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SmithKline Beecham

Paroxetine

BRL-029060

A Randomized, Multicenter, 8-Week, Double-blind, Placebo-Controlled Flexible-Dose Study to Evaluate the Efficacy and Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder

701

Final Clinical Report

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Signature Page

Report Title: A Randomized, Multicenter, 8-Week, Double-blind, Placebo-Controlled Flexible-Dose Study to Evaluate the Efficacy and Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder

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

Report Synopsis

Study Title: A Randomized, Multicenter, 8-Week, Double-blind, Placebo-Controlled Flexible-Dose Study to Evaluate the Efficacy and Safety of Paroxetine in Children and Adolescents with Major Depressive Disorder (29060/701)

Investigators and Centers: The study was conducted in 40 centers in the US and 1 in Canada.

Publication: No publication as of 20 July 2001.

Study Dates: The first dose of randomized study medication was administered on 20 March 2000 and the last dose of study medication (excluding Taper) was administered on 24 January 2001.

Objectives: To compare the efficacy of paroxetine versus placebo in the treatment of children and adolescents with Major Depressive Disorder (MDD), as measured by the change from Baseline in the Children's Depression Rating Scale–Revised (CDRS–R) Total Score at Week 8 last observation carried forward (LOCF) endpoint.

To compare the safety and tolerability of paroxetine versus placebo in the treatment of children and adolescents with MDD.

Study Design: This was an 8-week multicenter, randomized, double-blind, placebo-controlled, parallel-group, flexible-dose trial in children (ages 7 through 11) and adolescents (ages 12 through 17). 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 Major Depressive Disorder (single episode [296.2] or recurrent [296.3]) and who satisfied all other entrance criteria were eligible for 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 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 (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 level, up to a maximum of 50 mg per day (DL 5), according to the judgment of the investigator 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 Taper Phase, was a maximum of 15 weeks.

Evaluation Criteria

Efficacy Parameters: The primary efficacy variable was the change from Baseline in the CDRS–R total score.

The secondary efficacy variables were the change from Baseline in the Clinical Global Impression (CGI) Severity of Illness item score; the proportion of responders based on the CGI Global Improvement item (where response was defined as a score of 1 [very much improved] or 2 [much improved]); and the change from Baseline on the Global Assessment of Functioning (GAF) Scale. An additional efficacy variable was the change from Baseline in the Kutcher Adolescent Depression Rating Scale (KADS) total score in the 12- to 17-year-old patients. The KADS is a non-validated self-report instrument under development.

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

Pharmacokinetics: Pharmacokinetic (PK) blood samples were drawn from consenting patients at Weeks 4 and 8 (or early withdrawal from the study, if applicable) for paroxetine assay. These results will be combined with similar data from studies 704 (Obsessive-Compulsive Disorder) and 676 (Social Anxiety Disorder) at a later date 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 one post-dose safety (including AEs) or efficacy assessments were included in the ITT population. Statistical conclusions concerning the efficacy of paroxetine were made using data obtained from the last assessment of the ITT population and the observed cases (OC) dataset. 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.

Patient Disposition and Key Demographic Data

A total of 305 patients were screened and 206 patients randomized, 104 (50.5%) to paroxetine and 102 (49.5%) to placebo. Of these, 203 patients were included in the intention-to-treat (ITT) population, defined as all patients who were randomized into the study, who received at least one dose of double-blind medication, and who had at least one safety or efficacy post-Baseline assessment. The all-randomized population comprised 47.1% children and 52.9% adolescents.

Study Stage/Population	Paroxetine	Placebo	Total
Screened	—	—	305
Randomized	104 (100.0%)	102 (100.0%)	206 (100.0%)
Withdrawn	34 (32.7%)	23 (22.5%)	57 (27.7%)
Completed Study	70 (67.3%)	79 (77.5%)	149 (72.3%)
Intention-to-Treat *	101 (97.1%)	102 (100.0%)	203 (98.5%)
Per Protocol **	74 (71.2%)	83 (81.4%)	157 (76.2%)
Entered Long-term Study 29060/716	50 (48.1%)	63 (61.8%)	113 (54.9%)

* Randomized patients with at least one on-therapy safety or efficacy assessment. The Safety Population was the same as the ITT population.
** Per protocol (PP) patients were those patients in the ITT population not identified as protocol violators during blind review.

The percentage of randomized patients who were withdrawn prematurely from the study was slightly higher for the paroxetine group (32.7%) than the placebo group (22.5%). The primary reason for withdrawal in the ITT population was AE (9/101, 8.9%) in the paroxetine group and lack of efficacy (11/102, 10.8%) in the placebo group.

The two treatment groups showed no marked imbalances in any of the patient characteristics, although there was a slightly higher proportion of patients with comorbid psychiatric illnesses in the paroxetine group than in the placebo group.

Demography and Baseline Characteristics (ITT Population)

	Paroxetine	Placebo	Total
Age Group: Total	101	102	203
Females:Males	48:53	47:55	95:108
Mean age (SD): years	11.9 (3.00)	12.1 (2.95)	12.0 (2.97)
White: n (%)	76.2%	82.4%	79.3%
Baseline CDRS–R Total Score: Mean (SD)	60.7 (9.37)	62.6 (8.96)	61.7 (9.19)
Psychiatric Comorbidity Yes:No	28:73	18:84	46:157
Age Group: Children	49	47	96
Females:Males	23:26	18:29	41:55
Mean age (SD): years	9.2 (1.28)	9.4 (1.28)	9.3 (1.28)
White: n (%)	69.4%	83.0%	76.0%
Age Group: Adolescents	52	55	107
Females:Males	25:27	29:26	54:53
Mean age (SD): years	14.4 (1.60)	14.5 (1.72)	14.4 (1.66)
White: n (%)	82.7%	81.8%	82.2%

Efficacy Results

Datasets: Primary inferences from efficacy analyses were based on the ITT population at Week 8 LOCF. In addition, the primary efficacy variable was analyzed using the Per Protocol (PP) population.

Primary Efficacy Variable: Analysis of the primary endpoint provided no evidence that paroxetine was more efficacious than placebo in the treatment of MDD in the pediatric population. Although there was a large mean change from Baseline in CDRS–R total score in paroxetine-treated patients, there was also a large placebo effect. The adjusted mean difference between paroxetine and placebo in change from Baseline in CDRS–R total score at Week 8 LOCF for the ITT population was 0.8 points in favor of placebo (95% confidence interval [-3.09, 4.69], $p = 0.684$). This result was supported by the analysis of the PP population and the analysis of the Week 8 OC dataset in each population.

There was evidence of a statistically significant treatment by age group interaction ($p = 0.049$), indicating varying treatment effect across the age groups; therefore the analysis was carried out separately for each age group. Children (ages 7 through 11) exhibited a 5.3-point difference in favor of placebo in the CDRS–R total score change from Baseline, although this difference was not statistically significant ($p = 0.054$). Adolescents (ages 12 through 17) exhibited a 2.6-point difference in favor of paroxetine in the CDRS–R total score change from Baseline; again this difference was not statistically significant ($p = 0.375$).

Secondary Efficacy Variables: None of the secondary efficacy variables (CGI Severity of Illness, CGI Global Improvement, GAF) provided evidence that paroxetine is more efficacious than placebo in the treatment of children and adolescents with MDD.

Other Efficacy Variable: Analysis of the additional variable of interest (KADS, adolescents only) provided no evidence of a statistically significant benefit of paroxetine over placebo.

Safety Results

Adverse Events: In the ITT population, 71 patients (70.3%) in the paroxetine group and 62 patients (60.8%) in the placebo group reported non-gender-specific Treatment Phase-emergent AEs. The five most common non-gender-specific AEs on paroxetine were headache, nausea, trauma, respiratory disorder and insomnia; the five most common AEs on placebo were headache, respiratory disorder, nausea, asthenia and trauma. Only 3 patients reported gender-specific AEs, 1 male (impotence) and 1 female (menstrual disorder) on paroxetine and 1 female (dysmenorrhea) on placebo.

In the paroxetine group, the overall incidence of AEs was comparable between children and adolescents (69.4% vs. 71.2%, respectively). However, somnolence (19.2% vs. 0%), insomnia (15.4% vs. 6.1%) and pharyngitis (13.5% vs. 2.0%) were each reported more frequently in the adolescents subgroup. Abdominal pain (8.2% vs. 0%) and infection (10.2% vs. 3.8%) were the only AEs reported more frequently in the younger (7- to 11-year-old) patients than in adolescent (12- to 17-year-old) patients in the paroxetine group.

Most AEs were mild to moderate in intensity. The most frequent AEs reported to be related or possibly related to study medication in the paroxetine group were headache, nausea, somnolence, and insomnia. Of these, only insomnia had an incidence in the paroxetine group (10/101, 9.9%) that approached twice that in the placebo group (6/102, 5.9%). Nine of 101 patients in the paroxetine group (8.9%) and 5/102 patients in the placebo group (4.9%) had AEs that led to dose reductions during the Treatment Phase.

Serious Adverse Events: No deaths were reported to the sponsor during the course of the study or at any time since the last dose of study medication

A total of 6 patients in the paroxetine group and 1 patient in the placebo group were reported to have serious adverse events (SAEs) during this trial, including the 30-day period following the last dose of study medication. Emotional lability and depression were experienced by more than one patient (3 patients each in the paroxetine group, and emotional lability 1 patient in the placebo group). Emotional lability and hypertension in one patient in the paroxetine group were considered severe and related to study medication.

Withdrawals Due to Adverse Events: In total, 8.9% (9/101) of paroxetine patients and 2.0% (2/102) of placebo patients in the ITT population were withdrawn during the treatment phase due to an AE. The only AEs leading to withdrawal that occurred in more than 1 patient in the same treatment group were depression, experienced by 4 patients in the paroxetine group, and emotional lability, experienced by 2 patients in the placebo group and 1 patient in the paroxetine group. Nervousness leading to withdrawal was experienced by 1 patient in each treatment group.

Vital Signs: Changes in vital signs values from Baseline to Week 8 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 sponsor-defined clinical concern criteria (9 patients in the paroxetine group and 6 in the placebo group). The most common concern values were decreased pulse rate and increased weight (3 patients in the paroxetine group and 2 patients in the placebo group for each parameter).

Laboratory Data: In total, 10/101 patients in the paroxetine group (9.9%) and 12/102 patients in the placebo group (11.8%) had laboratory values that met the sponsor's definition of potential clinical concern at any time during the study. For the majority of cases, the values were consistent with values obtained at the Screening or Baseline Visits. No remarkable mean changes in laboratory parameters were observed in either treatment group.

Electrocardiograms: No abnormal ECGs (as assessed by the investigator) were seen at Week 8 or Early Withdrawal in either treatment group.

Conclusions

The results of this study failed to provide evidence for the primary and secondary endpoints that paroxetine is more efficacious than placebo in treating children and adolescents with MDD.

Paroxetine was generally well tolerated in this pediatric population compared to placebo, with no unexpected adverse events or findings in laboratory tests, vital signs, or ECGs. More paroxetine patients than placebo patients withdrew due to adverse events, and more children than adolescents withdrew due to AEs in the paroxetine group. The safety profile appeared similar to that previously reported for adults except that there were few gender-specific adverse events.

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List of Abbreviations & Definitions

Abbreviation	Unabridged Terms
ADECS	Adverse Drug Experience Coding System (based on COSTART) system)
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
CDRS–R	Children's Depression Rating Scale–Revised
CFR	Code of Federal Regulations
CGI	Clinical Global Impression
CGS	Clinical Global Severity
CI	confidence interval
CRF	case report form
DL	dose level
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, fourth edition
ECG	electrocardiogram
ECT	electroconvulsive therapy
ERB	Ethics Review Board
EU CPMP	European Union Committee for Proprietary Medicinal Products
FDA	Food and Drug Administration
GAD	Generalized Anxiety Disorder
GAF	Global Assessment of Functioning
GCP	Good Clinical Practice
HAM-D	Hamilton Depression Rating Scale
Hb	hemoglobin
HCG	human chorionic gonadotropin
HDPE	high-density polyethylene
IRB	Institutional Review Board

Abbreviation	Unabridged Terms
ITT	Intention-to-treat
KADS	Kutcher Adolescent Depression Rating Scale
K-SADS-L	Kiddie-Sads [Schedule for Affective Disorders and Schizophrenia for School-Age Children (6–18 years)]–Lifetime Version
K-SADS-PL	Kiddie-Sads [Schedule for Affective Disorders and Schizophrenia for School-Age Children (6–18 years)]–Present and Lifetime Version
LOCF	last observation carried forward
LOE	lack of efficacy
MADRS	Montgomery Asberg Depression Rating Scale
MAOI	monoamine oxidase inhibitor
mcmol	micromole
mmol	millimole
MDD	Major Depressive Disorder
mg	milligram
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
OTC	over-the-counter
p	probability
PID	patient identifier
PK	pharmacokinetic
PP	Per Protocol
PTSD	Post-Traumatic Stress Disorder
RBC	red blood cell
SAD	Social Anxiety Disorder
SAE	serious adverse event
SAS	Statistical Analysis System
SB	SmithKline Beecham
SD	standard deviation
SE	standard error of the mean
SGOT	serum glutamic oxaloacetic transaminase (AST)
SGPT	serum glutamic pyruvic transaminase (ALT)

Abbreviation	Unabridged Terms
SOPs	Standard Operating Procedures
SSRI	selective serotonin reuptake inhibitor
TCA	tricyclic antidepressant
TSH	thyroid stimulating hormone
WBC	white blood cell
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 re-uptake inhibitor (SSRI) registered for use in adults in the treatment of Major Depressive Disorder (MDD), Obsessive-Compulsive Disorder (OCD), 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 MDD.

The prevalence of MDD is estimated to be approximately 2% in children and 4% to 8% in adolescents [1]. Depression in children can lead to school failure, alcohol or other drug use, and even suicide.

Although the efficacy of antidepressant medication for the treatment of MDD in adults is well established, randomized controlled clinical trials in depressed pediatric populations generally have not distinguished the antidepressant under study from placebo. For example, although tricyclic antidepressants (TCAs) are effective in the treatment of depressed adults, controlled clinical trials have not demonstrated efficacy in either children or adolescents [2], [3], [4], [5], [6], [7]. Additionally, there were concerns about the safety of TCAs in light of the risks of cardiovascular morbidity and the danger of toxic overdose. Therefore, TCAs have not been viewed as first-line agents for depression in the pediatric population [8], [9]. A recent double-blind study comparing venlafaxine and placebo in a small sample of children and adolescents showed no differences in outcome or adverse effects between venlafaxine and placebo [10]. Other studies of other non-SSRI antidepressants, namely bupropion, venlafaxine, nefazodone and monoamine oxidase inhibitors (MAOIs), in the treatment of depressed children and adolescents have been mainly uncontrolled [1].

The SSRIs, although not specifically indicated for use in depressed pediatric patients, may be effective and generally well tolerated in this population [9]. In the largest controlled pediatric depression study using an SSRI other than paroxetine published to date, Emslie et al. show that the SSRI fluoxetine was superior to placebo in the acute treatment of MDD in 96 children and adolescents [11]. In fact, results based on the Children's Depression Rating Scale–Revised (CDRS–R) demonstrated response rates for patients 12 years of age and younger similar to response rates in patients 13 years and older. A second study in 219 children and adolescents showed fluoxetine to be statistically significantly

better than placebo at Week 9 endpoint ($p < 0.05$), as measured by mean change in CDRS–R scores [12].

An open-label study with the SSRI paroxetine in 45 depressed patients younger than 14 years old suggested that paroxetine effectively reduced depressive symptom severity, as measured by reduction in the Clinical Global Severity (CGS) scale [13]; however, two placebo-controlled studies of paroxetine in adolescent patients with depression yielded equivocal results. One of the two controlled studies suggested that paroxetine was efficacious (329) [14], while there was little evidence of benefit in the other study (377) [15]. In study 329, 275 patients 12 to 18 years of age were treated with paroxetine (20 to 40 mg per day), imipramine (50 to 300 mg per day), or placebo for 8 weeks. Supportive psychotherapy (45-minute sessions at each weekly visit) was provided for all patients. This study had eight prospectively defined endpoints; for each of these measures, the analysis at the Week 8 LOCF endpoint showed that the response in the paroxetine group was numerically superior to the placebo group. However, the placebo response was positive as well, perhaps in part due to the supportive psychotherapy, and the protocol-defined primary endpoints did not achieve statistical significance: the change in the Hamilton Depression Rating Scale (HAM-D) total score ($p = 0.133$) and the responder analysis (percentage of patients with at least 50% reduction in HAM-D score or a HAM-D score of 8 or less, $p = 0.112$). Statistical significance over placebo ($p < 0.05$) was achieved, however, for four of the six secondary measures: change from Baseline in the 9-item Kiddie-Sads [Schedule for Affective Disorders and Schizophrenia for School-Age Children (6–18 years)]–Lifetime Version (K-SADS–L) depression subscore, change in the depression item score of the HAM-D, percentage of patients rated "very much improved" or "much improved" on the Global Improvement item of the Clinical Global Impression (CGI) scale, and percentage of patients in remission, defined as patients with a final HAM-D score of 8 or less. The changes in the depressed mood item of both the HAM-D and the K-SADS–L suggest a meaningful clinical benefit.

In the second study (377), 286 depressed patients 13 to 18 years of age were treated for 12 weeks with either paroxetine (20 to 40 mg/day) or placebo (2:1). The primary efficacy parameters were the proportion of patients with a 50% or greater reduction in Montgomery Asberg Depression Rating Scale (MADRS) score at LOCF endpoint and the change from Baseline in K-SADS–L depression subscale at LOCF endpoint. None of the two primary or four secondary efficacy variables indicated any clinically or statistically significant treatment effect.

Regarding safety, both studies were generally unremarkable with regard to the nature and frequency of adverse events (AEs). The AE profile of paroxetine in children and adolescents with depression appeared generally comparable to that reported in depressed adults in controlled clinical trials with paroxetine.

The differences in antidepressant treatment response between adult and pediatric populations in clinical trials have been the subject of much discussion, and recent reviews have focused on three major areas of concern [16][17][18]. These include (a) deficiencies in study design, methodology and conduct; (b) the adequacy of diagnostic criteria; and (c) developmental issues, in that children and adolescents who suffer from adult-like depression may respond in a pharmacologically different manner due to quantitative and/or qualitative developmental differences in neurotransmitter systems. Despite the relative lack of evidence of efficacy in depressed pediatric patients, antidepressant medications continue to be prescribed off-label for children and adolescents based on the adult data, underscoring the importance of conducting additional controlled studies to better characterize the efficacy and safety of these agents in pediatric populations.

The benefit of paroxetine in treating depressed pediatric patients has not been conclusively demonstrated; therefore the present study was conducted to further evaluate the efficacy and safety of paroxetine in the treatment of children and adolescents with MDD. Potential design limitations of the two prior studies were taken into account, concurrent psychotherapy was disallowed, and a depression severity rating instrument more suitable for pediatric patients than those used in previous studies 329 and 377 was utilized. The CDRS–R was selected as the primary outcome measure. It is a validated instrument that has been used to assess changes in depression severity in children and adolescents [19], [20], including distinguishing fluoxetine from placebo in the studies referred to above [11], [12]. Its use in pediatric depression studies has also been endorsed by FDA.

2 Objectives

2.1 Primary Objective

To compare the efficacy of paroxetine versus placebo in the treatment of children and adolescents with MDD, as measured by the change from Baseline in the Children's Depression Rating Scale–Revised (CDRS–R) total score at the Week 8 LOCF endpoint.

2.2 Secondary Objective

To compare the safety and tolerability of paroxetine versus placebo in the treatment of children and adolescents with MDD.

3 Methodology

3.1 Study Design

This was a multicenter, randomized, double-blind, placebo-controlled, flexible-dose, parallel-group trial with an 8-week Treatment Phase. Children (ages 7 through 11) and adolescents (ages 12 through 17) who met DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, fourth edition) [21] criteria for MDD (single episode [296.2] or recurrent [296.3]) and who fulfilled the entrance criteria entered a 1-week Screening Phase. At the end of this period, Baseline evaluations were performed to determine eligibility for randomization to the Treatment Phase of the study. Eligible patients were 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 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 increments of 10 mg/day (1 dose level) at intervals of at least 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 DL 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 8 weeks followed by a Taper Phase of up to 4 weeks.

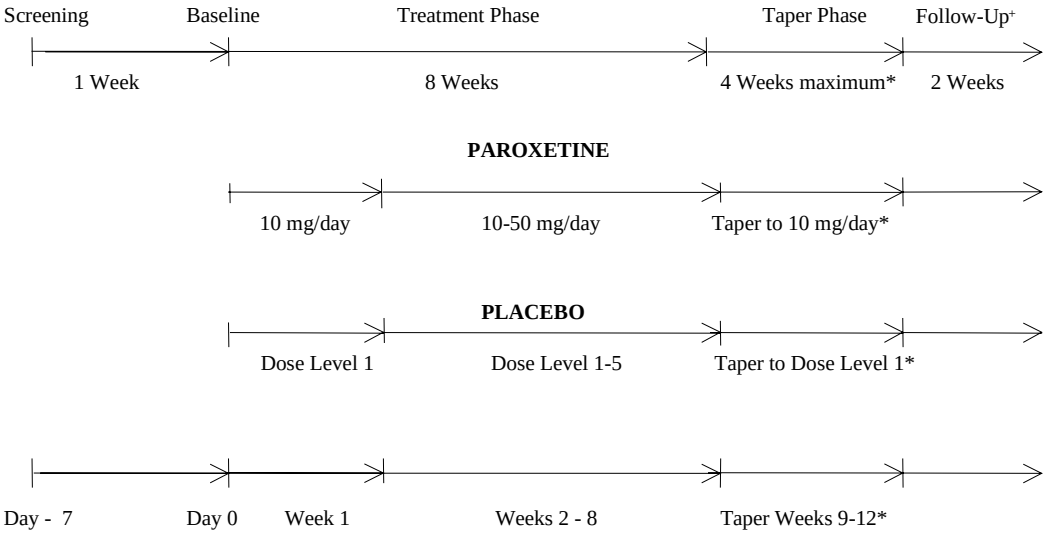
Dose reductions to the next lowest level consequent to an AE were permitted after Week 2. The patient could then return to the previous dose level upon resolution of the AE. Patients who were unable to tolerate DL 1 (10 mg/day or placebo) were withdrawn from the study. Patients who required more than one dose reduction were 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 8-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 safety 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 8-Week Treatment Phase and elected to enter the separate, open-label extension study (Study 29060/716).

The study design is depicted in Figure 1.

Figure 1 Schematic for Study Design



* The Taper Phase duration is dependent on ending Dose Level at Week 8 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 29060/701 was finalized on 1 February 2000, with one subsequent protocol amendment.[1] Amendment 1, dated 8 December 2000, clarified the language in the statistical evaluation section at the request of 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 made clear that investigation of

[1] Appendix A contains the protocol and amendment.

interactions would be limited to the 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 192 patients in the United States and Canada would be randomized (96 per treatment arm). Each center was to aim to recruit a minimum of approximately 8 patients; therefore, approximately 30 centers in the United States and Canada were initially expected to participate. 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 each investigator's qualifications and experience.

Table 1 lists the principal investigators who actively participated in the study, their center numbers, their affiliated institution and their geographic location.

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				
	148			
M.D.				
			Maitland	FL
		Center		
	150		Clearwater	FL
M.D.		Florida		
			Cleveland	OH
		LLC		
	152	A		
M.D.				
			Charleston	SC
		Carolina		
	155			
M.D.				
	156		Dallas	TX
M.D.				
	157			
M.D.				
			Eugene	OR
			Lake Oswego	OR
	160		Los Angeles	CA
M.D.				
			Boise	ID
	163		St. Louis	MO
			Columbia	MO
	166		Philadelphia	PA
M.D.				
M.D.				

(Table continues)

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

Investigator	Center	Affiliated Institution	City	State
United States (cont'd)				
	167			
M.D.				
	168			
M.D.				
	169		Lynn	MA
	170		Decatur	GA
M.D.		Research		
	171	l	St. Simons	GA
		Health System	Island	
	174			
M.D.				
			Shreveport	LA
	176			KS
M.D.			Village	
	178		Galveston	TX
M.D., Ph.D.				
	179		Philadelphia	PA
M.D.				
			Orlando	FL
		PA		
			Medina	OH
		Associates, Inc.		
			Washington	DC
		Center		
			Richmond	VA
		Associates, Inc.		
	188			
M.D.*				
	189			
D.O.				
Canada				
	192			
M.D.				

* Center 188 screened one patient but did not enroll any.

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 (IRB) (or Ethics Committee) prior to each center's initiation. Written informed consent and/or assent was obtained from each parent/guardian and/or patient prior to entry into the study.[3] Case report forms (CRFs) were provided for each patient's data to be recorded.

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 diagnosis of MDD 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 diagnosis of MDD and to determine the presence of any other comorbid psychiatric disorders [22].[4] All parents (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:

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[2] As stated in EU CPMP 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 and assent are appendices to the protocol.

[4] The DSM-IV Diagnostic Criteria for Major Depressive Disorder, Single Episode (296.2) or Recurrent (296.3) may be found in Appendix F of the protocol. The Kiddie-Sads [Schedule for Affective Disorders and Schizophrenia for School-Age Children (6–18 years)]-Present and Lifetime Version (K-SADS–PL) interview may be found in Appendix J of the Protocol.

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

2 Diagnosis of MDD, either single episode or recurrent according to DSM-IV (296.2 or 296.3, respectively) confirmed by the K-SADS–PL semi-structured diagnostic interview

3 Patients with a total raw summary score of 45 or greater on the Children's Depression Rating Scale–Revised (CDRS–R) at the Screening and Baseline Visits

4 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 MDD

2 Patients with any history of a psychotic episode or psychotic disorder

3 Patients with a history of Bipolar Disorder

4 Patients with Mental Retardation or Pervasive Developmental Disorder

5 Patients diagnosed with Substance Abuse or Dependence within 3 months prior to the Screening Visit

6 Patients who tested positive for illicit drug use at the Screening Visit

7 Patients who, in the investigator's judgment, posed a suicidal or homicidal risk

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

- Fluoxetine, MAOIs–4 weeks or less
- Depot antipsychotics–12 weeks or less
- Antidepressants other than MAOIs or fluoxetine (e.g., TCAs, noradrenergic serotonin reuptake inhibitors [NSRIs], SSRIs), lithium and oral antipsychotics–14 days or less
- Hypnotics, benzodiazepines, and all other sedatives (including sedating antihistamines)–5 half-lives or 14 days (whichever is longer) or less
- Any CNS-active herbal/natural supplement or preparation known or thought to have any psychoactive effects–14 days or less

9 Patients with epilepsy

10 Patients who, in the opinion of the investigator, would be non-compliant with the visit schedule or other study procedures

11 Patients with clinically significant abnormalities in hematology, blood chemistry, electrocardiogram (ECG) or physical examination at Screening that was not resolved by the Baseline Visit

12 Patients who in the opinion of the investigator had a serious medical condition that would preclude the administration of paroxetine

13 Patients with known hypersensitivity to SSRIs

14 Patients who had electroconvulsive therapy (ECT) within 3 months of Screening

15 Female patients who had a positive serum HCG pregnancy test or who were lactating

16 Sexually active female patients who were not using a reliable method of contraception (e.g., oral contraception, condom in conjunction with spermicidal foam)

17 Patients who had received paroxetine in any previous investigational study or who received any investigational drug within 6 months prior to Screening

18 Patient requiring concurrent psychotherapy

19 Patients who, in the judgment of the investigator, had a clear history of non-response to SSRI treatment for their MDD, defined as non-response to at least two different SSRIs following adequate courses of treatment, (i.e., received recommended doses for 4 to 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 that were 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 29060/701 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 *

*Manufactured at SmithKline Beecham site in Puerto Rico, Lot No. X9-6B10PL
Source: Certificates of Analysis, 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, and 6 in the Treatment Phase and at Week 8 or Early Withdrawal if the patient entered the Taper Phase. Each bottle dispensed during the Treatment and Taper Phases 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 and 6, and one bottle per week of taper medication required at Week 8 or Early Withdrawal, each containing the appropriate number of tablets for the designated week, plus 3 days' extra supply for each week.

The sponsor 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-blind 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 (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 medication 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

Once randomized, patients, under parental supervision, were instructed to take from 1 to 5 tablets (depending on dose level) each morning with food throughout the double-blind Treatment Phase of the study (Weeks 1 to 8) and the Taper Phase, if necessary (Weeks 9 to 12). Study medication was dispensed at each scheduled visit in the Treatment Phase. Patients were supplied all medication required for the Taper Phase, one bottle per week, at the Week 8 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 dose 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 8 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 per day of placebo for Week 1. Beginning with Week 2, depending on clinical response and tolerability, the dose could be increased by increments of 10 mg/day (i.e., 1 dose level) for both paroxetine and placebo patients, no more frequently than every 7 days and up to maximum dose of 50 mg/day (DL 5). Dose increases 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 at least DL 2 (20 mg/day paroxetine or matching placebo) and was brought in for a visit. The patient could return to the elevated 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) over a period of up to 4 weeks for patients who either completed the Treatment Phase or were prematurely withdrawn at DL 2 or greater. Patients at DL 1 at study completion or withdrawal 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 with one week of dosing at DL 1, as shown in Table 4.

In certain instances, for patients who were entering the open-label extension study 29060/716, the investigator, with the agreement of the sponsor, permitted accelerated down-titration so that the patient could be returned to the optimal dose level more quickly.

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

Dose level* at the end of treatment	**Week 9 ****	**Week 10 ****	**Week 11 ****	**Week 12 ****
DL 1 = 10 mg	**No Taper medication**			
DL 2 = 20 mg	DL 1 = 10 mg	**No further Taper medication**		
DL 3 = 40 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

All Taper Phase medication was dispensed at the Week 8 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.

3.5.4 Method of Blinding

Blinding of study medication was maintained by referring to the daily medication dose as Dose Levels. Active paroxetine and placebo tablets were identical in appearance. 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: 03001–03252 (children) and 03253–03504 (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 be 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 blind 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. As drugs were dispensed, this information was entered in the CRF along with the tear-off portion of the medication label. These CRF pages were brought in-house at study completion.

Patients who missed more than three consecutive days of dosing on more than one occasion were to be withdrawn from the study. Likewise, patients who, in the investigator's opinion, had significant irregularities in compliance were 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 generic term and drug name, total daily dose, route of administration, medical illness/diagnosis, start date, and end date or notation that medication was continuing.

All psychoactive medications taken within three months prior to the Screening Visit and any psychoactive medication ever taken for MDD were recorded in the CRF with a pharmacotherapy class identification (SSRI, MAOI, TCA, benzodiazepine or other), indication (if other than MDD), generic and verbatim name, start date and end date. In order to be eligible for the study, patients were required to meet specific discontinuation time periods 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 8 Visit (or Early Withdrawal Visit, if applicable). The double-blind Taper Phase was the time period after the Week 8 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 8 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).

Table 5 Outline of Study Procedures for 29060/701

	Study Visits										
	Scrn Visit Day -7	Base-Line Visit Day 0	Week 1	Week 2	Week 3	Week 4	Week 6	Week 8	Early W/D	Taper End Visit	14-Day Study F/U[a]
Screen/Baseline Evaluations											
Informed Consent/Assent	X										
Patient Demography	X										
Inclusion/Exclusion Criteria	X	X									
Psychiatric Interview	X										
Full K-SADS–PL Interview	X										
Major Depressive Disorder	X										
Depression History/Med	X										
Medical/Surgical History	X										
Patient Randomization		X									
Efficacy Parameters											
CDRS–R	X	X	X	X	X	X	X	X	X		
CGI Severity of Illness		X	X	X	X	X	X	X	X		
CGI Global Improvement			X	X	X	X	X	X	X		
GAF		X				X	X	X	X		
KADS		X	X	X	X	X	X	X	X		
Safety Evaluations											
12-Lead Electrocardiogram	X							X	X	X[b]	X[b]
Vital Signs[c]	X	X	X	X	X	X	X	X	X	X	X
Height and Weight	X							X	X		
Adverse Event monitoring		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		
Serum Pregnancy Test[d]	X							X	X		
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
Dispense Study Medication		X	X	X	X	X	X	X[f]	X[f]		
Medical Procedures		X	X	X	X	X	X	X	X	X	X
Study Medication record		X	X	X	X	X	X	X	X	X	
Study Conclusion								X	X		

K-SADS–PL = Kiddie Schedule for Affective Disorders and Schizophrenia for School-Aged Children–Present and Lifetime Version; CDRS–R = Children's Depression Rating Scale–Revised; CGI = Clinical Global Impression; GAF = Global Assessment of Functioning Scale; KADS = Kutcher Adolescent Depression Rating Scale

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

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

c. 3-minute sitting systolic and diastolic blood pressure (BP) and heart rate measured in the same arm and, where possible, by the same person throughout the study

d. For females of child-bearing potential

e. Repeat Laboratory Evaluations were performed only if clinically significantly abnormal results and with the agreement of the investigator/sponsor. Results of repeat evaluation were required to be interpreted prior to randomization. Hematology (hemoglobin, hematocrit, white blood cell [WBC] count with differential, red blood cell [RBC] count, and platelet count); Blood Chemistry (creatinine, BUN [blood urea nitrogen], total bilirubin, alkaline phosphatase, SGPT [alanine aminotransferase (ALT)], SGOT [aspartate aminotransferase (AST)], electrolytes, thyroid stimulating hormone [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 to 5.

g. Pharmacokinetic (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 consent and/or patient 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 major depression and assessment versus DSM-IV criteria for MDD, single episode (296.2) or recurrent (296.3), 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 Depression Rating Scale–Revised (CDRS–R)
- Vital signs (3-minute sitting blood pressure [BP] and heart rate). 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 and surgical history and physical examination
- Serum HCG pregnancy test for patients of child-bearing potential
- Laboratory evaluations, consisting of hematology (hemoglobin, hematocrit, white blood cell [WBC] count with differential, red blood cell [RBC] count, and platelet count); blood chemistry (creatinine, blood urea nitrogen [BUN], 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)

- Concomitant medication and medication history (including psychoactive and MDD medication history)

Patients who satisfied the criteria for eligibility at the Screening Visit entered a 1-week Screening Phase. The Screening Phase of the study was the time period between the Screening Visit (Day -7) and the Baseline Visit (Day 0), inclusive. 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 in the Study Reference Manual. All patients interviewed as possible candidates for this study were entered on the Patient Log. This log captured patient initials, interview date, screening date, and reason, if any, the patient was ineligible for Screening. All patients who signed consent received a patient number, which was then entered on the Patient Log. When patients were randomized at the Baseline Visit they were entered on the Patient Assignment Sheet. The Patient Assignment Sheet captured patient initials, patient number, drug code, patient age as of the Baseline Visit, initial date of dosing (date dispensed), and patient status in the trial (complete or withdrawn).

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 assessments/procedures 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 BP and heart rate)

- Laboratory evaluations (only if clinically significantly abnormal at the Screening Visit). Results had to be interpreted and deemed clinically non-significant by investigator prior to randomization.
- Baseline AEs (Baseline signs and symptoms)
- CDRS–R
- CGI Severity of Illness item
- Global Assessment of Functioning (GAF) Scale
- Kutcher Adolescent Depression Rating Scale (KADS)
- Concomitant medications
- Medical Procedures Record
- Study Medication record
- Patient randomization–study medication dispensed

3.8.4 Double-Blind Treatment Phase (Weeks 1 to 8)

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

- Vital signs (3-minute sitting BP and heart rate)
- Height (cm) and weight (kg) measurements without shoes–Week 8 (or Early Withdrawal Visit, if applicable)
- CDRS–R
- CGI Severity of Illness item
- CGI Global Improvement item
- GAF–Weeks 4, 6, and 8 (or Early Withdrawal Visit, if applicable)
- KADS
- 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 and 6, a supply of study medication sufficient for a 2-week period was dispensed; at Week 8 or Early Withdrawal, Taper medication was dispensed to patients ending or withdrawing from treatment at DL 2 or greater.
- Physical examination–Week 8 (or Early Withdrawal Visit, if applicable)
- Serum HCG pregnancy test for females of child-bearing potential–Week 8 (or Early Withdrawal Visit, if applicable)
- Laboratory evaluations, consisting of hematology (hemoglobin, hematocrit, RBC, WBC with differential and platelet count); blood chemistry (creatinine, BUN, total bilirubin, alkaline phosphatase, SGPT [ALT], SGOT [AST] and electrolytes); and dipstick urinalysis (if dipstick method was positive for blood or protein, full microscopy was performed)–Week 8 (or Early Withdrawal Visit, if applicable)
- Blood draws (optional) for pharmacokinetic (PK) assessments, from consenting patients only–Weeks 4 and 8 (or Early Withdrawal Visit, if applicable)
- 12-Lead ECG–Week 8 (or Early Withdrawal Visit, if applicable)
- Study Medication record
- Medical Procedures Record
- Study Conclusion module completed–Week 8 (or Early Withdrawal Visit, if applicable)

3.8.5 Taper Phase (Weeks 9 to 12)

Patients completing or withdrawing from the Treatment Phase at DL 2 or greater, had their blinded study medication gradually reduced by 1 dose level increments (10 mg/day) 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 this visit, with the following assessments performed:

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

3.8.7 Follow-up Visit

All patients not entering the paroxetine open-label extension study (29060/716) 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 Definitions

A patient was considered to have completed the study if the Week 8 Visit was completed.

A withdrawal was considered to be any patient who did not complete the Week 8 Visit.

3.9.2 Reasons for Withdrawal

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

1 Adverse event (AE section had to be completed)

2 Lack of efficacy

3 Protocol deviation (including non-compliance)

4 Lost to Follow-up (reason recorded if possible)

5 Other (reason had to be specified)

The reason for termination was recorded in the study conclusion section of the CRF. If a patient was withdrawn, every attempt was made to carry out the assessments at the patient's last visit that were scheduled for the Week 8 visit.

3.10 Efficacy Assessments

Further information on 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 H (CDRS–R) for the primary efficacy parameter; Appendix K (CGI Severity of Illness), Appendix L (CGI Global Improvement) and Appendix M (GAF) for the secondary efficacy parameters; and Appendix I (KADS) for the other efficacy parameter.

3.10.1 Primary Efficacy Parameter

The primary measure of efficacy was the Children's Depression Rating Scale–Revised (CDRS–R). The CDRS–R is a clinician-rated instrument designed to measure the severity of depression in children 6 to 12 years of age. The CDRS–R has been shown to be a reliable measure of the severity of depression that is able to discriminate depressed from non-depressed children and that is insensitive to the age of the child being evaluated. Although it was designed for 6- to 12-year-olds, it has been used successfully with adolescents. It has high interrater reliability, good test–retest reliability, good internal consistency and good convergent and discriminant validity [20]. Its use in this study has been endorsed by FDA. The CDRS–R can capture slight but notable changes in a child's symptoms, thus making the scale useful for monitoring symptoms during illness or remission.

In this study, the CDRS–R was administered to all patients 7 to 17 years of age. The procedure for conducting the CDRS-R and recording data was reviewed with all attendees during the pre-study multicenter investigators' meeting, as well as with site personnel unable to attend the meeting. Rater training was also conducted to insure proper use of the scale during the study.

The CDRS–R assesses 17 symptom areas including those that serve as the criteria in the DSM-IV [21] for the diagnosis of Major Depression. It can be administered by a clinician or trained interviewer in a semi-standard fashion to the child directly and to the parent(s), teacher or guardian in approximately 30 minutes. The first 14 items of the scale are rated on the basis of the child's verbal responses to interview questions. The remaining 3 symptom areas of the CDRS–R, Depressed Facial Affect, Listless Speech, and Hypoactivity, are rated by the clinician on the basis of the child's nonverbal behavior. Fifteen of the symptom areas are rated on a 7-point scale, with two on a 5-point scale. Following separate CDRS-R evaluation sessions with the patient and any informant(s), the clinician summarizes the best overall description of the patient and entered the data on the CRF.

The CDRS–R summary score ranges from 17 to 113. A summary score of 45 or above on the CDRS–R is a strong indicator of the presence or potential for a Major Depressive Disorder. Although the score of 45 is a reliable indicator of depression, it should serve as a heuristic, not as a criterion by which the child is diagnosed with Major Depressive Disorder or not.

In this study, the CDRS–R was used only as a measure of severity of the depression and provided the basis for comparison of the treatments over time.

3.10.2 Secondary Efficacy Parameters

The secondary measures of efficacy were the Clinical Global Impression (CGI) Severity of Illness item score, the CGI Global Improvement item, where response was defined as a score of 1 ("very much improved") or 2 ("much improved"), and the Global Assessment of Functioning (GAF).

The Clinical Global Impression (CGI) 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 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, 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 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.

3.10.3 Other Efficacy Variable

An additional efficacy variable was the Kutcher Adolescent Depression Rating Scale (KADS). The KADS is a self-report instrument under development (not validated) for the purpose of diagnosis and assessment of the severity of depression in adolescents. Structurally, the KADS consists of a) items corresponding to the core symptoms of depression, called stem responses, and b) for each item, sub-items, called subsidiary responses, that reflect the intensity of the stem response. The full version of the KADS (as used in this study) encompasses 14 items. Items 1, 2, 5, 6, 7, 8, 9, 10, 11, and 12 are two-part questions each containing a stem response and a subsidiary response. Items 13 and 14 consist of one part only in the stem response without any subsidiary responses. Item 3 consists of four subparts in the stem response only without any subsidiary responses. The purpose of Item 3 is to determine the patient's most troublesome sleep problem that is subsequently rated in Item 4 to determine the corresponding subsidiary response. All responses use a 0 to 3 scale.

The total score of the responses to the stem items ranges from 0 to 39 (1 to 14, excluding Item 4); a score of 12 to 14 and above is an indicator of clinically significant depressive symptomatology. The KADS is used as a measure of severity of depression to provide the basis for comparison of treatments over time in adolescents only.

3.11 Safety Assessments

Safety was assessed primarily through AE monitoring and vital sign measurements at every visit; physical examinations, including height and weight, and a serum HCG pregnancy test (females of child-bearing potential only) at Screening and at Week 8 (or Early Withdrawal, if applicable); and clinical laboratory evaluations and ECGs at Screening (and Baseline for laboratory evaluation if abnormal) and Week 8 or Early Withdrawal (and at Taper and/or Follow-up if abnormal at previous visit).

3.11.1 Adverse Events

Adverse events (AEs) were elicited by the investigator asking the patient a non-leading question such as, "Do you feel different in any way since starting the treatment or since the last visit?"

Additionally, if the patient was not old enough to answer appropriately, the patient's parent or legal guardian was asked a non-leading question such as, "Does your child feel or seem different in any way since the last visit?" If the response was "Yes," details of the AE and its severity, including any change in study medication administration, investigator attribution to study medication, any corrective therapy given, and outcome status were documented on the CRF. Attribution or relationship to study medication was judged by the investigator to be unrelated, probably unrelated, possibly related, or related.

All AEs were coded from the verbatim term according to the World Health Organization (WHO) Adverse Reaction Terminology (ART) dictionary and then mapped by body system and preferred term according to the COSTART-based Adverse Drug Experience Coding System (ADECS).

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.

3.11.1.1 Serious Adverse Events

A serious adverse event (SAE) was any event that was fatal, life threatening, or disabling/incapacitating, or resulted in hospitalization, prolonged a hospital stay or was associated with 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.

3.11.2 Other Safety Assessments

The other assessments relating to safety were as follows:

- Full physical examination

Physical examinations were required at the Screening Visit and again at Week 8 or Early Withdrawal. Any adverse changes in the physical examination were to be recorded in the AE pages of the CRF.

- Vital signs (height, weight, sitting BP, and heart rate)

Height and weight were measured at Screening and again at Week 8 or Early Withdrawal. Sitting BP and heart rate were assessed at every visit.

- Laboratory assessments (hematology, blood chemistry and urinalysis)

Routine laboratory safety assessments (hematological, blood chemistry and urinalysis parameters) were assessed at Screening (and at Baseline only if clinically indicated by screening abnormalities) and at Week 8 or at the patient's Early Withdrawal Visit if withdrawn early from the study; they were repeated at Taper End and Follow-up only if clinically indicated. Analyses were performed by a central laboratory (Quest Diagnostics). Laboratory tests included hematology (hemoglobin, hematocrit, RBC, WBC with differential and platelet count); blood chemistry (creatinine, BUN, total bilirubin, alkaline phosphatase, SGPT (ALT), SGOT (AST) and electrolytes); and dipstick urinalysis (if dipstick method was positive for blood or protein, full microscopy was performed). 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.

- Pregnancy testing

Serum HCG pregnancy tests were performed at Screening and again at Week 8 or Early Withdrawal for patients of child-bearing potential.

- Electrocardiogram

A 12-lead ECG was carried out at Screening. An additional ECG was performed at Week 8 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.

3.12 Pharmacokinetic Assessments

The collection of PK samples was optional (i.e., it was not required by the protocol) and only patients consenting to this additional assessment had samples obtained. The PK data from this study will be combined with data from other relevant studies (studies 704 and 676 [23], [24]) and reported separately at a later time.

3.12.1 Sampling Times

Venous blood samples were drawn from consenting patients at Weeks 4 and 8 (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 all 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 [25] 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 multi-investigator meeting was held on 25 February 2000 in New Orleans, LA, USA.

Adherence to the protocol requirements and verification of data generation accuracy was achieved through monitoring visits to each investigator site. Subsequent data handling and reporting processes were subject to in-process Quality Control and this final clinical report has, in addition, been subject to an end-stage Quality Control review. All the above procedures were performed according to methodologies detailed in SmithKline Beecham Standard Operating Procedures (SOPs).

This study was subject to audit by the department of Worldwide Regulatory Compliance–GCP (WRC–GCP) at SmithKline Beecham. 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 may be found in Appendix A.

3.14 Statistical Evaluation

3.14.1 Target Sample Size

A total of 85 evaluable patients per treatment group was sufficient to detect a mean difference of 8 units between paroxetine and placebo in the change from Baseline to LOCF endpoint in CDRS–R total score. This was based on an estimated standard deviation of 15.94, which was obtained from pooling the results of the standard deviations in each group at endpoint, presented in a randomized study conducted in children and adolescents with depression [11]. This assumed a correlation between endpoint and Baseline of 0.5 and was the best estimate given available information. This mean difference is detectable with a power of 90%, given a significance level of 5% and using two-sided significance tests.

Assuming a 10% attrition rate between randomization and first post-dose assessment, it was necessary to randomize 192 patients (96 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) 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 eight patients (four 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

The primary inference was based on the last observation carried forward (LOCF) dataset at the Week 8 endpoint. Efficacy evaluations were collected for the following:

- Children's Depression Rating Scale–Revised (CDRS–R) total score at each visit
- Clinical Global Impression (CGI) Severity of Illness at each visit except Screening
- CGI Global Improvement at each visit except Screening and Baseline
- Global Assessment of Functioning (GAF) at Baseline and Weeks 4, 6, and 8 (or Early Withdrawal Visit, if applicable)
- Kutcher Adolescent Depression Rating Scale (KADS) total score (adolescents only) at each visit except Screening

3.14.3.1 Primary Efficacy Variable

The primary measure of efficacy was the following:

- Change from Baseline in CDRS–R total score at the Week 8 LOCF endpoint

3.14.3.2 Secondary Efficacy Variables

The secondary measures of efficacy were the following:

- Change from Baseline in the CGI Severity of Illness item score at Week 8 LOCF endpoint
- Proportion of responders based on the CGI Global Improvement item, where response is defined as a score of 1 ("very much improved") or 2 ("much improved") on the scale at the Week 8 LOCF endpoint
- Change from Baseline in GAF at Week 8 LOCF endpoint

3.14.3.3 Other Efficacy Variable

Another variable of interest was the following:

- Change from Baseline in the KADS total score at Week 8 LOCF endpoint (adolescents only)

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 were assessed during the model building process at the 10% level of significance.

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

The null hypothesis for this study was: There is no difference between paroxetine and placebo in the change from Baseline of the CDRS–R total score at the Week 8 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 CDRS–R total score at the Week 8 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 (children / adolescents)
- Gender
- Baseline efficacy score for each variable
- Comorbidity category (Yes / 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 were analyzed using parametric analysis of variance. The statistical model on which the primary inference was based included terms for each of the covariates 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 explored and, where necessary, results were reported for each level of the covariate. Investigation of interactions were confined to the primary variable using the Week 8 LOCF dataset.

Results were presented as the mean and 95% confidence interval 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.

Where the assumptions of normality and homogeneity of variance were not met, appropriate non-parametric methods were 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 (i.e., proportion of patients scoring 1 or 2 on the CGI global improvement scale) were analyzed by logistic regression. The statistical model on which inference was based included terms for each of the covariates 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 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.

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.

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

3.14.5 Populations/Datasets 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 Population

The Per Protocol (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
- 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 total number of patients in 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 8 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 8 endpoint. A decision on whether to analyze these datasets was to be agreed between Biometrics and the Neurosciences Clinical Group prior to breaking the study blind, when the total number of patients in the datasets was known.

In the LOCF dataset, the last available on-therapy observation for a patient was used to estimate missing data points. In the OC dataset, efficacy data were evaluated only at the timepoint when they were collected; no data were carried forward to estimate missing data points. In both datasets, data for patients who were withdrawn 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 number (%) 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 treatment and before or on the last day of 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 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 Phase, Taper Phase and Follow-up Phase 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 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 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 values of potential clinical concern predefined 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 again at Week 8 or Early Withdrawal, and assessments at both timepoints are presented. ECGs were repeated at 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. 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. Sponsor-defined criteria for clinical concern values may be found in Section 6.9, Laboratory Data.

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 scheduling 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 randomization.

Visit	Proposed day relative to Baseline	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 70
Post-Week 8	—	Greater than 70 days

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

Screening (Visit 1) data is all data that was collected on the Screening page of the CRF. Similarly, Baseline (Visit 2) data is all data that was collected on the Baseline page of the CRF.

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 4, 6, and 8 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 was recorded at the Early Withdrawal Visit, it was handled in the same way as scheduled data and was slotted using the predefined 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 were excluded from the summary tables and analyses. However, all data were listed. Efficacy data slotted as post-Week 8 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 was 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

Patient 701.161.25909, an 11-year-old female, was classified by the investigator for purposes of randomization as an adolescent, although she was appropriately a child, based on the protocol and the FDA definition "children are aged 11 or less at their last birthday."

Data for this patient have been reported and analyzed in the children age group. However, KADS was assessed for this patient by the investigator. Thus this patient is included in the KADS listings, tables and analyses. Therefore, there is

one extra patient in the KADS output compared to all other adolescent age group summaries.

4 Study Population

4.1 Study Dates

The first dose of double-blind study medication was taken on 20 March 2000 and the last dose of study medication (excluding Taper) was taken on 24 January 2001 (Listing 13.14.1, Appendix B). The last study visit for the last patient to complete participation occurred on 12 February 2001 (Listing 15.2.1, Appendix E).

4.2 Patient Disposition

4.2.1 Number and Distribution of Patients

A total of 305 patients completed the Screening Visit and 206 were randomized to double-blind treatment.[5] The 99 patients not randomized included 52 adolescents (52.5%) and 47 children (47.5%) (Table 6 and Table 13.1.1, Section 11). The primary reason for pre-randomization withdrawal was failure to meet inclusion/exclusion criteria. Reasons for all pre-randomization withdrawals are shown in Table 6, which provides data for both age groups combined (age group: total).

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

Total withdrawn	**99 (100.0%)**
Reason for Pre-randomization Withdrawal	n (%)
Baseline AE	1 (1.0%)
Did not meet inclusion/exclusion criteria	72 (72.7%)
Protocol deviation	1 (1.0%)
Lost to Follow-up	12 (12.1%)
Other *	13 (13.1%)

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

A total of 206 patients were randomized to treatment, 97 children (47.1%) and 109 adolescents (52.9%) (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.

Three patients (701.162.25788, 701.168.25659, and 701.176.25737) were randomized to the paroxetine group but did not return for a subsequent visit. These patients are not included in the ITT population since no post-baseline assessments were obtained for any of them (Listing 13.1.1, Appendix B).

The ITT population consisted of 101 paroxetine patients (104 patients randomized less the 3 patients who had no post-baseline assessments) and 102 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, and exposure to a minimum duration of 2 weeks of randomized study medication (see Section 4.3, Protocol Violations). The PP population consisted of 74 paroxetine patients and 83 placebo patients.

Overall, of all patients randomized, more patients in the placebo group (79/102, 77.5%) completed the study than in the paroxetine group (70/104, 67.3%). However, there was an imbalance in the age subgroups. Among children, more placebo patients than paroxetine patients completed the study (41/102, 87.2%, vs. 30/104, 60.0%, respectively), whereas among adolescents, slightly more paroxetine patients than placebo patients completed the study (40/104, 74.1%, vs. 38/102, 69.1%, respectively).

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

	Treatment Group		
Number of Patients, n (%)	**Paroxetine**	**Placebo**	**Total**
Age Group: Total	(N = 104)	(N = 102)	(N = 305)
Screened only	—	—	99
Randomized	104 * (100.0%)	102 (100.0%)	206 * (100.0%)
Completed Study	70 (67.3%)	79 (77.5%)	149 (72.3%)
Early Withdrawal	34 (32.7%)	23 (22.5%)	57 (27.7%)
Intention-to-treat Population	101 (97.1%)	102 (100.0%)	203 (98.5%)
Per Protocol Population	74 (71.2%)	83 (81.4%)	157 (76.2%)
Entered Long-term Study 29060/716	50 (48.1%)	63 (61.8%)	113 (54.9%)
Age Group: Children	(N = 50)	(N = 47)	(N = 144)
Screened only	—	—	47
Randomized	50 (100.0%)	47 (100.0%)	97 (100.0%)
Completed Study	30 (60.0%)	41 (87.2%)	71 (73.2%)
Early Withdrawal	20 (40.0%)	6 (12.8%)	26 (26.8%)
Intention-to-treat Population	49 (98.0%)	47 (100.0%)	96 (99.0%)
Per Protocol Population	39 (78.0%)	41 (87.2%)	80 (82.5%)
Entered Long-term Study 29060/716	24 (48.0%)	34 (72.3%)	58 (60.0%)
Age Group: Adolescents	(N = 54)	(N = 55)	(N = 161)
Screened only	—	—	52
Randomized	54 (100.0%)	55 (100.0%)	109 (100.0%)
Completed Study	40 (74.1%)	38 (69.1%)	78 (71.6%)
Early Withdrawal	14 (25.9%)	17 (30.9%)	31 (28.4%)
Intention-to-treat Population	52 (96.3%)	55 (100.0%)	107 (98.2%)
Per Protocol Population	35 (64.8%)	42 (76.4%)	77 (70.6%)
Entered Long-term Study 29060/716	26 (48.1%)	29 (52.7%)	55 (50.5%)

*Includes 3 patients who were randomized (all in the paroxetine group) but withdrew before any post-baseline assessments were obtained. Numerator for percentages is the number of patients randomized.
Source: Table 13.1.1, Section 11; Listings 13.1.1, 13.3.1a, 13.3.1b, Appendix B.

The study was conducted in 40 centers in the US (one of which screened but did not randomize any patients) and 1 center 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 21 patients at Center 181. A total of 10 centers each randomized at least 8 patients.

