)
Number of Patients with Assessment	82 (100.0%)	89 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Sodium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	82 (100.0%)	89 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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
Number of Patients with Assessment	82 (100.0%)	89 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	82 (100.0%)	89 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Creatinine, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	82 (100.0%)	89 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Alkaline Phosphatase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	82 (100.0%)	89 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
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	82	(100.0%)	89	(100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	82 (100.0%)	89 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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
Number of Patients with Assessment	82 (100.0%)	89 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined, no patients fell into these respective categories.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, 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	2 (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.

Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase,
Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Free T3, Unit : PMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	2 (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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Table 15.3.1.4

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase, Taper Phase or Follow-up Phase
Intention-To-Treat Population
Age Group : Total
Parameter : Total Free Thyroxine, Unit : PMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	2 (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.

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

Parameter : Hemoglobin Unit : Grams per Litre
Treatment Group : Paroxetine

		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	0	62	1	3	66	0	0	11	1	0	12
L	n	0	0	0	2	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	50	50	0	0	100	0	0	0	0	0	0
I	%	0	0	94	2	5	100	0	0	92	8	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Hemoglobin Unit : Grams per Litre
Treatment Group : Placebo

		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	0	74	1	1	76	0	0	11	0	0	11
L	n	0	0	1	2	1	4	0	0	0	1	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	100	0	0	0	100	0	0	0	0	0	0
I	%	0	0	97	1	1	100	0	0	100	0	0	100
L	%	0	0	25	50	25	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

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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

Parameter : Hematocrit Unit : Percentage
Treatment Group : Paroxetine

		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	58	0	6	64	0	0	12	0	0	12
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	1	0	5	6	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	91	0	9	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	17	0	83	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Hematocrit Unit : Percentage
Treatment Group : Placebo

		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	71	0	5	76	0	0	11	0	0	11
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	3	0	2	5	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	93	0	7	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	60	0	40	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Red Blood Cell Count Unit : 10^12 per Litre
Treatment Group : Paroxetine

		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	0	0	0	2	0	0	0	0	0	0
I	n	0	0	61	5	0	66	0	0	12	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	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	0	92	8	0	100	0	0	100	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

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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

Parameter : Red Blood Cell Count Unit : 10^12 per Litre
Treatment Group : Placebo

		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	2	68	5	0	75	0	0	11	0	0	11
L	n	0	0	3	3	0	6	0	0	1	0	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	3	91	7	0	100	0	0	100	0	0	100
L	%	0	0	50	50	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

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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

Parameter : White Blood Cell Count Unit : 10^9 per Litre
Treatment Group : Paroxetine

		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	0	61	5	0	66	0	0	11	0	0	11
L	n	0	0	2	1	0	3	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	1	0	0	1
+	%	0	0	100	0	0	100	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	92	8	0	100	0	0	100	0	0	100
L	%	0	0	67	33	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	100	0	0	100

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : White Blood Cell Count Unit : 10^9 per Litre
Treatment Group : Placebo

		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	70	3	0	74	0	0	10	0	0	10
L	n	0	0	6	1	0	7	0	0	2	0	0	2
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	1	95	4	0	100	0	0	100	0	0	100
L	%	0	0	86	14	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Platelets Unit : 10^9 per Litre
Treatment Group : Paroxetine

		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	2	67	0	0	69	0	0	11	0	0	11
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	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Platelets Unit : 10^9 per Litre
Treatment Group : Placebo

		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	3	0	0	6	0	0	0	0	0	0
I	n	0	2	72	0	0	74	0	1	11	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	50	50	0	0	100	0	0	0	0	0	0
I	%	0	3	97	0	0	100	0	8	92	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Basophils Absolute Unit : 10^9 per Litre
Treatment Group : Paroxetine

		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	70	0	0	70	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	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

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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

Parameter : Basophils Absolute Unit : 10^9 per Litre
Treatment Group : Placebo

		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	81	0	0	81	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	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Eosinophils Absolute Unit : 10^9 per Litre
Treatment Group : Paroxetine

		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	1	0	0	0	1
I	n	0	2	55	3	0	60	0	0	9	1	0	10
L	n	0	0	7	0	0	7	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	50	50	0	0	100	0	100	0	0	0	100
I	%	0	3	92	5	0	100	0	0	90	10	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Eosinophils Absolute Unit : 10^9 per Litre
Treatment Group : Placebo

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	n	1	0	1	0	0	2	0	0	0	0	0	0
H	n	1	1	2	0	0	4	0	1	1	0	0	2
I	n	0	1	70	1	0	72	0	0	10	0	0	10
L	n	0	0	1	2	0	3	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	50	0	50	0	0	100	0	0	0	0	0	0
H	%	25	25	50	0	0	100	0	50	50	0	0	100
I	%	0	1	97	1	0	100	0	0	100	0	0	100
L	%	0	0	33	67	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Lymphocytes Absolute Unit : 10^9 per Litre
Treatment Group : Paroxetine

		Endpoint (incl. Taper)						Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	n	0	0	1	0	0	1	0	0	1	0	0	1
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	1	1	67	0	0	69	0	0	11	0	0	11
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	100	0	0	100
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	1	1	97	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Lymphocytes Absolute Unit : 10^9 per Litre
Treatment Group : Placebo

		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	1	78	1	0	81	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	0	0	0	0	0	0	0	0	0	0
I	%	1	1	96	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Monocytes Absolute Unit : 10^9 per Litre
Treatment Group : Paroxetine