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

	Treatment Group				Total (N = 203)	
	Paroxetine (N = 101)		Placebo (N = 102)			
Center No.	Random-ized	Completed*	Random-ized	Completed*	Random-ized	Total Completed*
148	2 (2.0%)	1 (1.0%)	0	0	2 (1.0%)	1 (0.5%)
149	4 (4.0%)	2 (2.0%)	4 (3.9%)	3 (2.9%)	8 (3.9%)	5 (2.5%)
150	2 (2.0%)	2 (2.0%)	1 (1.0%)	1 (1.0%)	3 (1.5%)	3 (1.5%)
151	1 (1.0%)	0	2 (2.0%)	2 (2.0%)	3 (1.5%)	2 (1.0%)
152	1 (1.0%)	1 (1.0%)	1 (1.0%)	0	2 (1.0%)	1 (0.5%)
153	0	0	1 (1.0%)	1 (1.0%)	1 (0.5%)	1 (0.5%)
154	2 (2.0%)	2 (2.0%)	1 (1.0%)	0	3 (1.5%)	2 (1.0%)
155	0	0	1 (1.0%)	1 (1.0%)	1 (0.5%)	1 (0.5%)
156	1 (1.0%)	1 (1.0%)	1 (1.0%)	1 (1.0%)	2 (1.0%)	2 (1.0%)
157	1 (1.0%)	1 (1.0%)	0	0	1 (0.5%)	1 (0.5%)
158	1 (1.0%)	1 (1.0%)	0	0	1 (0.5%)	1 (0.5%)
159	6 (5.9%)	4 (4.0%)	6 (5.9%)	5 (4.9%)	12 (5.9%)	9 (4.4%)
160	2 (2.0%)	1 (1.0%)	0	0	2 (1.0%)	1 (0.5%)
161	5 (5.0%)	1 (1.0%)	5 (4.9%)	4 (3.9%)	10 (4.9%)	5 (2.5%)
162	7 (6.9%)	6 (5.9%)	8 (7.8%)	4 (3.9%)	15 (7.4%)	10 (4.9%)
163	2 (2.0%)	0	1 (1.0%)	0	3 (1.5%)	0
164	3 (3.0%)	3 (3.0%)	3 (2.9%)	3 (2.9%)	6 (3.0%)	6 (3.0%)
165	1 (1.0%)	1 (1.0%)	2 (2.0%)	2 (2.0%)	3 (1.5%)	3 (1.5%)
166	0	0	2 (2.0%)	2 (2.0%)	2 (1.0%)	2 (1.0%)
167	1 (1.0%)	1 (1.0%)	3 (2.9%)	2 (2.0%)	4 (2.0%)	3 (1.5%)
168	3 (3.0%)	3 (3.0%)	3 (2.9%)	2 (2.0%)	6 (3.0%)	5 (2.5%)
169	0	0	1 (1.0%)	1 (1.0%)	1 (0.5%)	1 (0.5%)
170	4 (4.0%)	1 (1.0%)	3 (2.9%)	3 (2.9%)	7 (3.4%)	4 (2.0%)
171	0	0	1 (1.0%)	1 (1.0%)	1 (0.5%)	1 (0.5%)
172	2 (2.0%)	1 (1.0%)	2 (2.0%)	0	4 (2.0%)	1 (0.5%)
173	2 (2.0%)	2 (2.0%)	0	0	2 (1.0%)	2 (1.0%)
174	1 (1.0%)	1 (1.0%)	1 (1.0%)	0	2 (1.0%)	1 (0.5%)
175	2 (2.0%)	2 (2.0%)	1 (1.0%)	0	3 (1.5%)	2 (1.0%)
176	6 (5.9%)	4 (4.0%)	6 (5.9%)	5 (4.9%)	12 (5.9%)	9 (4.4%)
178	4 (4.0%)	4 (4.0%)	4 (3.9%)	4 (3.9%)	8 (3.9%)	8 (3.9%)
179	0	0	1 (1.0%)	1 (1.0%)	1 (0.5%)	1 (0.5%)
180	4 (4.0%)	2 (2.0%)	3 (2.9%)	1 (1.0%)	7 (3.4%)	3 (1.5%)
181	10 (9.9%)	7 (6.9%)	11 (10.8%)	8 (7.8%)	21 (10.3%)	15 (7.4%)
182	2 (2.0%)	0	1 (1.0%)	1 (1.0%)	3 (1.5%)	1 (0.5%)
183	6 (5.9%)	4 (4.0%)	9 (8.8%)	8 (7.8%)	15 (7.4%)	12 (5.9%)
184	1 (1.0%)	1 (1.0%)	0	0	1 (0.5%)	1 (0.5%)
185	4 (4.0%)	2 (2.0%)	5 (4.9%)	5 (4.9%)	9 (4.4%)	7 (3.4%)
186	3 (3.0%)	3 (3.0%)	3 (2.9%)	3 (2.9%)	6 (3.0%)	6 (3.0%)
189	0	0	1 (1.0%)	1 (1.0%)	1 (0.5%)	1 (0.5%)
192	5 (5.0%)	5 (5.0%)	4 (3.9%)	4 (3.9%)	9 (4.4%)	9 (4.4%)

* A patient was considered to have completed the study if the Week 8 Visit was completed. Three patients were considered completers at the Week 6 visit. See Errata, Table 16.0, Section 15.
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 149/203 patients (73.4%) completed the study (i.e., completed the Week 8 visit). In the ITT population, 70 patients in the paroxetine group completed the study (68 at Week 8 and 2 at Week 6) of 101 (denominator does not include the 3 patients who were randomized but were not in the ITT population); this percentage (69.3%) was lower than for the placebo group (79/102, 77.5%).

A slightly higher percentage of patients were withdrawn from the study at Week 4 (8.8% total, 11.4% 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)

	Paroxetine (N = 101)	**Placebo (N = 102)**	**Total (N = 203)**
Visit	n (%)	n (%)	n (%)
Baseline	101 (100.0%)	102 (100.0%)	203 (100.0%)
Week 1	98 (97.0%)	98 (96.1%)	196 (96.6%)
Week 2	93 (92.1%)	97 (95.1%	190 (93.6%)
Week 3	88 (87.1%)	93 (91.2%)	181 (89.2%)
Week 4	78 (77.2%)	87 (85.3%)	165 (81.3%)
Week 6 *	74 * (71.3%)	81 * (78.4%)	155 * (74.9%)
Week 8 **	68 ** (67.3%)	78 ** (76.5%)	146 ** (71.9%)

Note: Percentages for patients still in the study at each visit are based on the total number of patients at Baseline
* 3 patients (2 paroxetine and 1 placebo) completed the study at the Week 8 visit, but the completions were slotted to Week 6 because of windowing (see Section 3.14.7, Defined Visit Timepoints). These 3 patients are included in this table as remaining in the study at Week 6. See Table 16.0, Errata, Section **Error! Reference source not found.**.
** These numbers represent patients who completed the study at the Week 8 visit, and do not include the 3 patients who completed at the Week 6 visit.
Source: Tables 13.1.1, 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 26.6% (54/203) of patients were withdrawn during the treatment phase. Overall, the percentage of patients who were withdrawn prematurely was slightly higher in the paroxetine group (30.7%, 31/101) than in the placebo group (22.5%, 23/102). The primary

reason for withdrawal in the paroxetine group was AE (8.9%, 9/101, compared to 2.0%, 2/102, in the placebo group). In the placebo group the primary reason for withdrawal was lack of efficacy (10.8%, 11/102, compared to 6.9%, 7/101, in the paroxetine group).

The withdrawal rates were similar for children (25/96, 26.0%) and adolescents (29/107, 27.1%). However, among children, approximately 3 times more paroxetine-treated patients were withdrawn (19/49, 38.8%) than placebo patients (6/47, 12.8%). The primary reason for withdrawal in the paroxetine group among children was AE (7/49, 14.3%, compared to none in the placebo group). Contrary to the findings in the children subgroup, among adolescents, more placebo patients were withdrawn (17/55, 30.9%) than paroxetine-treated patients (12/52, 23.1%). The primary reason for withdrawal in the placebo group among adolescents was lack of efficacy (7/55, 12.7%, compared to 3/52, 5.8%, in the paroxetine group). Among adolescents in the paroxetine group, AEs, lack of efficacy, and lost to follow-up (3/52 patients each, 5.8%) were the most frequent reasons 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 = 101)	**Placebo** (N = 102)	**Total** (N = 203)	**Paroxetine** (N = 49)	**Placebo** (N = 47)	**Paroxetine** (N = 52)	**Placebo** (N = 55)
Adverse event	10 * (9.9%)	2 (2.0%)	12 (5.9%)	7 (14.3%)	0	3 * (5.8%)	2 (3.6%)
Lack of efficacy	7 * (6.9%)	11 (10.8%)	18 (8.9%)	4 (8.2%)	4 (8.5%)	3 * (5.8%)	7 (12.7%)
Protocol deviation (including non-compliance)	3 (3.0%)	3 (2.9%)	6 (3.0%)	2 (4.1%)	0	1 (1.9%)	3 (5.5%)
Lost to follow-up	8 (7.9%)	4 (3.9%)	12 (5.9%)	5 (10.2%)	2 (4.3%)	3 (5.8%)	2 (3.6%)
Other **	3 (3.0%)	3 (2.9%)	6 (3.0%)	1 (2.0%)	0	2 (3.8%)	3 (5.5%)
Total withdrawn	31 (30.7%)	23 (22.5%)	54 (26.6%)	19 (38.8%)	6 (12.8%)	12 (23.1%)	17 (30.9%)
Completed study †	70 (69.3%)	79 (77.5%)	149 (73.4%)	30 (61.2%)	41 (87.2%)	40 (76.9%)	38 (69.1%)

* Patient 701.163.25718, in the paroxetine group, was incorrectly coded as having withdrawn from study medication due to an AE of emotional lability. This AE occurred during the Taper Phase. The patient withdrew for lack of efficacy. See Errata, Table 16.0, Section 15. This discrepancy is not accounted for in this table.

** Includes non-study-related personal reasons: withdrew consent (4 patients); patient placed in juvenile facility, unable to make visits (1 patient); patient moved, unable to participate (1 patient).

† Patients were considered to have completed the study if they completed the Week 8 visit. The total of 149 completers includes the 3 patients who completed at Week 6.

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 4 overall. The most common reason for withdrawal at Week 4 varied for both treatment groups, with no single reason predominant. Children in the paroxetine group who were withdrawn from the study did so early; of the 19/101 who withdrew, 16 withdrew at or before Week 4.

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 Patient Withdrawals by Reason and by Visit–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group								
	Paroxetine				Placebo				
Visit	AE *	LOE *	Other **	Total	AE	LOE	Other **	Total	Total
Age Group: Total				(N = 101)				(N = 102)	(N = 203)
Week 1	1 (1.0%)	0	2 (2.0%)	3 (3.0%)	2 (2.0%)	1 (1.0%)	1 (1.0%)	4 (3.9%)	7 (3.4%)
Week 2	2 (2.0%)	1 (1.0%)	5 (5.0%)	8 (7.9%)	2 (2.0%)	2 (2.0%)	1 (1.0%)	5 (4.9%)	13 (6.4%)
Week 3	3 (3.0%)	4 (4.0%)	6 (5.9%)	13 (12.9%)	2 (2.0%)	3 (2.9%)	4 (3.9%)	9 (8.8%)	22 (10.8%)
Week 4	6 (5.9%)	6 (5.9%)	11 (10.9%)	23 (22.8%)	2 (2.0%)	7 (6.9%)	6 (5.9%)	15 (14.7%)	38 (18.7%)
Week 6	8 (7.9%)	6 (5.9%)	13 (12.9%)	27 (26.7%)	2 (2.0%)	10 (9.8%)	9 (8.8%)	21 (20.6%)	48 (23.6%)
Week 8	10 (9.9%)	7 (6.9%)	14 (13.9%)	31 (30.7%)	2 (2.0%)	11 (10.8%)	10 (9.8%)	23 (22.5%)	54 (26.6%)
Age Group: Children				(N = 49)				(N = 47)	(N = 96)
Week 1	1 (2.0%)	0	1 (2.0%)	2 (4.1%)	0	0	0	0	2 (2.1%)
Week 2	2 (4.1%)	1 (2.0%)	4 (8.2%)	7 (14.3%)	0	0	0	0	7 (7.3%)
Week 3	3 (6.1%)	3 (6.1%)	4 (8.2%)	10 (20.4%)	0	0	1 (2.1%)	1 (2.1%)	11 (11.5%)
Week 4	6 (12.2%)	4 (8.2%)	6 (12.2%)	16 (32.7%)	0	2 (4.3%)	1 (2.1%)	3 (6.4%)	19 (19.8%)
Week 6	7 (14.3%)	4 (8.2%)	7 (14.3%)	18 (36.7%)	0	3 (6.4%)	2 (4.3%)	5 (10.6%)	23 (24.0%)
Week 8	7 (14.3%)	4 (8.2%)	8 (16.3%)	19 (38.8%)	0	4 (8.5%)	2 (4.3%)	6 (12.8%)	25 (26.0%
Age Group: Adolescents				(N = 52)				(N = 55)	(N = 107)
Week 1	0	0	1 (1.9%)	1 (1.9%)	2 (3.6%)	1 (1.8%)	1 (1.8%)	4 (7.3%)	5 (4.7%)
Week 2	0	0	1 (1.9%)	1 (1.9%)	2 (3.6%)	2 (3.6%)	1 (1.8%)	5 (9.1%)	6 (5.6%)
Week 3	0	1 (1.9%)	2 (3.8%)	3 (5.8%)	2 (3.6%)	3 (5.5%)	3 (5.5%)	8 (14.5%)	11 (10.3%)
Week 4	0	2 (3.8%)	5 (9.6%)	7 (13.5%)	2 (3.6%)	5 (9.1%)	5 (9.1%)	12 (21.8%)	19 (17.8%)
Week 6	1 (1.9%)	2 (3.8%)	6 (11.5%)	9 (17.3%)	2 (3.6%)	7 (12.7%)	7 (12.7%)	16 (29.1%)	25 (23.4%)
Week 8	3 (5.8%)	3 (5.8%)	6 (11.5%)	12 (23.1%)	2 (3.6%)	7 (12.7%)	8 (14.5%)	17 (30.9%)	29 (27.1%)

AE = adverse event; LOE = lack of efficacy

* Patient 701.163.25718, in the paroxetine group, was incorrectly coded as having withdrawn from study medication due to an AE of emotional lability. This AE occurred during the Taper Phase. The patient withdrew for lack of efficacy. See Errata, Table 16.0, Section 15. This discrepancy is not accounted for in this table.

** 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.

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 46/203 (22.7%). More major protocol violators were in the paroxetine group (27/101, 26.7%) than in the placebo group (19/102, 18.6%). More adolescents (30/107, 28.0%) were major protocol violators than children (16/96, 16.7%). The most frequent violation in both treatment groups and both age subgroups was missing more than 3 consecutive days of study medication.

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

- **Patient took less than 2 weeks of study medication.** Nine patients were so identified before unblinding, 5 in the paroxetine group and 4 in the placebo group (Listing PV14, Appendix B).

- **Patient missed more than 3 consecutive days of study medication**. Thirty-two patients were so identified before unblinding, 20 in the paroxetine group and 12 in the placebo group. Of these, 3 patients missed more than 3 consecutive days of study medication on more than one occasion; such patients were to be withdrawn from the study by the investigator. Two of these patients were withdrawn from the study, and the third patient was considered to have completed the study since the second occasion was at Week 8 (Listing 13.2.1, Appendix B; Listing PV13, Appendix B). These 32 patients were all considered protocol violators.

- **Patient had a history of drug abuse or dependence.** One placebo patient was so identified before unblinding (Listing PV07, Appendix B).

- **Patient had a CDRS–R score at Baseline less than 45.** One paroxetine patient was so identified before unblinding (score of 48 at Screening and 44 at Baseline) (Listing PV04, Appendix B).

- **Patient took a prohibited medication.** Eight patients, 4 in each treatment group, were so identified before unblinding (Listing 13.2.1, Appendix B). Seven of these patients had taken antidepressant or other psychoactive medications; one of these patients (701.181.27688) appears also in Listing PV08, Appendix B, having tested positive for illicit drugs at Screening. The eighth patient, 701.154.25769 had taken diphenhydramine HCl for 12 consecutive days for allergies and for difficulty sleeping, and was also considered a protocol violator. Seven other patients who took diphenhydramine HCl for 3 days or less for allergies or congestion were not considered protocol violators or deviators.

Patient 701.159.25748 was diagnosed at Screening with concurrent eating disorder NOS and anxiety disorder NOS (Listing PV06, Appendix B). It was determined that neither of these was a clinically predominant Axis I disorder and the patient was not considered a protocol violator.

No randomized patient had any other protocol violation considered a major violation (Listings PV01, PV02, PV03, PV05, PV10, PV11, and PV12, Appendix B).

Deviations are failures of criteria that are not considered to adversely affect the efficacy evaluation; patients with deviations only were not excluded from the PP population. Only one patient (701.181.25801, an 8-year-old male in the paroxetine group) was considered to have a protocol deviation, which was clinically significant abnormalities in hematology (Listing PV09, Appendix B). However, since this patient also had a major protocol violation (missed more than 3 consecutive days of study medication), the patient was excluded from the PP population. Thus Table 13.2.2, Section 11, shows that no patients with protocol deviations were included in the PP analysis, but that there was one patient with a protocol deviation in the study.

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 = 101)	**Placebo** (N = 102)	**Paroxetine** (N = 49)	**Placebo** (N = 47)	**Paroxetine** (N = 52)	**Placebo** (N = 55)
Total number of patients excluded*	27 (26.7%)	19 (18.6%)	10 (20.4%)	6 (12.8%)	17 (32.7%)	13 (23.6%)
Patient took prohibited medication	4 (4.0%)	4 (3.9%)	0	3 (6.4%)	4 (7.7%)	1 (1.8%)
Patient took <2 weeks study medication	5 (5.0%)	4 (3.9%)	4 (8.2%)	0	1 (1.9%)	4 (7.3%)
CDRS–R score at Baseline <45	1 (1.0%)	0	0	0	1 (1.9%)	0
History of substance abuse/dependence	0	1 (1.0%)	0	0	0	1 (1.8%)
Patient missed >3 consecutive days study medication	20 (19.8%)	12 (11.8%)	8 (16.3%)	3 (6.4%)	12 (23.1%)	9 (16.4%)
Total number of patients with no protocol violations	74 (73.3%)	83 (81.4%)	39 (79.6%)	41 (87.2%)	35 (67.3%)	42 (76.4%)

* A patient could have more than one protocol violation leading to exclusion.
Source: Table 13.2.1, Section 11; Listing 13.2.1, 13.2.2, Appendix B

4.4 Demographic and Baseline Characteristics

4.4.1 Demographic Characteristics

The demographic characteristics of the overall ITT population are summarized in Table 13. Table 14 summarizes the demographic data by age subgroup. The treatment groups showed no marked imbalances in any of the patient characteristics.

The proportion of males to females was generally similar in both treatment groups, with each group having slightly more males than females except among adolescents in the placebo group.

Mean ages of children were similar in both treatment groups, as were mean ages of adolescents, with an overall mean age of 12.0 years (SD 2.97). Overall, 79.3% of the patients (161/203) were white, with a greater proportion of black patients among the children in both treatment groups than among the adolescents. "Other" race included 15 Hispanic patients and 3 mixed Hispanic and white. Mean height, weight, and BMI of children were similar in both treatment groups, as were mean height, weight, and BMI of adolescents.

A greater proportion of patients in the paroxetine group had comorbid psychiatric illnesses (28:73) than in the placebo group (18:84).

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 = 101)	Placebo (N = 102)	Total (N = 203)
Gender n (%)			
Male	53 (52.5%)	55 (53.9%)	108 (53.2%)
Female	48 (47.5%)	47 (46.1%)	95 (46.8%)
Age (yrs)			
Mean (SD)	11.9 (3.00)	12.1 (2.95)	12.0 (2.97)
Range	7–17	7–17	7–17
Race n (%)			
White	77 (76.2%)	84 (82.4%)	161 (79.3%)
Black	12 (11.9%)	11 (10.8%)	23 (11.3%)
Oriental	1 (1.0%)	0	1 (0.5%)
Other *	11 (10.9%)	7 (6.9%)	18 (8.9%)
Height (cm)			
Mean (SD)	153.1 (16.68)	153.1 (16.51)	153.1 (16.56)
Range	116.8–185.4	119.4–185.4	116.8–185.4
Weight (kgs)**			
Mean (SD)	58.2 (23.63)	55.5 (22.4)	56.8 (23.00)
Range	20.4–132.6	21.8–131.4	20.4–132.6
BMI (kg/m^2)			
Mean (SD)	24.1 (7.0)	22.9 (6.22)	23.5 (6.62)
Range	12.6–46.0	13.6–45.4	12.6–46.0
Psychiatric Comorbidity			
yes:no	28:73	18:84	46:157

* Other race includes 15 Hispanic patients and 3 mixed Hispanic and white.
** 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)

Demographic Characteristics	Age Group: Children			Age Group: Adolescents		
	Paroxetine (N = 49)	Placebo (N = 47)	Total (N = 96)	Paroxetine (N = 52)	Placebo (N = 55)	Total (N = 107)
Gender n (%)						
Male	26 (53.1%)	29 (61.7%)	55 (57.3%)	27 (51.9%)	26 (47.3%)	53(49.5%)
Female	23 (46.9%)	18 (38.3%)	41 (42.7%)	25 (48.1%)	29 (52.7%)	54 (50.5%)
Age (yrs)						
Mean (SD)	9.2 (1.28)	9.4 (1.28)	9.3 (1.28)	14.4 (1.60)	14.5 (1.72)	14.4 (1.66)
Range	7–11	7–11	7–11	12–17 **	12–17	12–17
Race n (%)						
White	34 (69.4%)	39 (83.0%)	73 (76.0%)	43 (82.7%)	45 (81.8%)	88 (82.2%)
Black	9 (18.4%)	6 (12.8%)	15 (15.6%)	3 (5.8%)	5 (9.1%)	8 (7.5%)
Oriental	0	0	0	1 (1.9%)	0	1 (0.9%)
Other *	6 (12.2%)	2 (4.3%)	8 (8.3%)	5 (9.6%)	5 (9.1%)	10 (9.3%)
Height (cm)						
Mean (SD)	139.3 (11.02)	138.4 (10.30)	138.9 (10.63)	166.1 (8.82)	165.6 (8.59)	165.8 (8.66)
Range	116.8–165.0	119.4–160.0	116.8–165.0	143.5–185.4	149.0–185.4	143.5–185.4
Weight (kgs)						
Mean (SD)	43.7 (16.33)	41.2 (15.32)	42.5 (15.81)	71.8 (21.27)	67.8 (20.17)	69.7 (20.72)
Range	20.4– 94.5	21.8– 89.0	20.4– 94.5	36.8–132.6	35.3–131.4	35.3–132.6
BMI (kg/m^2)						
Mean (SD)	22.1 (6.44)	21.1 (6.00)	21.6 (6.22)	25.9 (7.02)	24.5 (6.03)	25.2 (6.54)
Range	12.6– 40.7	13.6–35.6	12.6– 40.7	17.4–46.0	15.3–45.4	15.3–46.0

* Other race includes 15 Hispanic patients and 3 mixed Hispanic and white.

** One patient who was 11 years old was administered the KADS scale but is counted as a child in this table and all other tables, except for those tables reporting KADS results. See Section 3.14.10, Data Irregularities.

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.

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 depression severity.

Table 15 summarizes the mean Baseline scores by treatment group and by age subgroup for the efficacy scales CDRS–R, GAF, and KADS. The mean total CDRS–R score was 61.7 (SD 9.19) and the mean total GAF score was 52.8 (SD 6.77) at Baseline for the two treatment groups combined. The mean total KADS score (adolescents only) was 17.9 (SD 6.82) at Baseline for the two treatment groups combined.

Summary statistics for total CDRS–R scores at entry for the PP population were similar to those in the ITT population (Table 14.1.1c, Section 12).

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

	Treatment Group								
	Paroxetine (N = 101)			Placebo (N = 102)			Total (N = 203)		
Instrument	**n**	**Mean**	**SD**	**n**	**Mean**	**SD**	**n**	**Mean**	**SD**
CDRS–R Total Score									
Age Group: Total	101	60.7	(9.37)	102	62.6	(8.96)	203	61.7	(9.19)
Age Group: Children	49	58.4	(8.29)	47	61.3	(9.23)	96	59.8	(8.83)
Age Group: Adolescents	52	62.9	(9.87)	55	63.7	(8.66)	107	63.3	(9.23)
GAF									
Age Group: Total	101	53.4	(7.78)	102	52.3	(5.57)	203	52.8	(6.77)
Age Group: Children	49	53.2	(7.34)	47	52.3	(5.78)	96	52.7	(6.60)
Age Group: Adolescents	52	53.6	(8.24)	55	52.3	(5.43)	107	52.9	(6.94)
KADS									
Age Group: Adolescents	52*	17.6	(6.17)	55	18.1	(7.43)	107	17.9	(6.82)

* Fifty-three patients in the paroxetine group had a KADS test administered (see Section 3.14.10, Data Irregularities). One patient had either missing data at Baseline or insufficient data to calculate total.

Source: Tables 13.9.1, 13.11.1, 13.12.1, Section 11; Listings 14.1.1, 14.4.1, 14.5.1.1, 14.5.1.2, 14.5.1.3, Appendix C

Table 16 summarizes the proportion of patients in each category of CGI Severity of Illness item at Baseline by treatment group. The proportions of patients in each category (in the combined population and in each age subgroup) were generally similar between treatment groups. The majority of patients in both treatment groups were rated “moderately ill” at Baseline. Only 2 patients in each treatment group were rated "mildly ill," and the rest were rated "markedly ill" or "severely 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		
CGI Severity of Illness	**Paroxetine (N = 101)**	**Placebo (N = 102)**	**Total (N = 203)**
	n (%)	n (%)	n (%)
Age Group: Total	(n =101)	(n = 102)	(n = 203)
Not Assessed	0	0	0
Normal, Not Ill	0	0	0
Borderline Ill	0	0	0
Mildly Ill	2 (2.0%)	2 (2.0%)	4 (2.0%)
Moderately Ill	70 (69.3%)	67 (65.7%)	137 (67.5%)
Markedly Ill	26 (25.7%)	29 (28.4%)	55 (27.1%)
Severely Ill	3 (3.0%)	4 (3.9%)	7 (3.4%)
Most Extremely Ill	0	0	0
Age Group: Children	(n = 49)	(n = 47)	(n = 96)
Not Assessed	0	0	0
Normal, Not Ill	0	0	0
Borderline Ill	0	0	0
Mildly Ill	0	2 (4.3%)	2 (2.1%)
Moderately Ill	36 (73.5%)	33 (70.2%)	69 (71.9%)
Markedly Ill	12 (24.5%)	9 (19.1%)	21 (21.9%)
Severely Ill	1 (2.0%)	3 (6.4)	4 (4.2%)
Most Extremely Ill	0	0	0
Age Group: Adolescents	(n = 52)	(n = 55)	(n = 107)
Not Assessed	0	0	0
Normal, Not Ill	0	0	0
Borderline Ill	0	0	0
Mildly Ill	2 (3.8%)	0	2 (1.9%)
Moderately Ill	34 (65.4%)	34 (61.8%)	68 (63.6%)
Markedly Ill	14 (26.9%)	20 (36.4%)	34 (31.8%)
Severely Ill	2 (3.8%)	1 (1.8%)	3 (2.8%)
Most Extremely Ill	0	0	0

Source: Table 13.10.1, Section 11; Listing 14.2.1, Appendix C

4.5 Medical History

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

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: 56/101 patients (55.4%) in the paroxetine group and 58/102 patients (56.9%) in the placebo group. Most of the reported prior medical conditions were benign. The only past medical history reported for 10% or more of patients in either treatment group was asthma (11.9% of patients [12/101] in the paroxetine group and 9.8% of patients [10/102] in the placebo group). The only surgical procedure reported for 10% or more of patients in either treatment group was nose/mouth operation (9.9% in the paroxetine group [10/101] and 10.8% in the placebo group [11/102]). Consistent with these numbers, the body system with the highest proportion of patients having a medical history was the Respiratory System (26.7% of paroxetine-treated patients [27/101] and 25.5% of placebo patients [26/102]). 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 numbers of patients reporting active medical conditions at Screening (excluding psychiatric disorders) were also similar in both treatment groups: 70/101 (69.3%) in the paroxetine group and 61/102 (59.8%) in the placebo group (Table 17). The only active medical conditions reported for 10% or more of patients in either treatment group were headache (14.9% of patients [15/101] in the paroxetine group and 20.6% of patients [21/102] in the placebo group), asthma (13.9% of patients [14/101] in the paroxetine group and 8.8% of patients [9/102] in the placebo group) and rhinitis (12.9% of patients [13/101] in the paroxetine group and 15.7% of patients [16/102] in the placebo group). Consistent with these numbers, the body system with the highest proportion of patients having an active medical condition was General Body or Unspecified (26.7% of paroxetine-treated patients [27/101] and 32.4% of placebo patients [33/102]), mostly headache, followed by Respiratory (30.7% of paroxetine-treated patients [31/101] and 26.5% of placebo patients [27/102]), mostly asthma and rhinitis. 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 and Percentage of Patients with Active Medical Conditions (Occurring in ≥5% of Patients in Either Treatment Group) (ITT Population)

	Treatment Group		
Active Condition	**Paroxetine (N=101) n (%)**	**Placebo (N=102) n (%)**	**Total (N = 203) n (%)**
Total number of patients with active conditions	70 (69.3%)	61 (59.8%)	131 (64.5%)
Headache	15 (14.9%)	21 (20.6%)	36 (17.7%)
Asthma	14 (13.9%)	9 (8.8%)	23 (11.3%)
Rhinitis, Allergic	13 (12.9%)	16 (15.7%)	29 (14.3%)
Obesity	9 (8.9%)	6 (5.9%)	15 (7.4%)
Adverse Eff/Antibiotic	6 (5.9%)	4 (3.9%)	10 (4.9%)
Allergy, NEC	6 (5.9%)	3 (2.9%)	9 (4.4%)
Pain, Abdomino-Pelvic	5 (5.0%)	5 (4.9%)	10 (4.9%)
Insomnia	5 (5.0%)	3 (2.9%)	8 (3.9%)
Pain, Limb	5 (5.0%)	0	5 (2.5%)
Skin/Subcut Disord, Other	4 (4.0%)	7 (6.9%)	11 (5.4%)
Genital Female Disord, Other	0	6 (5.9%)	6 (3.0%)

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

4.5.2 Psychiatric History

Table 18, Table 19 and Table 20 summarize the history of MDD and other psychiatric conditions overall and by age group. The diagnosis of MDD, either single episode or recurrent, was based on DSM-IV (296.2 or 296.3, respectively). The K-SADS–PL semi-structured diagnostic interview was used to confirm the diagnosis of MDD and to assess current and past episodes of psychopathology according to DSM-III–R (Diagnostic and Statistical Manual of Mental Disorders, third edition revised) and DSM-IV criteria.

The diagnosis of any psychiatric disorder, including MDD, was made solely by the psychiatrist. Any randomized patient diagnosed with a clinically predominant Axis I disorder other than MDD 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 Violators).

The proportions of patients with a past or current history of psychiatric illness other than MDD was similar in both treatment groups except that more patients in the placebo group (19/102, 18.6%) had a history of ADHD (Attention-Deficit/Hyperactivity Disorder) than in the paroxetine group (12/101, 11.9%). The most common conditions in the psychiatric histories (past and current) of patients overall were ADHD (31/203, 15.3%), Oppositional Defiant Disorder (15/203, 7.4%), and enuresis (14/203, 6.9%) (Table 18). The most common

comorbid conditions in the paroxetine group were ADHD and GAD (7/101 each, 6.9%) and in the placebo group were Oppositional Defiant Disorder (9/102, 8.8%) and ADHD (7/102, 6.9%). There was a higher proportion of patients with comorbid psychiatric illnesses in the paroxetine group (28:73) than in the placebo group (18:84) (see Appendix, H, Statistical Appendix).

The mean age at onset of MDD in both age groups combined was 9.8 years (SD 3.21) in the paroxetine group and 9.9 years (SD 3.39) in the placebo group. The mean age at onset of MDD was also similar between treatment groups in both age subgroups: among children, 7.4 years for paroxetine-treated patients and 7.6 years for placebo patients, and among adolescents, 11.9 years in both treatment groups (Table 13.7.1, Section 11).

Based on the K-SADS–PL and the psychiatric interview, approximately 47% of patients in both treatment groups (47/101, 46.5%, in the paroxetine group and 48/102, 47.1%, in the placebo group) had a prior episode of MDD. Family history of MDD, number of times hospitalized, and prior treatment given for the current episode (psychotherapy and/or pharmacotherapy) were also similar between treatment groups both overall and in each age subgroup, except for prior treatment for the current episode of MDD among children: more patients in the placebo group (22/47, 46.8%) had already been treated with psychotherapy and/or pharmacotherapy than in the paroxetine group (13/49, 26.5%) (Table 13.7.2, Section 11). Prior intake of psychoactive medication is discussed in more detail in Section 4.7.1.2, Prior Psychoactive Medications.

Summary statistics for MDD psychiatric history are provided in Tables 13.7.1 and 13.7.2, Section 11; per-patient details 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.

Table 18 Summary of Psychiatric History from K-SADS–PL at Baseline–Age Group: Total (ITT Population)

	Treatment Group								
	Paroxetine (N = 101)			Placebo (N = 102)			Total (N = 203)		
Psychiatric Condition	**Past n (%)**	**Current n (%)**	**Both n (%)**	**Past n (%)**	**Current n (%)**	**Both n (%)**	**Past n (%)**	**Current n (%)**	**Both n (%)**
Major Depressive Disorder	0	54 (53.5%)	47 (46.5%)	0	54 (52.9%)	48 (47.1%)	0	108 (53.2%)	95 (46.8%)
Oppositional Defiant Disorder	1 (1.0%)	5 (5.0%)	0	0	4 (3.9%)	5 (4.9%)	1 (0.5%)	9 (4.4%)	5 (2.5%)
Generalized Anxiety Disorder	0	4 (4.0%)	3 (3.0%)	1 (1.0%)	1 (1.0%)	1 (1.0%)	1 (0.5%)	5 (2.5%)	4 (2.0%)
Overanxious Disorder	0	3 (3.0%)	1 (1.0%)	0	1 (1.0%)	1 (1.0%)	0	4 (2.0%)	2 (1.0%)
Attention Deficit Disorder	5 (5.0%)	3 (3.0%)	4 (4.0%)	12 (11.8%)	1 (1.0%)	6 (5.9%)	17 (8.4%)	4 (2.0%)	10 (4.9%)
Separation Anxiety Disorder	0	2 (2.0%)	1 (1.0%)	1 (1.0%)	0	2 (2.0%)	1 (0.5%)	2 (1.0%)	3 (1.5%)
Dysthymia	2 (2.0%)	2 (2.0%)	0	2 (2.0%)	0	0	4 (2.0%)	2 (1.0%)	0
Simple Phobia	0	1 (1.0%)	2 (2.0%)	0	0	1 (1.0%)	0	1 (0.5%)	3 (1.5%)
Post Traumatic Stress Disorder	2 (2.0%)	1 (1.0%)	1 (1.0%)	1 (1.0%)	0	1 (1.0%)	3 (1.5%)	1 (0.5%)	2 (1.0%)
Enuresis	3 (3.0%)	1 (1.0%)	2 (2.0%)	6 (5.9%)	0	2 (2.0%)	9 (4.4%)	1 (0.5%)	4 (2.0%)
Adjustment Disorder with Depressed Mood	0	0	0	0	1 (1.0%)	0	0	1 (0.5%)	0
Avoidant Disorder of Childhood	0	0	1 (1.0%)	0	0	0	0	0	1 (0.5%)
Agoraphobia	0	0	0	0	0	1 (1.0%)	0	0	1 (0.5%)
Conduct Disorder	0	0	0	0	0	1 (1.0%)	0	0	1 (0.5%)
Depressive Disorder NOS	0	0	0	0	0	1 (1.0%)	0	0	1 (0.5%)
Encopresis	1 (1.0%)	0	1 (1.0%)	0	0	0	1 (0.5%)	0	1 (0.5%)
Transient Tic Disorder	0	0	0	1 (1.0%)	0	0	1 (0.5%)	0	0
Alcohol Abuse	0	0	0	1 (1.0%)	0	0	1 (0.5%)	0	0
Substance Abuse	0	0	0	1 (1.0%)	0	0	1 (0.5%)	0	0
Other	0	0	1 (1.0%)	0	0	0	0	0	1 (0.5%)

Sorted by descending order of current conditions among patients in the paroxetine group
Note: A patient may have had more than one psychiatric condition
Source: Table 13.8.1, Section 11; Listing 13.8.1, Appendix B.

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

	Treatment Group								
	Paroxetine (N = 49)			Placebo (N = 47)			Total (N = 96)		
Psychiatric Condition	**Past n (%)**	**Current n (%)**	**Both n (%)**	**Past n (%)**	**Current n (%)**	**Both n (%)**	**Past n (%)**	**Current n (%)**	**Both n (%)**
Major Depressive Disorder	0	29 (59.2%)	20 (40.8%)	0	25 (53.2%)	22 (46.8%)	0	54 (56.3%)	42 (43.8%)
Generalized Anxiety Disorder	0	1 (2.0%)	3 (6.1%)	0	1 (2.1%)	1 (2.1%)	0	2 (2.1%)	4 (4.2%)
Attention Deficit Disorder	3 (6.1%)	1 (2.0%)	2 (4.1%)	5 (10.6%)	1 (2.1%)	4 (8.5%)	8 (8.3%)	2 (2.1%)	6 (6.3%)
Enuresis	0	1 (2.0%)	2 (4.1%)	2 (4.3%)	0	1 (2.1%)	2 (2.1%)	1 (1.0%)	3 (3.1%)
Separation Anxiety Disorder	0	1 (2.0%)	1 (2.0%)	1 (2.1%)	0	2 (4.3%)	1 (1.0%)	1 (1.0%)	3 (3.1%)
Oppositional Defiant Disorder	0	1 (2.0%)	0	0	2 (4.3%)	3 (6.4%)	0	3 (3.1%)	3 (3.1%)
Dysthymia	0	1 (2.0%)	0	0	0	0	0	1 (1.0%)	0
Simple Phobia	0	0	1 (2.0%)	0	0	0	0	0	1 (1.0%)
Overanxious Disorder	0	0	1 (2.0%)	0	1 (2.1%)	1 (2.1%)	0	1 (1.0%)	2 (2.1%)
Encopresis	0	0	1 (2.0%)	0	0	0	0	0	1 (1.0%)
Post Traumatic Stress Disorder	1 (2.0%)	0	0	0	0	0	1 (1.0%)	0	0
Adjustment Disorder with Depressed Mood	0	0	0	0	1 (2.1%)	0	0	1 (1.0%)	0
Avoidant Disorder of Childhood	0	0	0	0	0	0	0	0	0
Agoraphobia	0	0	0	0	0	0	0	0	0
Conduct Disorder	0	0	0	0	0	1 (2.1%)	0	0	1 (1.0%)
Depressive Disorder NOS	0	0	0	0	0	1 (2.1%)	0	0	1 (1.0%)
Transient Tic Disorder	0	0	0	0	0	0	0	0	0
Alcohol Abuse	0	0	0	0	0	0	0	0	0
Substance Abuse	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0

Note: A patient may have had more than one psychiatric condition
Sorted by descending order of current conditions among patients in the paroxetine group
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: Adolescents (ITT Population)

	Treatment Group								
	Paroxetine (N = 52)			Placebo (N = 55)			Total (N = 107)		
Psychiatric Condition	Past n (%)	Current n (%)	Both n (%)	Past n (%)	Current n (%)	Both n (%)	Past n (%)	Current n (%)	Both n (%)
Major Depressive Disorder	0	25 (48.1%)	27 (51.9%)	0	29 (52.7%)	26 (47.3%)	0	54 (50.5%)	53 (49.5%)
Oppositional Defiant Disorder	1 (1.9%)	4 (7.7%)	0	0	2 (3.6%)	2 (3.6%)	1 (0.9%)	6 (5.6%)	2 (1.9%)
Generalized Anxiety Disorder	0	3 (5.8%)	0	1 (1.8%)	0	0	1 (0.9%)	3 (2.8%)	0
Overanxious Disorder	0	3 (5.8%)	0	0	0	0	0	3 (2.8%)	0
Attention Deficit Disorder	2 (3.8%)	2 (3.8%)	2 (3.8%)	7 (12.7%)	0	2 (3.6%)	9 (8.4%)	2 (1.9%)	4 (3.7%)
Separation Anxiety Disorder	0	1 (1.9%)	0	0	0	0	0	1 (0.9%)	0
Dysthymia	2 (3.8%)	1 (1.9%)	0	2 (3.6%)	0	0	4 (3.7%)	1 (0.9%)	0
Simple Phobia	0	1 (1.9%)	1 (1.9%)	0	0	1 (1.8%)	0	1 (0.9%)	2 (1.9%)
Post Traumatic Stress Disorder	1 (1.9%)	1 (1.9%)	1 (1.9%)	1 (1.8%)	0	1 (1.8%)	2 (1.9%)	1 (0.9%)	2 (1.9%)
Enuresis	3 (5.8%)	0	0	4 (7.3%)	0	1 (1.8%)	7 (6.5%)	0	1 (0.9%)
Adjustment Disorder with Depressed Mood	0	0	0	0	0	0	0	0	0
Avoidant Disorder of Childhood	0	0	1 (1.9%)	0	0	0	0	0	1 (0.9%)
Agoraphobia	0	0	0	0	0	1 (1.8%)	0	0	1 (0.9%)
Conduct Disorder	0	0	0	0	0	0	0	0	0
Depressive Disorder NOS	0	0	0	0	0	0	0	0	0
Encopresis	1 (1.9%)	0	0	0	0	0	1 (0.9%)	0	0
Transient Tic Disorder	0	0	0	1 (1.8%)	0	0	1 (0.9%)	0	0
Alcohol Abuse	0	0	0	1 (1.8%)	0	0	1 (0.9%)	0	0
Substance Abuse	0	0	0	1 (1.8%)	0	0	1 (0.9%)	0	0
Other	0	0	1 (1.9%)	0	0	0	0	0	1 (0.9%)

Note: A patient may have had more than one psychiatric condition
Sorted by descending order of current conditions among patients in the paroxetine group
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 15/101 patients (14.9%) randomized to paroxetine and 16/102 patients (15.7%) in the placebo group reported one or more non-gender-specific Baseline signs/symptoms. No male patients in either treatment group and 1 female patient, in the paroxetine group, 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 3/101 paroxetine patients (3.0%) and 5/102 placebo patients (4.9%).

4.7 Prior and Concomitant Medications

4.7.1 Prior Medications

4.7.1.1 Prior Non-psychoactive Medications

Non-psychoactive medications that were taken within the month prior to entry into the trial are summarized in Table 13.13.3.1, 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 13.13.3.2, Section 11. In this tabulation, components are counted only once. Listing 13.13.3, 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 21 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 44/101 (43.6%) paroxetine patients and 45/102 (44.1%) 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, ibuprofen in the paroxetine group (13/101,12.9%, compared to 10/102, 9.8%, in the placebo group) and paracetamol in the placebo group (16/102, 15.7%, compared to 11/101, 10.9%, in the paroxetine group). There were no substantial differences between treatment groups relative to medication use prior to study entry.

Table 21 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			
Total Number of Patients	**Paroxetine (N = 101)**		**Placebo (N = 102)**	
Therapeutic Class and Medication	**n**	**%**	**n**	**%**
Total Patients with a Prior Medication *	44	(43.6%)	45	(44.1%)
Alimentary tract/metabolic	11	(10.9%)	11	(10.8%)
Vitamin NOS	5	(5.0%)	2	(2.0%)
Central nervous system	14	(13.9%)	19	(18.6%)
Paracetamol	11	(10.9%)	16	(15.7%)
Musculoskeletal	13	(12.9%)	13	(12.7%)
Ibuprofen	13	(12.9%)	10	(9.8%)
Respiratory	23	(22.8%)	16	(15.7%)
Salbutamol	7	(6.9%)	6	(5.9%)
Loratadine	6	(5.9%)	6	(5.9%)

Medications sorted by descending frequency in the paroxetine group within each body system
* Taken during the month prior to Screening
Source: Table 13.13.3.1, Section 11; Listing 13.13.3, Appendix B

4.7.1.2 Prior Psychoactive Medications

Table 22 summarizes psychoactive medications taken for MDD that were taken at any time in the past. A total of 26/101(25.7%) paroxetine-treated patients and 26/102 (25.5%) placebo patients used psychoactive medications for MDD at some time in the past. Previous use of SSRIs occurred in 21/101 (20.8%) paroxetine patients and 14/102 (13.7%) placebo patients. The previous use of psychoactive medication characterized as "other," which included psychoactive herbal medication (e.g., hypericum extract), was reported for 7/101 (6.9%) paroxetine patients and 12/102 (11.8%) placebo patients.

The most frequently used prior medication taken for MDD was sertraline, taken by 10/101 paroxetine patients (9.9%) and 8/102 placebo patients (7.8%).

Paroxetine had previously been used by 5/101 paroxetine patients (5.0%) and 3/102 placebo patients (2.9%).

A complete listing of previous psychoactive medication taken for MDD at any time by patient and class identification may be found in Table 13.13.1, Section 11, and Listing 13.13.1, Appendix B. The therapeutic classifications used in these source documents is incorrect for some of these medications; Table 22 has classified them correctly. See Errata, Table 16.0, Section 15.

Table 22 Major Depression Medication History by Psychoactive Class–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group					
	Paroxetine (N = 101)		Placebo (N = 102)		Total (N = 203)	
Previous MDD Medication *	**n**	**%**	**n**	**%**	**n**	**%**
Therapeutic Class and Medication **						
Age Group: Total						
Total Patients Taking Prior MDD Therapy †	26	(25.7%)	26	(25.5%)	52	(25.6%)
SSRI	21	(20.8%)	14	(13.7%)	35	(17.2%)
TCA	1	(1.0%)	3	(2.9%)	4	(2.0%)
Other psychoactive medications ††	7	(6.9%)	12	(11.8%)	19	(9.4%)
None	75	(74.3%)	76	(74.5%)	151	(74.4%)
Age Group: Children	(N = 49)		(N = 47)		(N = 96)	
Total Children Taking Prior MDD Therapy †	8	(16.3%)	9	(19.1%)	17	(17.7%)
SSRI	8	(16.3%)	6	(12.8%)	14	(14.6%)
TCA	1	(2.0%)	2	(4.3%)	3	(3.1%)
Other psychoactive medications ††	0		1	(2.1%)	1	(0.9%)
None	41	(83.7%)	38	(80.9%)	79	(82.3%)
Age Group: Adolescents	(N = 52)		N = 55)		(N = 107)	
Total Adolescents Taking Prior MDD Therapy †	18	(34.6%)	17	(30.9%)	35	(32.7%)
SSRI	13	(25%)	8	(14.5%)	21	(19.6%)
TCA	0		1	(1.8%)	1	(0.9%)
Other psychoactive medications ††	7	(13.5%)	11	(20.0%)	18	(16.8%)
None	34	(65.4%)	38	(69.1%)	72	(67.3%)

* Taken by the patient at any time prior to Screening
** Prior medications taken for MDD were classified incorrectly by therapeutic class in the data source table. See Errata, Table 16.0, Section 15.
† Patients could have taken more than one prior medication for MDD
†† Other includes amfebutamone, buspirone, cyanocobalamin, dexamphetamine, hypericum extract, methylphenidate, mirtazapine, nefazodone, risperidone and venlafaxine.
Source: Table 13.13.1, Section 11; Listing 13.13.1, Appendix B.

Table 23 presents prior psychoactive medication taken during the 3 months prior to Screening for indications other than MDD by psychoactive class. Psychoactive medication history for indications other than MDD may be found in Tables

13.13.2.1, presented by body system, and 13.13.2.2, in order of decreasing frequency, both in Section 11, and Listing 13.13.2, Appendix B.

The most frequent prior psychoactive medication was methylphenidate/ methylphenidate HCl (Ritalin®), taken by 6/101 (5.9%) paroxetine patients and 6/102 (5.9%) placebo patients. Adderall® (amphetamine aspartate, amphetamine sulfate, dextroamphetamine saccharate, and dextroamphetamine sulfate) was taken by 3/101 paroxetine patients (3.0%) and 5/102 placebo patients (4.9%). The indication for these medications was ADHD.

Table 23 Psychoactive Medication History for Indications Other than Major Depression–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group		
Previous Psychoactive Medication for Indications Other Than MDD*	**Paroxetine (N = 101)**	**Placebo (N = 102)**	**Total (N = 203)**
Therapeutic Class and Medication **	**n (%)**	**n (%)**	**n (%)**
Age Group: Total			
Total Patients Taking Prior Psychoactive Medication †	12 (11.9%)	14 (13.7%)	26 (12.8%)
SSRI	0	1 (1.0%)	1 (0.5%)
TCA	0	1 (1.0%)	1 (0.5%)
Other psychoactive medications ††	12 (11.9%)	13 (12.7%)	25 (12.3%)
None	89 (88.1%)	88 (86.3%)	177 (87.2%)
Age Group: Children	(N = 49)	(N = 47)	(N = 96)
Total Patients Taking Prior Psychoactive Medication †	5 (10.2%)	5 (10.6%)	10 (10.4%)
SSRI	0	0	0
TCA	0	1 (2.1%)	1 (1.0%)
Other psychoactive medications ††	5 (10.2%)	5 (10.6%)	10 (10.4%)
None	44 (89.8%)	42 (89.4%)	86 (89.6%)
Age Group: Adolescents	(N = 52)	(N = 55)	(N = 107)
Total Patients Taking Prior Psychoactive Medication †	7 (13.5%)	9 (16.4%)	16 (15.0%)
SSRI	0	1 (1.8%)	1 (0.9%)
TCA	0	0	0
Other psychoactive medications ††	7 (13.5%)	8 (14.5%)	15 (14.0%)
None	45 (86.5%)	46 (83.6%)	91 (85.0%)

* Taken during the 3 months prior to Screening

** Patient 701.192.25874, an adolescent in the placebo group, took trazodone incorrectly classified as a TCA in the data source table. See Errata, Table 16.0, Section 15.

† Patients could have taken more than one prior medication

†† Other includes amfebutamone, amphetamine aspartate, amphetamine sulfate, carisoprodol, chlordiazepoxide, clonidine, dexamphetamine, dextroamphetamine saccharate, dextroamphetamine sulfate, hydroxyzine, melatonin, methylphenidate, quetiapine, trazodone, and valproate.

Source: Table 13.13.2.1, Section 11; Listing 13.13.2, Appendix B

4.7.2 Concomitant Medications

Table 24 presents a summary of the most frequently reported (≥5%) concomitant medications taken during the Treatment Phase by therapeutic class. A total of 62.1% of the ITT population (126/203) were reported to have taken at least one concomitant medication, 67/101 patients (66.3%) in the paroxetine group and 59/102 patients (57.8%) in the placebo group. The proportion of patients taking each medication by therapeutic class was generally similar between treatment groups.

As was the case for prior medications, the most frequently reported concomitant medications by therapeutic class in the paroxetine group were respiratory agents (primarily cough, cold, and asthma or allergy medications, most frequently salbutamol, loratadine, and pseudoephedrine), taken by 35.6% of the patients (36/101) in the paroxetine group and 27.5% of patients (28/102) in the placebo group. The most frequent single medication used was paracetamol, taken by 21/101 patients (20.8%) in the paroxetine group and 27/102 patients (26.5%) in the placebo group.

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 3 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 13.13.3.3, 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 13.13.3.4, 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 13.13.3, Appendix B.

Table 24 Frequently Reported (≥5%) 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 = 101)**		**Placebo (N = 102)**	
Total Patients with a Concomitant Medication	**67 (66.3%)**		**59 (57.8%)**	
Therapeutic Class and Medication	**n (%)**		**n (%)**	
Alimentary tract/metabolic	14	(13.9%)	17	(16.7%)
Vitamins NOS	5	(5.0%)	1	(1.0%)
Anti-infectives, systemic	24	(23.8%)	16	(15.7%)
Amoxicillin	6	(5.9%)	5	(4.9%)
Amoxicillin Trihydrate	4	(4.0%)	7	(6.9%)
Central nervous system	27	(26.7%)	33	(32.4%)
Paracetamol	21	(20.8%)	27	(26.5%)
Acetylsalicylic acid	4	(4.0%)	7	(6.9%)
Dermatologicals	14	(13.9%)	15	(14.7%)
Diphenhydramine HCl	6	(5.9%)	2	(2.0%)
Musculoskeletal	20	(19.8%)	18	(17.6%)
Ibuprofen	19	(18.8%)	15	(14.7%)
Respiratory	36	(35.6%)	28	(27.5%)
Salbutamol	10	(9.9%)	6	(5.9%)
Loratadine	8	(7.9%)	7	(6.9%)
Pseudoephedrine HCl	6	(5.9%)	7	(6.9%)
Diphenhydramine HCl	6	(5.9%)	2	(2.0%)
Dextromethorphan Hydrobromide	2	(2.0%)	7	(6.9%)

Medications sorted by descending frequency in the paroxetine group within each body system
Source: Table 13.13.3.3, Section 11; Listing 13.13.3, Appendix B

During the Taper and Follow-up Phases, concomitant medication usage was reported for 61.4% (51/83) and 57.5% (42/73) of the paroxetine and placebo patients, respectively (Tables 13.13.3.5 and 13.13.3.6, Section 11; Listing 13.13.3, Appendix B). The most frequently used medication during the Taper and Follow-up Phases in the paroxetine group was ibuprofen (9/83 patients, 10.8%, compared to 9/73, 12.3%, in the placebo group) and in the placebo group was paracetamol (11/73 patients, 15.1%, vs. 8/83 patients, 9.6%, in the paroxetine group).

Eight patients in the paroxetine group and 7 patients in the placebo group took paroxetine prescribed by the physician during the Follow-up Phase, or during the Taper Phase in addition to or instead of blinded Taper medication. The reason for taking paroxetine was to continue the treatment of MDD/depression, except for patient 701.159.25629, in the placebo group, who was given paroxetine by the investigator after the Treatment Phase to treat "withdrawal symptoms," which was reported as an AE for this patient (Listing 13.13.3, Appendix B).

4.8 Treatment Compliance and Titration

4.8.1 Treatment Compliance

Table 25 presents a summary of the proportion of patients who missed more than 3 consecutive days study medication at any time during the study and by each visit interval. The percentage of patients who missed more than 3 consecutive days study medication at any time was greater in the paroxetine group, 19.8% of patients (20/101), than in the placebo group, 11.9% of patients (12/102) (Table 13.14.1, Section 11; Listing 13.14.1, Appendix B). This imbalance was more pronounced among children; 8/49 patients (16.3%) in the paroxetine group missed >3 consecutive days study medication at any time during the study, compared to 3/47 (6.4%) in the placebo group. Among adolescents, 12/52 paroxetine patients (23.1%) missed >3 consecutive days study medication, compared to 9/55 placebo patients (16.7%).

Patients missing >3 consecutive days of dosing on more than one occasion were to be withdrawn from the study. Of the total of 32 patients reported by the investigators as missing >3 consecutive days of dosing, only 3 patients did so on more than one occasion. One patient (701.175.25681, an adolescent in the placebo group) was withdrawn from the study for non-compliance and one patient (701.168.25655, an adolescent in the placebo group) was withdrawn for substance abuse; the third patient (701.184.25955, a child in the paroxetine group) was considered to have completed the study because the second occasion of missing >3 consecutive days occurred at Week 8. All patients who missed more than 3 consecutive days of study medication, even if on only one occasion, were excluded from the PP population.