		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	53	12	0	65	0	0	8	1	0	9
L	n	0	0	4	1	0	5	0	0	2	1	0	3
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	82	18	0	100	0	0	89	11	0	100
L	%	0	0	80	20	0	100	0	0	67	33	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Monocytes Absolute Unit : 10^9 per Litre
Treatment Group : Placebo

		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	0	62	9	0	71	0	0	9	2	0	11
L	n	0	0	6	3	0	9	0	0	0	1	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	100	0	0	100	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	87	13	0	100	0	0	82	18	0	100
L	%	0	0	67	33	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Neutrophils Absolute Unit : 10^9 per Litre
Treatment Group : Paroxetine

		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	1	0	0	1	0	0	0	0	0	0
I	n	0	0	64	0	2	66	1	0	10	0	0	11
L	n	0	0	1	0	0	1	0	0	0	0	0	0
-	n	0	0	1	0	0	1	0	0	1	0	0	1
+	%	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	97	0	3	100	9	0	91	0	0	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	100	0	0	100	0	0	100	0	0	100

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Neutrophils Absolute Unit : 10^9 per Litre
Treatment Group : Placebo

		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	72	1	1	75	0	0	9	1	0	10
L	n	0	0	2	0	0	2	0	0	0	0	0	0
-	n	0	0	3	0	0	3	0	0	2	0	0	2
+	%	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	96	1	1	100	0	0	90	10	0	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	100	0	0	100	0	0	100	0	0	100

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Sodium Unit : Millimoles per Litre
Treatment Group : Paroxetine

		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	2	0	0	2	0	1	0	0	0	1
I	n	0	1	69	0	0	70	0	0	11	0	0	11
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	100	0	0	0	100
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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Sodium Unit : Millimoles per Litre
Treatment Group : Placebo

		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	5	0	0	5	0	0	0	0	0	0
I	n	0	0	75	0	0	75	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	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

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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

Parameter : Potassium Unit : Millimoles per Litre
Treatment Group : Paroxetine

		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	72	0	0	72	0	0	11	0	0	11
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	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Potassium Unit : Millimoles per Litre
Treatment Group : Placebo

		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	79	0	0	80	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	0	0	0	0	0	0	0	0	0	0
I	%	0	1	99	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Blood Urea Nitrogen Unit : Millimoles per Litre
Treatment Group : Paroxetine

		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	2	0	0	2	0	0	0	0	0	0
I	n	0	1	67	2	0	70	0	0	11	0	0	11
L	n	0	0	0	0	0	0	0	0	1	0	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	1	96	3	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Blood Urea Nitrogen Unit : Millimoles per Litre
Treatment Group : Placebo

		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	2	74	2	0	78	0	0	12	0	0	12
L	n	0	0	2	0	0	2	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	3	95	3	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

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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

Parameter : Creatinine Unit : Micromoles per Litre
Treatment Group : Paroxetine

		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	70	1	0	71	0	0	12	0	0	12
L	n	0	0	1	0	0	1	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	99	1	0	100	0	0	100	0	0	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Creatinine Unit : Micromoles per Litre
Treatment Group : Placebo

		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	80	0	0	80	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	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Alkaline Phosphatase Unit : International Units per Litre
Treatment Group : Paroxetine

		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	2	0	0	2	0	0	0	0	0	0
I	n	0	2	68	0	0	70	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	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Alkaline Phosphatase Unit : International Units per Litre
Treatment Group : Placebo

		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	0	0	0	2	0	0	0	0	0	0
I	n	0	0	77	0	0	77	0	0	12	0	0	12
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	100	0	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Aspartate Aminotransferase Unit : International Units per Litre
Treatment Group : Paroxetine

		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	72	0	0	72	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	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Aspartate Aminotransferase Unit : International Units per Litre
Treatment Group : Placebo

		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	3	77	0	0	80	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	0	0	0	0	0	0	0	0	0	0
I	%	0	4	96	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Alanine Aminotransferase Unit : International Units per Litre
Treatment Group : Paroxetine

		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	70	0	0	71	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	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Alanine Aminotransferase Unit : International Units per Litre
Treatment Group : Placebo

		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	80	0	0	80	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	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Total Bilirubin Unit : Micromoles per Litre
Treatment Group : Paroxetine

		Endpoint (incl. Taper)					Follow Up					
BASELINE		+	H	I	L	-	T	+	H	I	L	-	T
+	n	0	1	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	71	0	0	71	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	100	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	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Total Bilirubin Unit : Micromoles per Litre
Treatment Group : Placebo

		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	0	78	0	0	78	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	50	50	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Thyroid Stimulating Hormone Unit : MU/L
Treatment Group : Paroxetine

		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	1	0	0	1	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Thyroid Stimulating Hormone Unit : MU/L
Treatment Group : Placebo

		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	1	0	0	1	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Free T3 Unit : Picomoles per Litre
Treatment Group : Paroxetine

		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	1	0	0	1	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Free T3 Unit : Picomoles per Litre
Treatment Group : Placebo

		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	1	0	0	1	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Total Free Thyroxine Unit : Picomoles per Litre
Treatment Group : Paroxetine

		Follow Up					
BASELINE		+	H	I	L	-	T
+	n	0	0	0	0	0	0
H	n	0	0	0	0	0	0
I	n	0	0	1	0	0	1
L	n	0	0	0	0	0	0
-	n	0	0	0	0	0	0
+	%	0	0	0	0	0	0
H	%	0	0	0	0	0	0
I	%	0	0	100	0	0	100
L	%	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