Table 25 Summary of Patients Missing >3 Consecutive Days Study Medication, Excluding Taper Phase–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group			
	Paroxetine		Placebo	
Consecutive Days Missed	≤3	>3	≤3	>3
	n (%)	n (%)	n (%)	n (%)
Age Group: Total	**(N = 101)**		**(N = 102)**	
Week 1	100 (99.0%)	1 (1.0%)	97 (97.0%)	3 (3.0%)
Week 2	93 (94.9%)	5 (5.1%)	95 (97.9%)	2 (2.1%)
Week 3	90 (94.7%)	5 (5.3%)	92 (97.9%)	2 (2.1%)
Week 4	87 (100.0%)	0	91 (98.9%)	1 (1.1%)
Week 6	73 (93.6%)	5 (6.4%)	83 (96.5%)	3 (3.5%)
Week 8	65 (92.9%)	5 (7.1%)	78 (96.3%)	3 (3.7%)
Overall	81 (80.2%)	20 (19.8%)	89 (88.1%)	12 (11.9%)
Age Group: Children	**(N = 49)**		**(N = 47)**	
Week 1	49 (100.0%)	0	47 (100.0%)	0
Week 2	43 (91.5%)	4 (8.5%)	47 (100.0%)	0
Week 3	41 (93.2%)	3 (6.8%)	46 (97.9%)	1 (2.1%)
Week 4	37 (100.0%)	0	46 (100.0%)	0
Week 6	33 (97.1%)	1 (2.9%)	42 (97.7%)	1 (2.3%)
Week 8	29 (96.7%)	1 (3.3%)	40 (97.6%)	1 (2.4%)
Overall	41 (83.7%)	8 (16.3%)	44 (93.6%)	3 (6.4%)
Age Group: Adolescents	**(N = 52)**		**(N = 55)**	
Week 1	51 (98.1%)	1 (1.9%)	50 (94.3%)	3 (5.7%)
Week 2	50 (98.0%)	1 (2.0%)	48 (96.0%)	2 (4.0%)
Week 3	49 (96.1%)	2 (3.9%)	46 (97.9%)	1 (2.1%)
Week 4	50 (100.0%)	0	45 (97.8%)	1 (2.2%)
Week 6	40 (90.0%)	4 (9.1%)	41 (95.3%)	2 (4.7%)
Week 8	36 (90.0%)	4 (10.0%)	38 (95.0%)	2 (5.0%)
Overall	40 (76.9%)	12 (23.1%)	45 (83.3%)	9 (16.7%)

Source: Table 13.14.1, Section 11; Listing 13.14.1, 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:

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

Between 73.5% and 81.2% of paroxetine patients and between 77.7% and 90.9% of placebo patients fell within the range of 80% to 120% accountability at each visit (Table 26). Accountability was generally higher among placebo patients than among paroxetine patients, especially during the last 4 weeks of the study.

Table 26 Tablet Accountability (Number (%) of Patients) at Each Visit–Age Group: Total/Adolescents/Children (ITT Population)

	Treatment Group					
Age Group: Total	**Paroxetine (N = 101)**		**Placebo (N = 102)**		**Total (N = 203)**	
Accountability, n (%)	**Accountable***	**Non-accountable**	**Accountable***	**Non-accountable**	**Accountable***	**Non-accountable**
Week 1	82 (81.2%)	19 (18.8%)	85 (83.3%)	17 (16.7%)	167 (82.3%)	36 (17.7%)
Week 2	79 (78.2%)	22 (21.8%)	84 (84.8%)	15 (15.2%)	163 (81.5%)	37 (18.5%)
Week 3	77 (81.1%)	18 (18.9%)	77 (80.2%)	19 (19.8%)	154 (80.6%)	37 (19.4%)
Week 4	70 (80.5%)	17 (19.5%)	73 (77.7%)	21 (22.3%)	143 (79.0%)	38 (21.0%)
Week 6	61 (73.5%)	22 (26.5%)	80 (90.9%)	8 (9.1%)	141 (82.5%)	30 (17.5%)
Week 8	54 (77.1%)	16 (22.9%)	70 (84.3%)	13 (15.7%)	124 (81.0%)	29 (19.0%)
Age Group: Children	**(N = 49)**		**(N = 47)**		**(N = 96)**	
Week 1	39 (79.6%)	10 (20.4%)	40 (85.1%)	7 (14.9%)	79 (82.3%)	17 (17.7%)
Week 2	37 (75.5%)	12 (24.5%)	42 (89.4%)	5 (10.6%)	79 (82.3%)	17 (17.7%)
Week 3	36 (81.8%)	8 (18.2%)	37 (78.7%)	10 (21.3%)	73 (80.2%)	18 (19.8%)
Week 4	30 (81.1%)	7 (18.9%)	37 (78.7%)	10 (21.3%)	67 (79.8%)	17 (20.2%)
Week 6	26 (72.2%)	10 (27.8%)	40 (88.9%)	5 (11.1%)	66 (81.5%)	15 (18.5%)
Week 8	23 (76.7%)	7 (23.3%)	35 (83.3%)	7 (16.7%)	58 (80.6%)	14 (19.4%)
Age Group: Adolescents	**(N = 52)**		**(N = 55)**		**(N = 107)**	
Week 1	43 (82.7%)	9 (17.3%)	45 (81.8%)	10 (18.2%)	88 (82.2%)	19 (17.8%)
Week 2	42 (80.8%)	10 (19.2%)	42 (80.8%)	10 (19.2%)	84 (80.8%)	20 (19.2%)
Week 3	41 (80.4%)	10 (19.6%)	40 (81.6%)	9 (18.4%)	81 (81.0%)	19 (19.0%)
Week 4	40 (80.0%)	10 (20.0%)	36 (76.6%)	11 (23.4%)	76 (78.4%)	21 (21.6%)
Week 6	35 (74.5%)	12 (25.5%)	40 (93.0%)	3 (7.0%)	75 (83.3%)	15 (16.7%)
Week 8	31 (77.5%)	9 (22.5%)	35 (85.4%)	6 (14.6%)	66 (81.5%)	15 (18.5%)

* 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

Source: Table 13.14.2, Section 11; Listing 13.14.1, Appendix B

4.8.2 Titration of Dose

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

Table 27 presents the number of patients exposed to each daily dose of study medication in both age groups combined. In the overall population, only 8/101 (7.9%) paroxetine patients took a maximum dose of 50 mg per day, compared to 18/102 (17.6%) patients in the placebo group who took study medication at DL 5. More adolescents than children were exposed to all daily doses of paroxetine >10 mg per day and dose levels >DL 1, except for children in the placebo group at DL 5. Among children, 3/49 (6.1%) paroxetine patients took a maximum dose of study medication (50 mg per day) for at least one dosing period compared to 9/47 (19.1%) placebo patients. Among adolescents, 5/52 (9.6%) paroxetine patients took a maximum dose of study medication (50 mg per day) for at least one dosing period compared to 9/55 (16.4%) placebo patients.

Table 27 The 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 = 101)**	**(N = 49)**	**(N = 52)**
10 mg/day	101 (100.0%)	49 (100.0%)	52 (100.0%)
20 mg/day	96 (95.0%)	44 (89.8%)	52 (100.0%)
30 mg/day	60 (59.4%)	24 (49.0%)	36 (69.2%)
40 mg/day	26 (25.7%)	11 (22.4%)	15 (28.8%)
50 mg/day	8 (7.9%)	3 (6.1%)	5 (9.6%)
Placebo	**(N = 102)**	**(N = 47)**	**(N = 55)**
DL 1	102 (100.0%)	47 (100.0%)	55 (100.0%)
DL 2	89 (87.3%)	39 (83.0%)	50 (90.9%)
DL 3	65 (63.7%)	28 (59.6%)	37 (67.3%)
DL 4	33 (32.4%)	13 (27.7%)	20 (36.4%)
DL 5	18 (17.6%)	9 (19.1%)	9 (16.4%)

Source: Table 13.14.4, Section 11; Listing 13.14.1, Appendix B

Table 28 presents a summary of patient dosing by visit (excluding Taper Phase) and also maximum dose for the paroxetine group; Table 29 presents the same summary for the placebo group. Patients in the placebo group reached higher dose levels earlier in the study compared to patients in the paroxetine group.

Less than half the children in the paroxetine group (24/49, 49.0%) took a dose higher than 20 mg per day, compared to 69.2% (36/52) of the adolescents.

Table 28 Summary of the Number of Patients Exposed to Each Dose of Paroxetine by Visit–Age Group: Total/Children/Adolescents (ITT Population)

	Paroxetine				
Daily Dose	**10 mg** n (%)	**20 mg** n (%)	**30 mg** n (%)	**40 mg** n (%)	**50 mg** n (%)
Age Group: Total (N = 101)					
Week 1	101 (100.0%)	0	0	0	0
Week 2	39 (38.6%)	62 (61.4%)	0	0	0
Week 3	13 (13.5%)	55 (57.3%)	28 (29.2%)	0	0
Week 4	7 (8.0%)	37 (42.5%)	32 (36.8%)	11 (12.6%)	0
Week 6	6 (7.2%)	31 (37.3%)	29 (34.9%)	10 (12.0%)	7 (8.4%)
Week 8	4 (5.7%)	26 (37.1%)	22 (31.4%)	14 (20.0%)	4 (5.7%)
Maximum *	5 (5.0%)	36 (35.6%)	34 (33.7%)	18 (17.8%)	8 (7.9%)
Age Group: Children (N = 49)					
Week 1	49 (100.0%)	0	0	0	0
Week 2	24 (49.0%)	25 (51.0%)	0	0	0
Week 3	9 (20.0%)	23 (51.1%)	13 (28.9%)	0	0
Week 4	7 (18.9%)	14 (37.8%)	11 (29.7%)	5 (13.5%)	0
Week 6	6 (16.7%)	11 (30.6%)	13 (36.1%)	3 (8.3%)	3 (8.3%)
Week 8	4 (13.3%)	11 (36.7%)	8 (26.7%)	6 (20.0%)	1 (3.3%)
Maximum *	5 (10.2%)	20 (40.8%)	13 (26.5%)	8 (16.3%)	3 (6.1%)
Age Group: Adolescents (N = 52)					
Week 1	52 (100.0%)	0	0	0	0
Week 2	15 (28.8%)	37 (71.2%)	0	0	0
Week 3	4 (7.8%)	32 (62.7%)	15 (29.4%)	0	0
Week 4	0	23 (46.0%)	21 (42.0%)	6 (12.0%)	0
Week 6	0	20 (42.6%)	16 (34.0%)	7 (14.9%)	4 (8.5%)
Week 8	0	15 (37.5%)	14 (35.0%)	8 (20.0%)	3 (7.5%)
Maximum *	0	16 (30.8%)	21 (40.4%)	10 (19.2%)	5 (9.6%)

Note: Percentages are based on the number of patients in the study at each visit
*Represents the number of patients for whom that dose was the maximum dosing during the study.
Source: Tables 13.14.3, 13.14.4, Section 11; Listing 13.14.1, Appendix B

Table 29 presents a summary of patient dosing by visit (excluding Taper Phase) and also maximum dose for the placebo group.

A total of 63.7% of patients in the placebo group (65/102) took a dose higher than DL 2 per day. Among children, 28/47 patients (59.6%) took a dose higher than DL 2; among adolescents, the proportion was 37/55 (67.3%). The proportion of adolescents who received a maximum dose level of DL 4 or DL 5 of placebo (20/55, 36.4%) was slightly greater than the proportion of children (13/47, 27.7%).

Table 29 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 = 102)					
Week 1	102 (100.0%)	0	0	0	0
Week 2	35 (35.7%)	63 (64.3%)	0	0	0
Week 3	16 (16.7%)	48 (50.0%)	32 (33.3%)	0	0
Week 4	13 (13.8%)	33 (35.1%)	27 (28.7%)	21 (22.3%)	0
Week 6	12 (13.6%)	21 (23.9%)	27 (30.7%)	16 (18.2%)	12 (13.6%)
Week 8	11 (13.3%)	19 (22.9%)	28 (33.7%)	10 (12.0%)	15 (18.1%)
Maximum *	13 (12.7%)	24 (23.5%)	32 (31.4%)	15 (14.7%)	18 (17.6%)
Age Group: Children (N = 47)					
Week 1	47 (100.0%)	0	0	0	0
Week 2	20 (42.6%)	27 (57.4%)	0	0	0
Week 3	12 (25.5%)	23 (48.9%)	12 (25.5%)	0	0
Week 4	11 (23.4%)	15 (31.9%)	12 (25.5%)	9 (19.1%)	0
Week 6	10 (22.2%)	11 (24.4%)	12 (26.7%)	6 (13.3%)	6 (13.3%)
Week 8	10 (23.8%)	9 (21.4%)	13 (31.0%)	3 (7.1%)	7 (16.7%)
Maximum *	8 (17.0%)	11 (23.4%)	15 (31.9%)	4 (8.5%)	9 (19.1%)
Age Group: Adolescents (N = 55)					
Week 1	55 (100.0%)	0	0	0	0
Week 2	15 (29.4%)	36 (70.6%)	0	0	0
Week 3	4 (8.2%)	25 (51.0%)	20 (40.8%)	0	0
Week 4	2 (4.3%)	18 (38.3%)	15 (31.9%)	12 (25.5%)	0
Week 6	2 (4.7%)	10 (23.3%)	15 (34.9%)	10 (23.3%)	6 (14.0%)
Week 8	1 (2.4%)	10 (24.4%)	15 (36.6%)	7 (17.1%)	8 (19.5%)
Maximum *	5 (9.1%)	13 (23.6%)	17 (30.9%)	11 (20.0%)	9 (16.4%)

Note: Percentages are based on the number of patients in the study at each visit.
*Represents the number of patients for whom that dose was the maximum dosing during the study.
Source: Tables 13.14.3, 13.14.4, Section 11; Listing 13.14.1, Appendix B

Table 30 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 20.4 mg per day overall: 18.9 mg per day among children, and 21.8 mg per day among adolescents.

Table 30 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	101	10.0	(0.00)
Week 2	101	16.1	(4.89)
Week 3	96	21.6	(6.38)
Week 4	87	25.4	(8.18)
Week 6	83	27.7	(10.40)
Week 8	70	28.3	(10.07)
Overall Mean	101	20.4	(5.69)
Age Group: Children			
Week 1	49	10.0	(0.00)
Week 2	49	15.1	(5.05)
Week 3	45	20.9	(7.01)
Week 4	37	23.8	(9.53)
Week 6	36	26.1	(11.28)
Week 8	30	26.3	(10.66)
Overall Mean	49	18.9	(6.02)
Age Group: Adolescents			
Week 1	52	10.0	(0.00)
Week 2	52	17.1	(4.57)
Week 3	51	22.2	(5.77)
Week 4	50	26.6	(6.88)
Week 6	47	28.9	(9.61)
Week 8	40	29.8	(9.47)
Overall Mean	52	21.8	(5.01)

Source: Table 13.14.6, Section 11; Listing 13.14.1, Appendix B

Duration of exposure to study medication may be found in Table 43, Section 6.1, Extent of Exposure, and Table 13.14.5, 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 101 patients in the paroxetine group and 102 patients in the placebo group.

Analysis of efficacy data derived from the PP population, which comprised 74 patients in the paroxetine group and 83 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 since more than 5% of the patients violated at least one criterion but represented no less 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.

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 two datasets: the Week 8 LOCF dataset and the OC dataset. Primary inference is based on the Week 8 LOCF dataset for the ITT population. In the LOCF datasets for change in CDRS-R score and change in total KADS 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 proportion of responders based on CGI Global Improvement Item, change in CGI Severity of Illness, and change in GAF, the last non-zero post-Baseline score for each patient was carried forward to estimate missing data points. The LOCF dataset contains all data for the Week 8 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. Since this occurred at Week 8, the 70% LOCF dataset was not created.

5.2 Primary Efficacy Variable–Change from Baseline in Children's Depression Rating Scale–Revised (Total Score)

5.2.1 CDRS–R (Total Score)–Intention-to-Treat Population

The protocol defined the primary efficacy variable as the change from Baseline in Children's Depression Rating Scale–Revised (CDRS–R) total score at the Week 8 LOCF endpoint. The Week 8 LOCF dataset based on the ITT population for change from Baseline in CDRS-R total score contained 101 patients treated with paroxetine and 100 patients given placebo. Two patients (701.174.25757 and 701.154.25768) who were in the ITT population and received placebo did not have any post-Baseline data for the CDRS-R and are thus not included in the change from Baseline analyses.

Table 31 presents the analysis of the primary variable at each assessment period for the Week 8 LOCF and OC datasets 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 predefined covariates: age group (children/adolescents), gender, Baseline CDRS–R total score, and comorbidity (yes/no).

For the LOCF dataset, the adjusted mean change from Baseline at the Week 8 endpoint in CDRS–R total score was -22.58 points (SE 1.47) for paroxetine patients and -23.38 points (SE 1.60) for placebo patients. The adjusted mean difference, 0.80 points in favor of placebo, was not statistically significant (95% confidence interval [-3.09, 4.69], $p = 0.684$).

Therefore, there is no evidence that patients treated with paroxetine have a greater improvement in change from Baseline to Week 8 LOCF endpoint in CDRS–R total score than patients given placebo.

This primary model for the analysis of change from Baseline in CDRS-R total score indicated that there was a statistically significant difference in response between patients with varying Baseline CDRS-R scores. However, there was no evidence of any variation in response due to age group, gender or presence/absence of comorbidity (Table 14.1.2.1, Section 12).

The Week 8 Observed Cases (OC) dataset analysis supported the conclusion of the LOCF analysis, in that there was no evidence of a statistically significant treatment effect.

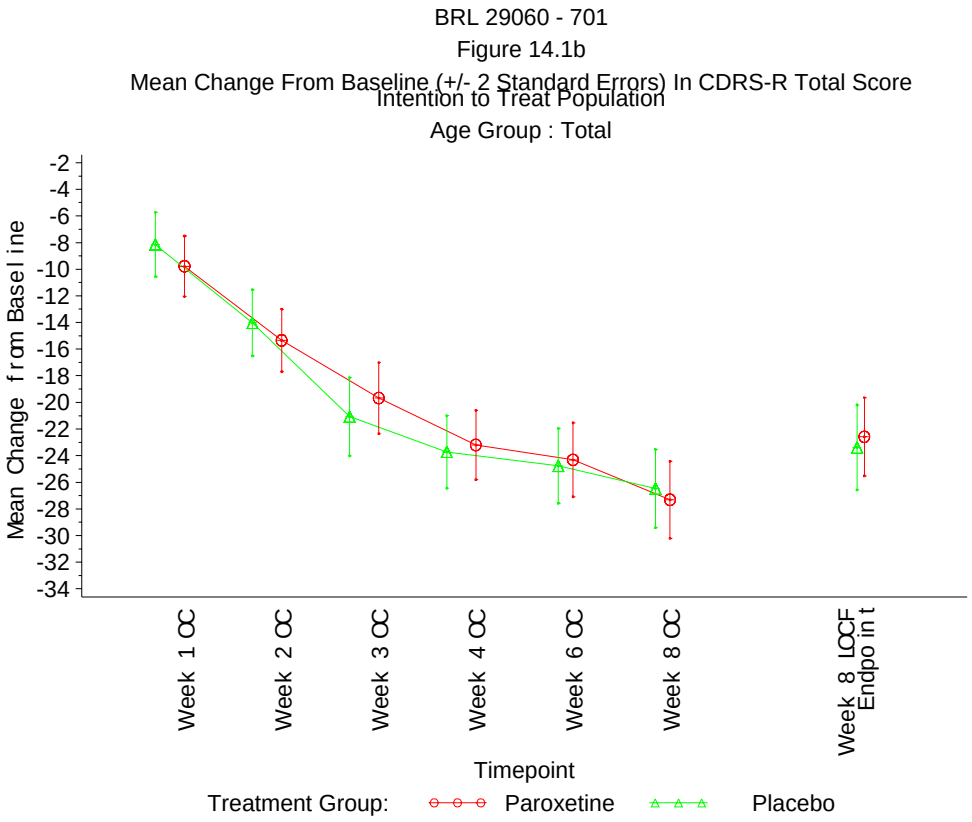
Table 31 Summary of Analysis for Change from Baseline in CDRS–R Total Score–Age Group: Total (ITT Population)

	Treatment Group								
	Paroxetine			Placebo			Treatment Comparison		
	N *	LS Mean **	(SE) †	N *	LS Mean **	(SE) †	Difference ††	95% CI	p-value
Baseline	101	60.7	(9.37)	102	62.6	(8.96)	—	—	—
Change from Baseline to:									
Week 1	97	-9.8	(1.13)	100	-8.1	(1.20)	—	—	—
Week 2	90	-15.4	(1.17)	91	-14.0	(1.24)	—	—	—
Week 3	89	-19.7	(1.34)	86	-21.1	(1.47)	—	—	—
Week 4	85	-23.2	(1.30)	91	-23.7	(1.36)	—	—	—
Week 6	73	-24.3	(1.39)	84	-24.8	(1.40)	—	—	—
Week 8 OC	68	-27.3	(1.45)	80	-26.5	(1.47)	-0.84	(-4.54, 2.87)	0.655
Week 8 LOCF	101	-22.6	(1.47)	100	-23.4	(1.60)	0.80	(-3.09, 4.69)	0.684

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

Figure 2 displays the adjusted mean change from Baseline (±2 standard errors) in CDRS–R total score at each visit by treatment group.

Figure 2 Change from Baseline in CDRS–R Total Score at Each Visit–Age Group: Total (ITT Population)



Adjusted for Baseline score, age group, gender and comorbidity
Source: Figure 14.1bz, 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 evidence of a statistically significant treatment by age group interaction (p = 0.049) (Appendix H), indicating varying treatment effect across the age groups. Therefore the analyses were carried out separately for each age group for the primary variable. In accordance with the pre-planned analysis, the significance of this interaction meant that all secondary endpoints were also analyzed for each age subgroup separately.

The analyses are presented separately for each age group in Table 32. The change from Baseline among placebo patients at Week 8 LOCF was similar for both the children and adolescents (-24.3 and -23.1, respectively). However, children on

paroxetine exhibited a smaller change from Baseline than did adolescents (-19.0 and -25.6, respectively).

The adjusted mean difference in change in CDRS-R score from Baseline for children at the Week 8 LOCF endpoint was 5.3 points in favor of placebo; this difference was not statistically significant (95% confidence interval [-0.08, 10.63], p = 0.054). The adjusted mean difference for adolescents at Week 8 LOCF endpoint was 2.6 points in favor of paroxetine; this difference was not statistically significant (95% confidence interval [-8.23, 3.13], p = 0.375).

The Week 8 OC dataset analyses within each age group supported the conclusion of the LOCF analyses, in that there was no evidence of a statistically significant treatment effect.

Table 32 Summary of Analysis for Change from Baseline in CDRS–R Total Score–Age Group: Children/Adolescents (ITT Population)

	Treatment Group						Treatment Comparison		
	Paroxetine			Placebo					
	N	LS Mean *	(SE) **	N	LS Mean *	(SE) **	Difference †	95% CI	p-value
Age Group: Children									
Baseline	49	58.4	(8.29)	47	61.3	(9.23)	—	—	—
Change from Baseline to:									
Week 1	45	-9.9	(1.67)	47	-10.4	(1.71)	—	—	—
Week 2	44	-16.0	(1.78)	43	-17.4	(1.89)	—	—	—
Week 3	41	-19.9	(2.02)	41	-24.3	(2.17)	—	—	—
Week 4	38	-22.1	(1.97)	45	-24.6	(1.97)	—	—	—
Week 6	30	-23.1	(2.03)	42	-27.0	(1.92)	—	—	—
Week 8 OC	29	-25.1	(2.25)	42	-25.5	(2.13)	0.41	(-5.23, 6.05)	0.885
Week 8 LOCF	49	-19.0	(2.03)	47	-24.3	(2.19)	5.27	(-0.08, 10.63)	0.054
Age Group: Adolescents									
Baseline	52	62.9	(9.87)	55	63.7	(8.66)	—	—	—
Change from Baseline to:									
Week 1	52	-9.3	(1.56)	53	-5.7	(1.72)	—	—	—
Week 2	46	-14.5	(1.56)	48	-10.6	(1.66)	—	—	—
Week 3	48	-19.0	(1.77)	45	-17.7	(2.02)	—	—	—
Week 4	47	-23.9	(1.75)	46	-22.8	(1.94)	—	—	—
Week 6	43	-24.6	(1.85)	42	-22.4	(2.03)	—	—	—
Week 8 OC	39	-29.0	(1.88)	38	-27.6	(2.08)	-1.40	(-6.46, 3.66)	0.582
Week 8 LOCF	52	-25.6	(2.10)	53	-23.1	(2.32)	-2.55	(-8.23, 3.13)	0.375

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

** For Baseline, standard deviations, not standard errors, are presented

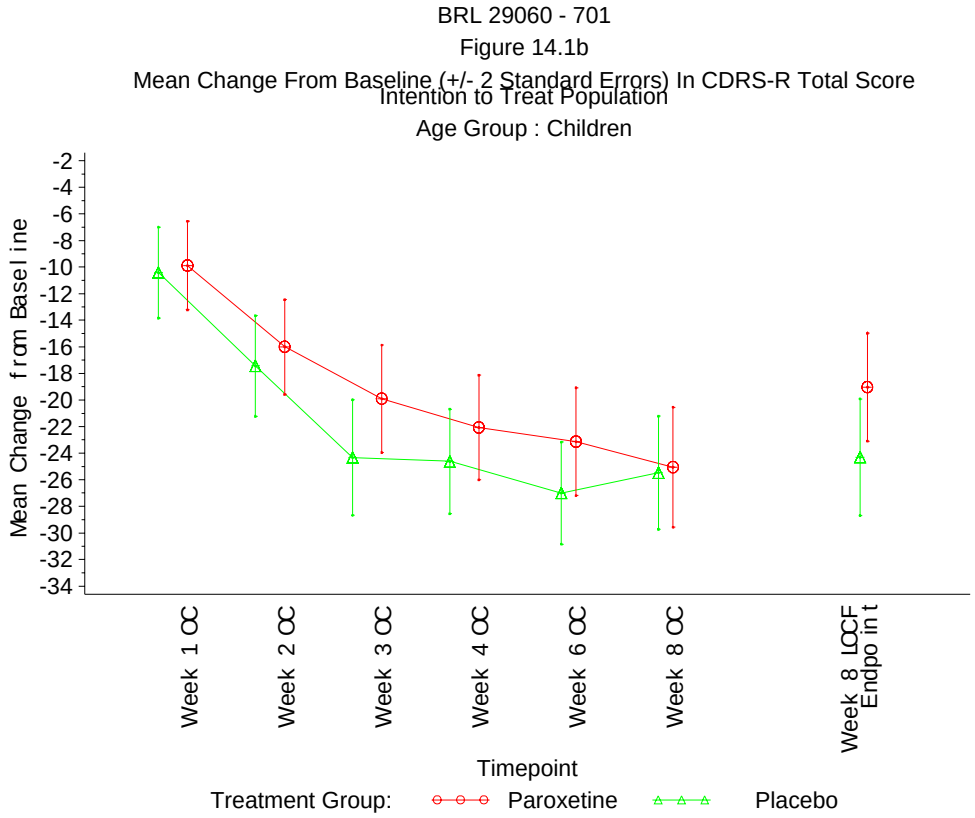
† Differences in adjusted (least square) means (paroxetine minus placebo)

Adjusted for Baseline score, gender and comorbidity

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

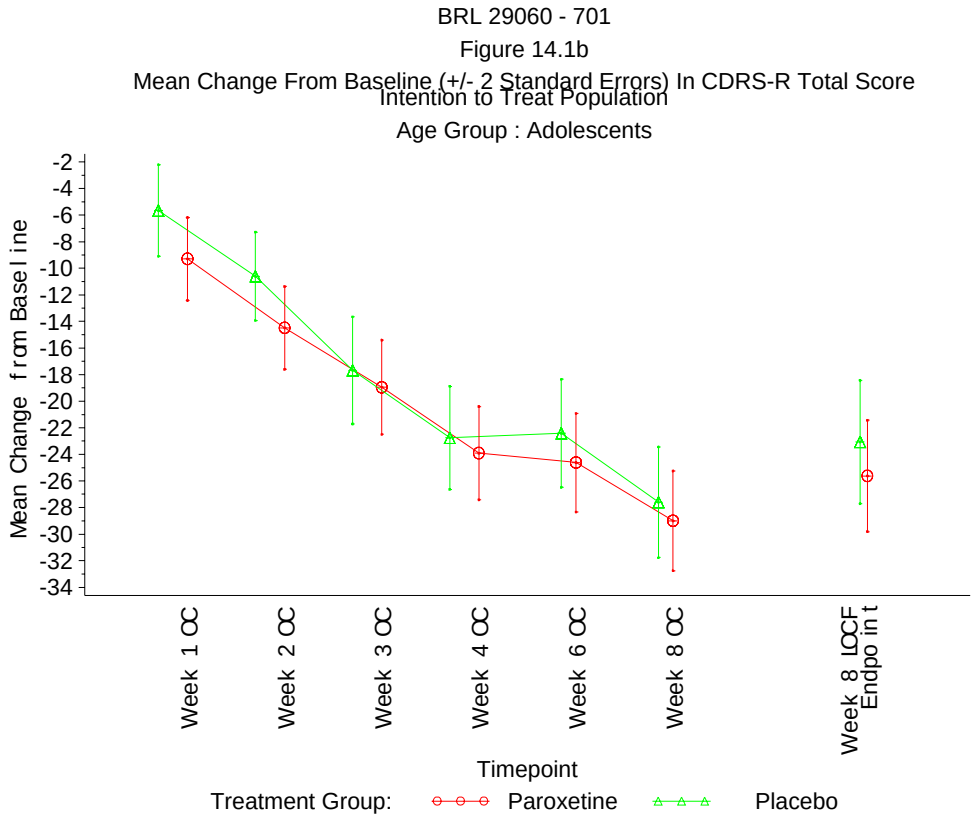
Figure 3 displays the adjusted mean change from Baseline (±2 standard errors) in CDRS–R total score at each visit for children, and Figure 4 displays the adjusted mean change from Baseline (±2 standard errors) for adolescents.

Figure 3 Change from Baseline in CDRS–R Total Score at Each Visit–Age Group: Children (ITT Population)



Adjusted for Baseline score, gender and comorbidity
Source: Figure 14.1bx, Section 14

Figure 4 Change from Baseline in CDRS–R Total Score at Each Visit–Age Group: Adolescents (ITT Population)



Adjusted for Baseline score, gender and comorbidity
Source: Figure 14.1by, Section 14

Table 33 presents summary statistics for CDRS–R total scores by visit for both age groups combined and separately for the ITT population. On average, scores decreased similarly and steadily over time in both treatment groups and in both age groups, with the exception that among children in the placebo group there was a slight mean increase at Week 8 compared to Week 6.

Table 33 Summary Statistics for CDRS–R Total Score at Each Visit (Observed Cases)–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group							
	Paroxetine (N = 101)				Placebo (N = 102)			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Age Group: Total								
Baseline	101	60.7	(9.37)	44 to 85	102	62.6	(8.96)	45 to 89
Week 1	97	51.6	(12.55)	20 to 83	100	55.0	(13.36)	20 to 89
Week 2	90	46.6	(12.21)	20 to 70	91	49.6	(14.28)	19 to 88
Week 3	89	43.2	(13.46)	18 to 85	86	43.1	(13.66)	18 to 78
Week 4	85	39.1	(11.87)	18 to 69	91	39.5	(12.88)	18 to 78
Week 6	73	37.8	(12.28)	18 to 70	84	37.3	(12.05)	17 to 75
Week 8 OC	68	34.1	(11.31)	18 to 71	80	35.1	(12.04)	18 to 75
Age Group: Children								
Baseline	49	58.4	(8.29)	45 to 85	47	61.3	(9.23)	45 to 85
Week 1	45	48.9	(12.25)	20 to 76	47	51.7	(13.38)	30 to 89
Week 2	44	44.0	(12.04)	20 to 67	43	45.3	(14.93)	19 to 88
Week 3	41	41.3	(14.51)	18 to 68	41	39.1	(13.64)	19 to 65
Week 4	38	38.2	(11.96)	18 to 69	45	37.1	(13.17)	18 to 70
Week 6	30	37.0	(12.86)	18 to 70	42	33.7	(11.64)	17 to 75
Week 8 OC	29	33.7	(11.79)	18 to 63	42	34.0	(12.15)	18 to 75
Age Group: Adolescents								
Baseline	52	62.9	(9.87)	44 to 84	55	63.7	(8.66)	46 to 89
Week 1	52	53.8	(12.47)	30 to 83	53	57.8	(12.80)	20 to 88
Week 2	46	49.1	(11.97)	23 to 70	48	53.5	(12.62)	24 to 88
Week 3	48	44.9	(12.41)	19 to 85	45	46.8	(12.75)	18 to 78
Week 4	47	39.9	(11.87)	19 to 67	46	41.8	(12.29)	20 to 78
Week 6	43	38.3	(11.98)	18 to 68	42	40.9	(11.50)	21 to 70
Week 8 OC	39	34.3	(11.09)	19 to 71	38	36.4	(11.94)	18 to 65

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

5.2.2 CDRS–R (Total Score)–Per Protocol Population

The PP population for the Week 8 LOCF dataset for change from Baseline in CDRS–R total score comprised 74 patients treated with paroxetine and 83 patients treated with placebo. Table 34 presents results from the analysis of the PP population, which are similar to those seen in the ITT population. For the LOCF dataset, the adjusted mean change from Baseline at the Week 8 endpoint in CDRS–R total score was -22.4 points (SE 1.71) for paroxetine patients and -24.1 points (SE 1.75) for placebo patients. The adjusted mean difference between the two treatment groups at Week 8 LOCF endpoint was 1.68 points in favor of placebo. This difference was not statistically significant (95% confidence interval [-2.59, 5.96], p = 0.437).

Therefore, there was no evidence from the PP analysis that patients on paroxetine had a greater improvement in change from Baseline to Week 8 LOCF endpoint in

CDRS–R total score than patients treated with placebo, which is consistent with the ITT analysis.

The Week 8 Observed Cases (OC) dataset analysis for the PP population supported the conclusion of the LOCF analysis, in that there was no evidence of a statistically significant treatment effect.

The change from Baseline at Week 8 LOCF among placebo patients was similar for both the children and adolescents age subgroups (-25.1 and -23.5, respectively). However, children treated with paroxetine exhibited a smaller change from Baseline than did adolescents (-20.8 and -24.3, respectively), as observed in the ITT population.

The adjusted mean difference for children at Week 8 LOCF endpoint was 4.32 points in favor of placebo. This difference was not statistically significant (95% confidence interval [-1.40, 10.05], p = 0.137). The adjusted mean difference for adolescents at Week 8 LOCF endpoint was -0.9 points in favor of paroxetine. This difference was also not statistically significant (95% confidence interval [-7.46, 5.72], p = 0.793).

Similar results were observed in the Week 8 OC datasets for the PP population. Summary statistics for CDRS-R total score at each visit for the PP population may be found in Table 14.1.1c, Section 12.

Table 34 Summary of Analysis for Change from Baseline in CDRS–R 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	74	60.7	(9.14)	83	62.0	(8.83)	—	—	—
Change from Baseline to:									
Wk 1	70	-11.3	(1.31)	83	-10.1	(1.30)	—	—	—
Wk 2	70	-15.8	(1.39)	79	-14.4	(1.40)	—	—	—
Wk 3	70	-18.8	(1.60)	73	-21.1	(1.70)	—	—	—
Wk 4	65	-22.9	(1.55)	78	-24.1	(1.55)	—	—	—
Wk 6	54	-22.5	(1.64)	74	-24.7	(1.54)	—	—	—
Wk 8 OC	54	-26.2	(1.71)	72	-26.1	(1.60)	-0.15	(-4.25, 3.95)	0.942
Wk 8 LOCF	74	-22.4	(1.71)	83	-24.1	(1.75)	1.68	(-2.59, 5.96)	0.437

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

5.3 Secondary Efficacy Parameters

The protocol defined secondary efficacy variables to support the primary variable: the proportion of responders based on the CGI Global Improvement item, change from Baseline in CGI Severity of Illness score, and change from Baseline in GAF score.

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

Table 35 summarizes the analyses of responders based on the 7-point CGI Global Improvement assessment for both age groups combined and for children and adolescents separately. 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 8 LOCF and OC datasets based on the ITT population.

The odds of being a CGI responder on paroxetine compared to placebo at Week 8 LOCF were 1.18 (95% CI: [0.67, 2.08], p = 0.563), indicating that the odds of responding on paroxetine were not statistically significantly different from the odds of responding on placebo.

For children, the odds of being a CGI responder on paroxetine compared to placebo at Week 8 LOCF were 0.97 (95% CI: [0.43, 2.20], p = 0.950), indicating that the odds of responding on paroxetine were not statistically significantly different from the odds of responding on placebo.

For adolescents, the odds of being a CGI responder on paroxetine compared to placebo at Week 8 LOCF were 1.46 (95% CI: [0.65, 3.24], p = 0.358), again indicating that the odds of responding on paroxetine were not statistically significantly different from the odds of responding on placebo.

Similar results were obtained from the Week 8 OC analysis. However, the proportion of paroxetine responders at Week 8 OC was higher compared to Week 8 LOCF (67.6% vs. 48.5%, respectively), while the proportions at Week 8 OC and Week 8 LOCF are more comparable for the placebo group (55.0% vs. 46.0%, respectively). Nevertheless, the Week 8 OC odds ratio was not statistically significant at the 5% level, indicating that the odds of responding are not statistically significantly different between the treatment groups.

Table 35 Proportion of Responders Based on the CGI Global Improvement Item–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Groups								
	Paroxetine			Placebo			Treatment Comparisons		
Age Group: Total	**N**	**n**	**%**	**N**	**n**	**%**	**Odds Ratio ***	**95% CI**	**p-value**
Week 1	97	11	(11.3%)	100	10	(10.0%)	—	—	—
Week 2	90	25	(27.8%)	91	17	(18.7%)	—	—	—
Week 3	89	35	(39.3%)	86	28	(32.6%)	—	—	—
Week 4	85	38	(44.7%)	91	36	(39.6%)	—	—	—
Week 6	73	43	(58.9%)	85	46	(54.1%)	—	—	—
Week 8 OC	68	46	(67.6%)	80	44	(55.0%)	1.85	0.92, 3.73	0.084
Week 8 LOCF	101	49	(48.5%)	100	46	(46.0%)	1.18	0.67, 2.08	0.563
Age Group: Children									
Week 1	45	7	(15.6%)	47	8	(17.0%)	—	—	—
Week 2	44	14	(31.8%)	43	13	(30.2%)	—	—	—
Week 3	41	19	(46.3%)	41	14	(34.1%)	—	—	—
Week 4	38	17	(44.7%)	45	19	(42.2%)	—	—	—
Week 6	30	17	(56.7%)	43	24	(55.8%)	—	—	—
Week 8 OC	29	20	(69.0%)	42	22	(52.4%)	2.38	0.82, 6.91	0.109
Week 8 LOCF	49	22	(44.9%)	47	22	(46.8%)	0.97	0.43, 2.20	0.950
Age Group: Adolescents									
Week 1	52	4	(7.7%)	53	2	(3.8%)	—	—	—
Week 2	46	11	(23.9%)	48	4	(8.3%)	—	—	—
Week 3	48	16	(33.3%)	45	14	(31.1%)	—	—	—
Week 4	47	21	(44.7%)	46	17	(37.0%)	—	—	—
Week 6	43	26	(60.5%)	42	22	(52.4%)	—	—	—
Week 8 OC	39	26	(66.7%)	38	22	(57.9%)	1.53	0.59, 3.96	0.381
Week 8 LOCF	52	27	(51.9%)	53	24	(45.3%)	1.46	0.65, 3.24	0.358

Responders are defined as patients with a score of 1 (very much improved) or 2 (much improved) on the scale at endpoint

* The odds ratio represents the odds of improving with paroxetine relative to that with placebo. Percentage of responders is unadjusted; the odds ratio is adjusted for terms in the model (Baseline score, age group, gender, and comorbidity). CGI Severity of Illness was used as Baseline, and age group is not applicable to the children and adolescents analyses.

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 8 OC are presented by treatment group for both age groups combined and by age subgroup in Table 36. A total of 67.6% of patients (46/68) treated with paroxetine were rated much or very much improved, compared to 55.0% of the placebo patients (44/80). Few patients in either treatment group became worse over the course of the study, and no patients were rated "very much worse."

Table 36 Number (%) of Patients in Each Category of the CGI Global Improvement Item Score at Week 8 (Observed Cases)–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group	
	Paroxetine (N = 101)	**Placebo (N = 102)**
	n (%)	**n (%)**
Age Group: Total	(N = 68)	(N = 80)
Very much improved	21 (30.9%)	17 (21.3%)
Much improved	25 (36.8%)	27 (33.8%)
Minimally improved	16 (23.5%)	22 (27.5%)
No change	5 (7.4%)	11 (13.8%)
Minimally worse	0	3 (3.8%)
Much worse	1 (1.5%)	0
Very much worse	0	0
Total	68 (100.0%)	80 (100.0%)
Age Group: Children	(N = 29)	(N = 42)
Very much improved	9 (31.0%)	7 (16.7%)
Much improved	11 (37.9%)	15 (35.7%)
Minimally improved	5 (17.2%)	11 (26.2%)
No change	4 (13.8%)	7 (16.7%)
Minimally worse	0	2 (4.8%)
Much worse	0	0
Very much worse	0	0
Total	29 (100.0%)	42 (100.0%)
Age Group: Adolescents	(N = 39)	(N = 38)
Very much improved	12 (30.8%)	10 (26.3%)
Much improved	14 (35.9%)	12 (31.6%)
Minimally improved	11 (28.2%)	11 (28.9%)
No change	1 (2.6%)	4 (10.5%)
Minimally worse	0	1 (2.6%)
Much worse	1 (2.6%)	0
Very much worse	0	0
Total	39 (100.0%)	38 (100.0%)

N = number of patients with a Week 8 assessment
Source: Table 14.3.1, Section 12; Listing 14.3.1, Appendix C

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

Table 37 presents the analyses of the change from Baseline in CGI Severity of Illness score for both the Week 8 LOCF and OC datasets 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 8 LOCF was 0 ($p = 0.780$), indicating no evidence of a statistically significant benefit of paroxetine over placebo.

Similarly, for adolescents, the median difference between paroxetine and placebo at Week 8 LOCF was 0 ($p = 0.485$), indicating no evidence of a statistically significant benefit of paroxetine over placebo.

Similar results were observed for the Week 8 OC analyses.

Table 37 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	49	4.3	4.0	4 to 6	47	4.3	4.0	3 to 6	—	
Change from Baseline to:										
Week 1	45	-0.4	0.0	-4 to 0	47	-0.3	0.0	-3 to 2	—	—
Week 2	44	-0.7	-0.5	-4 to 0	43	-0.7	0.0	-4 to 2	—	—
Week 3	41	-0.9	-1.0	-4 to 1	41	-0.9	0.0	-4 to 0	—	—
Week 4	38	-0.9	-1.0	-3 to 1	45	-1.1	-1.0	-5 to 0	—	—
Week 6	30	-1.3	-1.0	-4 to 0	43	-1.3	-1.0	-4 to 0	—	—
Week 8 OC	29	-1.7	-2.0	-4 to 0	42	-1.2	-1.0	-4 to 0	0	0.092
Week 8 LOCF	49	-1.0	-1.0	-4 to 1	47	-1.1	-1.0	-4 to 0	0	0.780
Adolescents										
Baseline	52	4.3	4.0	3 to 6	55	4.4	4.0	4 to 6	—	
Change from Baseline to:										
Week 1	52	-0.3	0.0	-2 to 1	53	-0.2	0.0	-4 to 1	—	—
Week 2	46	-0.7	-0.5	-3 to 1	48	-0.4	0.0	-4 to 1	—	—
Week 3	48	-0.7	-1.0	-3 to 2	45	-0.7	0.0	-4 to 1	—	—
Week 4	47	-1.2	-1.0	-4 to 1	46	-1.1	-1.0	-4 to 1	—	—
Week 6	43	-1.3	-1.0	-5 to 0	42	-1.2	-1.0	-3 to 1	—	—
Week 8 OC	39	-1.8	-2.0	-5 to 0	38	-1.7	-1.5	-4 to 0	0	0.691
Week 8 LOCF	52	-1.3	-1.0	-5 to 2	53	-1.2	-1.0	-4 to 1	0	0.485

* P-value from Wilcoxon Rank Sum Test

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

Table 38 and Table 39 summarize the percentage of patients in each treatment group categorized by CGI Severity of Illness item score at Baseline and at Week 8 OC for both age groups combined and for children and adolescents, respectively.

In both age groups combined, 36/68 paroxetine patients (52.9%) and 29/80 placebo patients (36.3%) were rated normal or borderline mentally ill at week 8, compared to no patients in either treatment group at Baseline. Three patients of 101 (3.0%) in the paroxetine group and 4/102 patients (3.9%) in the placebo group had been rated severely ill at Baseline; no patients in either treatment group were rated severely ill at Week 8 OC.

Table 38 Number (%) of Patients in Each Category of the CGI Severity of Illness Item Score at Baseline and Week 8 (Observed Cases)–Age Group: Total (ITT Population)

	Treatment Group			
	Paroxetine (N = 101)		Placebo (N = 102)	
	n	%	n	%
Baseline				
Normal, not at all ill (1)	0		0	
Borderline mentally ill (2)	0		0	
Mildly ill (3)	2	(2.0%)	2	(2.0%)
Moderately ill (4)	70	(69.3%)	67	(65.7%)
Markedly ill (5)	26	(25.7%)	29	(28.4%)
Severely ill (6)	3	(3.0%)	4	(3.9%)
Among the most extremely ill (7)	0		0	
Total	101	(100.0%)	102	(100.0%)
Week 8 OC				
Normal, not at all ill (1)	13	(19.1%)	13	(16.3%)
Borderline mentally ill (2)	23	(33.8%)	16	(20.0%)
Mildly ill (3)	15	(22.1%)	20	(25.0%)
Moderately ill (4)	14	(20.6%)	29	(36.3%)
Markedly ill (5)	3	(4.4%)	2	(2.5%)
Severely ill (6)	0		0	
Among the most extremely ill (7)	0		0	
Total	68	(100.0%)	80	(100.0%)

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

Among children, at Week 8, 17/29 (58.6%) paroxetine patients were rated normal or borderline mentally ill compared to 14/42 (33.3%) placebo patients. Among adolescents, at Week 8, 19/39 (48.7%) paroxetine patients were rated normal or borderline mentally ill compared to 15/38 (39.5%) placebo patients (Table 39).

Table 39 Number (%) of Patients in Each Category of the CGI Severity of Illness Item Score at Baseline and Week 8 (Observed Cases)–Age Group: Children/Adolescents (ITT Population)

	Treatment Group			
	Paroxetine (N = 49)		Placebo (N = 47)	
	n	%	n	%
Age Group: Children				
Baseline				
Normal, not at all ill (1)	0		0	
Borderline mentally ill (2)	0		0	
Mildly ill (3)	0		2	(4.3%)
Moderately ill (4)	36	(73.5%)	33	(70.2%)
Markedly ill (5)	12	(24.5%)	9	(19.1%)
Severely ill (6)	1	(2.0%)	3	(6.4%)
Among the most extremely ill (7)	0		0	
Total	49	(100.0%)	47	(100.0%)
Week 8 OC				
Normal, not at all ill (1)	6	(20.7%)	6	(14.3%)
Borderline mentally ill (2)	11	(37.9%)	8	(19.0%)
Mildly ill (3)	4	(13.8%)	9	(21.4%)
Moderately ill (4)	6	(20.7%)	17	(40.5%)
Markedly ill (5)	2	(6.9%)	2	(4.8%)
Severely ill (6)	0		0	
Among the most extremely ill (7)	0		0	
Total	29	(100.0%)	42	(100.0%)
Age Group: Adolescents				
Baseline				
Normal, not at all ill (1)	0		0	
Borderline mentally ill (2)	0		0	
Mildly ill (3)	2	(3.8%)	0	
Moderately ill (4)	34	(65.4%)	34	(61.8%)
Markedly ill (5)	14	(26.9%)	20	(36.4%)
Severely ill (6)	2	(3.8%)	1	(1.8%)
Among the most extremely ill (7)	0		0	
Total	52	(100.0%)	55	(100.0%)
Week 8 OC				
Normal, not at all ill (1)	7	(17.9%)	7	(18.4%)
Borderline mentally ill (2)	12	(30.8%)	8	(21.1%)
Mildly ill (3)	11	(28.2%)	11	(28.9%)
Moderately ill (4)	8	(20.5%)	12	(31.6%)
Markedly ill (5)	1	(2.6%)	0	
Severely ill (6)	0		0	
Among the most extremely ill (7)	0		0	
Total	39	(100.0%)	38	(100.0%)

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

5.3.3 Change from Baseline in Global Assessment of Functioning Score

Table 40 presents the analysis for change from Baseline in the Global Assessment of Functioning (GAF) score for the Week 8 LOCF and OC datasets based on the ITT population.

The adjusted mean difference between paroxetine and placebo at Week 8 LOCF for both age groups combined was 1.33 points in favor of paroxetine (95% CI: [-2.19, 4.86], p = 0.456), providing no evidence of a statistically significant benefit of paroxetine over placebo.

Among children, the adjusted mean difference between paroxetine and placebo at Week 8 LOCF was 0.82 points in favor of placebo (95% CI: [-6.33, 4.68], p = 0.767), providing no evidence of a statistically significant benefit of paroxetine over placebo.

Among adolescents, the adjusted mean difference between paroxetine and placebo at Week 8 LOCF was 3.26 points in favor of paroxetine (95% CI: [-1.40, 7.92], p = 0.168), again providing no evidence of a statistically significant benefit of paroxetine over placebo.

Table 40 Summary of Analysis for Change from Baseline in GAF Score–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Groups								
	Paroxetine (N = 101)			Placebo (N = 102)			Treatment Comparisons		
	N *	LS Mean **	(SE) †	N *	LS Mean **	(SE) †	Difference ††	95% CI	p-value
Age Group: Total									
Baseline	101	53.4	(7.78)	102	52.3	(5.57)	—	—	—
Change from Baseline to:									
Wk 4	81	10.2	(1.11)	86	9.1	(1.16)	—	—	—
Wk 6	73	11.8	(1.20)	85	10.7	(1.20)	—	—	—
Wk 8 OC	68	15.2	(1.49)	79	12.9	(1.50)	2.36	(-1.44, 6.16)	0.221
Wk 8 LOCF	92	12.0	(1.35)	95	10.6	(1.42)	1.33	(-2.19, 4.86)	0.456
Age Group: Children									
Baseline	49	53.2	(7.34)	47	52.3	(5.78)	—	—	—
Change from Baseline to:									
Wk 4	37	10.2	(1.69)	42	10.1	(1.72)	—	—	—
Wk 6	30	12.9	(2.08)	43	11.9	(1.95)	—	—	—
Wk 8 OC	29	15.9	(2.41)	41	13.3	(2.29)	2.58	(-3.44, 8.61)	0.395
Wk 8 LOCF	43	11.0	(2.14)	46	11.9	(2.19)	-0.82	(-6.33, 4.68)	0.767
Age Group: Adolescents									
Baseline	52	53.6	(8.24)	55	52.3	(5.43)	—	—	—
Change from Baseline to:									
Wk 4	44	10.3	(1.48)	44	8.2	(1.61)	—	—	—
Wk 6	43	10.7	(1.42)	42	9.4	(1.54)	—	—	—
Wk 8 OC	39	14.7	(1.88)	38	12.6	(2.07)	2.10	(-2.96, 7.15)	0.411
Wk 8 LOCF	49	12.9	(1.72)	49	9.6	(1.88)	3.26	(-1.40, 7.92)	0.168

***** 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
** 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 (age group is not applicable to the children and adolescents analyses)
Source: Table 14.4.2, Section 12; Listing 14.4.1, 14.4.2, Appendix C

Table 41 presents the summary statistics for GAF score at Baseline, Week 4, Week 6, and Week 8 by treatment group for both age groups combined and separately.

Mean GAF scores increased (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 8.

Table 41 Summary Statistics for GAF Score at Each Visit (Observed Cases)–Age Group: Total/Children/Adolescents (ITT Population)

	Treatment Group							
	Paroxetine (N = 101)				Placebo (N = 102)			
	N	Mean	(SD)	Range	N	Mean	(SD)	Range
Age Group: Total								
Baseline	101	53.4	(7.78)	35 to 77	102	52.3	(5.57)	40 to 70
Week 4	81	63.3	(10.63)	45 to 95	86	61.5	(9.35)	50 to 90
Week 6	73	65.0	(10.14)	40 to 95	85	63.7	(10.25)	48 to 91
Week 8 OC	68	68.5	(12.27)	40 to 95	79	65.9	(11.26)	50 to 92
Age Group: Children								
Baseline	49	53.2	(7.34)	35 to 71	47	52.3	(5.78)	40 to 70
Week 4	37	62.8	(9.42)	50 to 88	42	62.1	(10.30)	50 to 90
Week 6	30	66.1	(10.10)	40 to 83	43	64.8	(11.72)	48 to 91
Week 8 OC	29	68.8	(12.15)	40 to 90	41	65.9	(12.10)	50 to 91
Age Group: Adolescents								
Baseline	52	53.6	(8.24)	35 to 77	55	52.3	(5.43)	40 to 61
Week 4	44	63.6	(11.64)	45 to 95	44	61.0	(8.43)	50 to 90
Week 6	43	64.3	(10.23)	45 to 95	42	62.6	(8.48)	50 to 80
Week 8 OC	39	68.3	(12.51)	45 to 95	38	65.9	(10.44)	51 to 92

Source: Table 14.4.1, Section 12; Listing 14.4.1, Appendix C

5.4 Other Efficacy Parameter–Change from Baseline in the Kutcher Adolescent Depression Rating Scale (Total Score)

An additional efficacy variable was the change from Baseline in the Kutcher Adolescent Depression Rating Scale (KADS) total score at the Week 8 LOCF endpoint. The KADS scale is a self-report instrument under development (not validated) for the purpose of diagnosis and assessment of the severity of depression in adolescents.

This scale was to be administered to adolescents only. However, one patient, an 11-year-old female, was classified by the investigator for purposes of randomization as an adolescent. Data for this patient have been reported and

analyzed in the children age group, but this patient is included in the KADS listings, tables and analyses (see Section 3.14.10, Data Irregularities).

Table 42 presents the analysis for change from Baseline in KADS total score for the Week 8 LOCF and OC datasets based on the ITT population. The adjusted mean difference between paroxetine and placebo at Week 8 LOCF was 0.82 points in favor of paroxetine (95% CI: [-3.50, 1.85], p = 0.542) providing no evidence of a statistically significant benefit of paroxetine over placebo.

The Week 8 Observed Cases (OC) dataset analysis supported the conclusion of the LOCF analysis, in that there was no evidence of a statistically significant treatment effect.

Summary statistics for KADS total score at each visit, based on the ITT population, may be found in Table 14.5.1, Section 12, and Listings 14.5.1.1, 14.5.1.2, and 14.5.1.3, Appendix C.

Table 42 Summary of Analysis for Change from Baseline in KADS Total Score–Age Group: Adolescents (ITT Population)

	Treatment Groups								
	Paroxetine (N = 101)			Placebo (N = 102)			Treatment Comparisons		
	N	LS Mean *	(SE) **	N	LS Mean *	(SE) **	Difference †	95% CI	p-value
Baseline	52	17.6	(6.17)	55	18.1	(7.43)			
Change from Baseline to:									
Week 1	52	-4.5	(0.76)	53	-3.6	(0.83)	—	—	—
Week 2	46	-5.9	(0.93)	46	-5.7	(1.01)	—	—	—
Week 3	48	-6.0	(0.92)	43	-6.9	(1.07)	—	—	—
Week 4	46	-8.0	(0.89)	45	-8.2	(0.99)	—	—	—
Week 6	41	-7.0	(0.95)	41	-8.3	(1.03)	—	—	—
Week 8 OC	37	-8.3	(1.07)	38	-8.2	(1.14)	-0.04	(-2.84, 2.76)	0.977
Week 8 LOCF	52	-8.0	(0.99)	53	-7.2	(1.09)	-0.82	(-3.50, 1.85)	0.542

* 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, gender and comorbidity. Not adjusted for age group since only adolescents were administered the KADS scale.