Table 15.3.4

Number (%) of Patients with Transitions from Baseline to Endpoint and/or Follow-Up by Laboratory Parameter
Intention-To-Treat Population

Parameter : Total Free Thyroxine Unit : Picomoles per Litre
Treatment Group : Placebo

		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	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	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
For laboratory assessments, baseline data is the last pre-treatment assessment taken

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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
Number of Patients with Assessment	30 (100.0%)	32 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)
Intention-To-Treat Population

Parameter : Urine Blood - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Positive	3 (10.0%)	1 (3.2%)
Trace	0 (0.0%)	1 (3.2%)
Number of Patients with Assessment	30 (100.0%)	31 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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
Few	0 (0.0%)	1 (3.1%)
Many	3 (10.0%)	1 (3.1%)
Number of Patients with Assessment	30 (100.0%)	32 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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	2 (6.7%)	2 (6.3%)
Many	1 (3.3%)	0 (0.0%)
Number of Patients with Assessment	30 (100.0%)	32 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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	2 (66.7%)	4 (100.0%)
Moderate	1 (33.3%)	0 (0.0%)
Number of Patients with Assessment	3 (100.0%)	4 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)
Intention-To-Treat Population

Parameter : Urine Protein - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Positive	3 (10.0%)	2 (6.3%)
Trace	3 (10.0%)	3 (9.4%)
Number of Patients with Assessment	30 (100.0%)	32 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)
Intention-To-Treat Population

Parameter : Calcium Oxalate Crystals

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	6 (85.7%)	4 (100.0%)
Many	1 (14.3%)	0 (0.0%)
Number of Patients with Assessment	7 (100.0%)	4 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)
Intention-To-Treat Population

Parameter : Uric Acid Crystals

Result	Treatment Group Paroxetine
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

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	9 (50.0%)	16 (69.6%)
Many	5 (27.8%)	6 (26.1%)
Moderate	4 (22.2%)	1 (4.3%)
Number of Patients with Assessment	18 (100.0%)	23 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)
Intention-To-Treat Population

Parameter : Urine Generic - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Positive	8 (11.4%)	8 (10.5%)
Number of Patients with Assessment	70 (100.0%)	76 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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	11 (73.3%)	15 (88.2%)
Many	1 (6.7%)	0 (0.0%)
Moderate	3 (20.0%)	2 (11.8%)
Number of Patients with Assessment	15 (100.0%)	17 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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	10 (71.4%)	11 (78.6%)
Many	1 (7.1%)	1 (7.1%)
Moderate	3 (21.4%)	2 (14.3%)
Number of Patients with Assessment	14 (100.0%)	14 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.3

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	5 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis Findings, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Blood - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Positive	1 (20.0%)	2 (40.0%)
Trace	0 (0.0%)	1 (20.0%)
Number of Patients with Assessment	5 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.5.3

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
Few	1 (20.0%)	1 (20.0%)
Many	0 (0.0%)	2 (40.0%)
Number of Patients with Assessment	5 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis Findings, 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	2 (40.0%)	2 (40.0%)
Number of Patients with Assessment	5 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis Findings, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Bacteria

Result	Treatment Group Paroxetine
Moderate	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

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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
Positive	1 (20.0%)	3 (60.0%)
Number of Patients with Assessment	5 (100.0%)	5 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis Findings, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Calcium Oxalate Crystals

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	1 (100.0%)	1 (100.0%)
Number of Patients with Assessment	1 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis Findings, 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 (25.0%)
Many	0 (0.0%)	2 (50.0%)
Moderate	1 (50.0%)	1 (25.0%)
Number of Patients with Assessment	2 (100.0%)	4 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

Table 15.3.5.3

Number (%) of Patients with Abnormal Urinalysis Findings, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Parameter : Urine Coarse Granular Casts

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

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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 Generic - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Positive	1 (10.0%)	1 (10.0%)
Number of Patients with Assessment	10 (100.0%)	10 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

Table 15.3.5.3

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 (66.7%)	1 (100.0%)
Moderate	1 (33.3%)	0 (0.0%)
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

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	1 (33.3%)	2 (66.7%)
Many	1 (33.3%)	0 (0.0%)
Moderate	1 (33.3%)	1 (33.3%)
Number of Patients with Assessment	3 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

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Table 15.3.6

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	98	15.21429	6.466807	14.00000	6.0000	53.0000
		Week 10	63	17.74603	8.001952	15.00000	10.0000	54.0000
		Change to Week 10	63	2.55556	8.049800	2.00000	-15.0000	44.0000
		Endpoint	72	17.62500	7.660834	15.00000	10.0000	54.0000
		Change to Endpoint	72	2.27778	8.886169	2.00000	-36.0000	44.0000
Alkaline Phosphatase	IU/L	Baseline	98	225.73469	85.856095	229.50000	48.0000	448.0000
		Week 10	63	216.93651	87.450239	210.00000	68.0000	433.0000
		Change to Week 10	63	-10.50794	35.368052	-10.00000	-124.0000	104.0000
		Endpoint	72	218.79167	84.715587	209.50000	68.0000	433.0000
		Change to Endpoint	72	-9.37500	35.338778	-9.50000	-124.0000	104.0000
Aspartate Aminotransferase	IU/L	Baseline	98	24.29592	6.354168	24.00000	13.0000	42.0000
		Week 10	63	25.04762	5.326224	24.00000	15.0000	36.0000
		Change to Week 10	63	1.90476	5.575622	1.00000	-8.0000	17.0000
		Endpoint	72	25.15278	5.172135	25.00000	15.0000	36.0000
		Change to Endpoint	72	1.68056	5.688700	1.00000	-15.0000	17.0000
Basophils Absolute	10^9/L	Baseline	97	0.02010	0.014825	0.02000	0.0000	0.0800
		Week 10	64	0.01688	0.009900	0.02000	0.0000	0.0500
		Change to Week 10	63	-0.00063	0.014797	0.00000	-0.0400	0.0400
		Endpoint	71	0.01831	0.012871	0.02000	0.0000	0.0900
		Change to Endpoint	70	0.00014	0.016724	0.00000	-0.0400	0.0600
Blood Urea Nitrogen	MMOL/L	Baseline	98	4.76486	1.209942	4.64100	2.4990	7.8540
		Week 10	63	4.87333	1.213459	4.99800	1.7850	7.8540
		Change to Week 10	63	0.07367	1.024218	0.00000	-2.1420	2.8560
		Endpoint	72	4.78479	1.153564	4.64100	1.7850	7.8540
		Change to Endpoint	72	0.05454	0.989383	0.00000	-2.1420	2.8560
Creatinine	UMOL/L	Baseline	98	49.34163	13.548400	44.20000	26.5200	88.4000
		Week 10	63	51.35619	12.076745	53.04000	26.5200	79.5600
		Change to Week 10	63	0.70159	12.226568	0.00000	-35.3600	26.5200
		Endpoint	72	50.33889	11.457843	53.04000	26.5200	79.5600
		Change to Endpoint	72	0.73667	11.468511	0.00000	-35.3600	26.5200
Eosinophils Absolute	10^9/L	Baseline	97	0.22660	0.197636	0.17000	0.0300	1.4400
		Week 10	64	0.22422	0.157004	0.18000	0.0100	0.6600
		Change to Week 10	63	-0.00317	0.194354	0.02000	-0.9700	0.3100
		Endpoint	71	0.22366	0.149735	0.18000	0.0100	0.6600
		Change to Endpoint	70	-0.00471	0.189971	0.02500	-0.9700	0.3100

Endpoint is the last on treatment assessment (including Taper Phase)
Note: For laboratory assessments, the last pre-treatment assessment is taken as Baseline
Week 10 includes only assessments that are on-treatment (including taper)

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	95	5.68163	0.626815	5.71340	4.1118	7.6384
		Endpoint	1	3.63440	.	3.63440	3.6344	3.6344
		Change to Endpoint	1	-0.52360	.	-0.52360	-0.5236	-0.5236
Hematocrit	%	Baseline	97	38.71856	2.890622	38.30000	32.5000	48.9000
		Week 10	64	38.34531	3.088120	38.10000	31.8000	48.5000
		Change to Week 10	63	-0.42698	1.976736	-0.50000	-4.9000	4.3000
		Endpoint	71	38.37606	3.138720	38.40000	31.8000	48.5000
		Change to Endpoint	70	-0.43286	2.071807	-0.55000	-4.9000	4.3000
Hemoglobin	G/L	Baseline	97	131.15464	9.960694	130.00000	106.0000	164.0000
		Week 10	64	129.73438	11.061505	129.00000	104.0000	165.0000
		Change to Week 10	63	-2.33333	7.175226	-3.00000	-16.0000	14.0000
		Endpoint	71	129.84507	11.046199	130.00000	104.0000	165.0000
		Change to Endpoint	70	-2.14286	7.349033	-2.00000	-16.0000	14.0000
Lymphocytes Absolute	10^9/L	Baseline	97	2.52144	0.741453	2.41000	1.3900	5.0200
		Week 10	64	2.38875	0.762566	2.23000	0.9600	4.8600
		Change to Week 10	63	-0.02714	0.579420	0.01000	-1.5500	1.8100
		Endpoint	71	2.41845	0.740758	2.28000	0.9600	4.8600
		Change to Endpoint	70	-0.02229	0.665337	0.02000	-2.5700	1.8100
Monocytes Absolute	10^9/L	Baseline	97	0.40794	0.193213	0.39000	0.0300	1.0000
		Week 10	64	0.35203	0.163922	0.35000	0.0200	0.6900
		Change to Week 10	63	-0.06524	0.203833	-0.04000	-0.6100	0.3100
		Endpoint	71	0.36465	0.164897	0.35000	0.0200	0.7700
		Change to Endpoint	70	-0.05357	0.207462	-0.00500	-0.6100	0.3600
Neutrophils Absolute	10^9/L	Baseline	97	3.84402	1.664418	3.69000	0.7800	11.7600
		Week 10	64	3.56094	1.204751	3.52000	0.9300	6.7000
		Change to Week 10	63	-0.11825	1.205123	-0.07000	-4.4200	2.2100
		Endpoint	71	3.58394	1.169249	3.52000	1.4600	6.7000
		Change to Endpoint	70	-0.26271	1.591623	-0.08500	-8.7000	2.2100
Platelets	10^9/L	Baseline	97	280.25773	64.735725	274.00000	142.0000	433.0000
		Week 10	64	284.81250	60.448555	286.50000	184.0000	433.0000
		Change to Week 10	63	4.58730	42.088093	3.00000	-84.0000	148.0000
		Endpoint	71	287.66197	60.787438	287.00000	184.0000	433.0000
		Change to Endpoint	70	3.24286	41.742633	2.50000	-80.0000	148.0000
Potassium	MMOL/L	Baseline	98	4.30816	0.356869	4.25000	3.6000	5.6000
		Week 10	63	4.35079	0.409907	4.30000	3.5000	5.5000