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

6 Safety Results

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

6.1 Extent of Exposure

Table 43 shows the distribution of time (excluding Taper Phase) at 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 was approximately 50 days for both age groups combined. The range of exposure was also similar for the two treatment groups. However, among children, the placebo group had a higher overall mean duration, as a result of having fewer subjects with treatment durations less than 28 days compared to the paroxetine group. The adolescent age group generally had comparable durations of exposure to study medication across the two treatment groups.

Table 43 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 Exposure (Days)	**Paroxetine (N = 101)**		**Placebo (N = 102)**	
	n	**(%)**	**n**	**(%)**
Age Group: Total				
≥1	101	(100.0%)	102	(100.0%)
>7	101	(100.0%)	99	(97.1%)
>14	96	(95.0%)	98	(96.1%)
>21	90	(89.1%)	96	(94.1%)
>28	87	(86.1%)	92	(90.2%)
>42	75	(74.3%)	85	(83.3%)
>56	41	(40.6%)	40	(39.2%)
Overall mean duration (days)	49.0		51.4	
Range (days)	9–69		2–68	
Age Group: Children	(n= 49)		(n= 47)	
≥1	49	(100.0%)	47	(100.0%)
>7	49	(100.0%)	47	(100.0%)
>14	45	(91.8%)	47	(100.0%)
>21	40	(81.6%)	47	(100.0%)
>28	38	(77.6%)	46	(97.9%)
>42	33	(67.3%)	42	(89.4%)
>56	19	(38.8%)	20	(42.6%)
Overall mean duration (days)	45.0		55.0	
Range	9–65		22–68	
Age Group: Adolescents	(n= 52)		(n= 55)	
≥1	52	(100.0%)	55	(100.0%)
>7	52	(100.0%)	52	(94.5%)
>14	51	(98.1%)	51	(92.7%)
>21	50	(96.2%)	49	(89.1%)
>28	49	(94.2%)	46	(83.6%)
>42	42	(80.8%)	43	(78.2%)
>56	22	(42.3%)	20	(36.4%)
Overall mean duration (days)	52.7		48.2	
Range	10–69		2–68	

Source: Table 13.14.5, Section 11; Listing 13.14.1, Appendix B

6.2 Adverse Events

The methodology for coding and tabulating AEs is described in Section 3.14.6.1, Adverse Events. 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 8 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 Treatment 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 15.1.1.1X 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, and 15.1.1.5 and 15.1.1.5.X for combined 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 [Statistical Evaluation] for a definition of emergent AEs in each treatment phase.

6.2.1 Treatment Phase-emergent Adverse Events

Table 44 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 15.1.1.1X, Section 13, (by preferred term occurring in 1% or more of the population in descending order).

A total of 71/101 ITT patients (70.3%) randomized to paroxetine reported non-gender-specific emergent AEs during the treatment phase, compared with 62/102 patients receiving placebo (60.8%). The five most common non-gender-specific AEs for patients on paroxetine were headache, nausea, trauma, respiratory

disorder and insomnia, while the five most common AEs for patients on placebo were headache, respiratory disorder, nausea, asthenia and trauma.

Four AEs occurred with an incidence of 5% or greater in the paroxetine group and with an incidence at least twice that of placebo. These AEs were dizziness (5/101, 5.0%, in the paroxetine group and 1/102, 1.0%, in the placebo group); cough increased (6/101, 5.9%, in the paroxetine group and 3/102, 2.9%, in the placebo group); dyspepsia (6/101, 5.9%, in the paroxetine group and 3/102, 2.9%, in the placebo group); and vomiting (6/101, 5.9%, in the paroxetine group and 2/102, 2.0%, in the placebo group). Among children, AEs occurring with an incidence of 5% or greater in the paroxetine group and with an incidence at least twice that of placebo were vomiting and insomnia. Among adolescents, these AEs were somnolence, trauma, pharyngitis, respiratory disorder, fever, otitis media, dyspepsia, vomiting, contact dermatitis, increased cough, dizziness, and sweating (Table 15.1.1.1X, Section 13).

The overall AE frequency was similar among children and adolescents. A total of 64/96 children (66.7%) reported non-gender-specific emergent AEs during the Treatment Phase, 34/49 (69.4%) on paroxetine and 30/47 (63.8%) on placebo. A total of 69/107 adolescents (64.5%) reported non-gender-specific emergent AEs during the Treatment Phase, 37/52 (71.2%) on paroxetine and 32/55 (58.2%) on placebo.

One adolescent male patient on paroxetine (1/53, 1.9%) reported a male-specific AE (impotence); there were no male-specific Treatment Phase-emergent AEs for patients on placebo. One adolescent female patient on paroxetine (1/48, 2.1%) and one adolescent female patient on placebo (1/47, 2.1%) reported female-specific AEs (menstrual disorder and dysmenorrhea, respectively) (Table 15.1.1.1, Section 13).

In the paroxetine group, 3 of the more commonly reported (i.e., >10%) of AEs among adolescents occurred at an incidence at least twice that among children: somnolence (10/52, 19.2% vs. 0/49), insomnia (8/52, 15.4% vs. 3/49, 6.1%), and pharyngitis (7/52, 13.5%, vs. 1/49, 2.0%). However, in the placebo group, insomnia and somnolence also occurred at rates in adolescents that were at least twice that in the younger patients. Abdominal pain (4/49, 8.2% vs. 0/52) and infection (5/49, 10.2% vs. 2/52, 3.8%) were reported more frequently among children than among adolescents in the paroxetine group. For other AEs, the frequency of occurrence between the two age groups was generally similar.

Table 44 Most Frequent (≥5% in Any Treatment Group) Treatment-Phase Emergent Adverse Events–Age Group: Total/Children/Adolescents (ITT Population)

	Age Group: Total		Age Group: Children		Age Group: Adolescents	
AE Preferred Term	**Paroxetine (N = 101)**	**Placebo (N = 102)**	**Paroxetine (N = 49)**	**Placebo (N = 47)**	**Paroxetine (N = 52)**	**Placebo (N = 55)**
Patients with AEs	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Total Patients with AEs	71 (70.3%)	62 (60.8%)	34 (69.4%)	30 (63.8%)	37 (71.2%)	32 (58.2%)
Headache	20 (19.8%)	20 (19.6%)	10 (20.4%)	7 (14.9%)	10 (19.2%)	13 (23.6%)
Nausea	13 (12.9%)	9 (8.8%)	6 (12.2%)	3 (6.4%)	7 (13.5%)	6 (10.9%)
Trauma	13 (12.9%)	8 (7.8%)	5 (10.2%)	5 (10.6%)	8 (15.4%)	3 (5.5%)
Respiratory disorder	11 (10.9%)	11 (10.8%)	5 (10.2%)	8 (17.0%)	6 (11.5%)	3 (5.5%)
Insomnia	11 (10.9%)	7 (6.9%)	3 (6.1%)	0	8 (15.4%)	7 (12.7%)
Somnolence	10 (9.9%)	7 (6.9%)	0	2 (4.3%)	10 (19.2%)	5 (9.1%)
Pharyngitis	8 (7.9%)	6 (5.9%)	1 (2.0%)	4 (8.5%)	7 (13.5%)	2 (3.6%)
Asthenia	7 (6.9%)	9 (8.8%)	3 (6.1%)	4 (8.5%)	4 (7.7%)	5 (9.1%)
Infection	7 (6.9%)	6 (5.9%)	5 (10.2%)	5 (10.6%)	2 (3.8%)	1 (1.8%)
Fever	7 (6.9%)	4 (3.9%)	3 (6.1%)	3 (6.4%)	4 (7.7%)	1 (1.8%)
Nervousness	6 (5.9%)	4 (3.9%)	2 (4.1.%)	1 (2.1%)	4 (7.7%)	3 (5.5%)
Sinusitis	6 (5.9%)	4 (3.9%)	3 (6.1%)	2 (4.3%)	3 (5.8%)	2 (3.6%)
Cough increased	6 (5.9%)	3 (2.9%)	3 (6.1%)	3 (6.4%)	3 (5.8%)	0
Dyspepsia	6 (5.9%)	3 (2.9%)	3 (6.1%)	2 (4.3%)	3 (5.8%)	1 (1.8%)
Vomiting	6 (5.9%)	2 (2.0%)	3 (6.1%)	1 (2.1%)	3 (5.8%)	1 (1.8%)
Rhinitis	5 (5.0%)	3 (2.9%)	3 (6.1%)	3 (6.4%)	2 (3.8%)	0
Dizziness	5 (5.0%)	1 (1.0%)	2 (4.1%)	1 (2.1%)	3 (5.8%)	0
Abdominal pain	4 (4.0%)	3 (2.9%)	4 (8.2%)	2 (4.3%)	0	1 (1.8%)
Otitis media	4 (4.0%)	2 (2.0%)	0	1 (2.1%)	4 (7.7%)	1 (1.8%)
Sweating	4 (4.0%)	0	1 (2.0%)	0	3 (5.8%)	0
Contact dermatitis	3 (3.0%)	0	0	0	3 (5.8%)	0

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

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

Overall, AEs tended to be mild to moderate in intensity. Table 45 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, non-gender-specific severe AEs were reported in 8/101 patients (7.9%) in the paroxetine group and 4/102 patients (3.9%) in the placebo group. The only severe AEs occurring in more than one patient were trauma (3/101, 3.0% of patients in the paroxetine-treated group and 1/102, 1.0%, of patients in the placebo group) and migraine (2/102, 2.0% of patients in the placebo group). No severe gender-specific AEs occurred in either treatment group.

Table 45 Treatment Phase-emergent Severe Adverse Events–Age Group: Total (ITT Population)

	Treatment Group			
	Paroxetine (N = 101)		Placebo (N = 102)	
AE Preferred Term	**n**	**(%)**	**n**	**(%)**
Total	8	(7.9%)	4	(3.9%)
Trauma	3	(3.0%)	1	(1.0%)
Cystitis	1	(1.0%)	0	—
Headache	1	(1.0%)	0	—
Hostility	1	(1.0%)	0	—
Nervousness	1	(1.0%)	0	—
Urticaria	1	(1.0%)	0	—
Migraine	0	—	2	(2.0%)
Emotional lability	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

None of the severe AEs were considered by the investigator to be related to study medication except for a report of severe headache in a patient in the paroxetine group, which was deemed 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 46 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, 48/101 (47.5%) patients in the paroxetine group were reported to have at least one non-gender-specific AE related or possibly related to the use of study medication, compared to 36/102 (35.3%) patients in the placebo group. One male and one female in the paroxetine group each reported one gender-specific AE reported to be related or possibly related to study medication (impotence and menstrual disorder, respectively). The most frequent AEs reported to be related or possibly related to study medication in the paroxetine group were headache, nausea, somnolence, and insomnia. Of these, only insomnia had an incidence in the paroxetine group (10/101, 9.9%) that approached twice that in the placebo group (6/102, 5.9%).

One patient on paroxetine had a severe AE that was considered possibly related to study medication. Patient 701.158.25644, a 16-year-old male with a history of headache, had 3 occurrences of headache, each with a duration of one day, during the course of the study. Two instances were considered mild and probably unrelated, and one was considered severe and possibly related. The patient completed the study as planned.

Table 46 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 (N = 101)	Placebo (N = 102)
Adverse Event	**n (%)**	**n (%)**
Age Group: Total		
Total Patients with a related or possibly related AE	48 (47.5%)	36 (35.3%)
Headache	11 (10.9%)	12 (11.8%)
Nausea	11 (10.9%)	9 (8.8%)
Somnolence	10 (9.9%)	7 (6.9%)
Insomnia	10 (9.9%)	6 (5.9%)
Asthenia	5 (5.0%)	7 (6.9%)
Nervousness	5 (5.0%)	3 (2.9%)
Dizziness	5 (5.0%)	1 (1.0%)
Age Group: Children	(N = 49)	(N = 47)
Total Patients with a related or possibly related AE	21 (42.9%)	13 (27.7%)
Headache	5 (10.2%)	4 (8.5%)
Nausea	5 (10.2%)	3 (6.4%)
Abdominal pain	3 (6.1%)	1 (2.1%)
Dyspepsia	3 (6.1%)	1 (2.1%)
Insomnia	3 (6.1%)	0
Asthenia	2 (4.1%)	3 (6.4%)
Age Group: Adolescents	(N = 52)	(N = 55)
Total Patients with a related or possibly related AE	27 (51.9%)	23 (41.8%)
Somnolence	10 (19.2%)	5 (9.1%)
Insomnia	7 (13.5%)	6 (10.9%)
Headache	6 (11.5%)	8 (14.5%)
Nausea	6 (11.5%)	6 (10.9%)
Nervousness	4 (7.7%)	3 (5.5%)
Asthenia	3 (5.8%)	4 (7.3%)
Dizziness	3 (5.8%)	0
Sweating	3 (5.8%)	0

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

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

Table 47 summarizes 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. Table 15.1.6.1.X, Section 13, presents the time of first occurrence for all Treatment Phase-emergent AEs, categorized by body system.

The time to first occurrence for many of the common AEs in both treatment groups was within the initial 1 to 2 weeks of study medication. Trauma, pharyngitis, and infection (paroxetine patients) and respiratory disorder (placebo patients) were notable exceptions, occurring with greater frequency at or after Week 4 than before.

Table 47 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, n (%)	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 6**	**Week 8**	**Post-Week 8**	**Total**
Paroxetine (N = 101)								
Headache	9 (8.9%)	6 (5.9%)	3 (3.0%)	2 (2.0%)	0	0	0	20 (19.8%)
Nausea	7 (6.9%)	0	2 (2.0%)	1 (1.0%)	1 (1.0%)	2 (2.0%)	0	13 (12.9%)
Trauma	3 (3.0%)	0	3 (3.0%)	1 (1.0%)	4 (4.0%)	2 (2.0%)	0	13 (12.9%)
Insomnia	5 (5.0%)	2 (2.0%)	2 (2.0%)	1 (1.0%)	1 (1.0%)	0	0	11 (10.9%)
Respiratory Disorder	4 (4.0%)	2 (2.0%)	2 (2.0%)	2 (2.0%)	1 (1.0%)	0	0	11 (10.9%)
Somnolence	2 (2.0%)	2 (2.0%)	2 (2.0%)	4 (4.0%)	0	0	0	10 (9.9%)
Pharyngitis	1 (1.0%)	0	2 (2.0%)	1 (1.0%)	1 (1.0%)	3 (3.0%)	0	8 (7.9%)
Asthenia	3 (3.0%)	0	2 (2.0%)	2 (2.0%)	0	0	0	7 (6.9%)
Fever	2 (2.0%)	2 (2.0%)	1 (1.0%)	0	1 (1.0%)	1 (1.0%)	0	7 (6.9%)
Infection	1 (1.0%)	1 (1.0%)	0	1 (1.0%)	2 (2.0%)	2 (2.0%)	0	7 (6.9%)
Cough Increased	3 (3.0%)	1 (1.0%)	0	1 (1.0%)	1 (1.0%)	0	0	6 (5.9%)
Dyspepsia	3 (3.0%)	1 (1.0%)	0	1 (1.0%)	1 (1.0%)	0	0	6 (5.9%)
Nervousness	3 (3.0%)	1 (1.0%)	0	1 (1.0%)	1 (1.0%)	0	0	6 (5.9%)
Sinusitis	3 (3.0%)	1 (1.0%)	1 (1.0%)	1 (1.0%)	0	0	0	6 (5.9%)
Vomiting	1 (1.0%)	1 (1.0%)	3 (3.0%)	0	1 (1.0%)	0	0	6 (5.9%)
Dizziness	2 (2.0%)	0	1 (1.0%)	2 (2.0%)	0	0	0	5 (5.0%)
Rhinitis	2 (2.0%)	1 (1.0%)	1 (1.0%)	1 (1.0%)	0	0	0	5 (5.0%)

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

Table 48 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, n (%)	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 6**	**Week 8**	**Post-Week 8**	**Total**
Placebo (N = 102)								
Headache	12 (11.8%)	1 (1.0%)	1 (1.0%)	4 (3.9%)	0	2 (2.0%)	0	20 (19.6%)
Respiratory disorder	2 (2.0%)	1 (1.0%)	0	4 (3.9%)	3 (2.9%)	1 (1.0%)	0	11 (10.8%)
Asthenia	6 (5.9%)	0	1 (1.0%)	0	2 (2.0%)	0	0	9 (8.8%)
Nausea	6 (5.9%)	1 (1.0%)	2 (2.0%)	0	0	0	0	9 (8.8%)
Trauma	0	3 (2.9%)	3 (2.9%)	0	1 (1.0%)	1 (1.0%)	0	8 (7.8%)
Insomnia	5 (4.9%)	0	1 (1.0%)	0	1 (1.0%)	0	0	7 (6.9%)
Somnolence	6 (5.9%)	0	0	1 (1.0%)	0	0	0	7 (6.9%)
Pharyngitis	4 (3.9%)	0	1 (1.0%)	0	0	1 (1.0%)	0	6 (5.9%)
Infection	0	1 (1.0%)	2 (2.0%)	0	2 (2.0%)	1 (1.0%)	0	6 (5.9%)
Fever	0	1 (1.0%)	0	1 (1.0%)	1 (1.0%)	1 (1.0%)	0	4 (3.9%)
Cough Increased	1 (1.0%)	0	0	0	2 (2.0%)	0	0	3 (2.9%)
Dyspepsia	2 (2.0%)	0	1 (1.0%)	0	0	0	0	3 (2.9%)
Nervousness	2 (2.0%)	1 (1.0%)	0	1 (1.0%)	0	0	0	4 (3.9%)
Sinusitis	1 (1.0%)	1 (1.0%)	1 (1.0%)	0	0	0	0	4 (3.9%)
Vomiting	0	0	1 (1.0%)	1 (1.0%)	0	0	0	2 (2.0%)
Dizziness	0	0	0	0	1 (1.0%)	0	0	1 (1.0%)
Rhinitis	2 (2.0%)	0	1 (1.0%)	0	0	0	0	3 (2.9%)

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 49 presents the number (%) of patients 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. Nine of 101 patients (8.9%) in the paroxetine group had dose reductions due to an AE compared to 5/102 patients (4.9%) in the placebo group.

The only AE that led to a dose reduction in more than one patient in the paroxetine group was agitation (2/101, 2.0%), compared to no patients in the placebo group. In the placebo group, the only AE that led to a dose reduction in more than one patient was somnolence (2/102, 2.0%), compared to 1/101 patient (1.0%) in the paroxetine group.

AEs leading to dose reduction occurred with greatest frequency in the body system Nervous System. No patient had more than one dose reduction during the Treatment Phase.

Table 49 Treatment Phase-emergent Adverse Events That Led to Dose Reductions by Body System–Age Group: Total (ITT Population)

		Treatment Group	
Body system	**Preferred Term**	**Paroxetine (N = 101)**	**Placebo (N = 102)**
Total Patients with Dose Reductions		9 (8.9%)	5 (4.9%)
Nervous System	**Total**	6 (5.9%)	2 (2.0%)
	Agitation	2 (2.0%)	0
	Somnolence	1 (1.0%)	2 (2.0%)
	Dizziness	1 (1.0%)	0
	Hyperkinesia	1 (1.0%)	0
	Insomnia	1 (1.0%)	0
	Nervousness	1 (1.0%)	0
Digestive System	**Total**	2 (2.0%)	1 (1.0%)
	Nausea	1 (1.0%)	1 (1.0%)
	Vomiting	1 (1.0%)	0
Cardiovascular System	**Total**	1 (1.0%)	0
	Vasodilatation	1 (1.0%)	0
Skin and Appendages	**Total**	1 (1.0%)	1 (1.0%)
	Sweating	1 (1.0%)	0
	Pruritus	0	1 (1.0%)
Special Senses	**Total**	1 (1.0%)	0
	Abnormal vision	1 (1.0%)	0
Urogenital System	**Total**	1 (1.0%)	0
	Urination impaired	1 (1.0%)	0
	Impotence *	1 (1.9%)	0
Body as a Whole	**Total**	0	1 (1.0%)
	Asthenia	0	1 (1.0%)

* Percentage corrected for gender
Source: Table 15.1.8, Section 13; Listing 15.1.1, Appendix D

Table 50 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 were for AEs considered related or possibly related to study medication.

Table 50 Treatment-Phase Emergent Adverse Events That Led to Dose Reductions by Patient (ITT Population)

Patient No	Gender	Age	Dose Reduction From	Dose Reduction To	Adverse Event	Severity	Investigator Attribution to Study Medication
Paroxetine							
701.149.27654	M	14	40 mg	30 mg	Insomnia	Moderate	Related
701.158.25644	M	16	30 mg	20 mg	Somnolence	Moderate	Possibly Related
701.159.25748	M	17	20 mg	10 mg	Hyperkinesia	Mild	Possibly Related
			20 mg	10 mg	Urination impaired	Moderate	Possibly Related
			10 mg	0 mg	Impotence	Mild	Possibly Related
			20 mg	10 mg	Nervousness	Moderate	Possibly Related
701.162.25601	F	17	30 mg	20 mg	Agitation	Moderate	Possibly Related
701.162.25789	F	8	40 mg	30 mg	Nausea	Mild	Possibly Related
701.178.25944	M	9	20 mg	10 mg	Agitation	Moderate	Possibly Related
701.180.25776	M	7	20 mg	10 mg	Dizziness	Mild	Possibly Related
					Abnormal Vision	Moderate	Possibly Related
701.186.25991	F	10	30 mg	20 mg	Vomiting	Mild	Possibly Related
701.192.25946	F	11	30 mg	20 mg	Vasodilatation	Moderate	Possibly Related
					Sweating	Moderate	Possibly Related
Placebo							
701.167.25693	F	16	DL 4	DL 3	Somnolence	Mild	Related
701.168.25807	F	14	DL 4	DL 3	Asthenia	Moderate	Possibly Related
701.169.25781	F	10	DL 2	DL 1	Pruritus	Mild	Possibly Related
701.170.25632	F	16	DL 3	DL 2	Nausea	Moderate	Related
701.186.25993	M	11	DL 2	DL 1	Somnolence	Mild	Possibly Related

Source: Table 15.1.8, Section 13; Listings 13.5.1, 13.14.1, 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 in a blinded fashion at the conclusion of the Treatment Phase unless they were at DL 1. The blind was not broken for patients entering the Taper Phase. The duration of treatment in the Taper Phase varied from 1 to 4 weeks depending on the dose level from which the patient would be down-titrated. No taper was required for patients at DL 1. See Section 3.5.3, Dosage and Administration, for details about down-titration. All patients, whether or not they completed the study and whether or not they required down-titration, were to return for a Follow-up visit 14 days after the last dose of study medication unless they entered open-label extension study 29060/716.

Of the 101 paroxetine patients in the Treatment Phase, 83 entered the Taper Phase and/or the Follow-up Phase. Of the 102 placebo patients in the Treatment Phase, 73 entered either the Taper Phase and/or the Follow-up Phase.

Table 51 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 non-gender-specific AEs during the Taper or Follow-up Phase were similar, 16/83 (19.3%) in the paroxetine group and 13/73 (17.8%) in the placebo group. The most common AEs in the paroxetine group were emotional lability and depression (3/83 patients each, 3.6%) and dizziness and nervousness (2/83 patients each, 2.4%). The most common AE in the placebo group was nausea (2/73 patients, 2.7%).

The only gender-specific AE reported during the Taper or Follow-up Phases was abnormal ejaculation, reported by one adolescent patient in the placebo group.

Taper or Follow-up Phase-emergent AEs may be found in Table 15.1.1.5, Section 13, (by body system and preferred term) and Table 15.1.1.5.X, Section 13, (by descending order and preferred term).

Table 51 Number (%) of Patients with the Most Frequent (≥2%) Taper or Follow-up Phase-emergent Adverse Events–Age Group: Total (ITT Population Entering the Taper or Follow-up Phase)

	Treatment Group	
AE Preferred Term	**Paroxetine (N = 83) n (%)**	**Placebo (N = 73) n (%)**
Total Patients with at Least One Non-Gender-Specific AE	16 (19.3%)	13 (17.8%)
Emotional lability	3 (3.6%)	1 (1.4%)
Depression	3 (3.6%)	0
Dizziness	2 (2.4%)	0
Nervousness	2 (2.4%)	0
Nausea	1 (1.2%)	2 (2.7%)
Male-Specific AEs	(N = 43)	(N = 41)
Abnormal ejaculation*	0	1 (2.4%)

N = number of patients entering the Taper Phase or Follow-up Phase
* Percentage corrected for gender
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 52 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, 8/55 patients in the paroxetine group (14.5%) and 10/62 patients in the placebo group (16.1%). No single event was experienced by more than one patient in either treatment group. No gender-specific Taper Phase-emergent AEs were reported.

Four AEs emerged during the Taper Phase that had not occurred in either treatment group during the Treatment Phase. In the paroxetine group, one patient (701.192.25946) had thrombocythemia, considered by the investigator to be unrelated to study medication; in the placebo group, one patient (701.180.25969) had palpitation and tachycardia, considered by the investigator to be possibly related to study medication, and one patient (701.165.25662) had syncope, considered by the investigator to be unrelated to study medication (Tables 15.1.1.1X and 15.1.1.2.X, Section 13; Listing 15.1.2, Appendix D). All were considered mild and non-serious.

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 in Section 13.

Table 52 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 = 55) n (%)**	**Placebo (N = 62) n (%)**
Total Patients with an AE	8 (14.5%)	10 (16.1%)
Allergic reaction	1 (1.8%)	0
Constipation	1 (1.8%)	0
Depression	1 (1.8%)	0
Emotional lability	1 (1.8%)	0
Infection	1 (1.8%)	0
Nervousness	1 (1.8%)	0
Otitis media	1 (1.8%)	0
Pharyngitis	1 (1.8%)	0
Thrombocythemia	1 (1.8%)	0
Anxiety	0	1 (1.6%)
Asthenia	0	1 (1.6%)
Bronchitis	0	1 (1.6%)
Cough increased	0	1 (1.6%)
Diarrhea	0	1 (1.6%)
Headache	0	1 (1.6%)
Hematuria	0	1 (1.6%)
Hyperkinesia	0	1 (1.6%)
Myalgia	0	1 (1.6%)
Nausea	0	1 (1.6%)
Palpitation	0	1 (1.6%)
Respiratory disorder	0	1 (1.6%)
Rhinitis	0	1 (1.6%)
Somnolence	0	1 (1.6%)
Syncope	0	1 (1.6%)
Tachycardia	0	1 (1.6%)
Withdrawal syndrome	0	1 (1.6%)

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 C.

Tables 15.1.4.2, Section 13, presents Taper Phase-emergent AEs that are related or possibly related to study medication by body system. Three patients in the paroxetine group and 4 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 53). No event judged to be related or possibly related to study medication was experienced by more than one patient in either treatment group.

Table 15.1.4.3, Section 13, presents patients with related or possibly related emergent adverse experiences during the Treatment Phase or Taper Phase by body system.

Table 53 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 = 55) n (%)	Placebo (N = 62) n (%)
Total patients with an AE	3 (5.5%)	4 (6.5%)
Constipation	1 (1.8%)	0
Depression	1 (1.8%)	0
Emotional lability	1 (1.8%)	0
Nervousness	1 (1.8%)	0
Anxiety	0	1 (1.6%)
Asthenia	0	1 (1.6%)
Diarrhea	0	1 (1.6%)
Headache	0	1 (1.6%)
Hyperkinesia	0	1 (1.6%)
Nausea	0	1 (1.6%)
Palpitation	0	1 (1.6%)
Somnolence	0	1 (1.6%)
Tachycardia	0	1 (1.6%)
Withdrawal syndrome	0	1 (1.6%)

N = number of patients entering the Taper Phase
Source: Table 15.1.4.2, Section 13; Listing 15.1.2, Appendix D

Tables 15.1.3.2 and 15.1.7.2, Section 13, present Taper Phase-emergent AEs by body system by intensity, and by maximum intensity, respectively. Table 15.1.3.2.X, Section 13, presents Taper Phase-emergent AEs by intensity by preferred term occurring in 1% or more of the population in descending order. Tables 15.1.3.3 and 15.1.7.3, Section 13, present patients with emergent adverse experiences during the Treatment Phase or Taper Phase by intensity by body system, and by maximum intensity, respectively.

Only one patient had a Taper Phase-emergent AE that was considered severe by the investigator. Patient 701.163.25718, in the paroxetine group, had a Taper Phase-emergent AE of emotional lability judged to be severe and also an SAE (see Section 6.4, Serious Adverse Events).

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. Forty-six paroxetine patients and 30 placebo patients entered the Follow-up Phase. Fifty patients in the paroxetine group and 63 patients in the placebo group did not have a Follow-up Visit because they entered the open-label extension study.

Of the 76 patients who entered the Follow-up Phase, 9 patients in the paroxetine group (19.6%) and 3 patients in the placebo group (10.0%) had an AE during the Follow-up Phase (Table 54). Emotional lability, depression, and dizziness were each experienced by 2 patients in the paroxetine group; no other AEs were experienced by more than one patient in either treatment group. In both treatment groups, half the total number of AEs were in the body system Nervous System. 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.

Five AEs that emerged during the Follow-up Phase had not occurred in either treatment group during the Treatment or Taper Phase: hypertension, manic depression, and psychosis in the paroxetine group and glycosuria and abnormal ejaculation in the placebo group (Tables 15.1.1.1X, 15.1.1.2.X, and 15.1.1.4.X, Section 13). The manic depressive reaction, the hypertension, and the abnormal ejaculation were considered related or possibly related to the use of study medication (Table 15.1.4.4, Section 13). The hypertension was also considered severe (Tables 15.1.3.4 and 15.1.3.4.X, Section 13).

Table 54 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 = 46) n (%)**	**Placebo (N = 30) n (%)**
Total Patients with an AE	9 (19.6%)	3 (10.0%)
Emotional lability	2 (4.3%)	1 (3.3%)
Depression	2 (4.3%)	0
Dizziness	2 (4.3%)	0
Nausea	1 (2.2%)	1 (3.3%)
Abnormal vision	1 (2.2%)	0
Anemia	1 (2.2%)	0
Arthralgia	1 (2.2%)	0
Headache	1 (2.2%)	0
Hypertension	1 (2.2%)	0
Manic depressive reaction	1 (2.2%)	0
Nervousness	1 (2.2%)	0
Psychosis	1 (2.2%)	0
Rash	1 (2.2%)	0
Respiratory disorder	1 (2.2%)	0
Somnolence	1 (2.2%)	0
Sweating	1 (2.2%)	0
Tachycardia	1 (2.2%)	0
Trauma	1 (2.2%)	0
Tremor	1 (2.2%)	0
Agitation	0	1 (3.3%)
Glycosuria	0	1 (3.3%)
Male-Specific AEs	N = 25	N = 17
Abnormal Ejaculation *	0	1 (5.9%)

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

Three patients in the paroxetine group had a total of 12 AEs among them during the Follow-up Phase that were considered by the investigator to be related or possibly related to study medication. One patient in the placebo group had 2 AEs during the Follow-up Phase judged by the investigator to be related or possibly related to study medication; these events were nausea and abnormal ejaculation. 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.

Three patients in the paroxetine group had a total of 4 Follow-up Phase-emergent AEs that were judged by the investigator to be severe in intensity, compared to no patients in the placebo group. No severe AE was experienced in the Follow-up Phase by more than one patient. Severe AEs emergent in the Follow-up Phase may be found in Table 15.1.3.4, Section 13, by body system, and in Table 15.1.3.4.X, Section 13, ordered by preferred term occurring in 1% or more

of the population in descending order. Table 15.1.7.4 presents Follow-up Phase-emergent AEs by maximum intensity by body system.

6.3 Deaths

No deaths were reported to the sponsor 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 adverse event (SAE) was defined as any event that 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 that the investigator regarded as serious or that suggested any significant hazard, contraindication, side effect or precaution that may have been associated with the use of the drug was documented as a serious event. Important medical events that may not result in death, be life-threatening, or require hospitalization could be considered an SAE when, based upon appropriate medical judgment, they jeopardized the patient or patients and required medical or surgical intervention to prevent one of the outcomes listed in this definition.

Six patients (5.8%) of all 104 patients randomized to paroxetine reported 8 SAEs during the Treatment Phase or within 30 days post-therapy compared to 1 placebo patient (1.0%). Emotional lability and depression each occurred in 3 patients in the paroxetine group, and emotional lability occurred in 1 patient in the placebo group as well. All other SAEs occurred in one patient each. No gender-specific SAEs were reported for either treatment group. Table 55 presents all SAEs occurring at any time post-randomization.

[6] 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.

Table 55 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 = 104)	**Placebo (N = 102)**
SAE Preferred Term	n (%)	n (%)
Total Patients with an SAE *	6 (5.8%)	1 (1.0%)
Emotional lability	3 (2.9%)	1 (1.0%)
Depression	3 (2.9%)	0
Trauma	1 (1.0%)	0
Hypertension	1 (1.0%)	0

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

In addition, 1 patient had an SAE during the Pre-treatment Phase of the study (Listing 15.1.3.1, Appendix D). Patient 701.162.25786, an 11-year-old female, was hospitalized for severe depression after Screening. The patient was treated with prescription paroxetine 10 mg once daily, and the event resolved 3 days later. This patient was not randomized into the study. A narrative for this patient may be found in Table 15.1.2, Section 13.

Table 56 presents a listing of all patients with an SAE occurring at any time post-randomization.

Four paroxetine patients were withdrawn from the study due to an SAE, although in all cases the SAE was considered unrelated to study medication.

Patient 701.180.25639, a 15-year-old female, was randomized to paroxetine and was titrated up to 30 mg. The patient stopped taking study medication on Day 51; no reason has been provided. Two days later, the patient reportedly took 12 Extra Strength Tylenol (paracetamol) and half a bottle of Tylenol Cold medicine (chlorpheniramine/pseudoephedrine/dextromethorphan/acetaminophen), and she also cut open her arm. The patient was hospitalized in intensive care and underwent stomach lavage. Treatment included prescription paroxetine and trazodone. The emotional lability was reported to have resolved in 1 day, and the arm lacerations in 43 days.

Patient 701.182.25818, a 9-year-old male, was randomized to paroxetine. He was titrated up to 20 mg per day at the Week 1 visit, but was admitted to the hospital

4 days later for an exacerbation of depressive symptoms, and it was not known at that time whether the patient had continued to take study medication. The event was reported to be resolved 9 days later. Several weeks later, the bottle of tablets was returned to the investigator with 4 days' worth of tablets missing, indicating compliance at 20 mg per day up until the day of the AE.

Patient 701.185.25963, an 11-year-old male, was randomized to paroxetine and was titrated up to 30 mg per day. The patient stopped taking study medication on Day 28; no reason has been provided. Two days later, the patient threatened to harm himself and was hospitalized with an acute exacerbation of major depressive disorder. The event was reported to be resolved after 6 days.

Patient 701.185.25965, a 10-year-old female, was randomized to paroxetine and was titrated up to 30 mg per day. On Day 20, the patient was hospitalized after a 5-day history of extreme uncontrolled aggression and was diagnosed with exacerbation of symptoms of major depressive disorder. The patient was treated with 2.5 mg olanzapine and 20 mg paroxetine. The event was reported to be resolved 7 days later.

Two patients randomized to paroxetine had SAEs after withdrawal from the study.

Patient 701.163.25718, a 16-year-old female, was randomized to paroxetine and was titrated up to 50 mg per day. The patient was withdrawn from the study on Day 41 due to lack of efficacy and 100 10-mg tablets of the taper study medication were dispensed. The next day, she claimed to have ingested all the taper medication after a fight with her mother, and she was taken to the emergency room. Her pulse was 100, with a blood pressure of 140/104. A urine drug screen was administered, which was found to be negative for approximately 700 compounds, including paroxetine and other antidepressants. No explanation has been provided as why the drug screen did not show any paroxetine after the patient reportedly ingested one gram of paroxetine. The possibility that the patient did not actually take 100 tablets of paroxetine cannot be discounted. The drug screen was positive for caffeine in an unspecified amount. The blind was broken prior to the patient's admission to an inpatient psychiatric unit. The investigator considered the overdose and hypertension to be related to treatment with study medication.

Patient 701.183.27620, an 11-year-old female, was randomized to paroxetine and was titrated up to 20 mg. The patient did not return for the Week 3 visit and was considered lost to follow-up. On Day 20, 4 days after the last known dose of

study medication, the patient was admitted to the hospital for suicidal ideation, although the patient's mother thought that her daughter was "attention seeking." The investigator considered this event to be mild and to be unrelated to treatment with study medication.

One placebo patient was withdrawn from the study due to an SAE. Patient 701.154.25768, a 13-year-old male, was randomized to placebo. Five days later, the patient drove his parent's car and had an accident. The patient was hospitalized for emotional lability (verbatim: suicidality) and was withdrawn from the study. Four days later, the event resolved, and the patient was discharged from the hospital to a juvenile detention center. The investigator reported the event as moderately severe 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.

Table 56 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)	Verbatim Term (Enhanced Term)	Intensity	Relationship	Day of Onset *	Duration
Paroxetine								
701.163.25718	16	F	Emotional lability	Overdose (intentional) **	Severe	Related	Day 42 (1)	6 days
			Hypertension	Hypertension (secondary to overdose)	Severe	Related	Day 43 (2)	1 day
701.180.25639	15	F	Emotional lability	Overdose (intentional) †, ††	Severe	Unrelated	Day 53 (2)	1 day
			Trauma	Arm lacerations †, ††	Severe	Unrelated	Day 53 (2)	43 days
701.182.25818	9	M	Depression	Exacerbation of depressive symptoms ††	Severe	Unrelated	Day 12 (2) ‡	10 days
701.183.27620	11	F	Emotional lability	Suicidal ideation	Mild	Unrelated	Day 20 (4)	6 days
701.185.25963	11	M	Depression	Acute exacerbation of MDD ††	Moderate	Unrelated	Day 30 (2)	6 days
701.185.25965	10	F	Depression	Exacerbation of symptoms of MDD ††	Moderate	Unrelated	Day 20 (0)	7 days
Placebo								
701.154.25768	13	M	Emotional lability	Suicidality ††	Moderate	Unrelated	Day 6 (1)	5 days

* 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 listed as having withdrawn from study medication due to an AE; patient had withdrawn the previous day due to lack of efficacy. See Errata, Table 16.0, Section 15.
† AE was incorrectly coded as post-therapy. Patient had been non-compliant for 2 days prior to the AE but was still considered on therapy. See Errata, Table 16.0, Section 15.
†† Patient was withdrawn from the study because of this AE.
‡ At the time of the AE, it was unknown how much study medication the patient had taken, and the last day of study medication defaulted to the day of the last visit. The patient's mother subsequently returned the unused portion, a count of which indicated that the patient had taken study medication every day until the day of the AE.
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 9/101 paroxetine patients (8.9%) and 2/102 placebo patients (2.0%) were withdrawn from the study because of one or more AEs. Table 57 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.

The only AEs leading to withdrawal that occurred in more than 1 patient in the same treatment group for both age groups combined were depression, experienced by 4 patients in the paroxetine group, and emotional lability, experienced by 1 patient in the paroxetine group and 2 patients in the placebo group. Nervousness was experienced by 1 patient in each treatment group. All other AEs leading to withdrawal were each experienced by a single patient (Table 58).

Complete narratives for patients with AEs leading to withdrawal may be found in Table 15.1.5, Section 13.

Table 57 Number (%) of Patients Withdrawn for at Least One AE Regardless of Treatment Attribution–Age Group: Total (ITT Population)

	Treatment Group			
	Paroxetine (N = 101)		Placebo (N = 102)	
Adverse Events by Preferred Term	**n**	**(%)**	**n**	**(%)**
Total Patients with an AE Leading to Withdrawal	9 *†	(8.9%)	2 †	(2.0%)
Depression	4 †	(4.0%)	0	
Emotional Lability	1 * †	(1.0%)	2 †	(2.0%)
Agitation	1	(1.0%)	0	
Epistaxis	1	(1.0%)	0	
Hostility	1	(1.0%)	0	
Pyelonephritis	1	(1.0%)	0	
Nervousness	1	(1.0%)	1	(1.0%)
Insomnia	0		1	(1.0%)

Note: A patient may have more than one AE leading to withdrawal.
* Patient 701.163.25718, in the paroxetine group, was incorrectly coded as having withdrawn from study medication due to an AE of emotional lability. This AE occurred during the Taper Phase. See Errata, Table 16.0, Section 15. This patient is not included in this table.
† Three additional patients (701.180.25639 and 701.182.25818 in the paroxetine group and 701.154.25768 in the placebo group) were withdrawn due to adverse events (emotional lability, depression and emotional lability, respectively) that occurred one or more days after the last dose of study medication, and do not appear in the source table. See Errata, Table 16.0, Section 15. These patients are reflected in this table.
Source: Table 15.1.5.1.X, Section 13; Listing 15.1.4, Appendix D. Table 15.1.5.1.X reflects all Treatment-Phase emergent AEs for these patients, not just the AEs that led to withdrawal.

Table 58 presents per-patient information about patients withdrawn from the study due to an AE. Seven of the 11 patients withdrawn were children, all in the paroxetine group. All but 1 of the AEs leading to withdrawal (14/15) were considered moderate or severe in intensity, and 7 of these 14 moderate or severe AEs were considered by the investigator to be related or possibly related to study medication.

Four patients in the paroxetine group and 1 in the placebo group experienced a serious AE that led to withdrawal (Table 58). Detailed narratives for these patients may be found in Table 15.1.2, Section 13. Four of these patients (701.180.25639, 701.182.25818 and 701.185.25963 in the paroxetine group and 701.154.25768 in the placebo group) were withdrawn due to adverse events that occurred one or more days after the last dose of study medication, these AEs do not appear in Table 15.1.5.1, Section 13 (Patient 701.185.25963 is included as the patient had an on-treatment AE); patients 701.180.25639, and 701.154.25768 do not appear in Listing 15.1.4, Appendix D. However, Table 13.3.1b, Number (%) of Randomized Patients Who Completed the Study or Were Withdrawn (by reason), shows that these patients were withdrawn from the study due to an adverse event. See Errata, Table 16.0, Section 15.

Five patients in the paroxetine group experienced non-serious AEs that led to withdrawal from the study. Patient 701.148.27660, a 9-year-old male, experienced severe hostility (increased aggression) on Day 2 that lasted for 32 days. The dose was increased on Day 15 to 20 mg per day, but the hostility did not diminish and the patient was withdrawn from the study on Day 30. The investigator considered the AE to be possibly related to treatment with study medication. Patient 701.149.27665, a 9-year-old female, was titrated up to a dose of 30 mg per day. On Day 16, the patient experienced moderately severe epistaxis (nose bleed) that resolved within 4 days. The patient was withdrawn from the study on Day 17. The investigator considered the event to be related to treatment with study medication. Patient 701.161.25650, a 15-year-old female, was titrated up to a dose of 40 mg per day. On Day 44, the patient experienced moderately severe pyelonephritis. The patient was withdrawn from the study on Day 65. The pyelonephritis resolved within 28 days. This event was considered by the investigator to be unrelated to treatment with study medication. Patient 701.161.25653, an 8-year-old male, was titrated up to a dose of 50 mg per day. On Day 47, the patient experienced moderately severe agitation and nervousness (irritability) that continued beyond the end of the study. The patient was withdrawn from the study on Day 47. The investigator considered the events to

be possibly related to treatment with study medication. Patient 701.182.25816, an 8-year-old female, experienced a moderately severe exacerbation of depressive symptoms on Day 28. The dose was titrated up to 20 mg per day but the AE continued. The patient was withdrawn from the study on Day 34. The event was considered by the investigator to be probably unrelated to treatment with study medication.

One patient in the placebo group experienced a non-serious AE that led to withdrawal from the study. Patient 701.162.25970, a 17-year-old female, experienced severe emotional lability (mood swings) on Day 1. On Day 3, mild insomnia and moderately severe nervousness (restlessness) were reported. All three of these non-serious events resulted in withdrawal from the study on Day 7. The investigator considered all events to be possibly related to treatment with study medication.

Detailed narratives for patients with non-serious adverse events that led to withdrawal may be found in Table 15.1.5, Section 13.

Table 58 Patients Withdrawn from Study at Any Time Because of 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
Paroxetine								
701.148.27660	M	9	10 mg	Hostility (Increased Aggression)	Severe	Possibly Related	Day 2 (-28)	32 days
701.149.27665	F	9	30 mg	Epistaxis (Nose Bleed)	Moderate	Related	Day 16 (-1)	4 days
701.161.25650	F	15	40 mg	Pyelonephritis (Pyelonephritis)	Moderate	Unrelated	Day 44 (-21)	28 days
701.161.25653	M	8	50 mg	Agitation (Agitation/Irritable)	Moderate	Possibly Related	Day 47 (0)	Ongoing
				Nervousness (Agitation/Irritable)	Moderate	Possibly Related	Day 47 (0)	Ongoing
701.180.25639	F	15	30 mg	Emotional lability (Overdose [Intentional]) ** †	Severe	Unrelated	Day 53 (2)	1 day
701.182.25816	F	8	10 mg	Depression (Exacerbation of Depressive Symptoms)	Moderate	Probably Unrelated	Day 28 (-6)	Ongoing
701.182.25818	M	9	10 mg	Depression (Exacerbation of Depressive symptoms) †	Moderate	Probably Unrelated	Day 11 (1)	1 day
				Depression (Acute Exacerbation of MDD) **	Severe	Unrelated	Day 12 (2)	10 days
701.185.25963	M	11	30 mg	Depression (Acute Exacerbation of MDD) ** †	Moderate	Unrelated	Day 30 (2)	6 days
701.185.25965	F	10	30 mg	Depression (Exacerbation of Symptoms of MDD) **	Moderate	Unrelated	Day 20 (0)	7 days
Placebo								
701.162.25970	F	17	DL 1	Emotional Lability (Mood Swings)	Severe	Possibly Related	Day 1 (-6)	9 days
				Insomnia (Insomnia)	Mild	Possibly Related	Day 3 (-4)	7 days
				Nervousness (Restlessness)	Moderate	Possibly Related	Day 3 (-4)	7 days
701.154.25768	M	13	DL 1	Emotional lability (Suicidality) ** †	Moderate	Unrelated	Day 6 (1)	5 days

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

** AE leading to withdrawal was considered to be a serious, nonfatal AE. AE is also listed in Section 6.4, Serious, Nonfatal Adverse Events, and in Table 56

† Patients 701.180.25639, 701.182.25818, and 701.185.25963 in the paroxetine group and 701.154.25768 in the placebo group were withdrawn due to adverse events that occurred one or more days after the last dose of study medication, and do not appear in the source table. See Errata, Table 16.0, Section 15.

Note: One additional patient (701.163.25718), in the paroxetine group, is listed in the source documents as having withdrawn due to an AE. However, the AE occurred after the patient was withdrawn from the study due to lack of efficacy. See Errata, Table 16.0, Section 15.

Source: Table 15.1.5.1, Section 13; Listings 13.5.1, 13.14.1, Appendix B, Listing 15.1.4, Appendix D

6.6 Medical Procedures

Elective therapeutic, diagnostic or surgical procedures that required hospitalization but were not the result of an AE, and were completed without complication as planned, were not to be considered as AEs and were to be recorded on the medical procedures page of the CRF. A listing of non-medication therapeutic, diagnostic or surgical procedures performed during this study may be found in Listing 15.5.1, Appendix D.

Of the 16 paroxetine patients (26 procedures) and the 9 placebo patients (12 procedures) in Listing 15.5.1, Appendix D, 3 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 AE.

Four patients in the paroxetine group (701.163.25718, 701.180.25639, 701.185.25963 and 701.185.25965) had medical procedures of diagnostic laboratory work and/or other diagnostic testing consequent to SAEs of hospitalization for depression or emotional lability. Detailed narratives for these patients may be found in Table 15.1.2, Section 13.

Patient 701.182.25818 is listed as having a medical procedure of hospitalization, which was consequent to an SAE of exacerbation of depressive symptoms. The hospitalization was not to have been considered a medical procedure. See Errata, Table 16.0, Section 15.

All other patients with medical procedures in both treatment groups had either non-routine dental work, treatment for injury, or diagnostic procedures for concurrent non-serious AEs.

6.7 Pregnancy

None of the randomized patients in this study had a positive serum HCG pregnancy test. No patient became pregnant during the course of the study (Listing PV11, Appendix B).

Two patients, 701.181.25825 and 701.171.25675, both 16-year-old females, had a positive serum HCG pregnancy test at screening. Neither patient was randomized into the study (Listing 15.3.1, Appendix F).

6.8 Vital Signs

6.8.1 Vital Signs of Potential Clinical Concern

The number of patients in each treatment group with values of BP, heart rate, and weight meeting clinical concern criteria predefined by the sponsor and with increases or decreases from Baseline meeting predefined criteria were tabulated. In addition, summary statistics for changes from Baseline for BP, heart rate, weight, height and body mass index (BMI) are presented by treatment group. Table 59 shows the pre-determined levels of potential clinical concern.

Table 59 Sponsor-Defined Vital Sign and Body Weight Values and Changes in Value of Clinical Concern

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

* 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 8 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. Vital signs by post-randomization treatment phase may be found in Tables 15.2.1.1, 15.2.1.2, and 15.2.2, Section 13; Listing 15.2.1, Appendix E.

Table 60 presents a summary of the number and percentage of patients within each treatment group with vital sign measurements meeting the predefined clinical concern criteria (i.e., both an absolute value of concern and a significant increase or decrease on therapy in the same direction). There were no important differences between the treatment groups in the number or the type of vital signs meeting this combination of clinical concern criteria.

Nine patients in the paroxetine group and 6 in the placebo group were identified as having an on-therapy change and absolute value in one or more of the vital signs that met the concern criteria. Two patients in each treatment group had more than one value of concern.

In the paroxetine group, patient 701.181.27687, an 8-year-old male, had a decrease at Week 2 in both systolic and diastolic blood pressure (from 96/51 mmHg at Screening and 120/89 mmHg at Baseline to 85/45 mmHg at Week 2) and at Week 3 in systolic only (80 mmHg) that met the criteria for potential clinical concern. No AE was reported in association with the low blood pressure; the patient was withdrawn at Week 3 for lack of efficacy. Patient 701.185.25965, a 10-year-old female, had a decrease at Week 3 in pulse rate (from 76 bpm at Screening and 92 bpm at Baseline to 62 bpm at Week 3) and an increase in weight (from 54.5 kg at Screening to 59.8 kg at Week 3) of clinical concern; the patient withdrew from study at that time due to an SAE of exacerbation of depression.

In the placebo group, patient 701.182.25817, an 8-year-old male, had a decrease in systolic blood pressure at Weeks 1 and 8 (from 110 mmHg at Screening and 118 mmHg at Baseline to 74 mmHg at Week 1 and 79 mmHg at Week 3) and a decrease in pulse at Week 8 (from 87 bpm at Screening and 107 bpm at Baseline to 61 bpm at Week 8) that were of clinical concern. No AEs were reported in association with these values, and the patient completed the study. Patient 701.159.25628, a 14-year-old male, had an increase in systolic blood pressure at Week 6 (from 112 mmHg at Screening and 100 mmHg at Baseline to 152 mmHg at Week 6) and an increase in weight at Week 8 (from 95.0 kg at Screening to 103.6 kg at Week 8) that were of clinical concern. The patient had elevated liver function values at Baseline, at Week 8, and at retest; none were elevated to the level of clinical concern but they were reported as AEs. No other AEs were reported in association with the vital sign values, and the patient completed the study.

Table 60 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 = 101)		Placebo (N = 102)	
Total Patients with a Vital Sign of Clinical Concern		9 (8.9%)		6 (5.9%)
Systolic BP (mmHg)				
>145, and increase ≥40	101	0	100	1 (1.0%)
<95, and decrease ≥30	101	1 (1.0%)	100	1 (1.0%)
Diastolic BP (mmHg)				
>85, and increase ≥30	101	2 (2.0%)	100	0
<50, and decrease ≥20	101	1 (1.0%)	100	2 (2.0%)
Pulse (bpm [beats per minute])				
Ages 7 to 12 >115, ages 13 to 17 >110, and increase ≥30	101	0	100	0
Ages 7 to 12 <65, ages 13 to 17, <55, and decrease ≥30	101	3 (3.0%)	100	2 (2.0%)
Weight (kg)				
Above normal range,* and increase ≥7%	68	3 (4.4%)	85	2 (2.4%)
Below normal range,* and decrease ≥7%	68	1 (1.5%)	85	0

N = Number of patients with Baseline and post-Baseline assessment
* Normal ranges for weight may be found in Table 59.
Source: Table 15.2.2, Section 13; Listing 15.2.1, Appendix E

One additional patient in the paroxetine group and 2 in the placebo group had vital signs meeting potential clinical concern criteria that do not appear in Table 60 or Table 15.2.2, Section 13, because they occurred one or more days after the last dose of study medication. In the paroxetine group, patient 701.178.25943, a 7-year-old female, had a low and significant decrease in pulse rate at Week 8 (1 day after completion of the study at DL 1); no AE was associated with these out-of-range values.

In the placebo group, patient 701.152.25614, a 13-year-old male, had a high and significant increase in diastolic blood pressure at Week 8 (5 days after the patient became non-compliant); no AE was associated with this out-of-range value. Patient 701.166.25710, a 14-year-old male, had a high and significant increase in weight at Week 8 (1 day after the last dose at DL 4). This patient also had glycosuria at Week 8 (see Section 6.9.3, Urinalysis Results). Vital signs for these patients appear in Listing 15.2.1, Appendix E.

Table 60 does not necessarily include all vital sign changes determined to be clinically significant by the investigator. 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. In no cases where the patient had vital signs of concern did the investigators report these changes or out-of-range values as an AE.

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.

Two patients had AEs associated with absolute values of clinical concern, but not changes in value of concern. Patient, 701.172.25619, a 10-year-old male in the paroxetine group, had an AE of mild cardiac disorders (Verbatim: systolic ejection murmur per physical exam) on Day 62, considered unrelated to study medication. The patient had absolute values of concern (but not changes of concern) of low systolic blood pressure at Baseline and post-Week 8, low pulse at Baseline, Week 2, and Week 4, and high weight at Baseline and Week 8. ECGs were normal at Baseline, Day 62, and Day 89 (Taper End). Patient 701.165.25662, a 15-year-old male in the placebo group, had an AE of mild syncope (Verbatim: fainted) on day 55 (6 days after the last dose of study medication), considered unrelated to study medication. The patient had absolute values of concern (but not changes of concern) of low systolic blood pressure at Week 4, high diastolic at Week 6, low pulse at Week 4 and an unscheduled visit at Week 7.

6.8.2 Changes in Vital Signs

Table 61 presents a summary of BP, pulse and body weight values at Baseline and change from Baseline at Week 8. Data are included in the summary for those patients who had a value both at Baseline and at Week 8. Slightly fewer than half the patients in the paroxetine group and approximately 70% 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 generally comparable between groups.