Endpoint is the last on treatment assessment (including Taper Phase)
Note: For laboratory assessments, the last pre-treatment assessment is taken as Baseline
Week 10 includes only assessments that are on-treatment (including taper)

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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
Potassium	MMOL/L	Change to Week 10	63	0.05079	0.432872	0.00000	-0.9000	1.2000
		Endpoint	72	4.37778	0.399726	4.30000	3.5000	5.5000
		Change to Endpoint	72	0.06667	0.418246	0.00000	-0.9000	1.2000
Red Blood Cell Count	10^12/L	Baseline	97	4.53918	0.321311	4.50000	3.9000	5.6000
		Week 10	64	4.49062	0.357557	4.50000	3.9000	5.8000
		Change to Week 10	63	-0.05556	0.231250	-0.10000	-0.5000	0.5000
		Endpoint	71	4.49155	0.367519	4.50000	3.7000	5.8000
		Change to Endpoint	70	-0.05000	0.238807	-0.05000	-0.5000	0.5000
Sodium	MMOL/L	Baseline	98	141.53061	2.333989	141.00000	137.0000	149.0000
		Week 10	63	141.82540	1.699523	142.00000	138.0000	145.0000
		Change to Week 10	63	0.38095	2.660515	0.00000	-7.0000	7.0000
		Endpoint	72	141.72222	1.777973	142.00000	138.0000	147.0000
		Change to Endpoint	72	0.18056	2.681845	0.00000	-7.0000	7.0000
Thyroid Stimulating Hormone	MU/L	Baseline	98	2.43061	1.821318	2.10000	0.6000	17.0000
		Endpoint	1	1.40000	.	1.40000	1.4000	1.4000
		Change to Endpoint	1	0.20000	.	0.20000	0.2000	0.2000
Total Bilirubin	UMOL/L	Baseline	98	7.72990	5.233147	6.84000	0.0000	41.0400
		Week 10	63	6.67714	3.953623	5.13000	0.0000	29.0700
		Change to Week 10	63	-1.35714	3.687531	-1.71000	-11.9700	8.5500
		Endpoint	72	6.76875	3.897683	5.13000	0.0000	29.0700
		Change to Endpoint	72	-1.23500	3.587181	-1.71000	-11.9700	8.5500
Total Free Thyroxine	PMOL/L	Baseline	93	13.59355	1.990834	12.90000	9.0300	20.6400
		Endpoint	1	12.90000	.	12.90000	12.9000	12.9000
		Change to Endpoint	0	.	.	.	.	.
White Blood Cell Count	10^9/L	Baseline	97	7.01340	2.109237	6.90000	2.5000	17.3000
		Week 10	64	6.54375	1.608595	6.45000	2.7000	10.1000
		Change to Week 10	63	-0.21270	1.419165	-0.20000	-4.8000	2.4000
		Endpoint	71	6.60986	1.472913	6.50000	3.9000	10.1000
		Change to Endpoint	70	-0.33429	1.904448	-0.30000	-11.0000	2.4000

Endpoint is the last on treatment assessment (including Taper Phase)
Note: For laboratory assessments, the last pre-treatment assessment is taken as Baseline
Week 10 includes only assessments that are on-treatment (including taper)

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	105	17.07619	8.710841	14.00000	7.0000	59.0000
		Week 10	73	16.35616	6.600442	15.00000	7.0000	37.0000
		Change to Week 10	73	-0.80822	5.569404	-1.00000	-20.0000	16.0000
		Endpoint	80	15.92500	6.525073	15.00000	7.0000	37.0000
		Change to Endpoint	80	-0.80000	5.615079	0.00000	-20.0000	16.0000
Alkaline Phosphatase	IU/L	Baseline	105	235.52381	96.580586	222.00000	55.0000	548.0000
		Week 10	73	230.58904	85.914498	223.00000	66.0000	426.0000
		Change to Week 10	73	-9.50685	45.685557	-8.00000	-142.0000	102.0000
		Endpoint	80	227.72500	88.382938	222.00000	60.0000	426.0000
		Change to Endpoint	80	-8.52500	43.866880	-7.50000	-142.0000	102.0000
Aspartate Aminotransferase	IU/L	Baseline	105	24.55238	7.131972	25.00000	9.0000	43.0000
		Week 10	73	24.78082	7.104863	24.00000	12.0000	46.0000
		Change to Week 10	73	0.01370	5.029063	-1.00000	-12.0000	16.0000
		Endpoint	80	24.18750	7.246289	24.00000	11.0000	46.0000
		Change to Endpoint	80	-0.12500	5.052572	-1.00000	-13.0000	16.0000
Basophils Absolute	10^9/L	Baseline	105	0.01990	0.014968	0.02000	0.0000	0.0900
		Week 10	71	0.01901	0.019135	0.02000	0.0000	0.1400
		Change to Week 10	71	-0.00183	0.019735	0.00000	-0.0700	0.0700
		Endpoint	81	0.01864	0.018422	0.02000	0.0000	0.1400
		Change to Endpoint	81	-0.00123	0.019518	0.00000	-0.0700	0.0700
Blood Urea Nitrogen	MMOL/L	Baseline	105	4.46080	1.228855	4.28400	1.4280	8.9250
		Week 10	73	4.73881	1.380426	4.64100	2.1420	9.6390
		Change to Week 10	73	0.20051	1.322435	0.35700	-3.2130	2.8560
		Endpoint	80	4.69901	1.355486	4.64100	2.1420	9.6390
		Change to Endpoint	80	0.20528	1.277463	0.35700	-3.2130	2.8560
Creatinine	UMOL/L	Baseline	105	50.09333	13.354110	44.20000	26.5200	79.5600
		Week 10	73	52.07123	13.224071	53.04000	26.5200	79.5600
		Change to Week 10	73	1.81644	10.620159	0.00000	-35.3600	26.5200
		Endpoint	80	52.26650	12.829185	53.04000	26.5200	79.5600
		Change to Endpoint	80	1.76800	10.278372	0.00000	-35.3600	26.5200
Eosinophils Absolute	10^9/L	Baseline	105	0.23800	0.181968	0.18000	0.0000	0.9800
		Week 10	71	0.24549	0.198248	0.18000	0.0000	1.1700
		Change to Week 10	71	-0.01014	0.139791	-0.01000	-0.3900	0.3900
		Endpoint	81	0.23062	0.194013	0.18000	0.0000	1.1700
		Change to Endpoint	81	-0.00889	0.135978	-0.01000	-0.3900	0.3900

Endpoint is the last on treatment assessment (including Taper Phase)
Note: For laboratory assessments, the last pre-treatment assessment is taken as Baseline
Week 10 includes only assessments that are on-treatment (including taper)

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	100	5.71017	0.630993	5.69800	3.9886	8.0388
		Endpoint	3	5.52347	0.578748	5.68260	4.8818	6.0060
		Change to Endpoint	1	-0.12320	.	-0.12320	-0.1232	-0.1232
Hematocrit	%	Baseline	105	39.33048	2.891570	39.10000	31.8000	46.2000
		Week 10	71	38.92817	3.065811	38.10000	33.0000	48.8000
		Change to Week 10	71	-0.52254	2.320726	-0.40000	-6.7000	4.8000
		Endpoint	81	38.82222	3.004081	38.10000	33.0000	48.8000
		Change to Endpoint	81	-0.44444	2.265502	-0.40000	-6.7000	4.8000
Hemoglobin	G/L	Baseline	105	133.51429	10.479021	134.00000	104.0000	163.0000
		Week 10	71	131.71831	11.083041	129.00000	103.0000	165.0000
		Change to Week 10	71	-2.19718	6.473285	-2.00000	-16.0000	18.0000
		Endpoint	81	131.33333	10.758717	129.00000	103.0000	165.0000
		Change to Endpoint	81	-1.70370	6.491233	-1.00000	-16.0000	18.0000
Lymphocytes Absolute	10^9/L	Baseline	105	2.37800	0.680061	2.35000	1.0400	4.6000
		Week 10	71	2.27563	0.667862	2.24000	0.8400	4.5400
		Change to Week 10	71	-0.03070	0.443287	0.02000	-1.0400	1.5800
		Endpoint	81	2.30247	0.723772	2.24000	0.8400	4.5400
		Change to Endpoint	81	0.00012	0.464727	0.02000	-1.0400	1.5800
Monocytes Absolute	10^9/L	Baseline	105	0.36333	0.177448	0.36000	0.0100	1.4000
		Week 10	71	0.35113	0.149681	0.37000	0.0000	0.6600
		Change to Week 10	71	-0.00352	0.182123	-0.01000	-0.4500	0.5300
		Endpoint	81	0.35284	0.152825	0.35000	0.0000	0.7200
		Change to Endpoint	81	-0.00494	0.220341	-0.01000	-1.0500	0.5300
Neutrophils Absolute	10^9/L	Baseline	105	3.62267	1.433859	3.31000	0.9900	8.6500
		Week 10	71	3.78831	1.438160	3.61000	1.2000	8.2600
		Change to Week 10	71	0.20239	1.766951	0.35000	-4.5000	4.8000
		Endpoint	81	3.77309	1.402655	3.51000	1.2000	8.2600
		Change to Endpoint	81	0.15827	1.753836	0.35000	-4.5000	4.8000
Platelets	10^9/L	Baseline	105	295.12381	63.532804	282.00000	177.0000	463.0000
		Week 10	70	291.45714	73.191170	280.00000	157.0000	525.0000
		Change to Week 10	70	-5.34286	46.225624	0.50000	-131.0000	132.0000
		Endpoint	80	289.90000	71.340084	279.00000	157.0000	525.0000
		Change to Endpoint	80	-3.40000	45.936555	2.00000	-131.0000	132.0000
Potassium	MMOL/L	Baseline	105	4.39524	0.357443	4.40000	3.7000	5.5000
		Week 10	73	4.37123	0.392102	4.30000	3.7000	5.8000

Endpoint is the last on treatment assessment (including Taper Phase)
Note: For laboratory assessments, the last pre-treatment assessment is taken as Baseline
Week 10 includes only assessments that are on-treatment (including taper)