Table 61 Mean Change from Baseline to Week 8 in Vital Signs, Weight, and BMI–Age Group: Total (ITT Population)

	Treatment Group			
	Paroxetine (N = 101)		Placebo (N = 102)	
Vital Sign	**N**	**Mean (SD)**	**N**	**Mean (SD)**
Systolic BP (mmHg)				
Baseline	101	108.0 (11.77)	102	107.7 (11.73)
Change at Week 8	49	2.5 (10.31)	72	1.1 (11.35)
BP Diastolic (mmHg)				
Baseline	101	68.1 (8.36)	102	68.1 (10.05)
Change at Week 8	49	1.7 (9.53)	72	0.0 (8.26)
Pulse (bpm)				
Baseline	101	81.6 (12.23)	102	77.9 (11.87)
Change at Week 8	49	0.1 (11.66)	72	1.5 (12.03)
Weight (kg)				
Baseline	101	58.2 (23.63)	102	55.5 (22.40)
Change at Week 8	47	0.7 (2.10)	71	0.92 (1.74)
BMI (kg/m^2)				
Baseline	101	24.1 (6.98)	102	22.9 (6.22)
Change at Week 8	47	0.1 (0.84)	71	0.1 (1.02)

N = patients who had a value both at Baseline and at Week 8
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 62 shows these values.

Table 62 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	<0.531 or >4.428
Monocytes		$x10^{9}$/L	>1.375
Basophils		$x10^{9}$/L	>0.40
Eosinophils		$x10^{9}$/L	>0.7865
Neutrophils		$x10^{9}$/L	<1.575 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 8 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 Treatment Phase if the patient did enter the Taper Phase. Laboratory values by post-randomization treatment phase may be found in Tables 15.3.1.1, 15.3.1.2, 15.3.1.3, 15.3.2, 15.3.4, 15.3.5.2, 15.3.5.3, and 15.3.6, Section 13; Listings 15.3.1, 15.3.2, and 15.3.3, Appendix F.

Table 63 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. Pre-treatment laboratory values of potential clinical concern may be found in Table 15.3.1.1, Section 13.

A maximum of 67 patients in the paroxetine group and 80 patients in the placebo group had at least one laboratory assessment for any parameter during the

Treatment or Taper Phase. A total of 10 patients in the paroxetine group and 12 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 63). The most common value of concern was decreased hematocrit (8 patients in the paroxetine group and 7 patients in the placebo group); of these, 4 paroxetine patients and 1 placebo patient had low hematocrit at Screening (Listing 15.3.1, Appendix F). The only other laboratory parameter for which more than one patient in either treatment group had a value of concern was low neutrophils (3 patients in the paroxetine group and 5 patients in the placebo group); of these, 1 placebo patient had low neutrophils at Screening.

Table 63 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)

		Treatment Group			
Laboratory Parameter		**Paroxetine**		**Placebo**	
Patients with at least one value of clinical concern	**High/Low**	**N**	**n (%)**	**N**	**n (%)**
		101	10 (9.9%)	102	12 (11.8%)
Hemoglobin	Low	66	1 (1.5%)	76	0
Hematocrit	Low	66	8 (12.1%)	76	7 (9.2%)
WBC	Low	66	0	76	1 (1.3%)
Neutrophils, Absolute	Low	66	3 (4.5%)	76	5 (6.6%)
Eosinophils	High	66	0	76	1 (1.3%)
Potassium	High	67	0	80	1 (1.3%)

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

For laboratory assessments, baseline data is the last pre-treatment assessment. Patients whose only laboratory assessment after Baseline occurred after the last dose of treatment or taper medication were considered to have a Follow-up Phase assessment, and do not appear in the Treatment or Taper Phase laboratory table. Sixteen patients in the paroxetine group and 8 patients in the placebo group had laboratory assessments categorized in this way (Table 15.3.1.3, Section 13). Of these patients, 6 paroxetine patients and 2 placebo patients had laboratory values meeting the sponsor's predefined criteria for clinical concern. In the paroxetine group, patient 701.185.25963 had low hemoglobin; patients 701.152.25613, 701.165.25661, and 701.178.25943 had low hematocrit; patient 701.184.25955 had low neutrophils; and patient 701.178.25943 had high lymphocytes. In the placebo group, patients 701.151.25609 and 701.172.25623 had low hematocrit (Listing 15.3.1, 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. Detailed narratives for patients with a laboratory value meeting potential clinical concern criteria and with an AE that is related to that laboratory parameter are presented in Table 15.3.1.2.1, Section 13.

Table 63 does not necessarily include values determined by the investigator to be clinically significant. If a laboratory finding was judged to be clinically significant by the investigator, the finding was to be recorded as an AE in the CRF. For patients identified in Table 63, 4 patients had a laboratory value reported as an AE. In the paroxetine group, one patient (701.170.25633) had decreased hemoglobin and hematocrit at Screening and Week 8, with AEs of mild abnormal erythrocytes and moderate anemia reported at Day 55, considered by the investigator to be unrelated to study medication. In the placebo group, 3 patients had laboratory values of concern reported as an AE. Patient 701.185.25964 had decreased hematocrit on Day 56, with mild hematuria reported with an onset of Day 63, considered by the investigator to be unrelated to study medication. Patient 701.153.25698 had decreased neutrophils and an AE of mild leukopenia reported at Week 8, considered by the investigator to be possibly related to study medication. Patient 701.164.25831 had decreased neutrophils at Screening and Week 8, and an AE of moderate leukopenia reported on Day 56, considered by the investigator to be possibly related to study medication.

Abnormal findings at Follow-up may be found in Table 15.3.1.3, Section 13.

6.9.2 Changes in Laboratory Values

Table 64 presents descriptive statistics (means, standard deviations, and ranges) for Baseline, Week 8, endpoint (last on-therapy assessment including Taper Phase), and change at endpoint for each of the laboratory parameters monitored during the study. The treatment groups were comparable at Baseline and there were no substantial differences between the paroxetine and the placebo groups at Week 8, at endpoint, or in the change from Baseline at endpoint.

Three patients in each treatment group had thyroid tests conducted at endpoint, which was not required by the protocol (See Errata, Table 16.0, Section 15). One patient (701.186.27667) in the placebo group who was accepted into the study with an out-of-range TSH value of 11.7 mu/L at Baseline (reference range 0.4–5.5 mu/L) had an in-range TSH value of 3.6 mu/L at Week 8.

Table 64 Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 101) N	Mean	(SD)	Range	Placebo (N = 102) N	Mean	(SD)	Range
Hemoglobin (g/L)								
Baseline	101	132.7	(12.32)	102.0 to 173.0	100	132.5	(11.14)	111.0 to 162.0
Week 8	57	133.8	(11.23)	107.0 to 164.0	70	130.4	(9.46)	109.0 to 159.0
Endpoint	66	132.6	(11.28)	107.0 to 164.0	76	130.6	(10.04)	109.0 to 159.0
Change at Endpoint	66	-0.8	(5.81)	-11.0 to 16.0	74	-1.1	(6.54)	-24.0 to 13.0
Hematocrit (%)								
Baseline	101	39.7	(3.63)	31.2 to 52.5	100	39.5	(3.48)	32.7 to 48.8
Week 8	57	40.0	(3.15)	32.9 to 48.7	70	38.6	(3.01)	30.7 to 47.6
Endpoint	66	39.6	(3.29)	32.9 to 48.7	76	38.7	(3.07)	30.7 to 47.6
Change at Endpoint	66	-0.3	(2.20)	-5.9 to 5.7	74	-0.6	(2.55)	-9.4 to 7.3
RBC Count (10^{12}/L)								
Baseline	101	4.64	(0.359)	3.5 to 5.5	100	4.58	(0.392)	3.7 to 5.6
Week 8	57	4.69	(0.324)	4.1 to 5.6	70	4.52	(0.355)	3.7 to 5.3
Endpoint	66	4.65	(0.333)	4.0 to 5.6	76	4.51	(0.343)	3.7 to 5.3
Change at Endpoint	66	-0.04	(0.231)	-0.6 to 0.6	74	-0.04	(0.263)	-0.8 to 0.7
WBC (10^{9}/L)								
Baseline	101	7.05	(1.977)	3.9 to 14.9	100	6.73	(1.637)	3.8 to 13.2
Week 8	57	6.88	(1.709)	3.9 to 11.0	70	6.59	(1.861)	2.5 to 12.7
Endpoint	66	6.76	(1.721)	3.7 to 11.0	76	6.72	(1.699)	4.1 to 12.7
Change at Endpoint	66	-0.32	(1.611)	-6.0 to 3.4	74	-0.09	(1.419)	-3.2 to 5.0

Baseline = last pre-treatment assessment
Endpoint = last on-therapy assessment (including Taper Phase)
Source: Table 15.3.6, Section 13; Listing 15.3.1 and 15.3.2, Appendix F

(Table continues)

Table 64 (Continued) Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 101) N	Mean	(SD)	Range	Placebo (N = 102) N	Mean	(SD)	Range
Platelets (10^9/L)								
Baseline	101	294.0	(60.61)	159.0 to 455.0	100	279.4	(64.67)	94.0 to 468.0
Week 8	57	286.1	(63.25)	186.0 to 444.0	70	277.1	(54.13)	162.0 to 413.0
Endpoint	66	285.9	(60.66)	186.0 to 444.0	76	279.8	(58.38)	150.0 to 457.0
Change at Endpoint	66	-4.7	(39.78)	-136 to 166.0	74	-2.2	(45.94)	-163.0 to 167.0
Basophils (10^9/L)								
Baseline	101	0.021	(0.0170)	0.00 to 0.11	100	0.021	(0.0155)	0.00 to 0.10
Week 8	57	0.023	(0.0125)	0.00 to 0.07	70	0.017	(0.0115)	0.00 to 0.06
Endpoint	66	0.023	(0.0128)	0.00 to 0.07	76	0.018	(0.0113)	0.00 to 0.06
Change at Endpoint	66	0.002	(0.0215)	-0.10 to 0.04	74	-0.003	(0.0159)	-0.07 to 0.03
Eosinophils (10^9/L)								
Baseline	101	0.27	(0.201)	0.00 to 0.96	100	0.23	(0.199)	0.00 to 1.33
Week 8	57	0.29	(0.177)	0.04 to 0.73	70	0.24	(0.180)	0.04 to 1.04
Endpoint	66	0.27	(0.175)	0.04 to 0.73	76	0.23	(0.175)	0.03 to 1.04
Change at Endpoint	66	-0.02	(0.179)	-0.73 to 0.4	74	-0.01	(0.192)	-0.65 to 0.88
Lymphocytes (10^9/L)								
Baseline	101	2.60	(0.794)	1.48 to 5.80	100	2.35	(0.648)	0.80 to 4.87
Week 8	57	2.37	(0.644)	1.15 to 4.17	70	2.37	(0.637)	1.13 to 4.09
Endpoint	66	2.37	(0.631)	1.15 to 4.17	76	2.38	(0.631)	1.26 to 4.09
Change at Endpoint	66	-0.26	(0.637)	-1.98 to 0.80	74	0.02	(0.484)	-0.95 to 1.98

Baseline = last pre-treatment assessment
Endpoint = last on-therapy assessment (including Taper Phase)
Source: Table 15.3.6, Section 13; Listing 15.3.1 and 15.3.2, Appendix F

(Table continues)

Table 64 (Continued) Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 101) N	Mean	(SD)	Range	Placebo (N = 102) N	Mean	(SD)	Range
Monocytes (10^9/L)								
Baseline	101	0.38	(0.182)	0.01 to 0.89	100	0.35	(0.168)	0.00 to 0.80
Week 8	57	0.35	(0.149)	0.08 to 0.76	70	0.34	(0.159)	0.00 to 0.84
Endpoint	66	0.35	(0.142)	0.08 to 0.76	76	0.35	(0.158)	0.00 to 0.8400
Change at Endpoint	66	-0.05	(0.170)	-0.59 to 0.47	74	-0.01	(0.177)	-0.66 to 0.41
Neutrophils (10^9/L)								
Baseline	101	3.78	(1.387)	0.99 to 8.61	100	3.78	(1.277)	1.46 to 8.26
Week 8	57	3.84	(1.465)	1.54 to 8.09	70	3.62	(1.418)	1.06 to 7.39
Endpoint	66	3.74	(1.457)	1.17 to 8.09	76	3.75	(1.324)	1.57 to 7.39
Change at Endpoint	66	0.01	(1.249)	-3.64 to 3.31	74	-0.09	(1.205)	-2.72 to 2.65
Sodium (mmol/L)								
Baseline	101	141.9	(2.17)	135.0 to 149.0	101	141.8	(2.04)	138.0 to 147.0
Week 8	59	141.2	(1.86)	137.0 to 146.0	75	141.3	(2.18)	133.0 to 147.0
Endpoint	67	141.1	(2.07)	135.0 to 146.0	80	141.5	(1.96)	137.0 to 147.0
Change at Endpoint	67	-0.7	(2.63)	-8.0 to 4.0	79	-0.3	(2.35)	-6.0 to 5.0
Potassium (mmol/L)								
Baseline	101	4.39	(0.400)	3.7 to 5.6	101	4.40	(0.420)	3.3 to 6.1
Week 8	59	4.31	(0.378)	3.5 to 5.7	75	4.34	(0.392)	3.7 to 6.1
Endpoint	67	4.33	(0.382)	3.5 to 5.7	80	4.35	(0.410)	3.7 to 6.1
Change at Endpoint	67	-0.03	(0.445)	-1.4 to 1.8	79	-0.06	(0.409)	-1.3 to 1.0

Baseline = last pre-treatment assessment
Endpoint = last on-therapy assessment (including Taper Phase)
Source: Table 15.3.6, Section 13; Listing 15.3.1 and 15.3.2, Appendix F

(Table continues)

Table 64 (Continued) Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 101) N	Mean	(SD)	Range	Placebo (N = 102) N	Mean	(SD)	Range
BUN (mmol/L)								
Baseline	101	4.34	(1.025)	2.14 to 7.14	101	4.27	(1.289)	1.43 to 8.21
Week 8	59	4.31	(0.985)	2.14 to 6.43	75	4.36	(1.180)	2.14 to 7.50
Endpoint	67	4.33	(0.984)	2.14 to 6.43	80	4.33	(1.172)	2.14 to 7.50
Change at Endpoint	67	0.05	(1.053)	-3.2 to 2.50	79	0.11	(1.201)	-3.21 to 2.14
Creatinine (umol/L)								
Baseline	101	53.0	(15.84)	26.5 to 106.1	101	54.4	(15.30)	26.5 to 132.6
Week 8	59	56.6	(17.77)	35.4 to 141.4	75	53.2	(15.28)	26.5 to 97.2
Endpoint	67	55.9	(17.16)	35.4 to 141.4	80	53.4	(15.50)	26.5 to 97.2
Change at Endpoint	67	2.2	(10.92)	-26.5 to 53.0	79	-0.2	(15.11)	-79.6 to 53.0
Alkaline Phosphatase (IU/L)								
Baseline	101	222. 4	(97.82)	56.0 to 479.0	101	216.1	(98.30)	49.0 to 512.0
Week 8	59	199.5	(81.73)	69.0 to 380.0	75	222.0	(93.87)	58.0 to 466.0
Endpoint	67	206. 7	(83.57)	69.0 to 386.0	80	214.1	(95.67)	58.0 to 466.0
Change at Endpoint	67	-15.0	(29.22)	-98.0 to 60.0	79	-9.7	(36.15)	-127.0 to 51.0
SGOT (AST) (IU/L)								
Baseline	101	22.6	(6.55)	10.0 to 40.0	101	23.7	(6.53)	13.0 to 47.0
Week 8	59	21.4	(5.78)	12.0 to 38.0	75	24.0	(8.18)	12.0 to 53.0
Endpoint	67	22.0	(5.77)	12.0 to 38.0	80	23.0	(6.90)	12.0 to 46.0
Change at Endpoint	67	-0.8	(5.05)	-19.0 to 9.0	79	-0.6	(4.63)	-13.0 to 18.0

Baseline = last pre-treatment assessment
Endpoint = last on-therapy assessment (including Taper Phase)
Source: Table 15.3.6, Section 13; Listing 15.3.1 and 15.3.2, Appendix F

(Table continues)

Table 64 (Continued) Summary of Mean Endpoint Laboratory Values and Mean Change from Baseline–Age Group: Total (ITT Population)

Laboratory Test (Units)	Treatment Group: Paroxetine (N = 101) N	Mean	(SD)	Range	Placebo (N = 102) N	Mean	(SD)	Range
SGPT (ALT) (IU/L)								
Baseline	101	16.1	(6.96)	6.0 to 47.0	101	16.1	(8.63)	7.0 to 59.0
Week 8	59	15.9	(5.53)	8.0 to 31.0	75	18.0	(15.92)	6.0 to 115.0
Endpoint	67	16.0	(5.15)	8.0 to 31.0	80	16.3	(10.88)	6.0 to 84.0
Change at Endpoint	67	-0.3	(6.09)	-27.0 to 14.0	79	0.5	(7.24)	-18.0 to 33.0
Total Bilirubin (umol/L)								
Baseline	101	8.35	(3.787)	3.42 to 22.23	101	7.74	(4.158)	3.42 to 32.49
Week 8	59	7.88	(3.954)	3.42 to 23.94	75	8.21	(3.290)	3.42 to 20.52
Endpoint	67	7.99	(4.107)	3.42 to 23.94	80	8.19	(3.273)	3.42 to 20.52
Change at Endpoint	67	-0.46	(2.895)	-10.26 to 6.84	79	0.91	(2.667)	-5.13 to 8.55

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 comparable between the treatment groups. More values 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) than transitioned from normal to abnormal.

6.9.3 Urinalysis Results

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.

Three patients in the paroxetine group had urine abnormalities associated with an AE. Patient 701.150.27695 tested positive for urine blood by dipstick at Week 8; an AE of mild hematuria was reported, considered by the investigator to be unrelated to study medication. At retest 12 days later, urine dipstick parameters were negative. Patient 701.185.25962 had urine findings at Week 8 of few bacteria, few urine squamous epithelial cells, and positive generic findings by dipstick. An AE of mild pyuria (verbatim: leukocytes in urine by dipstick) was reported, considered by the investigator to be unrelated to study medication. Patient 701.162.25842 had an AE of moderate skin infection on Day 27 that remained ongoing, and a finding of urine squamous epithelial cells at Week 8.

Two patients in the placebo group had urine abnormalities associated with an AE. Patient 701.185.25964 had urine dipstick positive for protein, mucous threads, and generic on Day 56, with AEs of ketosis and albuminuria reported. At retest 7 days later, the same patient had an AE of hematuria reported, with a verbatim of trace blood in urine dipstick. However, only trace protein and amorphous sediment were positive laboratory findings. All events were mild and all were considered unrelated to study medication. Patient 701.167.25696 had a mild AE of albuminuria reported on Day 60, with a verbatim of urine dipstick test positive for protein. However, laboratory results show the dipstick test negative for protein; positive dipstick findings were urine bacteria, calcium oxalate crystals, amorphous sediment, and generic.

Patient 701.166.25710, in the placebo group, had a high and significant weight increase at Week 8, and also tested positive for glucose by urine dipstick, with an AE of glycosuria. No follow-up data are available.

Abnormal findings at Follow-up may be found in Table 15.3.5.3, Section 13.

6.10 Electrocardiographic Data

A 12-lead ECG was carried out at Screening on all patients. An additional ECG was performed at Week 8 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.

Patient 701.178.25749 had an abnormal ECG at Screening, and patient 701.181.25804 had an ECG at Screening that was categorized as Unknown. Neither of these patients was randomized. All other ECGs at Screening were normal (Listing 13.3.1a, Appendix B; Listing 15.4.1, Appendix E).

No abnormal ECG assessments (as assessed by the investigator) were seen at Week 8 or study endpoint in either treatment group (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 80 patients in this study provided blood samples for PK evaluation at Weeks 4 and 8.

Paroxetine plasma concentration data from this study will be determined by HPLC/MS/MS [25], and will be combined with similar data from studies 704 and 676 [23], [24]. 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 [26].

8 Discussion

This 8-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 MDD. The study objectives were prospectively defined and the trial used four validated measures and one non-validated measure of depression and/or illness to assess treatment effects: the Children's Depression Rating Scale–Revised (CDRS–R) as the primary measure of efficacy, and Clinical Global Impression (CGI) Severity of Illness, the proportion of responders based on the CGI Global Improvement item, the Global Assessment of Functioning (GAF) Scale as secondary measures, and the Kutcher Adolescent Depression Rating Scale (KADS), another clinical measure, to corroborate the findings established with the primary measure. The methodology used to statistically analyze the results employed standard practices. Although fewer than 30% of patients withdrew from the study, conservative analytical techniques, such as last observation carried forward, were used to estimate missing data.

Efficacy

In the present study, substantial improvement occurred by all measures in the paroxetine group. The mean change from baseline (reduction) in the CDRS Total score (the primary measure of efficacy) was 22.6 in the paroxetine group (Week 8 LOCF dataset). This magnitude of reduction in CDRS Total with paroxetine is very similar to that reported in two fluoxetine pediatric depression trials that also utilized the CDRS [11], [12]. Fluoxetine was reported to be significantly superior to placebo in improving depressive symptoms in these two studies. Similarly, the proportion of paroxetine patients meeting the CGI Global Improvement scale response criteria (much improved or very much improved) in this present trial (48%, Week 8 LOCF dataset) is also similar to that reported in the fluoxetine studies. However, because of comparable positive responses in the placebo group in the present study, none of the primary, secondary, or other efficacy variables indicated any statistically significant treatment effect of paroxetine compared to placebo in either the LOCF or completer (i.e., observed case) datasets.

Although there was no statistically significant evidence of a treatment effect in this study, in the Week 8 completer (observed case) dataset there was a suggestion of greater symptom reduction in the paroxetine group. The CGI response rate in the group of paroxetine patients that completed the 8-week treatment phase was 68%, compared to 55% in the placebo group completers ($p = 0.084$). Consistent

with this, the proportion of patients in the paroxetine group rated as normal ("not at all ill") or borderline mentally ill at Week 8 (again, observed case data) using the CGI Severity of Illness scale was 53% for the paroxetine group compared to 36% for the placebo group. These data suggest that paroxetine may offer benefit to some pediatric patients who are maintained on treatment for a sufficient period of time. Interestingly, this suggestion of greater response in the paroxetine group in patients who completed the 8-week trial was apparent for the CGI items only, as there was no suggestion of a treatment effect in CDRS change from baseline data in the Week 8 observed case dataset.

Several factors may have contributed to the nonsignificant treatment effect findings in this study. Most importantly, however, was that a statistically significant treatment by age interaction was observed for the primary efficacy parameter (change from baseline in CDRS Total in the LOCF dataset), indicating varying treatment effect across the age groups. In the 7- to 11-year-old age group, although the difference was not statistically significant, the placebo patients had a greater reduction from baseline in CDRS Total score than did the patients receiving paroxetine (-24.3 vs. -19.0, respectively, LOCF dataset, $p = 0.054$). In contrast, in the adolescent (ages 12-17) subgroup, the paroxetine patients had a slightly greater reduction from baseline in CDRS Total score than did the placebo patients (-25.6 vs. -23.1, respectively, LOCF dataset). This difference was also not statistically significant ($p = 0.375$).

In contrast to the LOCF data, in the 7- to 11-year-old age subgroup there was not a greater reduction in CDRS Total in the placebo group than in the paroxetine group in the observed case dataset. This result suggests that the finding in the LOCF data (i.e., that placebo patients actually achieved greater reduction in CDRS Total than the paroxetine patients) may be a result of the substantially higher withdrawal rate observed in the paroxetine group than in the placebo group. However, the Week 8 Observed Case results supported the LOCF conclusion that there was no significant difference between the treatment groups. The dropout rate in the paroxetine 7- to 11-year-old age group was essentially three times that of the placebo 7- to 11-year-old age group (39% vs. 13%, respectively). Because many of the paroxetine group dropouts occurred within the first few weeks, CDRS data that was fundamentally unchanged or only minimally changed from baseline was carried forward for a larger number of paroxetine group patients than for the placebo group patients. In the adolescent patients, the early withdrawal rate was lower in the paroxetine group than in the placebo group (23% vs. 31%, respectively).

Another factor that may have contributed to the nonsignificant finding in this study was the greater proportion of patients in the paroxetine group demonstrating non-adherence to the treatment regimen than in the placebo group (i.e., the proportion of patients missing more than 3 consecutive days of dosing on at least one occasion, which was 20% vs. 12%, respectively). In the 7- to 11-year-old age group, 16% of the paroxetine patients missed more than 3 consecutive days of dosing on at least one occasion, compared to only 6% of the placebo group. In addition, this flexible-dose design protocol allowed investigators to maintain the patients on a 10-mg daily dose of paroxetine. Although over half of the paroxetine patients in the trial were up-titrated to doses above 20 mg/day (49% of children and 69% of adolescents), the average daily dose of paroxetine overall was 20.4 mg/day (18.9 mg/day for children, 21.8 mg/day for adolescents), which is somewhat lower than the mean daily dose administered in a previous paroxetine adolescent depression trial (approx. 28 mg/day) that showed some evidence of efficacy [14].

Lastly, there were also more patients with comorbid psychiatric illness (28:73) in the paroxetine group than in the placebo group (18:84). The influence of this comborbidity imbalance was considered in the analysis of CDRS-R, CGI global improvement, GAF and KADS, and hence the estimated treatment differences were adjusted for this. Consideration was also given to the treatment by comorbidity interaction for the primary endpoint and showed no statistically significant difference in treatment effect between the levels of comorbidity. However, further exploratory analysis regarding specific comorbid condition was not evaluated in this study.

The results among adolescents in this trial are somewhat similar to those reported in another prior paroxetine adolescent depression study, in which 286 patients 13 to 18 years of age were treated for 12 weeks with either paroxetine (20 to 40 mg/day) or placebo [15]. In that study, there was also no statistically significant difference in change from Baseline in the depression scales utilized. However, a statistically significant treatment by age interaction was observed for both primary efficacy parameters (K-SADS-L and MADRS) and most of the four secondary parameters, where numerical trends indicated that for patients greater than 16 years of age, patients on paroxetine had better response rates. Whether older adolescents in this present trial (e.g., the subset of those patients $\geq$14 or 15 years of age) similarly achieved greater symptom reduction and better response rates than younger patients was not evaluated in this study.

In another prior paroxetine study in depressed adolescents, not all efficacy parameters achieved statistical significance also because of a substantial placebo

response, which may have been in part due to the concurrent supportive psychotherapy that was allowed [14]. In the present study, it is not known why the placebo response rate was so high, since the protocol disallowed concurrent psychotherapy. As was noted in this earlier study, a high placebo response rate is not unusual for clinical studies in MDD, in either pediatric or adult populations. The weekly assessments, which involved the subjects in responding to a number of questions in the efficacy instruments, may have contributed to improvement in both treatment groups. The lack of a placebo run-in period to exclude placebo responders may also have contributed to the high placebo response.

Safety

This study indicates that paroxetine is safe when used in children and adolescents over a period of up to eight weeks. There were no deaths or any other unexpected safety findings and paroxetine was generally well tolerated compared to placebo. The proportion of patients reporting at least one AE was comparable between the two treatment groups (70% in the paroxetine group vs. 61% in the placebo group). Although more paroxetine patients than placebo patients experienced adverse events rated as severe (8 vs. 4, respectively), serious (6 vs. 1, respectively), and or which led to withdrawal from the study (9 vs. 2, respectively), there were only three common (>5%) adverse events which occurred in the paroxetine group at an incidence at least twice that in the placebo group (i.e., dizziness, increased cough, dyspepsia, and vomiting). The overall safety profile of paroxetine (defined as adverse events and withdrawals due to adverse events) observed in pediatric patients in this trial does not differ substantially from that seen in adults suffering from depression and other anxiety disorders such as OCD, Panic, or Social Anxiety Disorder [27], except that there were no gender-specific adverse events in children and only a few in adolescents.

These data do suggest that some younger children (i.e., less than age 12) may not tolerate paroxetine treatment as well as adolescents. The incidence of adverse events leading to withdrawal was 14% in the 7- to 11-year-old paroxetine group (7/49), compared to 4% (2/52) in the 12- to 17-year-old paroxetine group. There were no patients in the 7- to 11-year-old placebo group withdrawn due to an AE and only two adolescent patients in the placebo group withdrawn due to an AE. Analysis of the incidence of specific adverse events by age subgroup suggests that certain events associated with the nervous system (somnolence and insomnia) were more likely to occur in both treatment groups among adolescents than among children. On the other hand, infection was reported with a greater incidence in both treatment groups among children than among adolescents.

Six patients on paroxetine and 1 on placebo were reported to have an adverse event that was serious; events in all but one patient (who intentionally overdosed on taper medication) were considered by the investigator to be unrelated to study medication. All the SAEs were psychiatric in nature and included emotional lability and depression. Six of the 8 SAEs in the 6 patients in the paroxetine group occurred 2 or more days after the patient's last dose of study medication.

Clinical laboratory abnormalities of concern were few in number and similar in both treatment groups, and none were identified by investigators as related to the study drug. Similarly, there were few changes in vital signs meeting the clinical concern criteria and none that were reported as an adverse event. No clinically significant changes were seen in the ECGs in either treatment group.

9 Conclusions

The results of this study failed to provide evidence for the primary and secondary endpoints that paroxetine is more efficacious than placebo in treating children and adolescents with MDD.

Paroxetine was generally well tolerated in this pediatric population compared to placebo, with no unexpected adverse events or findings in laboratory tests, vital signs, or ECGs. More paroxetine patients than placebo patients withdrew due to adverse events, and more children than adolescents withdrew due to AEs in the paroxetine group. The safety profile appeared similar to that previously reported for adults except that there were few gender-specific adverse events.

10 References

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11 Source Tables: Study Population

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Table 13.1.1

Number (%) of Patients by Population
All Patients

Age Group : Children

Study Stage/Population	Treatment Group Paroxetine (N=50)	 Placebo (N=47)	 Total (N=144)
Screened Only	0	0	47
Randomised	50 (100.0%)	47 (100.0%)	97 (100.0%)
Completed	30 (60.0%)	41 (87.2%)	71 (73.2%)
Early Withdrawal	20 (40.0%)	6 (12.8%)	26 (26.8%)
Intention-to-Treat Population	49 (98.0%)	47 (100.0%)	96 (99.0%)
Per-Protocol Population	39 (78.0%)	41 (87.2%)	80 (82.5%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)

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Table 13.1.1

Number (%) of Patients by Population
All Patients

Age Group : Adolescents

Study Stage/Population	Treatment Group Paroxetine (N=54)	 Placebo (N=55)	 Total (N=161)
Screened Only	0	0	52
Randomised	54 (100.0%)	55 (100.0%)	109 (100.0%)
Completed	40 (74.1%)	38 (69.1%)	78 (71.6%)
Early Withdrawal	14 (25.9%)	17 (30.9%)	31 (28.4%)
Intention-to-Treat Population	52 (96.3%)	55 (100.0%)	107 (98.2%)
Per-Protocol Population	35 (64.8%)	42 (76.4%)	77 (70.6%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)

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Table 13.1.1

Number (%) of Patients by Population
All Patients

Age Group : Total

Study Stage/Population	Treatment Group Paroxetine (N=104)	 Placebo (N=102)	 Total (N=305)
Screened Only	0	0	99
Randomised	104 (100.0%)	102 (100.0%)	206 (100.0%)
Completed	70 (67.3%)	79 (77.5%)	149 (72.3%)
Early Withdrawal	34 (32.7%)	23 (22.5%)	57 (27.7%)
Intention-to-Treat Population	101 (97.1%)	102 (100.0%)	203 (98.5%)
Per-Protocol Population	74 (71.2%)	83 (81.4%)	157 (76.2%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : Canada (1 Centres)
Age Group : Children

Study Stage/Population	Treatment Group Paroxetine (N=1)	 Placebo (N=1)	 Total (N=2)
Screened Only	0	0	0
Randomised	1 (100.0%)	1 (100.0%)	2 (100.0%)
Completed	1 (100.0%)	1 (100.0%)	2 (100.0%)
Early Withdrawal	0	0	0
Intention-to-Treat Population	1 (100.0%)	1 (100.0%)	2 (100.0%)
Per-Protocol Population	1 (100.0%)	1 (100.0%)	2 (100.0%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : Canada (1 Centres)
Age Group : Adolescents

Study Stage/Population	Treatment Group Paroxetine (N=4)	 Placebo (N=3)	 Total (N=8)
Screened Only	0	0	1
Randomised	4 (100.0%)	3 (100.0%)	7 (100.0%)
Completed	4 (100.0%)	3 (100.0%)	7 (100.0%)
Early Withdrawal	0	0	0
Intention-to-Treat Population	4 (100.0%)	3 (100.0%)	7 (100.0%)
Per-Protocol Population	3 (75.0%)	3 (100.0%)	6 (85.7%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : Canada (1 Centres)
Age Group : Total

Study Stage/Population	Treatment Group Paroxetine (N=5)	 Placebo (N=4)	 Total (N=10)
Screened Only	0	0	1
Randomised	5 (100.0%)	4 (100.0%)	9 (100.0%)
Completed	5 (100.0%)	4 (100.0%)	9 (100.0%)
Early Withdrawal	0	0	0
Intention-to-Treat Population	5 (100.0%)	4 (100.0%)	9 (100.0%)
Per-Protocol Population	4 (80.0%)	4 (100.0%)	8 (88.9%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : United States of America (40 Centres)
Age Group : Children

Study Stage/Population	Treatment Group Paroxetine (N=49)	 Placebo (N=46)	 Total (N=142)
Screened Only	0	0	47
Randomised	49 (100.0%)	46 (100.0%)	95 (100.0%)
Completed	29 (59.2%)	40 (87.0%)	69 (72.6%)
Early Withdrawal	20 (40.8%)	6 (13.0%)	26 (27.4%)
Intention-to-Treat Population	48 (98.0%)	46 (100.0%)	94 (98.9%)
Per-Protocol Population	38 (77.6%)	40 (87.0%)	78 (82.1%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : United States of America (40 Centres)
Age Group : Adolescents

Study Stage/Population	Treatment Group Paroxetine (N=50)	 Placebo (N=52)	 Total (N=153)
Screened Only	0	0	51
Randomised	50 (100.0%)	52 (100.0%)	102 (100.0%)
Completed	36 (72.0%)	35 (67.3%)	71 (69.6%)
Early Withdrawal	14 (28.0%)	17 (32.7%)	31 (30.4%)
Intention-to-Treat Population	48 (96.0%)	52 (100.0%)	100 (98.0%)
Per-Protocol Population	32 (64.0%)	39 (75.0%)	71 (69.6%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)

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Table 13.1.2

Number (%) of Patients by Population by Country
All Patients

Country : United States of America (40 Centres)
Age Group : Total

Study Stage/Population	Treatment Group Paroxetine (N=99)	Placebo (N=98)	Total (N=295)
Screened Only	0	0	98
Randomised	99 (100.0%)	98 (100.0%)	197 (100.0%)
Completed	65 (65.7%)	75 (76.5%)	140 (71.1%)
Early Withdrawal	34 (34.3%)	23 (23.5%)	57 (28.9%)
Intention-to-Treat Population	96 (97.0%)	98 (100.0%)	194 (98.5%)
Per-Protocol Population	70 (70.7%)	79 (80.6%)	149 (75.6%)

Note: Total (N) includes 'Screened Only' patients, hence may be greater than Paroxetine (N) + Placebo (N)

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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=49)	Placebo (N=47)	Total (N=96)
Total number of patients excluded*	10(20.4%)	6(12.8%)	16(16.7%)
Patient is taking or has taken pyschoactive medications	0	3(6.4%)	3(3.1%)
Patient Missed more than 3 Consecutive days Medication	8(16.3%)	3(6.4%)	11(11.5%)
Patient had exposure to less than 2 weeks Duration of Randomised Study Medication	4(8.2%)	0	4(4.2%)
Total number of patients with no protocol violations	39(79.6%)	41(87.2%)	80(83.3%)

* 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=52)	Placebo (N=55)	Total (N=107)
Total number of patients excluded*	17(32.7%)	13(23.6%)	30(28.0%)
CDRS-R Screening/Baseline observed total score is less than 45	1(1.9%)	0	1(0.9%)
Patient is diagnosed with Substance abuse or Dependence	0	1(1.8%)	1(0.9%)
Patient is taking or has taken pyschoactive medications	4(7.7%)	1(1.8%)	5(4.7%)
Patient Missed more than 3 Consecutive days Medication	12(23.1%)	9(16.4%)	21(19.6%)
Patient had exposure to less than 2 weeks Duration of Randomised Study Medication	1(1.9%)	4(7.3%)	5(4.7%)
Total number of patients with no protocol violations	35(67.3%)	42(76.4%)	77(72.0%)

* 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=101)	Placebo (N=102)	Total (N=203)
Total number of patients excluded*	27(26.7%)	19(18.6%)	46(22.7%)
CDRS-R Screening/Baseline observed total score is less than 45	1(1.0%)	0	1(0.5%)
Patient is diagnosed with Substance abuse or Dependence	0	1(1.0%)	1(0.5%)
Patient is taking or has taken pyschoactive medications	4(4.0%)	4(3.9%)	8(3.9%)
Patient Missed more than 3 Consecutive days Medication	20(19.8%)	12(11.8%)	32(15.8%)
Patient had exposure to less than 2 weeks Duration of Randomised Study Medication	5(5.0%)	4(3.9%)	9(4.4%)
Total number of patients with no protocol violations	74(73.3%)	83(81.4%)	157(77.3%)

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

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Table 13.2.2

Number (%) of Patients with Protocol Deviations Included in the Per-Protocol Analysis

Intention-To-Treat Population

Age Group:Children

	Treatment Group Paroxetine (N=49)	Placebo (N=47)	Total (N=96)
Total number of patients included with a deviation**	0	0	0
Total number of patients with no protocol deviations	48(98.0%)	47(100.0%)	95(99.0%)

** 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=52)	Placebo (N=55)	Total (N=107)
Total number of patients included with a deviation**	0	0	0
Total number of patients with no protocol deviations	52(100.0%)	55(100.0%)	107(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:Total

	Treatment Group Paroxetine (N=101)	Placebo (N=102)	Total (N=203)
Total number of patients included with a deviation**	0	0	0
Total number of patients with no protocol deviations	100(99.0%)	102(100.0%)	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=99)
Baseline Adverse Experience	1 (1%)
Does not meet inclusion/exclusion criteria	72 (72.7%)
Protocol deviation	1 (1%)
Lost to Follow-up	12 (12.1%)
Other+	13 (13.1%)
Total withdrawn	99 (100%)

+ Includes unknown and non-study-related personal reasons

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Table 13.3.1b

Number (%) of Randomised Patients Who Completed the Study or Were Withdrawn (by reason)

Intention-To-Treat Population

Age Group:Children

Reason For Study Conclusion	Treatment Group: Paroxetine (N=49)	Placebo (N=47)	Total (N=96)
Completed Study*	30 (61.2%)	41 (87.2%)	71 (74%)
Adverse Experience	7 (14.3%)	0 (0%)	7 (7.3%)
Lack of Efficacy	4 (8.2%)	4 (8.5%)	8 (8.3%)
Protocol deviation (including non-compliance)	2 (4.1%)	0 (0%)	2 (2.1%)
Lost to Follow-up	5 (10.2%)	2 (4.3%)	7 (7.3%)
Other+	1 (2%)	0 (0%)	1 (1%)
Total withdrawn	19 (38.8%)	6 (12.8%)	25 (26%)

Completed = Subjects who completed a week 8 visit CRF,
note three subjects attended the week 8 visit before relative day 50 and hence had their visit re-categorised as Week 6.
+ Includes unknown and non-study-related personal reasons

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Table 13.3.1b

Number (%) of Randomised Patients Who Completed the Study or Were Withdrawn (by reason)

Intention-To-Treat Population

Age Group:Adolescents

Reason For Study Conclusion	Treatment Group: Paroxetine (N=52)	Placebo (N=55)	Total (N=107)
Completed Study*	40 (76.9%)	38 (69.1%)	78 (72.9%)
Adverse Experience	3 (5.8%)	2 (3.6%)	5 (4.7%)
Lack of Efficacy	3 (5.8%)	7 (12.7%)	10 (9.3%)
Protocol deviation (including non-compliance)	1 (1.9%)	3 (5.5%)	4 (3.7%)
Lost to Follow-up	3 (5.8%)	2 (3.6%)	5 (4.7%)
Other+	2 (3.8%)	3 (5.5%)	5 (4.7%)
Total withdrawn	12 (23.1%)	17 (30.9%)	29 (27.1%)

Completed = Subjects who completed a week 8 visit CRF,
note three subjects attended the week 8 visit before relative day 50 and hence had their visit re-categorised as Week 6.
+ Includes unknown and non-study-related personal reasons

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Table 13.3.1b

Number (%) of Randomised Patients Who Completed the Study or Were Withdrawn (by reason)

Intention-To-Treat Population

Age Group:Total

Reason For Study Conclusion	Treatment Group: Paroxetine (N=101)	Placebo (N=102)	Total (N=203)
Completed Study*	70 (69.3%)	79 (77.5%)	149 (73.4%)
Adverse Experience	10 (9.9%)	2 (2%)	12 (5.9%)
Lack of Efficacy	7 (6.9%)	11 (10.8%)	18 (8.9%)
Protocol deviation (including non-compliance)	3 (3%)	3 (2.9%)	6 (3%)
Lost to Follow-up	8 (7.9%)	4 (3.9%)	12 (5.9%)
Other+	3 (3%)	3 (2.9%)	6 (3%)
Total withdrawn	31 (30.7%)	23 (22.5%)	54 (26.6%)

Completed = Subjects who completed a week 8 visit CRF,
note three subjects attended the week 8 visit before relative day 50 and hence had their visit re-categorised as Week 6.
+ Includes unknown and non-study-related personal reasons

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Table 13.3.1c

Number (%) of Randomised Patients Who Completed the Study or Were Withdrawn (by reason)

Per-Protocol Population

Age Group:Children

Reason For Study Conclusion	Treatment Group: Paroxetine (N=39)	Placebo (N=41)	Total (N=80)
Completed Study*	27 (69.2%)	38 (92.7%)	65 (81.3%)
Adverse Experience	5 (12.8%)	0 (0%)	5 (6.3%)
Lack of Efficacy	3 (7.7%)	1 (2.4%)	4 (5%)
Protocol deviation (including non-compliance)	0 (0%)	0 (0%)	0 (0%)
Lost to Follow-up	4 (10.3%)	2 (4.9%)	6 (7.5%)
Other+	0 (0%)	0 (0%)	0 (0%)
Total withdrawn	12 (30.8%)	3 (7.3%)	15 (18.8%)

Completed = Subjects who completed a week 8 visit CRF,
note three subjects attended the week 8 visit before relative day 50 and hence had their visit re-categorised as Week 6.
+ 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=35)	Placebo (N=42)	Total (N=77)
Completed Study*	27 (77.1%)	35 (83.3%)	62 (80.5%)
Adverse Experience	1 (2.9%)	0 (0%)	1 (1.3%)
Lack of Efficacy	3 (8.6%)	5 (11.9%)	8 (10.4%)
Protocol deviation (including non-compliance)	0 (0%)	0 (0%)	0 (0%)
Lost to Follow-up	2 (5.7%)	1 (2.4%)	3 (3.9%)
Other+	2 (5.7%)	1 (2.4%)	3 (3.9%)
Total withdrawn	8 (22.9%)	7 (16.7%)	15 (19.5%)

Completed = Subjects who completed a week 8 visit CRF,
note three subjects attended the week 8 visit before relative day 50 and hence had their visit re-categorised as Week 6.
+ 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=74)	Placebo (N=83)	Total (N=157)
Completed Study*	54 (73%)	73 (88%)	127 (80.9%)
Adverse Experience	6 (8.1%)	0 (0%)	6 (3.8%)
Lack of Efficacy	6 (8.1%)	6 (7.2%)	12 (7.6%)
Protocol deviation (including non-compliance)	0 (0%)	0 (0%)	0 (0%)
Lost to Follow-up	6 (8.1%)	3 (3.6%)	9 (5.7%)
Other+	2 (2.7%)	1 (1.2%)	3 (1.9%)
Total withdrawn	20 (27%)	10 (12%)	30 (19.1%)

Completed = Subjects who completed a week 8 visit CRF,
note three subjects attended the week 8 visit before relative day 50 and hence had their visit re-categorised as Week 6.
+ 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	Treatment Group: Paroxetine (N=101)	Placebo (N=102)	Total (N=203)
Baseline	Still in Study	101 (100.0%)	102 (100.0%)	203 (100.0%)
	Withdrawn	0	0	0
Week 1	Still in Study	98 (97.0%)	98 (96.1%)	196 (96.6%)
	Withdrawn	3 (3.0%)	4 (3.9%)	7 (3.4%)
Week 2	Still in Study	93 (92.1%)	97 (95.1%)	190 (93.6%)
	Withdrawn	5 (5.1%)	1 (1.0%)	6 (3.1%)
Week 3	Still in Study	88 (87.1%)	93 (91.2%)	181 (89.2%)
	Withdrawn	5 (5.4%)	4 (4.1%)	9 (4.7%)
Week 4	Still in Study	78 (77.2%)	87 (85.3%)	165 (81.3%)
	Withdrawn	10 (11.4%)	6 (6.5%)	16 (8.8%)
Week 6	Still in Study	72 (71.3%)	80 (78.4%)	152 (74.9%)
	Withdrawn	4 (5.1%)	6 (6.9%)	10 (6.1%)
	Completed	2 (2.0%)	1 (1.0%)	3 (1.5%)
Week 8	Withdrawn	4 (5.6%)	2 (2.5%)	6 (3.9%)
	Completed	68 (67.3%)	78 (76.5%)	146 (71.9%)

Date of withdrawal = date of last dose of study medication (excluding Taper)
Efficacy assessments up to 7 days after this date are considered evaluable

Note: Percentages for patients still in the study or completed at each visit are based on the total number of patients at baseline, percentages for patients withdrawing at each visit are based on the total number of patients at each visit.
Completed = Subjects who completed a week 8 visit CRF,
note three subjects attended the week 8 visit before relative day 50 and hence had their visit re-categorised as Week 6.

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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 = 49)								Placebo (N = 47)								Total (N = 96)							
	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	2.0	0	0.0	1	2.0	2	4.1	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0	2	2.1
Week 2	2	4.1	1	2.0	4	8.2	7	14.3	0	0.0	0	0.0	0	0.0	0	0.0	2	2.1	1	1.0	4	4.2	7	7.3
Week 3	3	6.1	3	6.1	4	8.2	10	20.4	0	0.0	0	0.0	1	2.1	1	2.1	3	3.1	3	3.1	5	5.2	11	11.5
Week 4	6	12.2	4	8.2	6	12.2	16	32.7	0	0.0	2	4.3	1	2.1	3	6.4	6	6.3	6	6.3	7	7.3	19	19.8
Week 6	7	14.3	4	8.2	7	14.3	18	36.7	0	0.0	3	6.4	2	4.3	5	10.6	7	7.3	7	7.3	9	9.4	23	24.0
Week 8	7	14.3	4	8.2	8	16.3	19	38.8	0	0.0	4	8.5	2	4.3	6	12.8	7	7.3	8	8.3	10	10.4	25	26.0

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 = 52)								Placebo (N = 55)								Total (N = 107)							
	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	0	0.0	0	0.0	1	1.9	1	1.9	2	3.6	1	1.8	1	1.8	4	7.3	2	1.9	1	0.9	2	1.9	5	4.7
Week 2	0	0.0	0	0.0	1	1.9	1	1.9	2	3.6	2	3.6	1	1.8	5	9.1	2	1.9	2	1.9	2	1.9	6	5.6
Week 3	0	0.0	1	1.9	2	3.8	3	5.8	2	3.6	3	5.5	3	5.5	8	14.5	2	1.9	4	3.7	5	4.7	11	10.3
Week 4	0	0.0	2	3.8	5	9.6	7	13.5	2	3.6	5	9.1	5	9.1	12	21.8	2	1.9	7	6.5	10	9.3	19	17.8
Week 6	1	1.9	2	3.8	6	11.5	9	17.3	2	3.6	7	12.7	7	12.7	16	29.1	3	2.8	9	8.4	13	12.1	25	23.4
Week 8	3	5.8	3	5.8	6	11.5	12	23.1	2	3.6	7	12.7	8	14.5	17	30.9	5	4.7	10	9.3	14	13.1	29	27.1

AE = adverse experience LE = lack of efficacy
Other = Protocol Deviation (including non-compliance), Lost to follow-up, Unknown and non-study related personal reasons

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 = 101)								Placebo (N = 102)								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	3.0	2	2.0	1	1.0	1	1.0	4	3.9	3	1.5	1	0.5	3	1.5	7	3.4
Week 2	2	2.0	1	1.0	5	5.0	8	7.9	2	2.0	2	2.0	1	1.0	5	4.9	4	2.0	3	1.5	6	3.0	13	6.4
Week 3	3	3.0	4	4.0	6	5.9	13	12.9	2	2.0	3	2.9	4	3.9	9	8.8	5	2.5	7	3.4	10	4.9	22	10.8
Week 4	6	5.9	6	5.9	11	10.9	23	22.8	2	2.0	7	6.9	6	5.9	15	14.7	8	3.9	13	6.4	17	8.4	38	18.7
Week 6	8	7.9	6	5.9	13	12.9	27	26.7	2	2.0	10	9.8	9	8.8	21	20.6	10	4.9	16	7.9	22	10.8	48	23.6
Week 8	10	9.9	7	6.9	14	13.9	31	30.7	2	2.0	11	10.8	10	9.8	23	22.5	12	5.9	18	8.9	24	11.8	54	26.6

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=49)	Placebo (N=47)	Total (N=96)
148	XXXXXXXXXXXXXXXXXX	Randomised	2 (4.1%)	0	2 (2.1%)
		Completed	1 (2.0%)	0	1 (1.0%)
149	XXXXXXXXXXXXXXXXXX	Randomised	2 (4.1%)	2 (4.3%)	4 (4.2%)
		Completed	0	2 (4.3%)	2 (2.1%)
150	XXXXXXXXXXXXXXXXXX	Randomised	2 (4.1%)	1 (2.1%)	3 (3.1%)
		Completed	2 (4.1%)	1 (2.1%)	3 (3.1%)
151	XXXXXXXXXXXXXXXXXX	Randomised	1 (2.0%)	1 (2.1%)	2 (2.1%)
		Completed	0	1 (2.1%)	1 (1.0%)
155	XXXXXXXXXXXXXXXXXX	Randomised	0	1 (2.1%)	1 (1.0%)
		Completed	0	1 (2.1%)	1 (1.0%)
156	XXXXXXXXXXXXXXXXXX	Randomised	0	1 (2.1%)	1 (1.0%)
		Completed	0	1 (2.1%)	1 (1.0%)
157	XXXXXXXXXXXXXXXXXX	Randomised	1 (2.0%)	0	1 (1.0%)
		Completed	1 (2.0%)	0	1 (1.0%)
159	XXXXXXXXXXXXXXXXXX	Randomised	2 (4.1%)	2 (4.3%)	4 (4.2%)
		Completed	2 (4.1%)	1 (2.1%)	3 (3.1%)
160	XXXXXXXXXXXXXXXXXX	Randomised	1 (2.0%)	0	1 (1.0%)
161	XXXXXXXXXXXXXXXXXX	Randomised	3 (6.1%)	2 (4.3%)	5 (5.2%)
		Completed	1 (2.0%)	2 (4.3%)	3 (3.1%)
162	XXXXXXXXXXXXXXXXXX	Randomised	3 (6.1%)	3 (6.4%)	6 (6.3%)
		Completed	2 (4.1%)	2 (4.3%)	4 (4.2%)
164	XXXXXXXXXXXXXXXXXX	Randomised	1 (2.0%)	2 (4.3%)	3 (3.1%)
		Completed	1 (2.0%)	2 (4.3%)	3 (3.1%)
165	XXXXXXXXXXXXXXXXXX	Randomised	0	1 (2.1%)	1 (1.0%)
		Completed	0	1 (2.1%)	1 (1.0%)
167	XXXXXXXXXXXXXXXXXX	Randomised	1 (2.0%)	1 (2.1%)	2 (2.1%)
		Completed	1 (2.0%)	1 (2.1%)	2 (2.1%)
169	XXXXXXXXXXXXXXXXXX	Randomised	0	1 (2.1%)	1 (1.0%)
		Completed	0	1 (2.1%)	1 (1.0%)

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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=49)	Placebo (N=47)	Total (N=96)
170	XXXXXXXXXXXXXXXXXX	Randomised	3 (6.1%)	2 (4.3%)	5 (5.2%)
		Completed	1 (2.0%)	2 (4.3%)	3 (3.1%)
171	XXXXXXXXXXXXXXXXXX	Randomised	0	1 (2.1%)	1 (1.0%)
		Completed	0	1 (2.1%)	1 (1.0%)
172	XXXXXXXXXXXXXXXXXX	Randomised	1 (2.0%)	1 (2.1%)	2 (2.1%)
		Completed	1 (2.0%)	0	1 (1.0%)
173	XXXXXXXXXXXXXXXXXX	Randomised	1 (2.0%)	0	1 (1.0%)
		Completed	1 (2.0%)	0	1 (1.0%)
175	XXXXXXXXXXXXXXXXXX	Randomised	1 (2.0%)	0	1 (1.0%)
		Completed	1 (2.0%)	0	1 (1.0%)
176	XXXXXXXXXXXXXXXXXX	Randomised	3 (6.1%)	3 (6.4%)	6 (6.3%)
		Completed	2 (4.1%)	2 (4.3%)	4 (4.2%)
178	XXXXXXXXXXXXXXXXXX	Randomised	3 (6.1%)	2 (4.3%)	5 (5.2%)
		Completed	3 (6.1%)	2 (4.3%)	5 (5.2%)
179	XXXXXXXXXXXXXXXXXX	Randomised	0	1 (2.1%)	1 (1.0%)
		Completed	0	1 (2.1%)	1 (1.0%)
180	XXXXXXXXXXXXXXXXXX	Randomised	2 (4.1%)	1 (2.1%)	3 (3.1%)
		Completed	1 (2.0%)	1 (2.1%)	2 (2.1%)
181	XXXXXXXXXXXXXXXXXX	Randomised	5 (10.2%)	5 (10.6%)	10 (10.4%)
		Completed	3 (6.1%)	3 (6.4%)	6 (6.3%)
182	XXXXXXXXXXXXXXXXXX	Randomised	2 (4.1%)	1 (2.1%)	3 (3.1%)
		Completed	0	1 (2.1%)	1 (1.0%)
183	XXXXXXXXXXXXXXXXXX	Randomised	2 (4.1%)	4 (8.5%)	6 (6.3%)
		Completed	1 (2.0%)	4 (8.5%)	5 (5.2%)
184	XXXXXXXXXXXXXXXXXX	Randomised	1 (2.0%)	0	1 (1.0%)
		Completed	1 (2.0%)	0	1 (1.0%)
185	XXXXXXXXXXXXXXXXXX	Randomised	3 (6.1%)	4 (8.5%)	7 (7.3%)
		Completed	1 (2.0%)	4 (8.5%)	5 (5.2%)
186	XXXXXXXXXXXXXXXXXX	Randomised	2 (4.1%)	2 (4.3%)	4 (4.2%)
		Completed	2 (4.1%)	2 (4.3%)	4 (4.2%)

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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=49)	Placebo (N=47)	Total (N=96)
189	XXXXXXXXXXXXXXXXXX	Randomised	0	1 (2.1%)	1 (1.0%)
		Completed	0	1 (2.1%)	1 (1.0%)
192	XXXXXXXXXXXXXXXXXX	Randomised	1 (2.0%)	1 (2.1%)	2 (2.1%)
		Completed	1 (2.0%)	1 (2.1%)	2 (2.1%)

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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=52)	Placebo (N=55)	Total (N=107)
149	XXXXXXXXXXXXXXXXX	Randomised	2 (3.8%)	2 (3.6%)	4 (3.7%)
		Completed	2 (3.8%)	1 (1.8%)	3 (2.8%)
151	XXXXXXXXXXXXXXXXX	Randomised	0	1 (1.8%)	1 (0.9%)
		Completed	0	1 (1.8%)	1 (0.9%)
152	XXXXXXXXXXXXXXXXX	Randomised	1 (1.9%)	1 (1.8%)	2 (1.9%)
		Completed	1 (1.9%)	0	1 (0.9%)
153	XXXXXXXXXXXXXXXXX	Randomised	0	1 (1.8%)	1 (0.9%)
		Completed	0	1 (1.8%)	1 (0.9%)
154	XXXXXXXXXXXXXXX	Randomised	2 (3.8%)	1 (1.8%)	3 (2.8%)
		Completed	2 (3.8%)	0	2 (1.9%)
156	XXXXXXXXXXXXX	Randomised	1 (1.9%)	0	1 (0.9%)
		Completed	1 (1.9%)	0	1 (0.9%)
158	XXXXXXXXXXXX	Randomised	1 (1.9%)	0	1 (0.9%)
		Completed	1 (1.9%)	0	1 (0.9%)
159	XXXXXXXXXXXX	Randomised	4 (7.7%)	4 (7.3%)	8 (7.5%)
		Completed	2 (3.8%)	4 (7.3%)	6 (5.6%)
160	XXXXXXXXXXXX	Randomised	1 (1.9%)	0	1 (0.9%)
		Completed	1 (1.9%)	0	1 (0.9%)
161	XXXXXXXXXXXXXXXXX	Randomised	2 (3.8%)	3 (5.5%)	5 (4.7%)
		Completed	0	2 (3.6%)	2 (1.9%)
162	XXXXXXXXXXXXXXXXX	Randomised	4 (7.7%)	5 (9.1%)	9 (8.4%)
		Completed	4 (7.7%)	2 (3.6%)	6 (5.6%)
163	XXXXXXXXXXXXXXXXX	Randomised	2 (3.8%)	1 (1.8%)	3 (2.8%)
164	XXXXXXXXXXXXXXXXX	Randomised	2 (3.8%)	1 (1.8%)	3 (2.8%)
		Completed	2 (3.8%)	1 (1.8%)	3 (2.8%)
165	XXXXXXXXXXXXXXXXX	Randomised	1 (1.9%)	1 (1.8%)	2 (1.9%)
		Completed	1 (1.9%)	1 (1.8%)	2 (1.9%)
166	XXXXXXXXXXXXXXXXX	Randomised	0	2 (3.6%)	2 (1.9%)
		Completed	0	2 (3.6%)	2 (1.9%)

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=52)	Placebo (N=55)	Total (N=107)
167	XXXXXXXXXXXXXXXXXX	Randomised	0	2 (3.6%)	2 (1.9%)
		Completed	0	1 (1.8%)	1 (0.9%)
168	XXXXXXXXXXXXXXXXXX	Randomised	3 (5.8%)	3 (5.5%)	6 (5.6%)
		Completed	3 (5.8%)	2 (3.6%)	5 (4.7%)
170	XXXXXXXXXXXXXXXXXX	Randomised	1 (1.9%)	1 (1.8%)	2 (1.9%)
		Completed	0	1 (1.8%)	1 (0.9%)
172	XXXXXXXXXXXXXXXXXX	Randomised	1 (1.9%)	1 (1.8%)	2 (1.9%)
173	XXXXXXXXXXXXXXXXXX	Randomised	1 (1.9%)	0	1 (0.9%)
		Completed	1 (1.9%)	0	1 (0.9%)
174	XXXXXXXXXXXXXXXXXX	Randomised	1 (1.9%)	1 (1.8%)	2 (1.9%)
		Completed	1 (1.9%)	0	1 (0.9%)
175	XXXXXXXXXXXXXXXXXX	Randomised	1 (1.9%)	1 (1.8%)	2 (1.9%)
		Completed	1 (1.9%)	0	1 (0.9%)
176	XXXXXXXXXXXXXXXXXX	Randomised	3 (5.8%)	3 (5.5%)	6 (5.6%)
		Completed	2 (3.8%)	3 (5.5%)	5 (4.7%)
178	XXXXXXXXXXXXXXXXXX	Randomised	1 (1.9%)	2 (3.6%)	3 (2.8%)
		Completed	1 (1.9%)	2 (3.6%)	3 (2.8%)
180	XXXXXXXXXXXXXXXXXX	Randomised	2 (3.8%)	2 (3.6%)	4 (3.7%)
		Completed	1 (1.9%)	0	1 (0.9%)
181	XXXXXXXXXXXXXXXXXX	Randomised	5 (9.6%)	6 (10.9%)	11 (10.3%)
		Completed	4 (7.7%)	5 (9.1%)	9 (8.4%)
183	XXXXXXXXXXXXXXXXXX	Randomised	4 (7.7%)	5 (9.1%)	9 (8.4%)
		Completed	3 (5.8%)	4 (7.3%)	7 (6.5%)
185	XXXXXXXXXXXXXXXXXX	Randomised	1 (1.9%)	1 (1.8%)	2 (1.9%)
		Completed	1 (1.9%)	1 (1.8%)	2 (1.9%)
186	XXXXXXXXXXXXXXXXXX	Randomised	1 (1.9%)	1 (1.8%)	2 (1.9%)
		Completed	1 (1.9%)	1 (1.8%)	2 (1.9%)
192	XXXXXXXXXXXXXXXXXX	Randomised	4 (7.7%)	3 (5.5%)	7 (6.5%)
		Completed	4 (7.7%)	3 (5.5%)	7 (6.5%)

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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=101)	Placebo (N=102)	Total (N=203)
148	XXXXXXXXXXXXXXXXXX	Randomised	2 (2.0%)	0	2 (1.0%)
		Completed	1 (1.0%)	0	1 (0.5%)
149	XXXXXXXXXXXXXXXXXX	Randomised	4 (4.0%)	4 (3.9%)	8 (3.9%)
		Completed	2 (2.0%)	3 (2.9%)	5 (2.5%)
150	XXXXXXXXXXXXXXXXXXXXX	Randomised	2 (2.0%)	1 (1.0%)	3 (1.5%)
		Completed	2 (2.0%)	1 (1.0%)	3 (1.5%)
151	XXXXXXXXXXXXXXXXXXXX	Randomised	1 (1.0%)	2 (2.0%)	3 (1.5%)
		Completed	0	2 (2.0%)	2 (1.0%)
152	XXXXXXXXXXXXXXXXXXXX	Randomised	1 (1.0%)	1 (1.0%)	2 (1.0%)
		Completed	1 (1.0%)	0	1 (0.5%)
153	XXXXXXXXXXXXXXXXXXXX	Randomised	0	1 (1.0%)	1 (0.5%)
		Completed	0	1 (1.0%)	1 (0.5%)
154	XXXXXXXXXXXXXXXXXXXXX	Randomised	2 (2.0%)	1 (1.0%)	3 (1.5%)
		Completed	2 (2.0%)	0	2 (1.0%)
155	XXXXXXXXXXXXXXXXXXXXX	Randomised	0	1 (1.0%)	1 (0.5%)
		Completed	0	1 (1.0%)	1 (0.5%)
156	XXXXXXXXXXXXXXXXXX	Randomised	1 (1.0%)	1 (1.0%)	2 (1.0%)
		Completed	1 (1.0%)	1 (1.0%)	2 (1.0%)
157	XXXXXXXXXXXXXXXXXX	Randomised	1 (1.0%)	0	1 (0.5%)
		Completed	1 (1.0%)	0	1 (0.5%)
158	XXXXXXXXXXXXXXXXXXXX	Randomised	1 (1.0%)	0	1 (0.5%)
		Completed	1 (1.0%)	0	1 (0.5%)
159	XXXXXXXXXXXXXXXXXXXX	Randomised	6 (5.9%)	6 (5.9%)	12 (5.9%)
		Completed	4 (4.0%)	5 (4.9%)	9 (4.4%)
160	XXXXXXXXXXXXXXXXXX	Randomised	2 (2.0%)	0	2 (1.0%)
		Completed	1 (1.0%)	0	1 (0.5%)
161	XXXXXXXXXXXXXXXXXXXX	Randomised	5 (5.0%)	5 (4.9%)	10 (4.9%)
		Completed	1 (1.0%)	4 (3.9%)	5 (2.5%)
162	XXXXXXXXXXXXXXXXXXXX	Randomised	7 (6.9%)	8 (7.8%)	15 (7.4%)
		Completed	6 (5.9%)	4 (3.9%)	10 (4.9%)

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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=101)	Placebo (N=102)	Total (N=203)
163	XXXXXXXXXXXXXXXXXX	Randomised	2 (2.0%)	1 (1.0%)	3 (1.5%)
164	XXXXXXXXXXXXXXXXXX	Randomised	3 (3.0%)	3 (2.9%)	6 (3.0%)
		Completed	3 (3.0%)	3 (2.9%)	6 (3.0%)
165	XXXXXXXXXXXXXXXXXX	Randomised	1 (1.0%)	2 (2.0%)	3 (1.5%)
		Completed	1 (1.0%)	2 (2.0%)	3 (1.5%)
166	XXXXXXXXXXXXXXXXX	Randomised	0	2 (2.0%)	2 (1.0%)
		Completed	0	2 (2.0%)	2 (1.0%)
167	XXXXXXXXXXXXXXXXXX	Randomised	1 (1.0%)	3 (2.9%)	4 (2.0%)
		Completed	1 (1.0%)	2 (2.0%)	3 (1.5%)
168	XXXXXXXXXXXXXXXXXX	Randomised	3 (3.0%)	3 (2.9%)	6 (3.0%)
		Completed	3 (3.0%)	2 (2.0%)	5 (2.5%)
169	XXXXXXXXXXXXXXXXXX	Randomised	0	1 (1.0%)	1 (0.5%)
		Completed	0	1 (1.0%)	1 (0.5%)
170	XXXXXXXXXXXXXXXXXX	Randomised	4 (4.0%)	3 (2.9%)	7 (3.4%)
		Completed	1 (1.0%)	3 (2.9%)	4 (2.0%)
171	XXXXXXXXXXXXXXXXXX	Randomised	0	1 (1.0%)	1 (0.5%)
		Completed	0	1 (1.0%)	1 (0.5%)
172	XXXXXXXXXXXXXXXXX	Randomised	2 (2.0%)	2 (2.0%)	4 (2.0%)
		Completed	1 (1.0%)	0	1 (0.5%)
173	XXXXXXXXXXXXXXXXXX	Randomised	2 (2.0%)	0	2 (1.0%)
		Completed	2 (2.0%)	0	2 (1.0%)
174	XXXXXXXXXXXXXXXXXX	Randomised	1 (1.0%)	1 (1.0%)	2 (1.0%)
		Completed	1 (1.0%)	0	1 (0.5%)
175	XXXXXXXXXXXXXXXXXX	Randomised	2 (2.0%)	1 (1.0%)	3 (1.5%)
		Completed	2 (2.0%)	0	2 (1.0%)
176	XXXXXXXXXXXXXXXXXX	Randomised	6 (5.9%)	6 (5.9%)	12 (5.9%)
		Completed	4 (4.0%)	5 (4.9%)	9 (4.4%)
178	XXXXXXXXXXXXXXXXXX	Randomised	4 (4.0%)	4 (3.9%)	8 (3.9%)
		Completed	4 (4.0%)	4 (3.9%)	8 (3.9%)

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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=101)	Placebo (N=102)	Total (N=203)
179	XXXXXXXXXXXXXXXXXX	Randomised	0	1 (1.0%)	1 (0.5%)
		Completed	0	1 (1.0%)	1 (0.5%)
180	XXXXXXXXXXXXXXXXX	Randomised	4 (4.0%)	3 (2.9%)	7 (3.4%)
		Completed	2 (2.0%)	1 (1.0%)	3 (1.5%)
181	XXXXXXXXXXXXXXXXX	Randomised	10 (9.9%)	11 (10.8%)	21 (10.3%)
		Completed	7 (6.9%)	8 (7.8%)	15 (7.4%)
182	XXXXXXXXXXXXXXXXXX	Randomised	2 (2.0%)	1 (1.0%)	3 (1.5%)
		Completed	0	1 (1.0%)	1 (0.5%)
183	XXXXXXXXXXXXXXXXX	Randomised	6 (5.9%)	9 (8.8%)	15 (7.4%)
		Completed	4 (4.0%)	8 (7.8%)	12 (5.9%)
184	XXXXXXXXXXXXXXXXX	Randomised	1 (1.0%)	0	1 (0.5%)
		Completed	1 (1.0%)	0	1 (0.5%)
185	XXXXXXXXXXXXXXXXX	Randomised	4 (4.0%)	5 (4.9%)	9 (4.4%)
		Completed	2 (2.0%)	5 (4.9%)	7 (3.4%)
186	XXXXXXXXXXXXXXXX	Randomised	3 (3.0%)	3 (2.9%)	6 (3.0%)
		Completed	3 (3.0%)	3 (2.9%)	6 (3.0%)
189	XXXXXXXXXXXXXXXXXX	Randomised	0	1 (1.0%)	1 (0.5%)
		Completed	0	1 (1.0%)	1 (0.5%)
192	XXXXXXXXXXXXXXXXXX	Randomised	5 (5.0%)	4 (3.9%)	9 (4.4%)
		Completed	5 (5.0%)	4 (3.9%)	9 (4.4%)

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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=49)	Placebo (N=47)	Total (N=96)
Gender	Female	23 (46.9%)	18 (38.3%)	41 (42.7%)
	Male	26 (53.1%)	29 (61.7%)	55 (57.3%)
Race	White	34 (69.4%)	39 (83.0%)	73 (76.0%)
	Black	9 (18.4%)	6 (12.8%)	15 (15.6%)
	Oriental	0	0	0
	Other	6 (12.2%)	2 (4.3%)	8 (8.3%)

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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=52)	Placebo (N=55)	Total (N=107)
Gender	Female	25 (48.1%)	29 (52.7%)	54 (50.5%)
	Male	27 (51.9%)	26 (47.3%)	53 (49.5%)
Race	White	43 (82.7%)	45 (81.8%)	88 (82.2%)
	Black	3 (5.8%)	5 (9.1%)	8 (7.5%)
	Oriental	1 (1.9%)	0	1 (0.9%)
	Other	5 (9.6%)	5 (9.1%)	10 (9.3%)

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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=101)	Placebo (N=102)	Total (N=203)
Gender	Female	48 (47.5%)	47 (46.1%)	95 (46.8%)
	Male	53 (52.5%)	55 (53.9%)	108 (53.2%)
Race	White	77 (76.2%)	84 (82.4%)	161 (79.3%)
	Black	12 (11.9%)	11 (10.8%)	23 (11.3%)
	Oriental	1 (1.0%)	0	1 (0.5%)
	Other	11 (10.9%)	7 (6.9%)	18 (8.9%)

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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=39)	Placebo (N=41)	Total (N=80)
Gender	Female	19 (48.7%)	17 (41.5%)	36 (45.0%)
	Male	20 (51.3%)	24 (58.5%)	44 (55.0%)
Race	White	28 (71.8%)	37 (90.2%)	65 (81.3%)
	Black	7 (17.9%)	3 (7.3%)	10 (12.5%)
	Oriental	0	0	0
	Other	4 (10.3%)	1 (2.4%)	5 (6.3%)

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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=35)	Placebo (N=42)	Total (N=77)
Gender	Female	16 (45.7%)	22 (52.4%)	38 (49.4%)
	Male	19 (54.3%)	20 (47.6%)	39 (50.6%)
Race	White	27 (77.1%)	35 (83.3%)	62 (80.5%)
	Black	3 (8.6%)	4 (9.5%)	7 (9.1%)
	Oriental	1 (2.9%)	0	1 (1.3%)
	Other	4 (11.4%)	3 (7.1%)	7 (9.1%)

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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=74)	Placebo (N=83)	Total (N=157)
Gender	Female	35 (47.3%)	39 (47.0%)	74 (47.1%)
	Male	39 (52.7%)	44 (53.0%)	83 (52.9%)
Race	White	55 (74.3%)	72 (86.7%)	127 (80.9%)
	Black	10 (13.5%)	7 (8.4%)	17 (10.8%)
	Oriental	1 (1.4%)	0	1 (0.6%)
	Other	8 (10.8%)	4 (4.8%)	12 (7.6%)

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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	Placebo	Total
Age (years)	N	49	47	96
	MEAN	9.2	9.4	9.3
	MEDIAN	9.0	10.0	9.0
	STD	1.28	1.28	1.28
	MINIMUM	7	7	7
	MAXIMUM	11	11	11
	MISSING	0	0	0
Height (cm)	N	49	47	96
	MEAN	139.33	138.44	138.90
	MEDIAN	137.80	137.20	137.50
	STD	11.024	10.303	10.630
	MINIMUM	116.8	119.4	116.8
	MAXIMUM	165.0	160.0	165.0
	MISSING	0	0	0
Weight (kg)	N	49	47	96
	MEAN	43.69	41.19	42.46
	MEDIAN	39.50	35.20	38.75
	STD	16.325	15.316	15.806
	MINIMUM	20.4	21.8	20.4
	MAXIMUM	94.5	89.0	94.5
	MISSING	0	0	0
BMI (kg/m2)	N	49	47	96
	MEAN	22.09	21.07	21.59
	MEDIAN	20.20	18.70	19.45
	STD	6.444	6.001	6.219
	MINIMUM	12.6	13.6	12.6
	MAXIMUM	40.7	35.6	40.7
	MISSING	0	0	0

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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	Placebo	Total
Age (years)	N	52	55	107
	MEAN	14.4	14.5	14.4
	MEDIAN	14.5	14.0	14.0
	STD	1.60	1.72	1.66
	MINIMUM	12	12	12
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	52	55	107
	MEAN	166.07	165.59	165.82
	MEDIAN	165.35	166.00	165.60
	STD	8.816	8.589	8.662
	MINIMUM	143.5	149.0	143.5
	MAXIMUM	185.4	185.4	185.4
	MISSING	0	0	0
Weight (kg)	N	52	55	107
	MEAN	71.83	67.77	69.74
	MEDIAN	67.35	61.80	63.20
	STD	21.273	20.171	20.716
	MINIMUM	36.8	35.3	35.3
	MAXIMUM	132.6	131.4	132.6
	MISSING	0	0	0
BMI (kg/m2)	N	52	55	107
	MEAN	25.91	24.48	25.17
	MEDIAN	24.45	23.00	23.70
	STD	7.017	6.027	6.536
	MINIMUM	17.4	15.3	15.3
	MAXIMUM	46.0	45.4	46.0
	MISSING	0	0	0

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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	Placebo	Total
Age (years)	N	101	102	203
	MEAN	11.9	12.1	12.0
	MEDIAN	12.0	12.0	12.0
	STD	3.00	2.95	2.97
	MINIMUM	7	7	7
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	101	102	203
	MEAN	153.10	153.08	153.09
	MEDIAN	156.00	153.35	154.30
	STD	16.683	16.512	16.556
	MINIMUM	116.8	119.4	116.8
	MAXIMUM	185.4	185.4	185.4
	MISSING	0	0	0
Weight (kg)	N	101	102	203
	MEAN	58.18	55.52	56.84
	MEDIAN	56.00	54.50	55.00
	STD	23.634	22.398	23.003
	MINIMUM	20.4	21.8	20.4
	MAXIMUM	132.6	131.4	132.6
	MISSING	0	0	0
BMI (kg/m2)	N	101	102	203
	MEAN	24.06	22.91	23.48
	MEDIAN	23.10	21.30	22.20
	STD	6.981	6.223	6.620
	MINIMUM	12.6	13.6	12.6
	MAXIMUM	46.0	45.4	46.0
	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 : Children

		Treatment Group		
	Statistic	Paroxetine	Placebo	Total
Age (years)	N	39	41	80
	MEAN	9.3	9.4	9.4
	MEDIAN	9.0	10.0	10.0
	STD	1.36	1.32	1.33
	MINIMUM	7	7	7
	MAXIMUM	11	11	11
	MISSING	0	0	0
Height (cm)	N	39	41	80
	MEAN	139.87	138.12	138.97
	MEDIAN	138.40	137.20	138.10
	STD	11.858	10.840	11.309
	MINIMUM	116.8	119.4	116.8
	MAXIMUM	165.0	160.0	165.0
	MISSING	0	0	0
Weight (kg)	N	39	41	80
	MEAN	44.71	41.85	43.24
	MEDIAN	41.80	38.50	40.20
	STD	16.212	15.883	16.007
	MINIMUM	22.2	21.8	21.8
	MAXIMUM	94.5	89.0	94.5
	MISSING	0	0	0
BMI (kg/m2)	N	39	41	80
	MEAN	22.49	21.46	21.96
	MEDIAN	22.20	19.40	20.60
	STD	6.444	6.100	6.252
	MINIMUM	14.4	13.6	13.6
	MAXIMUM	40.7	35.6	40.7
	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	Placebo	Total
Age (years)	N	35	42	77
	MEAN	14.4	14.5	14.4
	MEDIAN	15.0	14.0	14.0
	STD	1.57	1.78	1.68
	MINIMUM	12	12	12
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	35	42	77
	MEAN	167.05	166.09	166.53
	MEDIAN	166.00	166.40	166.40
	STD	8.393	9.033	8.704
	MINIMUM	143.5	149.0	143.5
	MAXIMUM	185.0	185.4	185.4
	MISSING	0	0	0
Weight (kg)	N	35	42	77
	MEAN	73.57	70.34	71.81
	MEDIAN	68.00	62.15	65.00
	STD	22.060	21.553	21.701
	MINIMUM	40.9	40.0	40.0
	MAXIMUM	132.6	131.4	132.6
	MISSING	0	0	0
BMI (kg/m2)	N	35	42	77
	MEAN	26.27	25.24	25.71
	MEDIAN	24.80	23.65	24.30
	STD	7.397	6.424	6.856
	MINIMUM	17.4	16.9	16.9
	MAXIMUM	46.0	45.4	46.0
	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 : Total

		Treatment Group		
	Statistic	Paroxetine	Placebo	Total
Age (years)	N	74	83	157
	MEAN	11.7	12.0	11.8
	MEDIAN	11.0	12.0	11.0
	STD	2.94	2.98	2.95
	MINIMUM	7	7	7
	MAXIMUM	17	17	17
	MISSING	0	0	0
Height (cm)	N	74	83	157
	MEAN	152.72	152.28	152.49
	MEDIAN	154.95	152.50	153.70
	STD	17.105	17.206	17.105
	MINIMUM	116.8	119.4	116.8
	MAXIMUM	185.0	185.4	185.4
	MISSING	0	0	0
Weight (kg)	N	74	83	157
	MEAN	58.36	56.27	57.25
	MEDIAN	55.80	54.30	55.00
	STD	23.958	23.680	23.758
	MINIMUM	22.2	21.8	21.8
	MAXIMUM	132.6	131.4	132.6
	MISSING	0	0	0
BMI (kg/m2)	N	74	83	157
	MEAN	24.28	23.37	23.80
	MEDIAN	23.20	21.80	22.80
	STD	7.121	6.513	6.799
	MINIMUM	14.4	13.6	13.6
	MAXIMUM	46.0	45.4	46.0
	MISSING	0	0	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=101)	Placebo (N=102)	Total (N=203)
Patients with at least one Prior Condition		56 (55.4%)	58 (56.9%)	114 (56.2%)
CARDIOVASCULAR	Total	1 (1.0%)	6 (5.9%)	7 (3.4%)
	CARDIAC MURMURS	1 (1.0%)	1 (1.0%)	2 (1.0%)
	CARDIOMYOPATHY, PRIMARY	1 (1.0%)	0	1 (0.5%)
	HYPERTENSION	1 (1.0%)	0	1 (0.5%)
	MIGRAINE	0	4 (3.9%)	4 (2.0%)
	OPERATION, OTHER VESSELS	0	1 (1.0%)	1 (0.5%)
CAUSES OF INJURY	Total	4 (4.0%)	3 (2.9%)	7 (3.4%)
	ADVERSE EFF/ANALGESIC	1 (1.0%)	0	1 (0.5%)
	ADVERSE EFF/ANTIBIOTIC	2 (2.0%)	2 (2.0%)	4 (2.0%)
	ADVERSE EFF/PSYCHOTROPICS	0	1 (1.0%)	1 (0.5%)
	ADVERSE EFF/VACCINE	1 (1.0%)	0	1 (0.5%)
DIAGNOSTIC/THERAPEUTIC PROCS	Total	2 (2.0%)	0	2 (1.0%)
	PROCEDURE, EYE/EAR	2 (2.0%)	0	2 (1.0%)
DIGESTIVE	Total	6 (5.9%)	12 (11.8%)	18 (8.9%)
	BACT FOOD POISONING	0	1 (1.0%)	1 (0.5%)
	DIARRHEA	1 (1.0%)	0	1 (0.5%)
	DIGESTIVE DISORD, OTHER	0	1 (1.0%)	1 (0.5%)
	DYSPEPSIA	2 (2.0%)	1 (1.0%)	3 (1.5%)
	GASTRITIS/DUODENITIS	1 (1.0%)	1 (1.0%)	2 (1.0%)
	INTEST MALABSORPTION	0	1 (1.0%)	1 (0.5%)
	MELENA	0	1 (1.0%)	1 (0.5%)
	OPERATION, APPENDIX	0	1 (1.0%)	1 (0.5%)
	OPERATION, NOSE/MOUTH	1 (1.0%)	2 (2.0%)	3 (1.5%)
	OPERATION, STOMACH	0	1 (1.0%)	1 (0.5%)
	ORAL SOFT TISSUE DIS	0	2 (2.0%)	2 (1.0%)
	PERIODONTAL DIS	0	1 (1.0%)	1 (0.5%)
	SHIGELLOSIS	0	1 (1.0%)	1 (0.5%)
	STOMACH/DUODENUM DISORD	1 (1.0%)	1 (1.0%)	2 (1.0%)
	TEETH DISORD	0	1 (1.0%)	1 (0.5%)
	TONGUE DISORD	1 (1.0%)	0	1 (0.5%)
	ULCER, GASTRIC	0	1 (1.0%)	1 (0.5%)
FACTORS INFLUENCING HEALTH	Total	0	2 (2.0%)	2 (1.0%)
	ALCOHOL INGESTION, OTHER	0	2 (2.0%)	2 (1.0%)
GENERAL BODY OR SYS UNSPEC	Total	21 (20.8%)	21 (20.6%)	42 (20.7%)
	ALLERGIC REACTION, FOOD	1 (1.0%)	2 (2.0%)	3 (1.5%)
	ALLERGY, NEC	0	1 (1.0%)	1 (0.5%)
	BACK PAIN	1 (1.0%)	0	1 (0.5%)
	BACT DIS, OTHER	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=101)	Placebo (N=102)	Total (N=203)
GENERAL BODY OR SYS UNSPEC	BURNS	0	1 (1.0%)	1 (0.5%)
	CELLULITIS/ABSCESS	1 (1.0%)	0	1 (0.5%)
	CONTUSION	0	1 (1.0%)	1 (0.5%)
	DEVELOPMENT, ABN	0	1 (1.0%)	1 (0.5%)
	HEADACHE	4 (4.0%)	1 (1.0%)	5 (2.5%)
	HERNIA, ABDOMINAL	1 (1.0%)	0	1 (0.5%)
	INJURY/POIS, OTHER	2 (2.0%)	4 (3.9%)	6 (3.0%)
	OPEN WOUND	0	3 (2.9%)	3 (1.5%)
	OPERATION, HERNIA REPAIR	2 (2.0%)	1 (1.0%)	3 (1.5%)
	OPERATION, OTHER MUSCULOSKEL	1 (1.0%)	0	1 (0.5%)
	OPERATION, RESP	1 (1.0%)	0	1 (0.5%)
	PAIN UNSP, CHEST	1 (1.0%)	0	1 (0.5%)
	PAIN, ABDOMINO-PELVIC	2 (2.0%)	0	2 (1.0%)
	PAIN, LIMB	1 (1.0%)	0	1 (0.5%)
	TOXIC EFFECTS, NONMEDICINAL	1 (1.0%)	0	1 (0.5%)
	TOXIC EFFECTS, VENOM	1 (1.0%)	0	1 (0.5%)
	TRAUMA/INJURIES, UNSPEC	0	1 (1.0%)	1 (0.5%)
	TRAUMATIC AMPUTATION	1 (1.0%)	0	1 (0.5%)
	VIRAL DIS/EXANTHEM	3 (3.0%)	6 (5.9%)	9 (4.4%)
	VIRUS/CHLAMYD DIS, OTHER	2 (2.0%)	0	2 (1.0%)
GENITOURINARY	Total	4 (4.0%)	6 (5.9%)	10 (4.9%)
	CONG ANOM, GU	0	1 (1.0%)	1 (0.5%)
	GENITAL FEMALE DISORD, OTHER	0	3 (2.9%)	3 (1.5%)
	GENITAL MALE DISORD, OTHER	1 (1.0%)	0	1 (0.5%)
	HEMATURIA	1 (1.0%)	0	1 (0.5%)
	OPERATION, BREAST	1 (1.0%)	0	1 (0.5%)
	OPERATION, MALE GENITAL	2 (2.0%)	0	2 (1.0%)
	PROTEINURIA	0	1 (1.0%)	1 (0.5%)
	URETHRAL DISORD	1 (1.0%)	0	1 (0.5%)
	URINARY TRACT INFECTION	0	1 (1.0%)	1 (0.5%)
HEMATIC/HEMATOPOIETIC/LYMPH	Total	2 (2.0%)	3 (2.9%)	5 (2.5%)
	ANEMIA, HEMOLYT, HERED	1 (1.0%)	0	1 (0.5%)
	ANEMIA, OTHER	1 (1.0%)	2 (2.0%)	3 (1.5%)
	LEUKOPENIA	0	1 (1.0%)	1 (0.5%)
	LYMPHADENOPATHY	0	1 (1.0%)	1 (0.5%)
INTEGUMENTARY	Total	9 (8.9%)	3 (2.9%)	12 (5.9%)
	IMPETIGO	1 (1.0%)	0	1 (0.5%)
	INFLAM SKIN/SUBCUT	2 (2.0%)	2 (2.0%)	4 (2.0%)
	MYCOSES	0	1 (1.0%)	1 (0.5%)
	OPERATION, SKIN/SUBCUT	2 (2.0%)	0	2 (1.0%)
	RASH/OTHER SKIN ERUPTION	2 (2.0%)	0	2 (1.0%)
	SCARRING	0	1 (1.0%)	1 (0.5%)
	SKIN/SUBCUT DISORD, OTHER	1 (1.0%)	0	1 (0.5%)

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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=101)	Placebo (N=102)	Total (N=203)
INTEGUMENTARY	URTICARIA	1 (1.0%)	0	1 (0.5%)
METABOLIC/NUTRITIONAL/IMMUNE	Total	5 (5.0%)	3 (2.9%)	8 (3.9%)
	HYPOGLYCEMIA	2 (2.0%)	1 (1.0%)	3 (1.5%)
	OBESITY	3 (3.0%)	1 (1.0%)	4 (2.0%)
	TRANSAMINASE/LDH, ELEVATION	0	1 (1.0%)	1 (0.5%)
MUSCULOSKELETAL	Total	5 (5.0%)	10 (9.8%)	15 (7.4%)
	BONE/CARTIL DISORD, OTHER	0	1 (1.0%)	1 (0.5%)
	CONG ANOM, MUSCULOSKEL	2 (2.0%)	0	2 (1.0%)
	FRACTURE, LOWER LIMB	1 (1.0%)	1 (1.0%)	2 (1.0%)
	FRACTURE, SKULL	0	1 (1.0%)	1 (0.5%)
	FRACTURE, UPPER LIMB	1 (1.0%)	2 (2.0%)	3 (1.5%)
	JOINT DISORD, OTHER	0	3 (2.9%)	3 (1.5%)
	OPERATION, BONE/JOINT	1 (1.0%)	2 (2.0%)	3 (1.5%)
	OPERATION, MUSCLE/TENDON	0	1 (1.0%)	1 (0.5%)
	RHEUMATIC DISORD	0	1 (1.0%)	1 (0.5%)
	SPRAINS/STRAINS	1 (1.0%)	1 (1.0%)	2 (1.0%)
NERVOUS/SENSE ORGANS	Total	20 (19.8%)	17 (16.7%)	37 (18.2%)
	AUT NERV SYST DISORD	0	1 (1.0%)	1 (0.5%)
	BLINDNESS	1 (1.0%)	0	1 (0.5%)
	CONDITIONS, PERINATAL	1 (1.0%)	0	1 (0.5%)
	CONGEN ANOM, HEAD/NECK	1 (1.0%)	0	1 (0.5%)
	CONTUSION	0	1 (1.0%)	1 (0.5%)
	CONVULSIONS	1 (1.0%)	1 (1.0%)	2 (1.0%)
	EAR/MASTOID DISORD	0	1 (1.0%)	1 (0.5%)
	HEARING LOSS	1 (1.0%)	0	1 (0.5%)
	INJURY, INTRACRANIAL	4 (4.0%)	1 (1.0%)	5 (2.5%)
	INJURY, NERVE	1 (1.0%)	0	1 (0.5%)
	INSOMNIA	1 (1.0%)	1 (1.0%)	2 (1.0%)
	MENINGITIS	1 (1.0%)	0	1 (0.5%)
	OPEN WOUND	1 (1.0%)	0	1 (0.5%)
	OPERATION, EAR	6 (5.9%)	8 (7.8%)	14 (6.9%)
	OPERATION, EYE	1 (1.0%)	0	1 (0.5%)
	OTITIS MEDIA	8 (7.9%)	6 (5.9%)	14 (6.9%)
	POLIO AND CNS DIS, VIRAL	1 (1.0%)	0	1 (0.5%)
	TREMOR	1 (1.0%)	0	1 (0.5%)
	VISUAL DISTURB	0	1 (1.0%)	1 (0.5%)
PSYCHOLOGICAL DISORDERS	Total	1 (1.0%)	5 (4.9%)	6 (3.0%)
	ANXIETY	1 (1.0%)	0	1 (0.5%)
	CONDUCT DISORD	0	1 (1.0%)	1 (0.5%)
	DRUG ABUSE	0	1 (1.0%)	1 (0.5%)
	MENTAL DEVELOP DISORD	0	1 (1.0%)	1 (0.5%)
	POSTCONCUSSION SYNDROME	0	1 (1.0%)	1 (0.5%)

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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=101)	Placebo (N=102)	Total (N=203)
PSYCHOLOGICAL DISORDERS	TOBACCO USE	0	1 (1.0%)	1 (0.5%)
RESPIRATORY	Total	27 (26.7%)	26 (25.5%)	53 (26.1%)
	ASTHMA	12 (11.9%)	10 (9.8%)	22 (10.8%)
	BRONCHITIS, OTHER	1 (1.0%)	0	1 (0.5%)
	FOREIGN BODY EFF	0	1 (1.0%)	1 (0.5%)
	INFECTION, BACTERIAL	1 (1.0%)	0	1 (0.5%)
	NASAL SEPTUM DEVIATED	0	1 (1.0%)	1 (0.5%)
	NASOPHARYNGITIS, ACUTE	0	1 (1.0%)	1 (0.5%)
	OPERATION, NOSE/MOUTH	9 (8.9%)	9 (8.8%)	18 (8.9%)
	OPERATION, RESP	0	1 (1.0%)	1 (0.5%)
	PHARYNGITIS, ACUTE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	PLEURISY	1 (1.0%)	0	1 (0.5%)
	PNEUMONIA, OTHER	2 (2.0%)	0	2 (1.0%)
	RHINITIS, ALLERGIC	3 (3.0%)	6 (5.9%)	9 (4.4%)
	SINUSITIS, OTHER	0	1 (1.0%)	1 (0.5%)
	SINUSITIS,NOS	1 (1.0%)	2 (2.0%)	3 (1.5%)
	TONSILLITIS, ACUTE	2 (2.0%)	1 (1.0%)	3 (1.5%)
	TONSILS/ADENOIDS DIS	1 (1.0%)	0	1 (0.5%)
	TUBERCULOSIS	1 (1.0%)	0	1 (0.5%)
	UPPER RESP DIS, OTHER	0	1 (1.0%)	1 (0.5%)
	UPPER RESP DISORD, OTHER	1 (1.0%)	0	1 (0.5%)
	UPPER RESP INFECT, ACUTE	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=101)	Placebo (N=102)	Total (N=203)
Patients with at least one Prior Condition	56 (55.4%)	58 (56.9%)	114 (56.2%)
ASTHMA	12 (11.9%)	10 (9.8%)	22 (10.8%)
OPERATION, NOSE/MOUTH	10 (9.9%)	11 (10.8%)	21 (10.3%)
OTITIS MEDIA	8 (7.9%)	6 (5.9%)	14 (6.9%)
OPERATION, EAR	6 (5.9%)	8 (7.8%)	14 (6.9%)
HEADACHE	4 (4.0%)	1 (1.0%)	5 (2.5%)
INJURY, INTRACRANIAL	4 (4.0%)	1 (1.0%)	5 (2.5%)
RHINITIS, ALLERGIC	3 (3.0%)	6 (5.9%)	9 (4.4%)
VIRAL DIS/EXANTHEM	3 (3.0%)	6 (5.9%)	9 (4.4%)
OBESITY	3 (3.0%)	1 (1.0%)	4 (2.0%)
INJURY/POIS, OTHER	2 (2.0%)	4 (3.9%)	6 (3.0%)
ADVERSE EFF/ANTIBIOTIC	2 (2.0%)	2 (2.0%)	4 (2.0%)
INFLAM SKIN/SUBCUT	2 (2.0%)	2 (2.0%)	4 (2.0%)
DYSPEPSIA	2 (2.0%)	1 (1.0%)	3 (1.5%)
HYPOGLYCEMIA	2 (2.0%)	1 (1.0%)	3 (1.5%)
OPERATION, HERNIA REPAIR	2 (2.0%)	1 (1.0%)	3 (1.5%)
TONSILLITIS, ACUTE	2 (2.0%)	1 (1.0%)	3 (1.5%)
CONG ANOM, MUSCULOSKEL	2 (2.0%)	0	2 (1.0%)
OPERATION, MALE GENITAL	2 (2.0%)	0	2 (1.0%)
OPERATION, SKIN/SUBCUT	2 (2.0%)	0	2 (1.0%)
PAIN, ABDOMINO-PELVIC	2 (2.0%)	0	2 (1.0%)
PNEUMONIA, OTHER	2 (2.0%)	0	2 (1.0%)
PROCEDURE, EYE/EAR	2 (2.0%)	0	2 (1.0%)
RASH/OTHER SKIN ERUPTION	2 (2.0%)	0	2 (1.0%)
VIRUS/CHLAMYD DIS, OTHER	2 (2.0%)	0	2 (1.0%)
OPEN WOUND	1 (1.0%)	3 (2.9%)	4 (2.0%)
ALLERGIC REACTION, FOOD	1 (1.0%)	2 (2.0%)	3 (1.5%)
ANEMIA, OTHER	1 (1.0%)	2 (2.0%)	3 (1.5%)
FRACTURE, UPPER LIMB	1 (1.0%)	2 (2.0%)	3 (1.5%)
OPERATION, BONE/JOINT	1 (1.0%)	2 (2.0%)	3 (1.5%)
SINUSITIS,NOS	1 (1.0%)	2 (2.0%)	3 (1.5%)
BACT DIS, OTHER	1 (1.0%)	1 (1.0%)	2 (1.0%)
CARDIAC MURMURS	1 (1.0%)	1 (1.0%)	2 (1.0%)
CONVULSIONS	1 (1.0%)	1 (1.0%)	2 (1.0%)
FRACTURE, LOWER LIMB	1 (1.0%)	1 (1.0%)	2 (1.0%)
GASTRITIS/DUODENITIS	1 (1.0%)	1 (1.0%)	2 (1.0%)
INSOMNIA	1 (1.0%)	1 (1.0%)	2 (1.0%)
OPERATION, RESP	1 (1.0%)	1 (1.0%)	2 (1.0%)
PHARYNGITIS, ACUTE	1 (1.0%)	1 (1.0%)	2 (1.0%)
SPRAINS/STRAINS	1 (1.0%)	1 (1.0%)	2 (1.0%)
STOMACH/DUODENUM DISORD	1 (1.0%)	1 (1.0%)	2 (1.0%)
ADVERSE EFF/ANALGESIC	1 (1.0%)	0	1 (0.5%)
ADVERSE EFF/VACCINE	1 (1.0%)	0	1 (0.5%)
ANEMIA, HEMOLYT, HERED	1 (1.0%)	0	1 (0.5%)
ANXIETY	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=101)	Placebo (N=102)	Total (N=203)
BACK PAIN	1 (1.0%)	0	1 (0.5%)
BLINDNESS	1 (1.0%)	0	1 (0.5%)
BRONCHITIS, OTHER	1 (1.0%)	0	1 (0.5%)
CARDIOMYOPATHY, PRIMARY	1 (1.0%)	0	1 (0.5%)
CELLULITIS/ABSCESS	1 (1.0%)	0	1 (0.5%)
CONDITIONS, PERINATAL	1 (1.0%)	0	1 (0.5%)
CONGEN ANOM, HEAD/NECK	1 (1.0%)	0	1 (0.5%)
DIARRHEA	1 (1.0%)	0	1 (0.5%)
GENITAL MALE DISORD, OTHER	1 (1.0%)	0	1 (0.5%)
HEARING LOSS	1 (1.0%)	0	1 (0.5%)
HEMATURIA	1 (1.0%)	0	1 (0.5%)
HERNIA, ABDOMINAL	1 (1.0%)	0	1 (0.5%)
HYPERTENSION	1 (1.0%)	0	1 (0.5%)
IMPETIGO	1 (1.0%)	0	1 (0.5%)
INFECTION, BACTERIAL	1 (1.0%)	0	1 (0.5%)
INJURY, NERVE	1 (1.0%)	0	1 (0.5%)
MENINGITIS	1 (1.0%)	0	1 (0.5%)
OPERATION, BREAST	1 (1.0%)	0	1 (0.5%)
OPERATION, EYE	1 (1.0%)	0	1 (0.5%)
OPERATION, OTHER MUSCULOSKEL	1 (1.0%)	0	1 (0.5%)
PAIN UNSP, CHEST	1 (1.0%)	0	1 (0.5%)
PAIN, LIMB	1 (1.0%)	0	1 (0.5%)
PLEURISY	1 (1.0%)	0	1 (0.5%)
POLIO AND CNS DIS, VIRAL	1 (1.0%)	0	1 (0.5%)
SKIN/SUBCUT DISORD, OTHER	1 (1.0%)	0	1 (0.5%)
TONGUE DISORD	1 (1.0%)	0	1 (0.5%)
TONSILS/ADENOIDS DIS	1 (1.0%)	0	1 (0.5%)
TOXIC EFFECTS, NONMEDICINAL	1 (1.0%)	0	1 (0.5%)
TOXIC EFFECTS, VENOM	1 (1.0%)	0	1 (0.5%)
TRAUMATIC AMPUTATION	1 (1.0%)	0	1 (0.5%)
TREMOR	1 (1.0%)	0	1 (0.5%)
TUBERCULOSIS	1 (1.0%)	0	1 (0.5%)
UPPER RESP DISORD, OTHER	1 (1.0%)	0	1 (0.5%)
UPPER RESP INFECT, ACUTE	1 (1.0%)	0	1 (0.5%)
URETHRAL DISORD	1 (1.0%)	0	1 (0.5%)
URTICARIA	1 (1.0%)	0	1 (0.5%)
MIGRAINE	0	4 (3.9%)	4 (2.0%)
GENITAL FEMALE DISORD, OTHER	0	3 (2.9%)	3 (1.5%)
JOINT DISORD, OTHER	0	3 (2.9%)	3 (1.5%)
ALCOHOL INGESTION, OTHER	0	2 (2.0%)	2 (1.0%)
CONTUSION	0	2 (2.0%)	2 (1.0%)
ORAL SOFT TISSUE DIS	0	2 (2.0%)	2 (1.0%)
ADVERSE EFF/PSYCHOTROPICS	0	1 (1.0%)	1 (0.5%)
ALLERGY, NEC	0	1 (1.0%)	1 (0.5%)
AUT NERV SYST DISORD	0	1 (1.0%)	1 (0.5%)
BACT FOOD POISONING	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=101)	Placebo (N=102)	Total (N=203)
BONE/CARTIL DISORD, OTHER	0	1 (1.0%)	1 (0.5%)
BURNS	0	1 (1.0%)	1 (0.5%)
CONDUCT DISORD	0	1 (1.0%)	1 (0.5%)
CONG ANOM, GU	0	1 (1.0%)	1 (0.5%)
DEVELOPMENT, ABN	0	1 (1.0%)	1 (0.5%)
DIGESTIVE DISORD, OTHER	0	1 (1.0%)	1 (0.5%)
DRUG ABUSE	0	1 (1.0%)	1 (0.5%)
EAR/MASTOID DISORD	0	1 (1.0%)	1 (0.5%)
FOREIGN BODY EFF	0	1 (1.0%)	1 (0.5%)
FRACTURE, SKULL	0	1 (1.0%)	1 (0.5%)
INTEST MALABSORPTION	0	1 (1.0%)	1 (0.5%)
LEUKOPENIA	0	1 (1.0%)	1 (0.5%)
LYMPHADENOPATHY	0	1 (1.0%)	1 (0.5%)
MELENA	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%)
NASAL SEPTUM DEVIATED	0	1 (1.0%)	1 (0.5%)
NASOPHARYNGITIS, ACUTE	0	1 (1.0%)	1 (0.5%)
OPERATION, APPENDIX	0	1 (1.0%)	1 (0.5%)
OPERATION, MUSCLE/TENDON	0	1 (1.0%)	1 (0.5%)
OPERATION, OTHER VESSELS	0	1 (1.0%)	1 (0.5%)
OPERATION, STOMACH	0	1 (1.0%)	1 (0.5%)
PERIODONTAL DIS	0	1 (1.0%)	1 (0.5%)
POSTCONCUSSION SYNDROME	0	1 (1.0%)	1 (0.5%)
PROTEINURIA	0	1 (1.0%)	1 (0.5%)
RHEUMATIC DISORD	0	1 (1.0%)	1 (0.5%)
SCARRING	0	1 (1.0%)	1 (0.5%)
SHIGELLOSIS	0	1 (1.0%)	1 (0.5%)
SINUSITIS, OTHER	0	1 (1.0%)	1 (0.5%)
TEETH DISORD	0	1 (1.0%)	1 (0.5%)
TOBACCO USE	0	1 (1.0%)	1 (0.5%)
TRANSAMINASE/LDH, ELEVATION	0	1 (1.0%)	1 (0.5%)
TRAUMA/INJURIES, UNSPEC	0	1 (1.0%)	1 (0.5%)
ULCER, GASTRIC	0	1 (1.0%)	1 (0.5%)
UPPER RESP DIS, OTHER	0	1 (1.0%)	1 (0.5%)
URINARY TRACT INFECTION	0	1 (1.0%)	1 (0.5%)
VISUAL DISTURB	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=101)	Placebo (N=102)	Total (N=203)
Patients with at least one Active Condition		70 (69.3%)	61 (59.8%)	131 (64.5%)
CARDIOVASCULAR	Total	5 (5.0%)	5 (4.9%)	10 (4.9%)
	CARDIAC MURMURS	1 (1.0%)	0	1 (0.5%)
	FLUSHING	0	1 (1.0%)	1 (0.5%)
	MIGRAINE	4 (4.0%)	3 (2.9%)	7 (3.4%)
	SYNCOPE AND COLLAPSE	0	1 (1.0%)	1 (0.5%)
CAUSES OF INJURY	Total	9 (8.9%)	5 (4.9%)	14 (6.9%)
	ADVERSE EFF/ANALGESIC	2 (2.0%)	1 (1.0%)	3 (1.5%)
	ADVERSE EFF/ANTI-INFECT	0	1 (1.0%)	1 (0.5%)
	ADVERSE EFF/ANTIBIOTIC	6 (5.9%)	4 (3.9%)	10 (4.9%)
	ADVERSE EFF/SKIN,MUC MEMB DRUG	1 (1.0%)	0	1 (0.5%)
	ADVERSE EFF/VACCINE	1 (1.0%)	0	1 (0.5%)
DIAGNOSTIC/THERAPEUTIC PROCS	Total	2 (2.0%)	1 (1.0%)	3 (1.5%)
	PROCEDURE, EYE/EAR	2 (2.0%)	1 (1.0%)	3 (1.5%)
DIGESTIVE	Total	6 (5.9%)	9 (8.8%)	15 (7.4%)
	CONSTIPATION	0	2 (2.0%)	2 (1.0%)
	DYSPEPSIA	4 (4.0%)	2 (2.0%)	6 (3.0%)
	GASTRIC RETENTION	0	1 (1.0%)	1 (0.5%)
	HEARTBURN	1 (1.0%)	0	1 (0.5%)
	INTEST MALABSORPTION	0	1 (1.0%)	1 (0.5%)
	NAUSEA	1 (1.0%)	1 (1.0%)	2 (1.0%)
	ORAL SOFT TISSUE DIS	0	1 (1.0%)	1 (0.5%)
	PERIODONTAL DIS	1 (1.0%)	0	1 (0.5%)
	TEETH DISORD	0	1 (1.0%)	1 (0.5%)
	VOMITING	1 (1.0%)	0	1 (0.5%)
ENDOCRINE	Total	2 (2.0%)	0	2 (1.0%)
	HYPOTHYROIDISM	1 (1.0%)	0	1 (0.5%)
	THYROIDITIS	1 (1.0%)	0	1 (0.5%)
GENERAL BODY OR SYS UNSPEC	Total	27 (26.7%)	33 (32.4%)	60 (29.6%)
	ADVERSE EFF/OTHER	0	1 (1.0%)	1 (0.5%)
	ALLERGIC REACTION, FOOD	4 (4.0%)	2 (2.0%)	6 (3.0%)
	ALLERGY, NEC	6 (5.9%)	3 (2.9%)	9 (4.4%)
	BACK PAIN	3 (3.0%)	1 (1.0%)	4 (2.0%)
	BACT DIS, OTHER	0	2 (2.0%)	2 (1.0%)
	CONG ANOM, OTHER	0	1 (1.0%)	1 (0.5%)
	CONTUSION	1 (1.0%)	0	1 (0.5%)
	HEADACHE	15 (14.9%)	21 (20.6%)	36 (17.7%)
	PAIN UNSP, CHEST	1 (1.0%)	0	1 (0.5%)
	PAIN, ABDOMINO-PELVIC	5 (5.0%)	5 (4.9%)	10 (4.9%)

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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=101)	Placebo (N=102)	Total (N=203)
GENERAL BODY OR SYS UNSPEC	PAIN, GENERAL	1 (1.0%)	1 (1.0%)	2 (1.0%)
	PAIN, LIMB	5 (5.0%)	0	5 (2.5%)
	TOXIC EFFECTS, VENOM	1 (1.0%)	0	1 (0.5%)
	TRAUMA/INJURIES, UNSPEC	0	1 (1.0%)	1 (0.5%)
GENITOURINARY	Total	4 (4.0%)	7 (6.9%)	11 (5.4%)
	BREAST HYPERTROPHY, UNSP	1 (1.0%)	0	1 (0.5%)
	GENITAL FEMALE DISORD, OTHER	0	6 (5.9%)	6 (3.0%)
	HEMATURIA	1 (1.0%)	2 (2.0%)	3 (1.5%)
	URETHRAL DISORD	1 (1.0%)	0	1 (0.5%)
	URINARY CASTS/WBC'S	1 (1.0%)	0	1 (0.5%)
HEMATIC/HEMATOPOIETIC/LYMPH	Total	2 (2.0%)	0	2 (1.0%)
	ANEMIA, HEMOLYT, HERED	1 (1.0%)	0	1 (0.5%)
	ANEMIA, OTHER	1 (1.0%)	0	1 (0.5%)
INTEGUMENTARY	Total	10 (9.9%)	13 (12.7%)	23 (11.3%)
	ALOPECIA	0	1 (1.0%)	1 (0.5%)
	DYSCHROMIA	0	2 (2.0%)	2 (1.0%)
	INFLAM SKIN/SUBCUT	2 (2.0%)	3 (2.9%)	5 (2.5%)
	PRURITUS DISORD, UNSPEC	0	1 (1.0%)	1 (0.5%)
	RASH/OTHER SKIN ERUPTION	3 (3.0%)	0	3 (1.5%)
	SKIN/SUBCUT DISORD, OTHER	4 (4.0%)	7 (6.9%)	11 (5.4%)
	URTICARIA	1 (1.0%)	0	1 (0.5%)
METABOLIC/NUTRITIONAL/IMMUNE	Total	10 (9.9%)	7 (6.9%)	17 (8.4%)
	CARBOHYDRATE DISORD	0	1 (1.0%)	1 (0.5%)
	CHOLEST/TRIGLYCERIDE, ELEVATED	1 (1.0%)	0	1 (0.5%)
	OBESITY	9 (8.9%)	6 (5.9%)	15 (7.4%)
MUSCULOSKELETAL	Total	2 (2.0%)	7 (6.9%)	9 (4.4%)
	BONE/CARTIL DISORD, OTHER	1 (1.0%)	0	1 (0.5%)
	DEFORMITY, ACQUIRED	1 (1.0%)	2 (2.0%)	3 (1.5%)
	FRACTURE, SKULL	0	1 (1.0%)	1 (0.5%)
	JOINT DISORD, OTHER	0	2 (2.0%)	2 (1.0%)
	MYALGIA	0	1 (1.0%)	1 (0.5%)
	SPRAINS/STRAINS	0	2 (2.0%)	2 (1.0%)
NERVOUS/SENSE ORGANS	Total	13 (12.9%)	13 (12.7%)	26 (12.8%)
	BLINDNESS	1 (1.0%)	0	1 (0.5%)
	CONGEN ANOM, HEAD/NECK	1 (1.0%)	0	1 (0.5%)
	CONJUNCTIVAL DISORD	1 (1.0%)	0	1 (0.5%)
	DISTURBANCE, SPEECH	0	1 (1.0%)	1 (0.5%)
	DIZZINESS AND GIDDINESS	1 (1.0%)	1 (1.0%)	2 (1.0%)
	EAR/MASTOID DISORD	0	1 (1.0%)	1 (0.5%)
	HEARING LOSS	1 (1.0%)	1 (1.0%)	2 (1.0%)