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	Change to Week 10	73	-0.04384	0.453684	0.00000	-1.0000	1.8000
		Endpoint	80	4.37625	0.387215	4.30000	3.7000	5.8000
		Change to Endpoint	80	-0.03000	0.452671	0.00000	-1.0000	1.8000
Red Blood Cell Count	10^12/L	Baseline	105	4.57429	0.341385	4.60000	3.8000	5.3000
		Week 10	71	4.52113	0.374515	4.50000	3.9000	5.4000
		Change to Week 10	71	-0.08169	0.245130	-0.10000	-0.7000	0.5000
		Endpoint	81	4.49753	0.369112	4.50000	3.9000	5.4000
		Change to Endpoint	81	-0.06420	0.248147	-0.10000	-0.7000	0.5000
Sodium	MMOL/L	Baseline	105	141.94286	2.522318	142.00000	137.0000	149.0000
		Week 10	73	141.08219	2.171491	141.00000	135.0000	146.0000
		Change to Week 10	73	-0.95890	3.190430	-1.00000	-11.0000	5.0000
		Endpoint	80	141.17500	2.220588	141.00000	135.0000	146.0000
		Change to Endpoint	80	-0.95000	3.153860	-1.00000	-11.0000	5.0000
Thyroid Stimulating Hormone	MU/L	Baseline	102	2.19608	0.927887	2.00000	0.6000	5.3000
		Endpoint	3	2.26667	0.838650	2.70000	1.3000	2.8000
		Change to Endpoint	1	0.00000	.	0.00000	0.0000	0.0000
Total Bilirubin	UMOL/L	Baseline	105	7.84971	4.503650	6.84000	3.4200	34.2000
		Week 10	73	7.75356	4.569628	6.84000	3.4200	32.4900
		Change to Week 10	73	0.14055	3.381227	0.00000	-15.3900	11.9700
		Endpoint	80	7.78050	4.394754	6.84000	3.4200	32.4900
		Change to Endpoint	80	0.14962	3.323325	0.00000	-15.3900	11.9700
Total Free Thyroxine	PMOL/L	Baseline	102	14.16471	2.310337	14.19000	9.0300	24.5100
		Endpoint	3	12.90000	0.000000	12.90000	12.9000	12.9000
		Change to Endpoint	2	-1.29000	0.000000	-1.29000	-1.2900	-1.2900
White Blood Cell Count	10^9/L	Baseline	105	6.62095	1.744480	6.40000	3.3000	13.1000
		Week 10	71	6.67887	1.776024	6.60000	4.0000	13.6000
		Change to Week 10	71	0.15634	2.006186	0.20000	-5.8000	6.3000
		Endpoint	81	6.67654	1.795499	6.30000	4.0000	13.6000
		Change to Endpoint	81	0.14321	1.955565	0.20000	-5.8000	6.3000

Endpoint is the last on treatment assessment (including Taper Phase)
Note: For laboratory assessments, the last pre-treatment assessment is taken as Baseline
Week 10 includes only assessments that are on-treatment (including taper)

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Table 15.4.1

Number (%) of Patients with ECG Assessment

All Patients

Visit		Treatement Group: No Therapy Dispensed (N=58)	Paroxetine (N=100)	Placebo (N=107)	Total (N=265)
Screening	Abnormal	0	0	0	0
	Normal	28 (48.3%)	100 (100.0%)	107 (100.0%)	235 (88.7%)
	Missing	30 (51.7%)	0	0	30 (11.3%)
	Total	58 (100.0%)	100 (100.0%)	107 (100.0%)	265 (100.0%)
Baseline	Abnormal	0	0	0	0
	Normal	0	3 (3.0%)	1 (0.9%)	4 (1.9%)
	Unknown*	0	0	1 (0.9%)	1 (0.5%)
	Not Applicable**	2 (100.0%)	97 (97.0%)	105 (98.1%)	204 (97.6%)
	Total	2 (100.0%)	100 (100.0%)	107 (100.0%)	209 (100.0%)
Last Study Treatment ECG	Abnormal	0	0	1 (1.6%)	1 (0.9%)
	Normal	0	52 (100.0%)	59 (93.7%)	111 (96.5%)
	Missing	0	0	2 (3.2%)	2 (1.7%)
	Not Applicable**	0	0	1 (1.6%)	1 (0.9%)
	Total	0	52 (100.0%)	63 (100.0%)	115 (100.0%)
Early Withdrawals ECG	Abnormal	0	0	0	0
	Normal	0	6 (60.0%)	5 (83.3%)	11 (68.8%)
	Missing	0	4 (40.0%)	1 (16.7%)	5 (31.3%)
	Total	0	10 (100.0%)	6 (100.0%)	16 (100.0%)
Taper End ECG	Abnormal	0	0	0	0
	Normal	0	10 (19.6%)	15 (26.8%)	25 (23.4%)
	Unknown*	0	0	0	0
	Not Applicable**	0	41 (80.4%)	41 (73.2%)	82 (76.6%)
	Total	0	51 (100.0%)	56 (100.0%)	107 (100.0%)
Follow Up ECG	Abnormal	0	0	0	0
	Normal	0	9 (19.1%)	9 (20.0%)	18 (19.6%)
	Missing	0	4 (8.5%)	0	4 (4.3%)
	Unknown*	0	1 (2.1%)	0	1 (1.1%)
	Not Applicable**	0	33 (70.2%)	36 (80.0%)	69 (75.0%)
	Total	0	47 (100.0%)	45 (100.0%)	92 (100.0%)

* Abnormal at previous visit, but re-test not done or result of re-test unknown
** Not applicable, Normal at previous visit
(ECGs collected on CRF pages other than Screening and Week 10/Early Withdrawal are performed only on patients who previously had an abnormal ECG)
Note: Percentages are based on number of patients with an assessment at that visit