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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=101)	Placebo (N=102)	Total (N=203)
NERVOUS/SENSE ORGANS	INJURY, NERVE	1 (1.0%)	0	1 (0.5%)
	INSOMNIA	5 (5.0%)	3 (2.9%)	8 (3.9%)
	OPERATION, EAR	0	2 (2.0%)	2 (1.0%)
	OTITIS MEDIA	4 (4.0%)	3 (2.9%)	7 (3.4%)
	VISUAL DISTURB	2 (2.0%)	5 (4.9%)	7 (3.4%)
PSYCHOLOGICAL DISORDERS	Total	6 (5.9%)	3 (2.9%)	9 (4.4%)
	AGITATION	3 (3.0%)	2 (2.0%)	5 (2.5%)
	ALCOHOLIC DEPEND	1 (1.0%)	0	1 (0.5%)
	ANXIETY	4 (4.0%)	2 (2.0%)	6 (3.0%)
	DRUG ABUSE	1 (1.0%)	0	1 (0.5%)
	NEUROSES	0	1 (1.0%)	1 (0.5%)
	TOBACCO USE	1 (1.0%)	0	1 (0.5%)
RESPIRATORY	Total	31 (30.7%)	27 (26.5%)	58 (28.6%)
	ASTHMA	14 (13.9%)	9 (8.8%)	23 (11.3%)
	DYSPNEA, OTHER	0	1 (1.0%)	1 (0.5%)
	INFECTION, BACTERIAL	0	1 (1.0%)	1 (0.5%)
	NASOPHARYNGITIS, ACUTE	1 (1.0%)	0	1 (0.5%)
	RHINITIS, ALLERGIC	13 (12.9%)	16 (15.7%)	29 (14.3%)
	SINUSITIS, OTHER	1 (1.0%)	1 (1.0%)	2 (1.0%)
	SINUSITIS,NOS	4 (4.0%)	3 (2.9%)	7 (3.4%)
	TUBERCULOSIS	1 (1.0%)	0	1 (0.5%)
	UPPER RESP DIS, OTHER	0	1 (1.0%)	1 (0.5%)
	UPPER RESP DISORD, OTHER	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=101)	Placebo (N=102)	Total (N=203)
Patients with at least one Active Condition	70 (69.3%)	61 (59.8%)	131 (64.5%)
HEADACHE	15 (14.9%)	21 (20.6%)	36 (17.7%)
ASTHMA	14 (13.9%)	9 (8.8%)	23 (11.3%)
RHINITIS, ALLERGIC	13 (12.9%)	16 (15.7%)	29 (14.3%)
OBESITY	9 (8.9%)	6 (5.9%)	15 (7.4%)
ADVERSE EFF/ANTIBIOTIC	6 (5.9%)	4 (3.9%)	10 (4.9%)
ALLERGY, NEC	6 (5.9%)	3 (2.9%)	9 (4.4%)
PAIN, ABDOMINO-PELVIC	5 (5.0%)	5 (4.9%)	10 (4.9%)
INSOMNIA	5 (5.0%)	3 (2.9%)	8 (3.9%)
PAIN, LIMB	5 (5.0%)	0	5 (2.5%)
SKIN/SUBCUT DISORD, OTHER	4 (4.0%)	7 (6.9%)	11 (5.4%)
MIGRAINE	4 (4.0%)	3 (2.9%)	7 (3.4%)
OTITIS MEDIA	4 (4.0%)	3 (2.9%)	7 (3.4%)
SINUSITIS,NOS	4 (4.0%)	3 (2.9%)	7 (3.4%)
ALLERGIC REACTION, FOOD	4 (4.0%)	2 (2.0%)	6 (3.0%)
ANXIETY	4 (4.0%)	2 (2.0%)	6 (3.0%)
DYSPEPSIA	4 (4.0%)	2 (2.0%)	6 (3.0%)
AGITATION	3 (3.0%)	2 (2.0%)	5 (2.5%)
BACK PAIN	3 (3.0%)	1 (1.0%)	4 (2.0%)
RASH/OTHER SKIN ERUPTION	3 (3.0%)	0	3 (1.5%)
VISUAL DISTURB	2 (2.0%)	5 (4.9%)	7 (3.4%)
INFLAM SKIN/SUBCUT	2 (2.0%)	3 (2.9%)	5 (2.5%)
ADVERSE EFF/ANALGESIC	2 (2.0%)	1 (1.0%)	3 (1.5%)
PROCEDURE, EYE/EAR	2 (2.0%)	1 (1.0%)	3 (1.5%)
DEFORMITY, ACQUIRED	1 (1.0%)	2 (2.0%)	3 (1.5%)
HEMATURIA	1 (1.0%)	2 (2.0%)	3 (1.5%)
DIZZINESS AND GIDDINESS	1 (1.0%)	1 (1.0%)	2 (1.0%)
HEARING LOSS	1 (1.0%)	1 (1.0%)	2 (1.0%)
NAUSEA	1 (1.0%)	1 (1.0%)	2 (1.0%)
PAIN, GENERAL	1 (1.0%)	1 (1.0%)	2 (1.0%)
SINUSITIS, OTHER	1 (1.0%)	1 (1.0%)	2 (1.0%)
ADVERSE EFF/SKIN,MUC MEMB DRUG	1 (1.0%)	0	1 (0.5%)
ADVERSE EFF/VACCINE	1 (1.0%)	0	1 (0.5%)
ALCOHOLIC DEPEND	1 (1.0%)	0	1 (0.5%)
ANEMIA, HEMOLYT, HERED	1 (1.0%)	0	1 (0.5%)
ANEMIA, OTHER	1 (1.0%)	0	1 (0.5%)
BLINDNESS	1 (1.0%)	0	1 (0.5%)
BONE/CARTIL DISORD, OTHER	1 (1.0%)	0	1 (0.5%)
BREAST HYPERTROPHY, UNSP	1 (1.0%)	0	1 (0.5%)
CARDIAC MURMURS	1 (1.0%)	0	1 (0.5%)
CHOLEST/TRIGLYCERIDE, ELEVATED	1 (1.0%)	0	1 (0.5%)
CONGEN ANOM, HEAD/NECK	1 (1.0%)	0	1 (0.5%)
CONJUNCTIVAL DISORD	1 (1.0%)	0	1 (0.5%)
CONTUSION	1 (1.0%)	0	1 (0.5%)
DRUG ABUSE	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=101)	Placebo (N=102)	Total (N=203)
HEARTBURN	1 (1.0%)	0	1 (0.5%)
HYPOTHYROIDISM	1 (1.0%)	0	1 (0.5%)
INJURY, NERVE	1 (1.0%)	0	1 (0.5%)
NASOPHARYNGITIS, ACUTE	1 (1.0%)	0	1 (0.5%)
PAIN UNSP, CHEST	1 (1.0%)	0	1 (0.5%)
PERIODONTAL DIS	1 (1.0%)	0	1 (0.5%)
THYROIDITIS	1 (1.0%)	0	1 (0.5%)
TOBACCO USE	1 (1.0%)	0	1 (0.5%)
TOXIC EFFECTS, VENOM	1 (1.0%)	0	1 (0.5%)
TUBERCULOSIS	1 (1.0%)	0	1 (0.5%)
UPPER RESP DISORD, OTHER	1 (1.0%)	0	1 (0.5%)
URETHRAL DISORD	1 (1.0%)	0	1 (0.5%)
URINARY CASTS/WBC'S	1 (1.0%)	0	1 (0.5%)
URTICARIA	1 (1.0%)	0	1 (0.5%)
VOMITING	1 (1.0%)	0	1 (0.5%)
GENITAL FEMALE DISORD, OTHER	0	6 (5.9%)	6 (3.0%)
BACT DIS, OTHER	0	2 (2.0%)	2 (1.0%)
CONSTIPATION	0	2 (2.0%)	2 (1.0%)
DYSCHROMIA	0	2 (2.0%)	2 (1.0%)
JOINT DISORD, OTHER	0	2 (2.0%)	2 (1.0%)
OPERATION, EAR	0	2 (2.0%)	2 (1.0%)
SPRAINS/STRAINS	0	2 (2.0%)	2 (1.0%)
ADVERSE EFF/ANTI-INFECT	0	1 (1.0%)	1 (0.5%)
ADVERSE EFF/OTHER	0	1 (1.0%)	1 (0.5%)
ALOPECIA	0	1 (1.0%)	1 (0.5%)
CARBOHYDRATE DISORD	0	1 (1.0%)	1 (0.5%)
CONG ANOM, OTHER	0	1 (1.0%)	1 (0.5%)
DISTURBANCE, SPEECH	0	1 (1.0%)	1 (0.5%)
DYSPNEA, OTHER	0	1 (1.0%)	1 (0.5%)
EAR/MASTOID DISORD	0	1 (1.0%)	1 (0.5%)
FLUSHING	0	1 (1.0%)	1 (0.5%)
FRACTURE, SKULL	0	1 (1.0%)	1 (0.5%)
GASTRIC RETENTION	0	1 (1.0%)	1 (0.5%)
INFECTION, BACTERIAL	0	1 (1.0%)	1 (0.5%)
INTEST MALABSORPTION	0	1 (1.0%)	1 (0.5%)
MYALGIA	0	1 (1.0%)	1 (0.5%)
NEUROSES	0	1 (1.0%)	1 (0.5%)
ORAL SOFT TISSUE DIS	0	1 (1.0%)	1 (0.5%)
PRURITUS DISORD, UNSPEC	0	1 (1.0%)	1 (0.5%)
SYNCOPE AND COLLAPSE	0	1 (1.0%)	1 (0.5%)
TEETH DISORD	0	1 (1.0%)	1 (0.5%)
TRAUMA/INJURIES, UNSPEC	0	1 (1.0%)	1 (0.5%)
UPPER RESP DIS, OTHER	0	1 (1.0%)	1 (0.5%)

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Table 13.7.1

History of Major Depression - Summary Statistics For Age at First Onset

Intention-To-Treat Population

Age Group:Children

		Treatment Group		
		Paroxetine (N=49)	Placebo (N=47)	Total (N=96)
Age at First Onset of Maj.Dep.Epi(Years)	N	48	47	95
	MEAN	7.4	7.6	7.5
	MEDIAN	7	7	7
	STD	1.89	2.06	1.97
	MINIMUM	3	3	3
	MAXIMUM	11	11	11
	MISSING	1	0	1

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Table 13.7.1

History of Major Depression - Summary Statistics For Age at First Onset

Intention-To-Treat Population

Age Group:Adolescents

		Treatment Group		
		Paroxetine (N=52)	Placebo (N=55)	Total (N=107)
Age at First Onset of Maj.Dep.Epi(Years)	N	52	55	107
	MEAN	11.9	11.9	11.9
	MEDIAN	13	12	12
	STD	2.58	3.04	2.82
	MINIMUM	5	3	3
	MAXIMUM	16	17	17
	MISSING	0	0	0

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Table 13.7.1

History of Major Depression - Summary Statistics For Age at First Onset

Intention-To-Treat Population

Age Group:Total

		Treatment Group		
		Paroxetine (N=101)	Placebo (N=102)	Total (N=203)
Age at First Onset of Maj.Dep.Epi(Years)	N	100	102	202
	MEAN	9.8	9.9	9.8
	MEDIAN	9	10	10
	STD	3.21	3.39	3.3
	MINIMUM	3	3	3
	MAXIMUM	16	17	17
	MISSING	1	0	1

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Table 13.7.2

History of Major Depression - Frequency Distribution for Family History, Hospitalisation and Current Treatment

Intention-To-Treat Population

Age Group : Children

		Treatment Group Paroxetine (N=49)	Placebo (N=47)	Total (N=96)
Family Members History*	None	10 (20.4%)	16 (34.0%)	26 (27.1%)
	Mother	27 (55.1%)	20 (42.6%)	47 (49.0%)
	Father	8 (16.3%)	7 (14.9%)	15 (15.6%)
	Sibling	4 (8.2%)	5 (10.6%)	9 (9.4%)
	Grandparent	16 (32.7%)	16 (34.0%)	32 (33.3%)
	Other	11 (22.4%)	5 (10.6%)	16 (16.7%)
No.of times Hospitalised for Maj.Dep.	Never	48 (98.0%)	47 (100.0%)	95 (99.0%)
	1 time	1 (2.0%)	0	1 (1.0%)
	2 times	0	0	0
	3 times	0	0	0
	4 times	0	0	0
	>=5 times	0	0	0
Treatment for Current Episode	No Therapy	36 (73.5%)	25 (53.2%)	61 (63.5%)
	Psychotherapy	5 (10.2%)	11 (23.4%)	16 (16.7%)
	Pharmacotherapy	4 (8.2%)	6 (12.8%)	10 (10.4%)
	Both Psychotherapy and Pharmacotherapy	4 (8.2%)	5 (10.6%)	9 (9.4%)

* More than one response possible

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Table 13.7.2

History of Major Depression - Frequency Distribution for Family History, Hospitalisation and Current Treatment

Intention-To-Treat Population

Age Group : Adolescents

		Treatment Group Paroxetine (N=52)	Placebo (N=55)	Total (N=107)
Family Members History*	None	13 (25.0%)	14 (25.5%)	27 (25.2%)
	Mother	26 (50.0%)	23 (41.8%)	49 (45.8%)
	Father	6 (11.5%)	15 (27.3%)	21 (19.6%)
	Sibling	8 (15.4%)	6 (10.9%)	14 (13.1%)
	Grandparent	17 (32.7%)	22 (40.0%)	39 (36.4%)
	Other	9 (17.3%)	10 (18.2%)	19 (17.8%)
No.of times Hospitalised for Maj.Dep.	Never	50 (96.2%)	53 (96.4%)	103 (96.3%)
	1 time	1 (1.9%)	1 (1.8%)	2 (1.9%)
	2 times	1 (1.9%)	0	1 (0.9%)
	3 times	0	1 (1.8%)	1 (0.9%)
	4 times	0	0	0
	>=5 times	0	0	0
Treatment for Current Episode	No Therapy	23 (44.2%)	28 (50.9%)	51 (47.7%)
	Psychotherapy	10 (19.2%)	12 (21.8%)	22 (20.6%)
	Pharmacotherapy	11 (21.2%)	7 (12.7%)	18 (16.8%)
	Both Psychotherapy and Pharmacotherapy	8 (15.4%)	8 (14.5%)	16 (15.0%)

* More than one response possible

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Table 13.7.2

History of Major Depression - Frequency Distribution for Family History, Hospitalisation and Current Treatment

Intention-To-Treat Population

Age Group : Total

		Treatment Group		
		Paroxetine (N=101)	Placebo (N=102)	Total (N=203)
Family Members History*	None	23 (22.8%)	30 (29.4%)	53 (26.1%)
	Mother	53 (52.5%)	43 (42.2%)	96 (47.3%)
	Father	14 (13.9%)	22 (21.6%)	36 (17.7%)
	Sibling	12 (11.9%)	11 (10.8%)	23 (11.3%)
	Grandparent	33 (32.7%)	38 (37.3%)	71 (35.0%)
	Other	20 (19.8%)	15 (14.7%)	35 (17.2%)
No.of times Hospitalised for Maj.Dep.	Never	98 (97.0%)	100 (98.0%)	198 (97.5%)
	1 time	2 (2.0%)	1 (1.0%)	3 (1.5%)
	2 times	1 (1.0%)	0	1 (0.5%)
	3 times	0	1 (1.0%)	1 (0.5%)
	4 times	0	0	0
	>=5 times	0	0	0
Treatment for Current Episode	No Therapy	59 (58.4%)	53 (52.0%)	112 (55.2%)
	Psychotherapy	15 (14.9%)	23 (22.5%)	38 (18.7%)
	Pharmacotherapy	15 (14.9%)	13 (12.7%)	28 (13.8%)
	Both Psychotherapy and Pharmacotherapy	12 (11.9%)	13 (12.7%)	25 (12.3%)

* 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=49)	Placebo (N=47)	Total (N=96)
Major Depressive Disorder	Current	29 (59.2%)	25 (53.2%)	54 (56.3%)
	Both	20 (40.8%)	22 (46.8%)	42 (43.8%)
Psychotic Features	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Dsthymia	Current	1 (2.0%)	0	1 (1.0%)
	N/A	48 (98.0%)	47 (100.0%)	95 (99.0%)
Depressive Disorder NOS	Both	0	1 (2.1%)	1 (1.0%)
	N/A	49 (100.0%)	46 (97.9%)	95 (99.0%)
Adj. Disorder w Depressed Mood	Current	0	1 (2.1%)	1 (1.0%)
	N/A	49 (100.0%)	46 (97.9%)	95 (99.0%)
Mania	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Hypomania	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Cyclothymia	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Bipolar NOS	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Bipolar I	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Bipolar II	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Schizoaffective Disorder - Manic	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Schizoaffective Disorder - Depressed	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Schizophrenia	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Schizophreniform Disorder	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Brief Reactive Psychosis	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Panic Disorder	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Separation Anxiety Disorder	Past	0	1 (2.1%)	1 (1.0%)
	Current	1 (2.0%)	0	1 (1.0%)
	Both	1 (2.0%)	2 (4.3%)	3 (3.1%)
	N/A	47 (95.9%)	44 (93.6%)	91 (94.8%)

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=49)	Placebo (N=47)	Total (N=96)
Avoidant Disorder of Childhood	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Simple Phobia	Both	1 (2.0%)	0	1 (1.0%)
	N/A	48 (98.0%)	47 (100.0%)	95 (99.0%)
Social Phobia	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Agoraphobia	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Overanxious Disorder	Current	0	1 (2.1%)	1 (1.0%)
	Both	1 (2.0%)	1 (2.1%)	2 (2.1%)
	N/A	48 (98.0%)	45 (95.7%)	93 (96.9%)
Generalized Anxiety Disorder	Current	1 (2.0%)	1 (2.1%)	2 (2.1%)
	Both	3 (6.1%)	1 (2.1%)	4 (4.2%)
	N/A	45 (91.8%)	45 (95.7%)	90 (93.8%)
Obsessive-Compulsive Disorder	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Post-Traumatic Stress Disorder	Past	1 (2.0%)	0	1 (1.0%)
	N/A	48 (98.0%)	47 (100.0%)	95 (99.0%)
Acute Stress Disorder	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Adj. Disorder w Anxious Mood	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Enuresis	Past	0	2 (4.3%)	2 (2.1%)
	Current	1 (2.0%)	0	1 (1.0%)
	Both	2 (4.1%)	1 (2.1%)	3 (3.1%)
	N/A	46 (93.9%)	44 (93.6%)	90 (93.8%)
Encopresis	Both	1 (2.0%)	0	1 (1.0%)
	N/A	48 (98.0%)	47 (100.0%)	95 (99.0%)
Anorexia Nervosa	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Bulimia	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Attention Deficit Disorder	Past	3 (6.1%)	5 (10.6%)	8 (8.3%)
	Current	1 (2.0%)	1 (2.1%)	2 (2.1%)
	Both	2 (4.1%)	4 (8.5%)	6 (6.3%)
	N/A	43 (87.8%)	37 (78.7%)	80 (83.3%)

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=49)	Placebo (N=47)	Total (N=96)
Conduct Disorder	Both	0	1 (2.1%)	1 (1.0%)
	N/A	49 (100.0%)	46 (97.9%)	95 (99.0%)
Oppositional Defiant Disorder	Current	1 (2.0%)	2 (4.3%)	3 (3.1%)
	Both	0	3 (6.4%)	3 (3.1%)
	N/A	48 (98.0%)	42 (89.4%)	90 (93.8%)
Adj. Disorder w Dist. of Conduct	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Adj. Dis w. Mixed Mood & Conduct	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Tourettes	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Chronic Motor or Vocal Tic Disorder	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Transient Tic Disorder	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Alcohol Abuse	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Alcohol Dependence	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Substance Abuse	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Substance Dependence	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Mental Retardation	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
Other Psychiatric Disorder	N/A	49 (100.0%)	47 (100.0%)	96 (100.0%)
No Psychiatric Disorder	N/A	49 (100.0%)	47 (100.0%)	96 (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=52)	Placebo (N=55)	Total (N=107)
Major Depressive Disorder	Current	25 (48.1%)	29 (52.7%)	54 (50.5%)
	Both	27 (51.9%)	26 (47.3%)	53 (49.5%)
Psychotic Features	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Dsthymia	Past	2 (3.8%)	2 (3.6%)	4 (3.7%)
	Current	1 (1.9%)	0	1 (0.9%)
	N/A	49 (94.2%)	53 (96.4%)	102 (95.3%)
Depressive Disorder NOS	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Adj. Disorder w Depressed Mood	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Mania	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Hypomania	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Cyclothymia	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Bipolar NOS	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Bipolar I	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Bipolar II	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Schizoaffective Disorder - Manic	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Schizoaffective Disorder - Depressed	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Schizophrenia	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Schizophreniform Disorder	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Brief Reactive Psychosis	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Panic Disorder	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Separation Anxiety Disorder	Current	1 (1.9%)	0	1 (0.9%)
	N/A	51 (98.1%)	55 (100.0%)	106 (99.1%)
Avoidant Disorder of Childhood	Both	1 (1.9%)	0	1 (0.9%)
	N/A	51 (98.1%)	55 (100.0%)	106 (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=52)	Placebo (N=55)	Total (N=107)
Simple Phobia	Current	1 (1.9%)	0	1 (0.9%)
	Both	1 (1.9%)	1 (1.8%)	2 (1.9%)
	N/A	50 (96.2%)	54 (98.2%)	104 (97.2%)
Social Phobia	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Agoraphobia	Both	0	1 (1.8%)	1 (0.9%)
	N/A	52 (100.0%)	54 (98.2%)	106 (99.1%)
Overanxious Disorder	Current	3 (5.8%)	0	3 (2.8%)
	N/A	49 (94.2%)	55 (100.0%)	104 (97.2%)
Generalized Anxiety Disorder	Past	0	1 (1.8%)	1 (0.9%)
	Current	3 (5.8%)	0	3 (2.8%)
	N/A	49 (94.2%)	54 (98.2%)	103 (96.3%)
Obsessive-Compulsive Disorder	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Post-Traumatic Stress Disorder	Past	1 (1.9%)	1 (1.8%)	2 (1.9%)
	Current	1 (1.9%)	0	1 (0.9%)
	Both	1 (1.9%)	1 (1.8%)	2 (1.9%)
	N/A	49 (94.2%)	53 (96.4%)	102 (95.3%)
Acute Stress Disorder	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Adj. Disorder w Anxious Mood	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Enuresis	Past	3 (5.8%)	4 (7.3%)	7 (6.5%)
	Both	0	1 (1.8%)	1 (0.9%)
	N/A	49 (94.2%)	50 (90.9%)	99 (92.5%)
Encopresis	Past	1 (1.9%)	0	1 (0.9%)
	N/A	51 (98.1%)	55 (100.0%)	106 (99.1%)
Anorexia Nervosa	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Bulimia	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Attention Deficit Disorder	Past	2 (3.8%)	7 (12.7%)	9 (8.4%)
	Current	2 (3.8%)	0	2 (1.9%)
	Both	2 (3.8%)	2 (3.6%)	4 (3.7%)
	N/A	46 (88.5%)	46 (83.6%)	92 (86.0%)

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 : Adolescents

Psychiatric Disorder	Past/Current/Both/NA	Treatment Group: Paroxetine (N=52)	Placebo (N=55)	Total (N=107)
Conduct Disorder	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Oppositional Defiant Disorder	Past	1 (1.9%)	0	1 (0.9%)
	Current	4 (7.7%)	2 (3.6%)	6 (5.6%)
	Both	0	2 (3.6%)	2 (1.9%)
	N/A	47 (90.4%)	51 (92.7%)	98 (91.6%)
Adj. Disorder w Dist. of Conduct	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Adj. Dis w. Mixed Mood & Conduct	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Tourettes	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Chronic Motor or Vocal Tic Disorder	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Transient Tic Disorder	Past	0	1 (1.8%)	1 (0.9%)
	N/A	52 (100.0%)	54 (98.2%)	106 (99.1%)
Alcohol Abuse	Past	0	1 (1.8%)	1 (0.9%)
	N/A	52 (100.0%)	54 (98.2%)	106 (99.1%)
Alcohol Dependence	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Substance Abuse	Past	0	1 (1.8%)	1 (0.9%)
	N/A	52 (100.0%)	54 (98.2%)	106 (99.1%)
Substance Dependence	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Mental Retardation	N/A	52 (100.0%)	55 (100.0%)	107 (100.0%)
Other Psychiatric Disorder	Both	1 (1.9%)	0	1 (0.9%)
	N/A	51 (98.1%)	55 (100.0%)	106 (99.1%)
No Psychiatric Disorder	N/A	52 (100.0%)	55 (100.0%)	107 (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 : Total

Psychiatric Disorder	Past/Current/Both/NA	Treatment Group: Paroxetine (N=101)	Placebo (N=102)	Total (N=203)
Major Depressive Disorder	Current	54 (53.5%)	54 (52.9%)	108 (53.2%)
	Both	47 (46.5%)	48 (47.1%)	95 (46.8%)
Psychotic Features	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Dsthymia	Past	2 (2.0%)	2 (2.0%)	4 (2.0%)
	Current	2 (2.0%)	0	2 (1.0%)
	N/A	97 (96.0%)	100 (98.0%)	197 (97.0%)
Depressive Disorder NOS	Both	0	1 (1.0%)	1 (0.5%)
	N/A	101 (100.0%)	101 (99.0%)	202 (99.5%)
Adj. Disorder w Depressed Mood	Current	0	1 (1.0%)	1 (0.5%)
	N/A	101 (100.0%)	101 (99.0%)	202 (99.5%)
Mania	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Hypomania	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Cyclothymia	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Bipolar NOS	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Bipolar I	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Bipolar II	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Schizoaffective Disorder - Manic	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Schizoaffective Disorder - Depressed	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Schizophrenia	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Schizophreniform Disorder	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Brief Reactive Psychosis	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Panic Disorder	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Separation Anxiety Disorder	Past	0	1 (1.0%)	1 (0.5%)
	Current	2 (2.0%)	0	2 (1.0%)
	Both	1 (1.0%)	2 (2.0%)	3 (1.5%)

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=101)	Placebo (N=102)	Total (N=203)
Separation Anxiety Disorder	N/A	98 (97.0%)	99 (97.1%)	197 (97.0%)
Avoidant Disorder of Childhood	Both	1 (1.0%)	0	1 (0.5%)
	N/A	100 (99.0%)	102 (100.0%)	202 (99.5%)
Simple Phobia	Current	1 (1.0%)	0	1 (0.5%)
	Both	2 (2.0%)	1 (1.0%)	3 (1.5%)
	N/A	98 (97.0%)	101 (99.0%)	199 (98.0%)
Social Phobia	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Agoraphobia	Both	0	1 (1.0%)	1 (0.5%)
	N/A	101 (100.0%)	101 (99.0%)	202 (99.5%)
Overanxious Disorder	Current	3 (3.0%)	1 (1.0%)	4 (2.0%)
	Both	1 (1.0%)	1 (1.0%)	2 (1.0%)
	N/A	97 (96.0%)	100 (98.0%)	197 (97.0%)
Generalized Anxiety Disorder	Past	0	1 (1.0%)	1 (0.5%)
	Current	4 (4.0%)	1 (1.0%)	5 (2.5%)
	Both	3 (3.0%)	1 (1.0%)	4 (2.0%)
	N/A	94 (93.1%)	99 (97.1%)	193 (95.1%)
Obsessive-Compulsive Disorder	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Post-Traumatic Stress Disorder	Past	2 (2.0%)	1 (1.0%)	3 (1.5%)
	Current	1 (1.0%)	0	1 (0.5%)
	Both	1 (1.0%)	1 (1.0%)	2 (1.0%)
	N/A	97 (96.0%)	100 (98.0%)	197 (97.0%)
Acute Stress Disorder	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Adj. Disorder w Anxious Mood	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Enuresis	Past	3 (3.0%)	6 (5.9%)	9 (4.4%)
	Current	1 (1.0%)	0	1 (0.5%)
	Both	2 (2.0%)	2 (2.0%)	4 (2.0%)
	N/A	95 (94.1%)	94 (92.2%)	189 (93.1%)
Encopresis	Past	1 (1.0%)	0	1 (0.5%)
	Both	1 (1.0%)	0	1 (0.5%)
	N/A	99 (98.0%)	102 (100.0%)	201 (99.0%)

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 : Total

Psychiatric Disorder	Past/Current/Both/NA	Treatment Group: Paroxetine (N=101)	Placebo (N=102)	Total (N=203)
Anorexia Nervosa	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Bulimia	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Attention Deficit Disorder	Past	5 (5.0%)	12 (11.8%)	17 (8.4%)
	Current	3 (3.0%)	1 (1.0%)	4 (2.0%)
	Both	4 (4.0%)	6 (5.9%)	10 (4.9%)
	N/A	89 (88.1%)	83 (81.4%)	172 (84.7%)
Conduct Disorder	Both	0	1 (1.0%)	1 (0.5%)
	N/A	101 (100.0%)	101 (99.0%)	202 (99.5%)
Oppositional Defiant Disorder	Past	1 (1.0%)	0	1 (0.5%)
	Current	5 (5.0%)	4 (3.9%)	9 (4.4%)
	Both	0	5 (4.9%)	5 (2.5%)
	N/A	95 (94.1%)	93 (91.2%)	188 (92.6%)
Adj. Disorder w Dist. of Conduct	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Adj. Dis w. Mixed Mood & Conduct	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Tourettes	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Chronic Motor or Vocal Tic Disorder	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Transient Tic Disorder	Past	0	1 (1.0%)	1 (0.5%)
	N/A	101 (100.0%)	101 (99.0%)	202 (99.5%)
Alcohol Abuse	Past	0	1 (1.0%)	1 (0.5%)
	N/A	101 (100.0%)	101 (99.0%)	202 (99.5%)
Alcohol Dependence	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Substance Abuse	Past	0	1 (1.0%)	1 (0.5%)
	N/A	101 (100.0%)	101 (99.0%)	202 (99.5%)
Substance Dependence	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Mental Retardation	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)
Other Psychiatric Disorder	Both	1 (1.0%)	0	1 (0.5%)
	N/A	100 (99.0%)	102 (100.0%)	202 (99.5%)

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=101)	Placebo (N=102)	Total (N=203)
No Psychiatric Disorder	N/A	101 (100.0%)	102 (100.0%)	203 (100.0%)

N/A = no prior/current history or information not available

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Table 13.9.1

Summary Statistics for CDRS-R Total Score at Screening and Baseline

Intention-To-Treat Population

Age Group : Children

Visit	Statistic	Treatment Group Paroxetine (N=49)	Placebo (N=47)	Total (N=96)
Screening	N	49	47	96
	MEAN	62.3	62.7	62.5
	MEDIAN	60.0	62.0	61.0
	STDDEV	10.44	9.02	9.72
	MINIMUM	46	45	45
	MAXIMUM	88	86	88
	MISSING	0	0	0
Baseline	N	49	47	96
	MEAN	58.4	61.3	59.8
	MEDIAN	57.0	61.0	58.0
	STDDEV	8.29	9.23	8.83
	MINIMUM	45	45	45
	MAXIMUM	85	85	85
	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 CDRS-R Total Score at Screening and Baseline

Intention-To-Treat Population

Age Group : Adolescents

Visit	Statistic	Treatment Group Paroxetine (N=52)	Placebo (N=55)	Total (N=107)
Screening	N	52	55	107
	MEAN	65.0	64.7	64.8
	MEDIAN	64.5	62.0	64.0
	STDDEV	9.41	9.59	9.46
	MINIMUM	48	45	45
	MAXIMUM	85	89	89
	MISSING	0	0	0
Baseline	N	52	55	107
	MEAN	62.9	63.7	63.3
	MEDIAN	62.5	63.0	63.0
	STDDEV	9.87	8.66	9.23
	MINIMUM	44	46	44
	MAXIMUM	84	89	89
	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 CDRS-R Total Score at Screening and Baseline

Intention-To-Treat Population

Age Group : Total

Visit	Statistic	Treatment Group Paroxetine (N=101)	Placebo (N=102)	Total (N=203)
Screening	N	101	102	203
	MEAN	63.7	63.8	63.7
	MEDIAN	62.0	62.0	62.0
	STDDEV	9.96	9.34	9.63
	MINIMUM	46	45	45
	MAXIMUM	88	89	89
	MISSING	0	0	0
Baseline	N	101	102	203
	MEAN	60.7	62.6	61.7
	MEDIAN	59.0	62.0	60.0
	STDDEV	9.37	8.96	9.19
	MINIMUM	44	45	44
	MAXIMUM	85	89	89
	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 = 49)		Placebo (N = 47)		Total (N = 96)	
	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	2	4.3	2	2.1
Moderately ill (4)	36	73.5	33	70.2	69	71.9
Markedly ill (5)	12	24.5	9	19.1	21	21.9
Severely ill (6)	1	2.0	3	6.4	4	4.2
Among the most extremely ill patients (7)	0	0.0	0	0.0	0	0.0

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 = 52)		Placebo (N = 55)		Total (N = 107)	
	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)	2	3.8	0	0.0	2	1.9
Moderately ill (4)	34	65.4	34	61.8	68	63.6
Markedly ill (5)	14	26.9	20	36.4	34	31.8
Severely ill (6)	2	3.8	1	1.8	3	2.8
Among the most extremely ill patients (7)	0	0.0	0	0.0	0	0.0

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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 = 101)		Placebo (N = 102)		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)	2	2.0	2	2.0	4	2.0
Moderately ill (4)	70	69.3	67	65.7	137	67.5
Markedly ill (5)	26	25.7	29	28.4	55	27.1
Severely ill (6)	3	3.0	4	3.9	7	3.4
Among the most extremely ill patients (7)	0	0.0	0	0.0	0	0.0

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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=49)	Placebo (N=47)	Total (N=96)
Baseline	N	49	47	96
	MEAN	53.2	52.3	52.7
	MEDIAN	55.0	52.0	54.5
	STDDEV	7.34	5.78	6.60
	MINIMUM	35	40	35
	MAXIMUM	71	70	71
	MISSING	0	0	0

Note: 'MISSING' row indicates number of patients with missing data or inadequate information at baseline.

Table 13.11.1

Summary Statistics for GAF Score at Baseline

Intention-To-Treat Population

Age Group : Adolescents

Visit	Statistic	Treatment Group Paroxetine (N=52)	Placebo (N=55)	Total (N=107)
Baseline	N	52	55	107
	MEAN	53.6	52.3	52.9
	MEDIAN	55.0	53.0	54.0
	STDDEV	8.24	5.43	6.94
	MINIMUM	35	40	35
	MAXIMUM	77	61	77
	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=101)	Placebo (N=102)	Total (N=203)
Baseline	N	101	102	203
	MEAN	53.4	52.3	52.8
	MEDIAN	55.0	52.5	54.0
	STDDEV	7.78	5.57	6.77
	MINIMUM	35	40	35
	MAXIMUM	77	70	77
	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

Summary Statistics for KADS Total Score at Baseline

Intention-To-Treat Population

Visit	Statistic	Treatment Group: Paroxetine (N=53)	Placebo (N=55)	Total (N=108)
Baseline	N	52	55	107
	MEAN	17.6	18.1	17.9
	STDDEV	6.17	7.43	6.82
	MEDIAN	17.0	17.0	17.0
	MINIMUM	4	1	1
	MAXIMUM	33	34	34
	MISSING	1	0	1

KADS assessed in patients >= 12 years

Note: 'MISSING' row indicates number of patients with either missing data at baseline or insufficient data to calculate total.

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Table 13.13.1

Major Depression 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=49)	Placebo (N=47)	Total (N=96)
SSRI	Total	7(14.3%)	6(12.8%)	13(13.5%)
	FLUOXETINE	0	1(2.1%)	1(1.0%)
	FLUVOXAMINE MALEATE	1(2.0%)	0	1(1.0%)
	PAROXETINE	1(2.0%)	1(2.1%)	2(2.1%)
	SERTRALINE HYDROCHLORIDE	5(10.2%)	4(8.5%)	9(9.4%)
MAOI	Total	0	0	0
TCA	Total	1(2.0%)	2(4.3%)	3(3.1%)
	IMIPRAMINE	1(2.0%)	0	1(1.0%)
	IMIPRAMINE HYDROCHLORIDE	0	1(2.1%)	1(1.0%)
	MIRTAZAPINE	0	1(2.1%)	1(1.0%)
Benzodiazepines	Total	0	0	0
Other psychoactive medications	Total	1(2.0%)	1(2.1%)	2(2.1%)
	CLOMIPRAMINE HYDROCHLORIDE	0	1(2.1%)	1(1.0%)
	PAROXETINE	1(2.0%)	0	1(1.0%)
Total *		8(16.3%)	9(19.1%)	17(17.7%)
None		41(83.7%)	38(80.9%)	79(82.3%)

* Total number of patients in one or more psychoactive class

Table 13.13.1

Major Depression 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=52)	Placebo (N=55)	Total (N=107)
SSRI	Total	15(28.8%)	9(16.4%)	24(22.4%)
	AMFEBUTAMONE HYDROCHLORIDE	1(1.9%)	1(1.8%)	2(1.9%)
	BUSPIRONE HYDROCHLORIDE	1(1.9%)	0	1(0.9%)
	CITALOPRAM	3(5.8%)	1(1.8%)	4(3.7%)
	FLUOXETINE	3(5.8%)	4(7.3%)	7(6.5%)
	PAROXETINE	4(7.7%)	2(3.6%)	6(5.6%)
	SERTRALINE HYDROCHLORIDE	5(9.6%)	4(7.3%)	9(8.4%)
	VENLAFAXINE	1(1.9%)	0	1(0.9%)
	VENLAFAXINE HYDROCHLORIDE	1(1.9%)	0	1(0.9%)
MAOI	Total	0	0	0
TCA	Total	1(1.9%)	1(1.8%)	2(1.9%)
	AMITRIPTYLINE	0	1(1.8%)	1(0.9%)
	MIRTAZAPINE	1(1.9%)	0	1(0.9%)
Benzodiazepines	Total	0	0	0
Other psychoactive medications	Total	3(5.8%)	9(16.4%)	12(11.2%)
	AMFEBUTAMONE HYDROCHLORIDE	2(3.8%)	4(7.3%)	6(5.6%)
	BUSPIRONE HYDROCHLORIDE	0	1(1.8%)	1(0.9%)
	CYANOCOBALAMIN	0	1(1.8%)	1(0.9%)
	DEXAMPHETAMINE SULFATE	0	1(1.8%)	1(0.9%)
	HYPERICUM EXTRACT	0	1(1.8%)	1(0.9%)
	METHYLPHENIDATE HYDROCHLORIDE	1(1.9%)	0	1(0.9%)
	NEFAZODONE	1(1.9%)	1(1.8%)	2(1.9%)
	RISPERIDONE	0	1(1.8%)	1(0.9%)
	VENLAFAXINE	0	1(1.8%)	1(0.9%)
Total *		18(34.6%)	17(30.9%)	35(32.7%)
None		34(65.4%)	38(69.1%)	72(67.3%)

* Total number of patients in one or more psychoactive class

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Table 13.13.1

Major Depression 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=101)	Placebo (N=102)	Total (N=203)
SSRI	Total	22(21.8%)	15(14.7%)	37(18.2%)
	AMFEBUTAMONE HYDROCHLORIDE	1(1.0%)	1(1.0%)	2(1.0%)
	BUSPIRONE HYDROCHLORIDE	1(1.0%)	0	1(0.5%)
	CITALOPRAM	3(3.0%)	1(1.0%)	4(2.0%)
	FLUOXETINE	3(3.0%)	5(4.9%)	8(3.9%)
	FLUVOXAMINE MALEATE	1(1.0%)	0	1(0.5%)
	PAROXETINE	5(5.0%)	3(2.9%)	8(3.9%)
	SERTRALINE HYDROCHLORIDE	10(9.9%)	8(7.8%)	18(8.9%)
	VENLAFAXINE	1(1.0%)	0	1(0.5%)
	VENLAFAXINE HYDROCHLORIDE	1(1.0%)	0	1(0.5%)
MAOI	Total	0	0	0
TCA	Total	2(2.0%)	3(2.9%)	5(2.5%)
	AMITRIPTYLINE	0	1(1.0%)	1(0.5%)
	IMIPRAMINE	1(1.0%)	0	1(0.5%)
	IMIPRAMINE HYDROCHLORIDE	0	1(1.0%)	1(0.5%)
	MIRTAZAPINE	1(1.0%)	1(1.0%)	2(1.0%)
Benzodiazepines	Total	0	0	0
Other psychoactive medications	Total	4(4.0%)	10(9.8%)	14(6.9%)
	AMFEBUTAMONE HYDROCHLORIDE	2(2.0%)	4(3.9%)	6(3.0%)
	BUSPIRONE HYDROCHLORIDE	0	1(1.0%)	1(0.5%)
	CLOMIPRAMINE HYDROCHLORIDE	0	1(1.0%)	1(0.5%)
	CYANOCOBALAMIN	0	1(1.0%)	1(0.5%)
	DEXAMPHETAMINE SULFATE	0	1(1.0%)	1(0.5%)
	HYPERICUM EXTRACT	0	1(1.0%)	1(0.5%)
	METHYLPHENIDATE HYDROCHLORIDE	1(1.0%)	0	1(0.5%)
	NEFAZODONE	1(1.0%)	1(1.0%)	2(1.0%)
	PAROXETINE	1(1.0%)	0	1(0.5%)
	RISPERIDONE	0	1(1.0%)	1(0.5%)
	VENLAFAXINE	0	1(1.0%)	1(0.5%)

* Total number of patients in one or more psychoactive class

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Table 13.13.1

Major Depression 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=101)	Placebo (N=102)	Total (N=203)
Total *		26(25.7%)	26(25.5%)	52(25.6%)
None		75(74.3%)	76(74.5%)	151(74.4%)

* Total number of patients in one or more psychoactive class

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Table 13.13.2.1

Psychoactive Medication History (for Indications Other Than Major Depression) by Psychoactive Class Identification and Generic Term

Intention-To-Treat Population

Age Group : Children

Psychoactive Class	Generic Term(s)	Treatment Group Paroxetine (N=49)	Placebo (N=47)	Total (N=96)
SSRI	Total	0	0	0
MAOI	Total	0	0	0
TCA	Total	0	1(2.1%)	1(1.0%)
	IMIPRAMINE	0	1(2.1%)	1(1.0%)
Benzodiazepines	Total	0	0	0
Other psychoactive medications	Total	5(10.2%)	5(10.6%)	10(10.4%)
	AMFEBUTAMONE HYDROCHLORIDE	1(2.0%)	0	1(1.0%)
	AMPHETAMINE ASPARTATE	2(4.1%)	2(4.3%)	4(4.2%)
	AMPHETAMINE SULFATE	2(4.1%)	2(4.3%)	4(4.2%)
	CLONIDINE	2(4.1%)	0	2(2.1%)
	DEXAMPHETAMINE SULFATE	0	1(2.1%)	1(1.0%)
	DEXTROAMPHETAMINE SACCHARATE	2(4.1%)	2(4.3%)	4(4.2%)
	DEXTROAMPHETAMINE SULFATE	2(4.1%)	2(4.3%)	4(4.2%)
	METHYLPHENIDATE HYDROCHLORIDE	2(4.1%)	2(4.3%)	4(4.2%)
Total *		5(10.2%)	5(10.6%)	10(10.4%)
None		44(89.8%)	42(89.4%)	86(89.6%)

* 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 13.13.2.1

Psychoactive Medication History (for Indications Other Than Major Depression) by Psychoactive Class Identification and Generic Term

Intention-To-Treat Population

Age Group : Adolescents

Psychoactive Class	Generic Term(s)	Treatment Group Paroxetine (N=52)	Placebo (N=55)	Total (N=107)
SSRI	Total	0	1(1.8%)	1(0.9%)
	SERTRALINE HYDROCHLORIDE	0	1(1.8%)	1(0.9%)
MAOI	Total	0	0	0
TCA	Total	0	1(1.8%)	1(0.9%)
	TRAZODONE	0	1(1.8%)	1(0.9%)
Benzodiazepines	Total	0	0	0
Other psychoactive medications	Total	7(13.5%)	7(12.7%)	14(13.1%)
	AMPHETAMINE ASPARTATE	1(1.9%)	3(5.5%)	4(3.7%)
	AMPHETAMINE SULFATE	1(1.9%)	3(5.5%)	4(3.7%)
	CARISOPRODOL	0	1(1.8%)	1(0.9%)
	CHLORDIAZEPOXIDE HYDROCHLORIDE	1(1.9%)	0	1(0.9%)
	CLONIDINE HYDROCHLORIDE	1(1.9%)	0	1(0.9%)
	DEXTROAMPHETAMINE SACCHARATE	1(1.9%)	3(5.5%)	4(3.7%)
	DEXTROAMPHETAMINE SULFATE	1(1.9%)	3(5.5%)	4(3.7%)
	HYDROXYZINE HYDROCHLORIDE	1(1.9%)	0	1(0.9%)
	MELATONIN	1(1.9%)	0	1(0.9%)
	METHYLPHENIDATE	2(3.8%)	0	2(1.9%)
	METHYLPHENIDATE HYDROCHLORIDE	2(3.8%)	4(7.3%)	6(5.6%)
	QUETIAPINE	0	1(1.8%)	1(0.9%)
	TRAZODONE	0	1(1.8%)	1(0.9%)
	VALPROATE SEMISODIUM	1(1.9%)	0	1(0.9%)
Total *		7(13.5%)	9(16.4%)	16(15.0%)
None		45(86.5%)	46(83.6%)	91(85.0%)

* 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 13.13.2.1

Psychoactive Medication History (for Indications Other Than Major Depression) by Psychoactive Class Identification and Generic Term

Intention-To-Treat Population

Age Group : Total

Psychoactive Class	Generic Term(s)	Treatment Group Paroxetine (N=101)	 Placebo (N=102)	 Total (N=203)
SSRI	Total	0	1(1.0%)	1(0.5%)
	SERTRALINE HYDROCHLORIDE	0	1(1.0%)	1(0.5%)
MAOI	Total	0	0	0
TCA	Total	0	2(2.0%)	2(1.0%)
	IMIPRAMINE	0	1(1.0%)	1(0.5%)
	TRAZODONE	0	1(1.0%)	1(0.5%)
Benzodiazepines	Total	0	0	0
Other psychoactive medications	Total	12(11.9%)	12(11.8%)	24(11.8%)
	AMFEBUTAMONE HYDROCHLORIDE	1(1.0%)	0	1(0.5%)
	AMPHETAMINE ASPARTATE	3(3.0%)	5(4.9%)	8(3.9%)
	AMPHETAMINE SULFATE	3(3.0%)	5(4.9%)	8(3.9%)
	CARISOPRODOL	0	1(1.0%)	1(0.5%)
	CHLORDIAZEPOXIDE HYDROCHLORIDE	1(1.0%)	0	1(0.5%)
	CLONIDINE	2(2.0%)	0	2(1.0%)
	CLONIDINE HYDROCHLORIDE	1(1.0%)	0	1(0.5%)
	DEXAMPHETAMINE SULFATE	0	1(1.0%)	1(0.5%)
	DEXTROAMPHETAMINE SACCHARATE	3(3.0%)	5(4.9%)	8(3.9%)
	DEXTROAMPHETAMINE SULFATE	3(3.0%)	5(4.9%)	8(3.9%)
	HYDROXYZINE HYDROCHLORIDE	1(1.0%)	0	1(0.5%)
	MELATONIN	1(1.0%)	0	1(0.5%)
	METHYLPHENIDATE	2(2.0%)	0	2(1.0%)
	METHYLPHENIDATE HYDROCHLORIDE	4(4.0%)	6(5.9%)	10(4.9%)
	QUETIAPINE	0	1(1.0%)	1(0.5%)
	TRAZODONE	0	1(1.0%)	1(0.5%)
	VALPROATE SEMISODIUM	1(1.0%)	0	1(0.5%)
Total *		12(11.9%)	14(13.7%)	26(12.8%)
None		89(88.1%)	88(86.3%)	177(87.2%)

* 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 13.13.2.2

Number (%) of Patients with Prior Psychoactive Medication (for indications other than Major Depression)
by Generic Term Ordered by Decreasing Frequency
Intention-To-Treat Population

Generic Term	Treatment Group: Paroxetine (N=101)	Placebo (N=102)	Total (N=203)
Total number of patients with at least one prior psychoactive medication	12 (11.9%)	14 (13.7%)	26 (12.8%)
METHYLPHENIDATE HYDROCHLORIDE	4 (4.0%)	6 (5.9%)	10 (4.9%)
AMPHETAMINE ASPARTATE	3 (3.0%)	5 (4.9%)	8 (3.9%)
AMPHETAMINE SULFATE	3 (3.0%)	5 (4.9%)	8 (3.9%)
DEXTROAMPHETAMINE SACCHARATE	3 (3.0%)	5 (4.9%)	8 (3.9%)
DEXTROAMPHETAMINE SULFATE	3 (3.0%)	5 (4.9%)	8 (3.9%)
CLONIDINE	2 (2.0%)	0	2 (1.0%)
METHYLPHENIDATE	2 (2.0%)	0	2 (1.0%)
AMFEBUTAMONE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
CHLORDIAZEPOXIDE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
CLONIDINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
HYDROXYZINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
MELATONIN	1 (1.0%)	0	1 (0.5%)
VALPROATE SEMISODIUM	1 (1.0%)	0	1 (0.5%)
TRAZODONE	0	2 (2.0%)	2 (1.0%)
CARISOPRODOL	0	1 (1.0%)	1 (0.5%)
DEXAMPHETAMINE SULFATE	0	1 (1.0%)	1 (0.5%)
IMIPRAMINE	0	1 (1.0%)	1 (0.5%)
QUETIAPINE	0	1 (1.0%)	1 (0.5%)
SERTRALINE HYDROCHLORIDE	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 13.13.3.1

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=101)	Placebo (N=102)	Total (N=203)
Total number of patients with at least one prior non-psychoactive medication	Total	44 (43.6%)	45 (44.1%)	89 (43.8%)
ALIMENTARY TRACT/METAB	Total	11 (10.9%)	11 (10.8%)	22 (10.8%)
	ACETYLSALICYLIC ACID	1 (1.0%)	1 (1.0%)	2 (1.0%)
	ALUMINIUM HYDROXIDE	2 (2.0%)	1 (1.0%)	3 (1.5%)
	ASCORBIC ACID	1 (1.0%)	2 (2.0%)	3 (1.5%)
	BISMUTH SUBSALICYLATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	CALCIUM	0	1 (1.0%)	1 (0.5%)
	CALCIUM CARBONATE	0	2 (2.0%)	2 (1.0%)
	DEXAMPHETAMINE SULFATE	0	1 (1.0%)	1 (0.5%)
	DICLOFENAC SODIUM	0	1 (1.0%)	1 (0.5%)
	DIMETICONE, ACTIVATED	0	1 (1.0%)	1 (0.5%)
	ERGOCALCIFEROL	0	1 (1.0%)	1 (0.5%)
	FLUORIDE NOS	0	1 (1.0%)	1 (0.5%)
	MAGNESIUM HYDROXIDE	2 (2.0%)	1 (1.0%)	3 (1.5%)
	MISOPROSTOL	0	1 (1.0%)	1 (0.5%)
	OXYBUTYNIN	1 (1.0%)	0	1 (0.5%)
	RANITIDINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	VITAMINS NOS	5 (5.0%)	2 (2.0%)	7 (3.4%)
ANTIINFECTIVES,SYSTEMIC	Total	9 (8.9%)	6 (5.9%)	15 (7.4%)
	AMOXICILLIN	1 (1.0%)	2 (2.0%)	3 (1.5%)
	AMOXICILLIN TRIHYDRATE	2 (2.0%)	2 (2.0%)	4 (2.0%)
	AZITHROMYCIN	0	1 (1.0%)	1 (0.5%)
	CEFALEXIN	1 (1.0%)	0	1 (0.5%)
	CEFALEXIN MONOHYDRATE	2 (2.0%)	0	2 (1.0%)
	CEFPROZIL MONOHYDRATE	1 (1.0%)	0	1 (0.5%)
	CLAVULANIC ACID	2 (2.0%)	1 (1.0%)	3 (1.5%)
	CLINDAMYCIN	1 (1.0%)	0	1 (0.5%)
	DOXYCYCLINE	1 (1.0%)	0	1 (0.5%)
	OFLOXACIN	1 (1.0%)	0	1 (0.5%)
	TETRACYCLINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	TOBRAMYCIN	0	1 (1.0%)	1 (0.5%)
ANTINEOPLASTIC & IMMUNOSUP	Total	1 (1.0%)	0	1 (0.5%)
	MEDROXYPROGESTERONE ACETATE	1 (1.0%)	0	1 (0.5%)
BLOOD/BLOOD FORM ORGANS	Total	1 (1.0%)	1 (1.0%)	2 (1.0%)
	ACETYLSALICYLIC ACID	1 (1.0%)	1 (1.0%)	2 (1.0%)
CENTRAL NERVOUS SYSTEM	Total	14 (13.9%)	19 (18.6%)	33 (16.3%)
	ACETYLSALICYLIC ACID	3 (3.0%)	4 (3.9%)	7 (3.4%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.13.3.1

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=101)	Placebo (N=102)	Total (N=203)
CENTRAL NERVOUS SYSTEM	AMITRIPTYLINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	CAFFEINE	2 (2.0%)	3 (2.9%)	5 (2.5%)
	CINNAMEDRINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
	DEXAMPHETAMINE SULFATE	0	1 (1.0%)	1 (0.5%)
	HYDROCODONE BITARTRATE	1 (1.0%)	0	1 (0.5%)
	LIDOCAINE	1 (1.0%)	0	1 (0.5%)
	PARACETAMOL	11 (10.9%)	16 (15.7%)	27 (13.3%)
	PRILOCAINE	1 (1.0%)	0	1 (0.5%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	SUMATRIPTAN	1 (1.0%)	0	1 (0.5%)
DERMATOLOGICALS	Total	6 (5.9%)	6 (5.9%)	12 (5.9%)
	BUDESONIDE	1 (1.0%)	0	1 (0.5%)
	DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	FLUTICASONE PROPIONATE	2 (2.0%)	3 (2.9%)	5 (2.5%)
	LIDOCAINE	1 (1.0%)	0	1 (0.5%)
	MOMETASONE FUROATE	0	1 (1.0%)	1 (0.5%)
	PRILOCAINE	1 (1.0%)	0	1 (0.5%)
	TETRACYCLINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
GU SYSTEM/SEX HORMONES	Total	5 (5.0%)	3 (2.9%)	8 (3.9%)
	DESOGESTREL	0	1 (1.0%)	1 (0.5%)
	ETHINYLESTRADIOL	2 (2.0%)	2 (2.0%)	4 (2.0%)
	FINASTERIDE	0	1 (1.0%)	1 (0.5%)
	MEDROXYPROGESTERONE ACETATE	1 (1.0%)	0	1 (0.5%)
	NITROFURANTOIN	1 (1.0%)	0	1 (0.5%)
	NORETHISTERONE	1 (1.0%)	0	1 (0.5%)
	NORETHISTERONE ACETATE	1 (1.0%)	0	1 (0.5%)
	NORGESTIMATE	0	1 (1.0%)	1 (0.5%)
	OFLOXACIN	1 (1.0%)	0	1 (0.5%)
	OXYBUTYNIN	1 (1.0%)	0	1 (0.5%)
MUSCULO-SKELETAL	Total	13 (12.9%)	13 (12.7%)	26 (12.8%)
	DICLOFENAC SODIUM	0	1 (1.0%)	1 (0.5%)
	IBUPROFEN	13 (12.9%)	10 (9.8%)	23 (11.3%)
	MISOPROSTOL	0	1 (1.0%)	1 (0.5%)
	NABUMETONE	0	1 (1.0%)	1 (0.5%)
	NAPROXEN SODIUM	0	2 (2.0%)	2 (1.0%)
RESPIRATORY	Total	23 (22.8%)	16 (15.7%)	39 (19.2%)
	ANTIHISTAMINE, NOS	1 (1.0%)	0	1 (0.5%)
	BROMPHENIRAMINE MALEATE	0	1 (1.0%)	1 (0.5%)
	BUDESONIDE	1 (1.0%)	0	1 (0.5%)
	CETIRIZINE HYDROCHLORIDE	2 (2.0%)	0	2 (1.0%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.13.3.1