14 Source Figures

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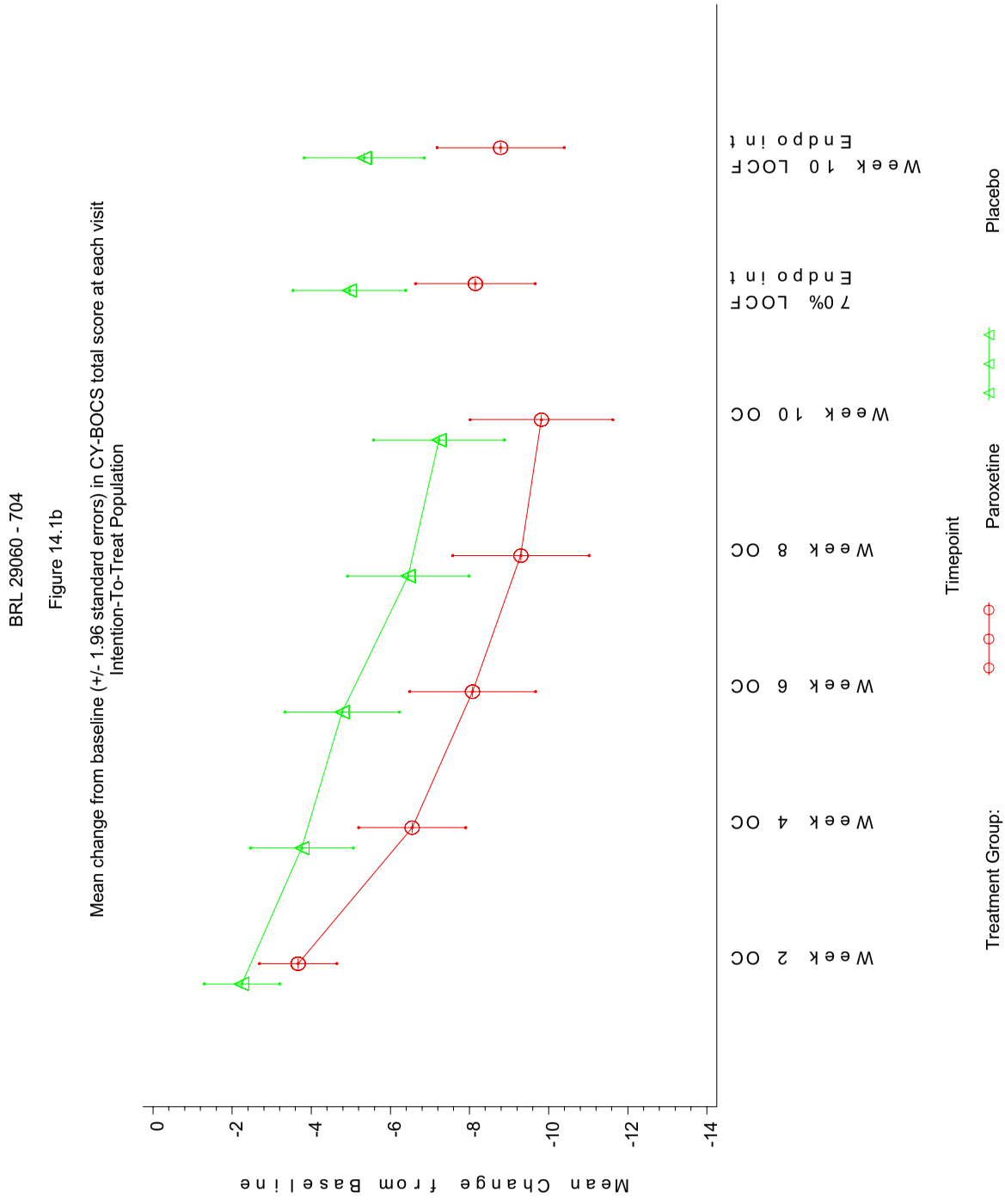
Figure 14.1b

Mean change from baseline (+/- 1.96 standard errors) in CY-BOCS total score at each visit
Intention-To-Treat Population



15 Errata

Table/Listing	Error
Tables 13.1.1, 13.1.2, 13.2.1, 13.2.2, 13.3.1c, 13.5.1c, 13.5.2c, Section 11; Tables 14.1.1c, 14.1.2c, 14.1.3c, Section 12; Listings 13.1.1, 13.2.1, 13.2.2, Appendix B; Listing 14.1.2c, Appendix C	Patient 704.055.28171, a child in the placebo group, was erroneously included in the per protocol population in demography and efficacy tables and listings. Audit reports from the site showed that the patient had a history of auditory and visual hallucinations that constituted a protocol violation. Patient 704.055.28190, an adolescent in the placebo group, was also erroneously included in the per protocol population in demography and efficacy tables and listings. CRF review showed that the patient should have been excluded due to non-compliance with study medication.
Table 13.8.1, Section 11; Listing 13.8.1, Appendix B	A diagnosis of OCD was not recorded for patients 704.029.27075 and 704.041.27138 in the psychiatric history table and listing based on the K-SADS-PL. However, the sites confirmed that the patients had past and current history of OCD.
Tables 13.12.3.5, 13.12.3.6, Section 11	The following footnote should have been included on these tables: 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 that was started before the last dose of study/taper medication and has a missing stop date.
Listings 15.3.1, 15.3.2, 15.3.3, Appendix F	The footnote for these listings erroneously indicates that the study medication stop date includes Taper Phase medication. The footnote should state that the stop date excludes Taper Phase medication.
Table 15.3.6, Section 13	Thyroid tests were to have been conducted at Screening only and should not appear in the table of mean changes in laboratory parameters.
Table 15.4.1, Section 13; Listing 15.4.1, Appendix E	Patient 704.010.25367 has a follow-up ECG result recorded as "unknown." Since the ECG result was "normal" at the previous visit, the follow-up ECG result should have been recorded as "not applicable."