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=101)	Placebo (N=102)	Total (N=203)
RESPIRATORY	CHLORPHENAMINE MALEATE	0	1 (1.0%)	1 (0.5%)
	CLEMASTINE FUMARATE	2 (2.0%)	0	2 (1.0%)
	DEXTROMETHORPHAN HYDROBROMIDE	0	1 (1.0%)	1 (0.5%)
	DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	FEXOFENADINE HYDROCHLORIDE	0	3 (2.9%)	3 (1.5%)
	FLUTICASONE PROPIONATE	2 (2.0%)	3 (2.9%)	5 (2.5%)
	HYDROCODONE BITARTRATE	1 (1.0%)	0	1 (0.5%)
	IPRATROPIUM BROMIDE	1 (1.0%)	0	1 (0.5%)
	LORATADINE	6 (5.9%)	6 (5.9%)	12 (5.9%)
	MOMETASONE FUROATE	0	1 (1.0%)	1 (0.5%)
	MONTELUKAST SODIUM	3 (3.0%)	1 (1.0%)	4 (2.0%)
	PARACETAMOL	2 (2.0%)	0	2 (1.0%)
	PHENYLEPHRINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	PREDNISONE	1 (1.0%)	0	1 (0.5%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	2 (2.0%)	2 (2.0%)	4 (2.0%)
	PSEUDOEPHEDRINE SULFATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	SALBUTAMOL	7 (6.9%)	6 (5.9%)	13 (6.4%)
	SALMETEROL HYDROXYNAPHTHOATE	1 (1.0%)	0	1 (0.5%)
	TRIPROLIDINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
SENSORY ORGANS	Total	2 (2.0%)	2 (2.0%)	4 (2.0%)
	OFLOXACIN	1 (1.0%)	0	1 (0.5%)
	TETRACYCLINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	TOBRAMYCIN	0	1 (1.0%)	1 (0.5%)
SYSTEMIC HORMONAL	Total	2 (2.0%)	1 (1.0%)	3 (1.5%)
	DESMOPRESSIN	0	1 (1.0%)	1 (0.5%)
	LEVOTHYROXINE SODIUM	1 (1.0%)	0	1 (0.5%)
	PREDNISONE	1 (1.0%)	0	1 (0.5%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.13.3.2

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=101)	Placebo (N=102)	Total (N=203)
Total number of patients with at least one prior non-psychoactive medication	44 (43.6%)	45 (44.1%)	89 (43.8%)
IBUPROFEN	13 (12.9%)	10 (9.8%)	23 (11.3%)
PARACETAMOL	11 (10.9%)	16 (15.7%)	27 (13.3%)
SALBUTAMOL	7 (6.9%)	6 (5.9%)	13 (6.4%)
LORATADINE	6 (5.9%)	6 (5.9%)	12 (5.9%)
VITAMINS NOS	5 (5.0%)	2 (2.0%)	7 (3.4%)
ACETYLSALICYLIC ACID	3 (3.0%)	4 (3.9%)	7 (3.4%)
MONTELUKAST SODIUM	3 (3.0%)	1 (1.0%)	4 (2.0%)
CAFFEINE	2 (2.0%)	3 (2.9%)	5 (2.5%)
FLUTICASONE PROPIONATE	2 (2.0%)	3 (2.9%)	5 (2.5%)
AMOXICILLIN TRIHYDRATE	2 (2.0%)	2 (2.0%)	4 (2.0%)
ETHINYLESTRADIOL	2 (2.0%)	2 (2.0%)	4 (2.0%)
PSEUDOEPHEDRINE HYDROCHLORIDE	2 (2.0%)	2 (2.0%)	4 (2.0%)
ALUMINIUM HYDROXIDE	2 (2.0%)	1 (1.0%)	3 (1.5%)
CLAVULANIC ACID	2 (2.0%)	1 (1.0%)	3 (1.5%)
MAGNESIUM HYDROXIDE	2 (2.0%)	1 (1.0%)	3 (1.5%)
CEFALEXIN MONOHYDRATE	2 (2.0%)	0	2 (1.0%)
CETIRIZINE HYDROCHLORIDE	2 (2.0%)	0	2 (1.0%)
CLEMASTINE FUMARATE	2 (2.0%)	0	2 (1.0%)
AMOXICILLIN	1 (1.0%)	2 (2.0%)	3 (1.5%)
ASCORBIC ACID	1 (1.0%)	2 (2.0%)	3 (1.5%)
BISMUTH SUBSALICYLATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
PHENYLPROPANOLAMINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
PSEUDOEPHEDRINE SULFATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
TETRACYCLINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
TRIPROLIDINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
AMITRIPTYLINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
ANTIHISTAMINE, NOS	1 (1.0%)	0	1 (0.5%)
BUDESONIDE	1 (1.0%)	0	1 (0.5%)
CEFALEXIN	1 (1.0%)	0	1 (0.5%)
CEFPROZIL MONOHYDRATE	1 (1.0%)	0	1 (0.5%)
CLINDAMYCIN	1 (1.0%)	0	1 (0.5%)
DOXYCYCLINE	1 (1.0%)	0	1 (0.5%)
HYDROCODONE BITARTRATE	1 (1.0%)	0	1 (0.5%)
IPRATROPIUM BROMIDE	1 (1.0%)	0	1 (0.5%)
LEVOTHYROXINE SODIUM	1 (1.0%)	0	1 (0.5%)
LIDOCAINE	1 (1.0%)	0	1 (0.5%)
MEDROXYPROGESTERONE ACETATE	1 (1.0%)	0	1 (0.5%)
NITROFURANTOIN	1 (1.0%)	0	1 (0.5%)
NORETHISTERONE	1 (1.0%)	0	1 (0.5%)
NORETHISTERONE ACETATE	1 (1.0%)	0	1 (0.5%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.13.3.2

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=101)	Placebo (N=102)	Total (N=203)
OFLOXACIN	1 (1.0%)	0	1 (0.5%)
OXYBUTYNIN	1 (1.0%)	0	1 (0.5%)
PREDNISONE	1 (1.0%)	0	1 (0.5%)
PRILOCAINE	1 (1.0%)	0	1 (0.5%)
RANITIDINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
SALMETEROL HYDROXYNAPHTHOATE	1 (1.0%)	0	1 (0.5%)
SUMATRIPTAN	1 (1.0%)	0	1 (0.5%)
FEXOFENADINE HYDROCHLORIDE	0	3 (2.9%)	3 (1.5%)
CALCIUM CARBONATE	0	2 (2.0%)	2 (1.0%)
NAPROXEN SODIUM	0	2 (2.0%)	2 (1.0%)
AZITHROMYCIN	0	1 (1.0%)	1 (0.5%)
BROMPHENIRAMINE MALEATE	0	1 (1.0%)	1 (0.5%)
CALCIUM	0	1 (1.0%)	1 (0.5%)
CHLORPHENAMINE MALEATE	0	1 (1.0%)	1 (0.5%)
CINNAMEDRINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
DESMOPRESSIN	0	1 (1.0%)	1 (0.5%)
DESOGESTREL	0	1 (1.0%)	1 (0.5%)
DEXAMPHETAMINE SULFATE	0	1 (1.0%)	1 (0.5%)
DEXTROMETHORPHAN HYDROBROMIDE	0	1 (1.0%)	1 (0.5%)
DICLOFENAC SODIUM	0	1 (1.0%)	1 (0.5%)
DIMETICONE, ACTIVATED	0	1 (1.0%)	1 (0.5%)
ERGOCALCIFEROL	0	1 (1.0%)	1 (0.5%)
FINASTERIDE	0	1 (1.0%)	1 (0.5%)
FLUORIDE NOS	0	1 (1.0%)	1 (0.5%)
MISOPROSTOL	0	1 (1.0%)	1 (0.5%)
MOMETASONE FUROATE	0	1 (1.0%)	1 (0.5%)
NABUMETONE	0	1 (1.0%)	1 (0.5%)
NORGESTIMATE	0	1 (1.0%)	1 (0.5%)
PHENYLEPHRINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
TOBRAMYCIN	0	1 (1.0%)	1 (0.5%)

Note that this tabulates medication taken during the month prior to screening

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Table 13.13.3.3

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=101)	Placebo (N=102)	Total (N=203)
Total number of patients with at least one concomitant medication	Total	67 (66.3%)	59 (57.8%)	126 (62.1%)
ALIMENTARY TRACT/METAB	Total	14 (13.9%)	17 (16.7%)	31 (15.3%)
	ACETYLSALICYLIC ACID	2 (2.0%)	5 (4.9%)	7 (3.4%)
	ALOES	1 (1.0%)	0	1 (0.5%)
	ALUMINIUM HYDROXIDE	2 (2.0%)	1 (1.0%)	3 (1.5%)
	ASCORBIC ACID	1 (1.0%)	2 (2.0%)	3 (1.5%)
	BISMUTH SUBSALICYLATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	CALCIUM	0	1 (1.0%)	1 (0.5%)
	CALCIUM CARBONATE	0	3 (2.9%)	3 (1.5%)
	CARMELLOSE SODIUM	1 (1.0%)	0	1 (0.5%)
	DEXAMPHETAMINE SULFATE	0	1 (1.0%)	1 (0.5%)
	ERGOCALCIFEROL	0	1 (1.0%)	1 (0.5%)
	FAMOTIDINE	0	1 (1.0%)	1 (0.5%)
	FLUORIDE NOS	0	1 (1.0%)	1 (0.5%)
	GELATINE	1 (1.0%)	0	1 (0.5%)
	LAXATIVES, NOS	0	1 (1.0%)	1 (0.5%)
	LOPERAMIDE HYDROCHLORIDE	0	2 (2.0%)	2 (1.0%)
	MAGNESIUM HYDROXIDE	2 (2.0%)	1 (1.0%)	3 (1.5%)
	OMEPRAZOLE	0	1 (1.0%)	1 (0.5%)
	OXYBUTYNIN	1 (1.0%)	0	1 (0.5%)
	PECTIN	1 (1.0%)	0	1 (0.5%)
	PHOSPHORUS	0	1 (1.0%)	1 (0.5%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	RANITIDINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	SODIUM	0	1 (1.0%)	1 (0.5%)
	SODIUM CHLORIDE	1 (1.0%)	0	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	0	1 (1.0%)	1 (0.5%)
	VITAMINS NOS	5 (5.0%)	1 (1.0%)	6 (3.0%)
ANTIINFECTIVES,SYSTEMIC	Total	24 (23.8%)	16 (15.7%)	40 (19.7%)
	AMOXICILLIN	6 (5.9%)	5 (4.9%)	11 (5.4%)
	AMOXICILLIN TRIHYDRATE	4 (4.0%)	7 (6.9%)	11 (5.4%)
	AZITHROMYCIN	1 (1.0%)	3 (2.9%)	4 (2.0%)
	CEFALEXIN	1 (1.0%)	0	1 (0.5%)
	CEFALEXIN MONOHYDRATE	2 (2.0%)	0	2 (1.0%)
	CEFUROXIME AXETIL	1 (1.0%)	0	1 (0.5%)
	CIPROFLOXACIN HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	CLARITHROMYCIN	2 (2.0%)	0	2 (1.0%)
	CLAVULANIC ACID	4 (4.0%)	5 (4.9%)	9 (4.4%)
	CLINDAMYCIN	1 (1.0%)	0	1 (0.5%)
	DOXYCYCLINE	1 (1.0%)	0	1 (0.5%)
	HEPATITIS B VACCINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	MICONAZOLE NITRATE	1 (1.0%)	0	1 (0.5%)
	MINOCYCLINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)

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Table 13.13.3.3

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=101)	Placebo (N=102)	Total (N=203)
ANTIINFECTIVES,SYSTEMIC	PENICILLIN NOS	1 (1.0%)	0	1 (0.5%)
	SULFAMETHOXAZOLE	3 (3.0%)	0	3 (1.5%)
	TETANUS TOXOID	1 (1.0%)	0	1 (0.5%)
	TETRACYCLINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	TOBRAMYCIN	0	1 (1.0%)	1 (0.5%)
	TRIMETHOPRIM	3 (3.0%)	0	3 (1.5%)
ANTINEOPLASTIC & IMMUNOSUP	Total	1 (1.0%)	0	1 (0.5%)
	MEDROXYPROGESTERONE ACETATE	1 (1.0%)	0	1 (0.5%)
BLOOD/BLOOD FORM ORGANS	Total	3 (3.0%)	5 (4.9%)	8 (3.9%)
	ACETYLSALICYLIC ACID	2 (2.0%)	5 (4.9%)	7 (3.4%)
	SODIUM CHLORIDE	1 (1.0%)	0	1 (0.5%)
CARDIOVASCULAR	Total	1 (1.0%)	2 (2.0%)	3 (1.5%)
	BENZOCAINE	0	1 (1.0%)	1 (0.5%)
	LIDOCAINE	1 (1.0%)	0	1 (0.5%)
	LIDOCAINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
CENTRAL NERVOUS SYSTEM	Total	27 (26.7%)	33 (32.4%)	60 (29.6%)
	ACETYLSALICYLIC ACID	4 (4.0%)	7 (6.9%)	11 (5.4%)
	CAFFEINE	2 (2.0%)	3 (2.9%)	5 (2.5%)
	CHLORPHENAMINE MALEATE	0	2 (2.0%)	2 (1.0%)
	CINNAMEDRINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
	CODEINE PHOSPHATE	0	1 (1.0%)	1 (0.5%)
	DEXAMPHETAMINE SULFATE	0	1 (1.0%)	1 (0.5%)
	DEXTROMETHORPHAN HYDROBROMIDE	1 (1.0%)	4 (3.9%)	5 (2.5%)
	DICHLORALPHENAZONE	0	1 (1.0%)	1 (0.5%)
	DIPHENHYDRAMINE CITRATE	0	1 (1.0%)	1 (0.5%)
	DOXYLAMINE SUCCINATE	1 (1.0%)	3 (2.9%)	4 (2.0%)
	HYDROCODONE BITARTRATE	0	1 (1.0%)	1 (0.5%)
	HYDROXYZINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	ISOMETHEPTENE	0	1 (1.0%)	1 (0.5%)
	LIDOCAINE	1 (1.0%)	0	1 (0.5%)
	LIDOCAINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
	LITHIUM	1 (1.0%)	0	1 (0.5%)
	OLANZAPINE	1 (1.0%)	0	1 (0.5%)
	PARACETAMOL	21 (20.8%)	27 (26.5%)	48 (23.6%)
	PAROXETINE	1 (1.0%)	2 (2.0%)	3 (1.5%)
	PHENAZONE	0	1 (1.0%)	1 (0.5%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.0%)	5 (4.9%)	6 (3.0%)
	RISPERIDONE	2 (2.0%)	0	2 (1.0%)
	SUMATRIPTAN	1 (1.0%)	0	1 (0.5%)
	TOPIRAMATE	1 (1.0%)	0	1 (0.5%)

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Table 13.13.3.3

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=101)	Placebo (N=102)	Total (N=203)
DERMATOLOGICALS	Total	14 (13.9%)	15 (14.7%)	29 (14.3%)
	ALOES	1 (1.0%)	0	1 (0.5%)
	BACITRACIN	1 (1.0%)	0	1 (0.5%)
	BENTONITE	1 (1.0%)	0	1 (0.5%)
	BENZOCAINE	0	1 (1.0%)	1 (0.5%)
	BUDESONIDE	1 (1.0%)	0	1 (0.5%)
	CALAMINE	1 (1.0%)	0	1 (0.5%)
	DIPHENHYDRAMINE CITRATE	0	1 (1.0%)	1 (0.5%)
	DIPHENHYDRAMINE HYDROCHLORIDE	6 (5.9%)	2 (2.0%)	8 (3.9%)
	ECONAZOLE NITRATE	0	1 (1.0%)	1 (0.5%)
	FLUOCINONIDE	1 (1.0%)	0	1 (0.5%)
	FLUTICASONE PROPIONATE	2 (2.0%)	4 (3.9%)	6 (3.0%)
	GLYCEROL	1 (1.0%)	1 (1.0%)	2 (1.0%)
	LIDOCAINE	1 (1.0%)	0	1 (0.5%)
	LIDOCAINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
	MICONAZOLE NITRATE	1 (1.0%)	0	1 (0.5%)
	MOMETASONE FUROATE	0	3 (2.9%)	3 (1.5%)
	PARACETAMOL	0	1 (1.0%)	1 (0.5%)
	PARAFFIN, SOFT	0	1 (1.0%)	1 (0.5%)
	PHENOL, LIQUEFIED	1 (1.0%)	0	1 (0.5%)
	POTASSIUM SORBATE	0	1 (1.0%)	1 (0.5%)
	PROMETHAZINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	PROPYLENE GLYCOL	0	1 (1.0%)	1 (0.5%)
	PURIFIED WATER	0	1 (1.0%)	1 (0.5%)
	SODIUM CITRATE	1 (1.0%)	0	1 (0.5%)
	SODIUM HYDROXIDE	0	1 (1.0%)	1 (0.5%)
	SULFACETAMIDE SODIUM	1 (1.0%)	0	1 (0.5%)
	SWEET ALMOND OIL	0	1 (1.0%)	1 (0.5%)
	TETRACYCLINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	TOCOPHERYL ACETATE	0	1 (1.0%)	1 (0.5%)
	TOLNAFTATE	0	1 (1.0%)	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	0	1 (1.0%)	1 (0.5%)
	ZINC OXIDE	1 (1.0%)	0	1 (0.5%)
GU SYSTEM/SEX HORMONES	Total	7 (6.9%)	4 (3.9%)	11 (5.4%)
	BACITRACIN	1 (1.0%)	0	1 (0.5%)
	CIPROFLOXACIN HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	DESOGESTREL	0	1 (1.0%)	1 (0.5%)
	ECONAZOLE NITRATE	0	1 (1.0%)	1 (0.5%)
	ETHINYLESTRADIOL	2 (2.0%)	1 (1.0%)	3 (1.5%)
	FINASTERIDE	0	1 (1.0%)	1 (0.5%)
	MEDROXYPROGESTERONE ACETATE	1 (1.0%)	0	1 (0.5%)
	MICONAZOLE NITRATE	1 (1.0%)	0	1 (0.5%)
	NITROFURANTOIN	1 (1.0%)	0	1 (0.5%)
	NORETHISTERONE	1 (1.0%)	0	1 (0.5%)
	NORETHISTERONE ACETATE	1 (1.0%)	0	1 (0.5%)

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Table 13.13.3.3

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=101)	Placebo (N=102)	Total (N=203)
GU SYSTEM/SEX HORMONES	OXYBUTYNIN	1 (1.0%)	0	1 (0.5%)
MUSCULO-SKELETAL	Total	20 (19.8%)	18 (17.6%)	38 (18.7%)
	IBUPROFEN	19 (18.8%)	15 (14.7%)	34 (16.7%)
	NABUMETONE	0	1 (1.0%)	1 (0.5%)
	NAPROXEN SODIUM	1 (1.0%)	4 (3.9%)	5 (2.5%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
RESPIRATORY	Total	36 (35.6%)	28 (27.5%)	64 (31.5%)
	ACETYLSALICYLIC ACID	0	1 (1.0%)	1 (0.5%)
	BENZOCAINE	0	1 (1.0%)	1 (0.5%)
	BROMPHENIRAMINE MALEATE	2 (2.0%)	0	2 (1.0%)
	BUDESONIDE	1 (1.0%)	0	1 (0.5%)
	CAFFEINE	0	1 (1.0%)	1 (0.5%)
	CETIRIZINE HYDROCHLORIDE	2 (2.0%)	2 (2.0%)	4 (2.0%)
	CHLORPHENAMINE MALEATE	1 (1.0%)	3 (2.9%)	4 (2.0%)
	CLEMASTINE FUMARATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	CODEINE	1 (1.0%)	0	1 (0.5%)
	COUGH SYRUP/MED	1 (1.0%)	0	1 (0.5%)
	CROMOGLICATE SODIUM	1 (1.0%)	0	1 (0.5%)
	CYPROHEPTADINE	0	1 (1.0%)	1 (0.5%)
	DEXTROMETHORPHAN	0	1 (1.0%)	1 (0.5%)
	DEXTROMETHORPHAN HYDROBROMIDE	2 (2.0%)	7 (6.9%)	9 (4.4%)
	DIMENHYDRINATE	1 (1.0%)	0	1 (0.5%)
	DIPHENHYDRAMINE CITRATE	0	1 (1.0%)	1 (0.5%)
	DIPHENHYDRAMINE HYDROCHLORIDE	6 (5.9%)	2 (2.0%)	8 (3.9%)
	DOXYLAMINE SUCCINATE	1 (1.0%)	3 (2.9%)	4 (2.0%)
	ETHANOL	0	1 (1.0%)	1 (0.5%)
	FEXOFENADINE HYDROCHLORIDE	1 (1.0%)	5 (4.9%)	6 (3.0%)
	FLUTICASONE PROPIONATE	2 (2.0%)	4 (3.9%)	6 (3.0%)
	GUAIFENESIN	2 (2.0%)	5 (4.9%)	7 (3.4%)
	HYDROCODONE BITARTRATE	0	1 (1.0%)	1 (0.5%)
	IBUPROFEN	1 (1.0%)	1 (1.0%)	2 (1.0%)
	IPRATROPIUM BROMIDE	1 (1.0%)	0	1 (0.5%)
	LIDOCAINE	1 (1.0%)	0	1 (0.5%)
	LIDOCAINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
	LORATADINE	8 (7.9%)	7 (6.9%)	15 (7.4%)
	MEPYRAMINE MALEATE	1 (1.0%)	0	1 (0.5%)
	MOMETASONE FUROATE	0	3 (2.9%)	3 (1.5%)
	MONTELUKAST SODIUM	3 (3.0%)	1 (1.0%)	4 (2.0%)
	PARACETAMOL	1 (1.0%)	8 (7.8%)	9 (4.4%)
	PHENIRAMINE MALEATE	1 (1.0%)	0	1 (0.5%)
	PHENYLEPHRINE HYDROCHLORIDE	2 (2.0%)	0	2 (1.0%)
	PHENYLPROPANOLAMINE	0	1 (1.0%)	1 (0.5%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	4 (4.0%)	2 (2.0%)	6 (3.0%)

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Table 13.13.3.3

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=101)	Placebo (N=102)	Total (N=203)
RESPIRATORY	PROMETHAZINE HYDROCHLORIDE	2 (2.0%)	1 (1.0%)	3 (1.5%)
	PSEUDOEPHEDRINE	1 (1.0%)	0	1 (0.5%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	6 (5.9%)	7 (6.9%)	13 (6.4%)
	PSEUDOEPHEDRINE SULFATE	3 (3.0%)	1 (1.0%)	4 (2.0%)
	SALBUTAMOL	10 (9.9%)	6 (5.9%)	16 (7.9%)
	SALMETEROL HYDROXYNAPHTHOATE	1 (1.0%)	0	1 (0.5%)
	SODIUM CHLORIDE	1 (1.0%)	0	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	0	1 (1.0%)	1 (0.5%)
	TRIPROLIDINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
SENSORY ORGANS	Total	9 (8.9%)	5 (4.9%)	14 (6.9%)
	ACETIC ACID	1 (1.0%)	0	1 (0.5%)
	BACITRACIN	1 (1.0%)	0	1 (0.5%)
	BENZETHONIUM CHLORIDE	1 (1.0%)	0	1 (0.5%)
	CIPROFLOXACIN HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	CROMOGLICATE SODIUM	1 (1.0%)	0	1 (0.5%)
	HYDROCORTISONE	1 (1.0%)	0	1 (0.5%)
	LIDOCAINE	1 (1.0%)	0	1 (0.5%)
	LIDOCAINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
	PROPYLENE GLYCOL DIACETATE	1 (1.0%)	0	1 (0.5%)
	PROXYMETACAINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
	SODIUM ACETATE	1 (1.0%)	0	1 (0.5%)
	SODIUM CHLORIDE	1 (1.0%)	0	1 (0.5%)
	SULFACETAMIDE SODIUM	1 (1.0%)	0	1 (0.5%)
	TETRACYCLINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
	TOBRAMYCIN	0	1 (1.0%)	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	0	1 (1.0%)	1 (0.5%)
SYSTEMIC HORMONAL	Total	1 (1.0%)	2 (2.0%)	3 (1.5%)
	DESMOPRESSIN	0	1 (1.0%)	1 (0.5%)
	LEVOTHYROXINE SODIUM	1 (1.0%)	0	1 (0.5%)
	TRIAMCINOLONE ACETONIDE	0	1 (1.0%)	1 (0.5%)
VARIOUS	Total	1 (1.0%)	0	1 (0.5%)
	PROTEINS NOS	1 (1.0%)	0	1 (0.5%)

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Table 13.13.3.4

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=101)	Placebo (N=102)	Total (N=203)
Total number of patients with at least one concomitant medication	67 (66.3%)	59 (57.8%)	126 (62.1%)
PARACETAMOL	21 (20.8%)	28 (27.5%)	49 (24.1%)
IBUPROFEN	19 (18.8%)	15 (14.7%)	34 (16.7%)
SALBUTAMOL	10 (9.9%)	6 (5.9%)	16 (7.9%)
LORATADINE	8 (7.9%)	7 (6.9%)	15 (7.4%)
PSEUDOEPHEDRINE HYDROCHLORIDE	6 (5.9%)	7 (6.9%)	13 (6.4%)
AMOXICILLIN	6 (5.9%)	5 (4.9%)	11 (5.4%)
DIPHENHYDRAMINE HYDROCHLORIDE	6 (5.9%)	2 (2.0%)	8 (3.9%)
VITAMINS NOS	5 (5.0%)	1 (1.0%)	6 (3.0%)
ACETYLSALICYLIC ACID	4 (4.0%)	8 (7.8%)	12 (5.9%)
AMOXICILLIN TRIHYDRATE	4 (4.0%)	7 (6.9%)	11 (5.4%)
CLAVULANIC ACID	4 (4.0%)	5 (4.9%)	9 (4.4%)
PHENYLPROPANOLAMINE HYDROCHLORIDE	4 (4.0%)	2 (2.0%)	6 (3.0%)
MONTELUKAST SODIUM	3 (3.0%)	1 (1.0%)	4 (2.0%)
PSEUDOEPHEDRINE SULFATE	3 (3.0%)	1 (1.0%)	4 (2.0%)
SULFAMETHOXAZOLE	3 (3.0%)	0	3 (1.5%)
TRIMETHOPRIM	3 (3.0%)	0	3 (1.5%)
DEXTROMETHORPHAN HYDROBROMIDE	2 (2.0%)	7 (6.9%)	9 (4.4%)
GUAIFENESIN	2 (2.0%)	5 (4.9%)	7 (3.4%)
CAFFEINE	2 (2.0%)	4 (3.9%)	6 (3.0%)
FLUTICASONE PROPIONATE	2 (2.0%)	4 (3.9%)	6 (3.0%)
CETIRIZINE HYDROCHLORIDE	2 (2.0%)	2 (2.0%)	4 (2.0%)
ALUMINIUM HYDROXIDE	2 (2.0%)	1 (1.0%)	3 (1.5%)
ETHINYLESTRADIOL	2 (2.0%)	1 (1.0%)	3 (1.5%)
MAGNESIUM HYDROXIDE	2 (2.0%)	1 (1.0%)	3 (1.5%)
PROMETHAZINE HYDROCHLORIDE	2 (2.0%)	1 (1.0%)	3 (1.5%)
BROMPHENIRAMINE MALEATE	2 (2.0%)	0	2 (1.0%)
CEFALEXIN MONOHYDRATE	2 (2.0%)	0	2 (1.0%)
CLARITHROMYCIN	2 (2.0%)	0	2 (1.0%)
PHENYLEPHRINE HYDROCHLORIDE	2 (2.0%)	0	2 (1.0%)
RISPERIDONE	2 (2.0%)	0	2 (1.0%)
FEXOFENADINE HYDROCHLORIDE	1 (1.0%)	5 (4.9%)	6 (3.0%)
NAPROXEN SODIUM	1 (1.0%)	4 (3.9%)	5 (2.5%)
AZITHROMYCIN	1 (1.0%)	3 (2.9%)	4 (2.0%)
CHLORPHENAMINE MALEATE	1 (1.0%)	3 (2.9%)	4 (2.0%)
DOXYLAMINE SUCCINATE	1 (1.0%)	3 (2.9%)	4 (2.0%)
ASCORBIC ACID	1 (1.0%)	2 (2.0%)	3 (1.5%)
PAROXETINE	1 (1.0%)	2 (2.0%)	3 (1.5%)
BISMUTH SUBSALICYLATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
CIPROFLOXACIN HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
CLEMASTINE FUMARATE	1 (1.0%)	1 (1.0%)	2 (1.0%)
GLYCEROL	1 (1.0%)	1 (1.0%)	2 (1.0%)
HEPATITIS B VACCINE	1 (1.0%)	1 (1.0%)	2 (1.0%)
TETRACYCLINE	1 (1.0%)	1 (1.0%)	2 (1.0%)

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Table 13.13.3.4

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=101)	Placebo (N=102)	Total (N=203)
TRIPROLIDINE HYDROCHLORIDE	1 (1.0%)	1 (1.0%)	2 (1.0%)
ACETIC ACID	1 (1.0%)	0	1 (0.5%)
ALOES	1 (1.0%)	0	1 (0.5%)
BACITRACIN	1 (1.0%)	0	1 (0.5%)
BENTONITE	1 (1.0%)	0	1 (0.5%)
BENZETHONIUM CHLORIDE	1 (1.0%)	0	1 (0.5%)
BUDESONIDE	1 (1.0%)	0	1 (0.5%)
CALAMINE	1 (1.0%)	0	1 (0.5%)
CARMELLOSE SODIUM	1 (1.0%)	0	1 (0.5%)
CEFALEXIN	1 (1.0%)	0	1 (0.5%)
CEFUROXIME AXETIL	1 (1.0%)	0	1 (0.5%)
CLINDAMYCIN	1 (1.0%)	0	1 (0.5%)
CODEINE	1 (1.0%)	0	1 (0.5%)
COUGH SYRUP/MED	1 (1.0%)	0	1 (0.5%)
CROMOGLICATE SODIUM	1 (1.0%)	0	1 (0.5%)
DIMENHYDRINATE	1 (1.0%)	0	1 (0.5%)
DOXYCYCLINE	1 (1.0%)	0	1 (0.5%)
FLUOCINONIDE	1 (1.0%)	0	1 (0.5%)
GELATINE	1 (1.0%)	0	1 (0.5%)
HYDROCORTISONE	1 (1.0%)	0	1 (0.5%)
HYDROXYZINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
IPRATROPIUM BROMIDE	1 (1.0%)	0	1 (0.5%)
LEVOTHYROXINE SODIUM	1 (1.0%)	0	1 (0.5%)
LIDOCAINE	1 (1.0%)	0	1 (0.5%)
LITHIUM	1 (1.0%)	0	1 (0.5%)
MEDROXYPROGESTERONE ACETATE	1 (1.0%)	0	1 (0.5%)
MEPYRAMINE MALEATE	1 (1.0%)	0	1 (0.5%)
MICONAZOLE NITRATE	1 (1.0%)	0	1 (0.5%)
NITROFURANTOIN	1 (1.0%)	0	1 (0.5%)
NORETHISTERONE	1 (1.0%)	0	1 (0.5%)
NORETHISTERONE ACETATE	1 (1.0%)	0	1 (0.5%)
OLANZAPINE	1 (1.0%)	0	1 (0.5%)
OXYBUTYNIN	1 (1.0%)	0	1 (0.5%)
PECTIN	1 (1.0%)	0	1 (0.5%)
PENICILLIN NOS	1 (1.0%)	0	1 (0.5%)
PHENIRAMINE MALEATE	1 (1.0%)	0	1 (0.5%)
PHENOL, LIQUEFIED	1 (1.0%)	0	1 (0.5%)
PROPYLENE GLYCOL DIACETATE	1 (1.0%)	0	1 (0.5%)
PROTEINS NOS	1 (1.0%)	0	1 (0.5%)
PROXYMETACAINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
PSEUDOEPHEDRINE	1 (1.0%)	0	1 (0.5%)
RANITIDINE HYDROCHLORIDE	1 (1.0%)	0	1 (0.5%)
SALMETEROL HYDROXYNAPHTHOATE	1 (1.0%)	0	1 (0.5%)
SODIUM ACETATE	1 (1.0%)	0	1 (0.5%)
SODIUM CHLORIDE	1 (1.0%)	0	1 (0.5%)
SODIUM CITRATE	1 (1.0%)	0	1 (0.5%)

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Table 13.13.3.4

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=101)	Placebo (N=102)	Total (N=203)
SULFACETAMIDE SODIUM	1 (1.0%)	0	1 (0.5%)
SUMATRIPTAN	1 (1.0%)	0	1 (0.5%)
TETANUS TOXOID	1 (1.0%)	0	1 (0.5%)
TOPIRAMATE	1 (1.0%)	0	1 (0.5%)
ZINC OXIDE	1 (1.0%)	0	1 (0.5%)
CALCIUM CARBONATE	0	3 (2.9%)	3 (1.5%)
MOMETASONE FUROATE	0	3 (2.9%)	3 (1.5%)
LOPERAMIDE HYDROCHLORIDE	0	2 (2.0%)	2 (1.0%)
BENZOCAINE	0	1 (1.0%)	1 (0.5%)
CALCIUM	0	1 (1.0%)	1 (0.5%)
CINNAMEDRINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
CODEINE PHOSPHATE	0	1 (1.0%)	1 (0.5%)
CYPROHEPTADINE	0	1 (1.0%)	1 (0.5%)
DESMOPRESSIN	0	1 (1.0%)	1 (0.5%)
DESOGESTREL	0	1 (1.0%)	1 (0.5%)
DEXAMPHETAMINE SULFATE	0	1 (1.0%)	1 (0.5%)
DEXTROMETHORPHAN	0	1 (1.0%)	1 (0.5%)
DICHLORALPHENAZONE	0	1 (1.0%)	1 (0.5%)
DIPHENHYDRAMINE CITRATE	0	1 (1.0%)	1 (0.5%)
ECONAZOLE NITRATE	0	1 (1.0%)	1 (0.5%)
ERGOCALCIFEROL	0	1 (1.0%)	1 (0.5%)
ETHANOL	0	1 (1.0%)	1 (0.5%)
FAMOTIDINE	0	1 (1.0%)	1 (0.5%)
FINASTERIDE	0	1 (1.0%)	1 (0.5%)
FLUORIDE NOS	0	1 (1.0%)	1 (0.5%)
HYDROCODONE BITARTRATE	0	1 (1.0%)	1 (0.5%)
ISOMETHEPTENE	0	1 (1.0%)	1 (0.5%)
LAXATIVES, NOS	0	1 (1.0%)	1 (0.5%)
LIDOCAINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
MINOCYCLINE HYDROCHLORIDE	0	1 (1.0%)	1 (0.5%)
NABUMETONE	0	1 (1.0%)	1 (0.5%)
OMEPRAZOLE	0	1 (1.0%)	1 (0.5%)
PARAFFIN, SOFT	0	1 (1.0%)	1 (0.5%)
PHENAZONE	0	1 (1.0%)	1 (0.5%)
PHENYLPROPANOLAMINE	0	1 (1.0%)	1 (0.5%)
PHOSPHORUS	0	1 (1.0%)	1 (0.5%)
POTASSIUM SORBATE	0	1 (1.0%)	1 (0.5%)
PROPYLENE GLYCOL	0	1 (1.0%)	1 (0.5%)
PURIFIED WATER	0	1 (1.0%)	1 (0.5%)
SODIUM	0	1 (1.0%)	1 (0.5%)
SODIUM HYDROXIDE	0	1 (1.0%)	1 (0.5%)
SWEET ALMOND OIL	0	1 (1.0%)	1 (0.5%)
TOBRAMYCIN	0	1 (1.0%)	1 (0.5%)
TOCOPHERYL ACETATE	0	1 (1.0%)	1 (0.5%)
TOLNAFTATE	0	1 (1.0%)	1 (0.5%)
TRIAMCINOLONE ACETONIDE	0	1 (1.0%)	1 (0.5%)

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Table 13.13.3.5

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=83)	Placebo (N=73)	Total (N=156)
Total number of patients with at least one concomitant medication during taper or follow-up	Total	51 (61.4%)	42 (57.5%)	93 (59.6%)
ALIMENTARY TRACT/METAB	Total	11 (13.3%)	9 (12.3%)	20 (12.8%)
	ACETYLSALICYLIC ACID	0	1 (1.4%)	1 (0.6%)
	ALOES	1 (1.2%)	0	1 (0.6%)
	ALUMINIUM HYDROXIDE	1 (1.2%)	0	1 (0.6%)
	ASCORBIC ACID	1 (1.2%)	2 (2.7%)	3 (1.9%)
	BISMUTH SUBSALICYLATE	0	2 (2.7%)	2 (1.3%)
	CALCIUM	0	1 (1.4%)	1 (0.6%)
	CALCIUM CARBONATE	0	2 (2.7%)	2 (1.3%)
	ERGOCALCIFEROL	1 (1.2%)	1 (1.4%)	2 (1.3%)
	FLUORIDE NOS	0	1 (1.4%)	1 (0.6%)
	MAGNESIUM HYDROXIDE	1 (1.2%)	0	1 (0.6%)
	OMEPRAZOLE	0	1 (1.4%)	1 (0.6%)
	OXYBUTYNIN	1 (1.2%)	0	1 (0.6%)
	PROMETHAZINE	1 (1.2%)	0	1 (0.6%)
	RANITIDINE HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
	RETINOL	1 (1.2%)	0	1 (0.6%)
	SODIUM CHLORIDE	1 (1.2%)	0	1 (0.6%)
	VITAMINS NOS	6 (7.2%)	1 (1.4%)	7 (4.5%)
ANTIINFECTIVES,SYSTEMIC	Total	10 (12.0%)	5 (6.8%)	15 (9.6%)
	AMOXICILLIN	3 (3.6%)	0	3 (1.9%)
	AMOXICILLIN TRIHYDRATE	1 (1.2%)	1 (1.4%)	2 (1.3%)
	AZITHROMYCIN	0	1 (1.4%)	1 (0.6%)
	CEFALEXIN MONOHYDRATE	1 (1.2%)	0	1 (0.6%)
	CEFUROXIME AXETIL	1 (1.2%)	1 (1.4%)	2 (1.3%)
	CIPROFLOXACIN HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
	CLAVULANIC ACID	1 (1.2%)	0	1 (0.6%)
	CLINDAMYCIN	1 (1.2%)	0	1 (0.6%)
	DOXYCYCLINE	1 (1.2%)	0	1 (0.6%)
	MINOCYCLINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.6%)
	SULFAMETHOXAZOLE	1 (1.2%)	0	1 (0.6%)
	TETRACYCLINE	1 (1.2%)	1 (1.4%)	2 (1.3%)
	TRIMETHOPRIM	1 (1.2%)	0	1 (0.6%)
ANTINEOPLASTIC & IMMUNOSUP	Total	1 (1.2%)	0	1 (0.6%)
	MEDROXYPROGESTERONE ACETATE	1 (1.2%)	0	1 (0.6%)
BLOOD/BLOOD FORM ORGANS	Total	3 (3.6%)	1 (1.4%)	4 (2.6%)
	ACETYLSALICYLIC ACID	0	1 (1.4%)	1 (0.6%)
	IRON	1 (1.2%)	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 13.13.3.5

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=83)	Placebo (N=73)	Total (N=156)
BLOOD/BLOOD FORM ORGANS	PHYTOMENADIONE	1 (1.2%)	0	1 (0.6%)
	SODIUM CHLORIDE	1 (1.2%)	0	1 (0.6%)
CARDIOVASCULAR	Total	1 (1.2%)	0	1 (0.6%)
	FUROSEMIDE	1 (1.2%)	0	1 (0.6%)
CENTRAL NERVOUS SYSTEM	Total	22 (26.5%)	22 (30.1%)	44 (28.2%)
	ACETYLSALICYLIC ACID	2 (2.4%)	3 (4.1%)	5 (3.2%)
	AMFEBUTAMONE HYDROCHLORIDE	1 (1.2%)	1 (1.4%)	2 (1.3%)
	AMPHETAMINE ASPARTATE	1 (1.2%)	0	1 (0.6%)
	AMPHETAMINE SULFATE	1 (1.2%)	0	1 (0.6%)
	BUSPIRONE HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
	CAFFEINE	2 (2.4%)	2 (2.7%)	4 (2.6%)
	CHLORPHENAMINE MALEATE	0	1 (1.4%)	1 (0.6%)
	CINNAMEDRINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.6%)
	CITALOPRAM	1 (1.2%)	0	1 (0.6%)
	DEXTROAMPHETAMINE SACCHARATE	1 (1.2%)	0	1 (0.6%)
	DEXTROAMPHETAMINE SULFATE	1 (1.2%)	0	1 (0.6%)
	DEXTROMETHORPHAN HYDROBROMIDE	0	1 (1.4%)	1 (0.6%)
	DICHLORALPHENAZONE	0	1 (1.4%)	1 (0.6%)
	FLUOXETINE	0	1 (1.4%)	1 (0.6%)
	HYDROCODONE BITARTRATE	0	1 (1.4%)	1 (0.6%)
	ISOMETHEPTENE	0	1 (1.4%)	1 (0.6%)
	LITHIUM	1 (1.2%)	0	1 (0.6%)
	LITHIUM CARBONATE	1 (1.2%)	0	1 (0.6%)
	LORAZEPAM	1 (1.2%)	0	1 (0.6%)
	METHYLPHENIDATE	1 (1.2%)	0	1 (0.6%)
	METHYLPHENIDATE HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
	OLANZAPINE	1 (1.2%)	0	1 (0.6%)
	PARACETAMOL	8 (9.6%)	11 (15.1%)	19 (12.2%)
	PAROXETINE	8 (9.6%)	7 (9.6%)	15 (9.6%)
	PROMETHAZINE	1 (1.2%)	0	1 (0.6%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.6%)
	RISPERIDONE	4 (4.8%)	0	4 (2.6%)
	SERTRALINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.6%)
	SUMATRIPTAN	1 (1.2%)	0	1 (0.6%)
	TOPIRAMATE	1 (1.2%)	0	1 (0.6%)
	TRAZODONE	2 (2.4%)	0	2 (1.3%)
	VALPROATE SEMISODIUM	1 (1.2%)	0	1 (0.6%)
DERMATOLOGICALS	Total	7 (8.4%)	9 (12.3%)	16 (10.3%)
	ALOES	1 (1.2%)	0	1 (0.6%)
	BACITRACIN	1 (1.2%)	0	1 (0.6%)
	BENTONITE	1 (1.2%)	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 13.13.3.5

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population

ATC Code Level 1	Generic Term(s)	Treatment Group: Paroxetine (N=83)	Placebo (N=73)	Total (N=156)
DERMATOLOGICALS	BUDESONIDE	1 (1.2%)	0	1 (0.6%)
	CALAMINE	1 (1.2%)	0	1 (0.6%)
	DERMATOLOGICALS NOS	0	1 (1.4%)	1 (0.6%)
	DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
	ERGOCALCIFEROL	1 (1.2%)	0	1 (0.6%)
	FLUTICASONE PROPIONATE	2 (2.4%)	4 (5.5%)	6 (3.8%)
	GLYCEROL	1 (1.2%)	0	1 (0.6%)
	MOMETASONE FUROATE	0	2 (2.7%)	2 (1.3%)
	PHENOL, LIQUEFIED	1 (1.2%)	0	1 (0.6%)
	PROMETHAZINE	1 (1.2%)	0	1 (0.6%)
	RETINOL	1 (1.2%)	0	1 (0.6%)
	SODIUM CITRATE	1 (1.2%)	0	1 (0.6%)
	TETRACYCLINE	1 (1.2%)	1 (1.4%)	2 (1.3%)
	TOLNAFTATE	0	1 (1.4%)	1 (0.6%)
	ZINC OXIDE	1 (1.2%)	0	1 (0.6%)
GU SYSTEM/SEX HORMONES	Total	6 (7.2%)	2 (2.7%)	8 (5.1%)
	BACITRACIN	1 (1.2%)	0	1 (0.6%)
	CIPROFLOXACIN HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
	DESOGESTREL	0	1 (1.4%)	1 (0.6%)
	ETHINYLESTRADIOL	2 (2.4%)	1 (1.4%)	3 (1.9%)
	FINASTERIDE	0	1 (1.4%)	1 (0.6%)
	MEDROXYPROGESTERONE ACETATE	1 (1.2%)	0	1 (0.6%)
	NITROFURANTOIN	1 (1.2%)	0	1 (0.6%)
	NORETHISTERONE	1 (1.2%)	0	1 (0.6%)
	NORETHISTERONE ACETATE	1 (1.2%)	0	1 (0.6%)
	OXYBUTYNIN	1 (1.2%)	0	1 (0.6%)
MUSCULO-SKELETAL	Total	9 (10.8%)	10 (13.7%)	19 (12.2%)
	IBUPROFEN	9 (10.8%)	9 (12.3%)	18 (11.5%)
	NABUMETONE	0	1 (1.4%)	1 (0.6%)
	NAPROXEN SODIUM	0	1 (1.4%)	1 (0.6%)
RESPIRATORY	Total	21 (25.3%)	19 (26.0%)	40 (25.6%)
	BROMPHENIRAMINE MALEATE	1 (1.2%)	0	1 (0.6%)
	BUDESONIDE	1 (1.2%)	0	1 (0.6%)
	CETIRIZINE HYDROCHLORIDE	2 (2.4%)	2 (2.7%)	4 (2.6%)
	CHLORPHENAMINE MALEATE	0	1 (1.4%)	1 (0.6%)
	CLEMASTINE FUMARATE	1 (1.2%)	0	1 (0.6%)
	DEXTROMETHORPHAN HYDROBROMIDE	0	1 (1.4%)	1 (0.6%)
	DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
	FEXOFENADINE HYDROCHLORIDE	0	3 (4.1%)	3 (1.9%)
	FLUTICASONE PROPIONATE	2 (2.4%)	4 (5.5%)	6 (3.8%)
	GUAIFENESIN	0	4 (5.5%)	4 (2.6%)

The N’s in the denominator relate to patients entering Taper Phase or Follow-up Phase

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Table 13.13.3.5

Number (%) of Patients with Concomitant Medication by ATC Classification and Generic Term
Taper Phase or Follow-up Phase
Intention-To-Treat Population

		Treatment Group		
ATC Code Level 1	Generic Term(s)	Paroxetine (N=83)	Placebo (N=73)	Total (N=156)
RESPIRATORY	HYDROCODONE BITARTRATE	0	1 (1.4%)	1 (0.6%)
	IPRATROPIUM BROMIDE	1 (1.2%)	0	1 (0.6%)
	LORATADINE	7 (8.4%)	6 (8.2%)	13 (8.3%)
	MOMETASONE FUROATE	0	2 (2.7%)	2 (1.3%)
	MONTELUKAST SODIUM	3 (3.6%)	1 (1.4%)	4 (2.6%)
	PARACETAMOL	0	2 (2.7%)	2 (1.3%)
	PHENYLEPHRINE HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
	PHENYLPROPANOLAMINE HYDROCHLORIDE	2 (2.4%)	0	2 (1.3%)
	PROMETHAZINE	1 (1.2%)	0	1 (0.6%)
	PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.2%)	1 (1.4%)	2 (1.3%)
	PSEUDOEPHEDRINE SULFATE	2 (2.4%)	0	2 (1.3%)
	SALBUTAMOL	8 (9.6%)	6 (8.2%)	14 (9.0%)
	SALMETEROL HYDROXYNAPHTHOATE	1 (1.2%)	0	1 (0.6%)
	SODIUM CHLORIDE	1 (1.2%)	0	1 (0.6%)
	TRIPROLIDINE HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
SENSORY ORGANS	Total	4 (4.8%)	1 (1.4%)	5 (3.2%)
	BACITRACIN	1 (1.2%)	0	1 (0.6%)
	CIPROFLOXACIN HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
	SODIUM CHLORIDE	1 (1.2%)	0	1 (0.6%)
	TETRACYCLINE	1 (1.2%)	1 (1.4%)	2 (1.3%)
SYSTEMIC HORMONAL	Total	1 (1.2%)	1 (1.4%)	2 (1.3%)
	DESMOPRESSIN	0	1 (1.4%)	1 (0.6%)
	LEVOTHYROXINE SODIUM	1 (1.2%)	0	1 (0.6%)
VARIOUS	Total	1 (1.2%)	0	1 (0.6%)
	PROTEINS NOS	1 (1.2%)	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 13.13.3.6

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase or Follow-up Phase
Intention-To-Treat Population

Generic Term	Treatment Group: Paroxetine (N=83)	Placebo (N=73)	Total (N=156)
Total number of patients with at least one concomitant medication during taper or follow-up	51 (61.4%)	42 (57.5%)	93 (59.6%)
IBUPROFEN	9 (10.8%)	9 (12.3%)	18 (11.5%)
PARACETAMOL	8 (9.6%)	11 (15.1%)	19 (12.2%)
PAROXETINE	8 (9.6%)	7 (9.6%)	15 (9.6%)
SALBUTAMOL	8 (9.6%)	6 (8.2%)	14 (9.0%)
LORATADINE	7 (8.4%)	6 (8.2%)	13 (8.3%)
VITAMINS NOS	6 (7.2%)	1 (1.4%)	7 (4.5%)
RISPERIDONE	4 (4.8%)	0	4 (2.6%)
MONTELUKAST SODIUM	3 (3.6%)	1 (1.4%)	4 (2.6%)
AMOXICILLIN	3 (3.6%)	0	3 (1.9%)
FLUTICASONE PROPIONATE	2 (2.4%)	4 (5.5%)	6 (3.8%)
ACETYLSALICYLIC ACID	2 (2.4%)	3 (4.1%)	5 (3.2%)
CAFFEINE	2 (2.4%)	2 (2.7%)	4 (2.6%)
CETIRIZINE HYDROCHLORIDE	2 (2.4%)	2 (2.7%)	4 (2.6%)
ETHINYLESTRADIOL	2 (2.4%)	1 (1.4%)	3 (1.9%)
PHENYLPROPANOLAMINE HYDROCHLORIDE	2 (2.4%)	0	2 (1.3%)
PSEUDOEPHEDRINE SULFATE	2 (2.4%)	0	2 (1.3%)
TRAZODONE	2 (2.4%)	0	2 (1.3%)
ASCORBIC ACID	1 (1.2%)	2 (2.7%)	3 (1.9%)
AMFEBUTAMONE HYDROCHLORIDE	1 (1.2%)	1 (1.4%)	2 (1.3%)
AMOXICILLIN TRIHYDRATE	1 (1.2%)	1 (1.4%)	2 (1.3%)
CEFUROXIME AXETIL	1 (1.2%)	1 (1.4%)	2 (1.3%)
ERGOCALCIFEROL	1 (1.2%)	1 (1.4%)	2 (1.3%)
PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.2%)	1 (1.4%)	2 (1.3%)
TETRACYCLINE	1 (1.2%)	1 (1.4%)	2 (1.3%)
ALOES	1 (1.2%)	0	1 (0.6%)
ALUMINIUM HYDROXIDE	1 (1.2%)	0	1 (0.6%)
AMPHETAMINE ASPARTATE	1 (1.2%)	0	1 (0.6%)
AMPHETAMINE SULFATE	1 (1.2%)	0	1 (0.6%)
BACITRACIN	1 (1.2%)	0	1 (0.6%)
BENTONITE	1 (1.2%)	0	1 (0.6%)
BROMPHENIRAMINE MALEATE	1 (1.2%)	0	1 (0.6%)
BUDESONIDE	1 (1.2%)	0	1 (0.6%)
BUSPIRONE HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
CALAMINE	1 (1.2%)	0	1 (0.6%)
CEFALEXIN MONOHYDRATE	1 (1.2%)	0	1 (0.6%)
CIPROFLOXACIN HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
CITALOPRAM	1 (1.2%)	0	1 (0.6%)
CLAVULANIC ACID	1 (1.2%)	0	1 (0.6%)
CLEMASTINE FUMARATE	1 (1.2%)	0	1 (0.6%)
CLINDAMYCIN	1 (1.2%)	0	1 (0.6%)
DEXTROAMPHETAMINE SACCHARATE	1 (1.2%)	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 13.13.3.6

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase or Follow-up Phase
Intention-To-Treat Population

Generic Term	Treatment Group: Paroxetine (N=83)	Placebo (N=73)	Total (N=156)
DEXTROAMPHETAMINE SULFATE	1 (1.2%)	0	1 (0.6%)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
DOXYCYCLINE	1 (1.2%)	0	1 (0.6%)
FUROSEMIDE	1 (1.2%)	0	1 (0.6%)
GLYCEROL	1 (1.2%)	0	1 (0.6%)
IPRATROPIUM BROMIDE	1 (1.2%)	0	1 (0.6%)
IRON	1 (1.2%)	0	1 (0.6%)
LEVOTHYROXINE SODIUM	1 (1.2%)	0	1 (0.6%)
LITHIUM	1 (1.2%)	0	1 (0.6%)
LITHIUM CARBONATE	1 (1.2%)	0	1 (0.6%)
LORAZEPAM	1 (1.2%)	0	1 (0.6%)
MAGNESIUM HYDROXIDE	1 (1.2%)	0	1 (0.6%)
MEDROXYPROGESTERONE ACETATE	1 (1.2%)	0	1 (0.6%)
METHYLPHENIDATE	1 (1.2%)	0	1 (0.6%)
METHYLPHENIDATE HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
NITROFURANTOIN	1 (1.2%)	0	1 (0.6%)
NORETHISTERONE	1 (1.2%)	0	1 (0.6%)
NORETHISTERONE ACETATE	1 (1.2%)	0	1 (0.6%)
OLANZAPINE	1 (1.2%)	0	1 (0.6%)
OXYBUTYNIN	1 (1.2%)	0	1 (0.6%)
PHENOL, LIQUEFIED	1 (1.2%)	0	1 (0.6%)
PHENYLEPHRINE HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
PHYTOMENADIONE	1 (1.2%)	0	1 (0.6%)
PROMETHAZINE	1 (1.2%)	0	1 (0.6%)
PROTEINS NOS	1 (1.2%)	0	1 (0.6%)
RANITIDINE HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
RETINOL	1 (1.2%)	0	1 (0.6%)
SALMETEROL HYDROXYNAPHTHOATE	1 (1.2%)	0	1 (0.6%)
SODIUM CHLORIDE	1 (1.2%)	0	1 (0.6%)
SODIUM CITRATE	1 (1.2%)	0	1 (0.6%)
SULFAMETHOXAZOLE	1 (1.2%)	0	1 (0.6%)
SUMATRIPTAN	1 (1.2%)	0	1 (0.6%)
TOPIRAMATE	1 (1.2%)	0	1 (0.6%)
TRIMETHOPRIM	1 (1.2%)	0	1 (0.6%)
TRIPROLIDINE HYDROCHLORIDE	1 (1.2%)	0	1 (0.6%)
VALPROATE SEMISODIUM	1 (1.2%)	0	1 (0.6%)
ZINC OXIDE	1 (1.2%)	0	1 (0.6%)
GUAIFENESIN	0	4 (5.5%)	4 (2.6%)
FEXOFENADINE HYDROCHLORIDE	0	3 (4.1%)	3 (1.9%)
BISMUTH SUBSALICYLATE	0	2 (2.7%)	2 (1.3%)
CALCIUM CARBONATE	0	2 (2.7%)	2 (1.3%)
MOMETASONE FUROATE	0	2 (2.7%)	2 (1.3%)
AZITHROMYCIN	0	1 (1.4%)	1 (0.6%)
CALCIUM	0	1 (1.4%)	1 (0.6%)

The N’s in the denominator relate to patients entering Taper Phase or Follow-up Phase

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Table 13.13.3.6

Number (%) of Patients with Concomitant Medication by Generic Term Ordered by Decreasing Frequency
Taper Phase or Follow-up Phase
Intention-To-Treat Population

Generic Term	Treatment Group: Paroxetine (N=83)	Placebo (N=73)	Total (N=156)
CHLORPHENAMINE MALEATE	0	1 (1.4%)	1 (0.6%)
CINNAMEDRINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.6%)
DERMATOLOGICALS NOS	0	1 (1.4%)	1 (0.6%)
DESMOPRESSIN	0	1 (1.4%)	1 (0.6%)
DESOGESTREL	0	1 (1.4%)	1 (0.6%)
DEXTROMETHORPHAN HYDROBROMIDE	0	1 (1.4%)	1 (0.6%)
DICHLORALPHENAZONE	0	1 (1.4%)	1 (0.6%)
FINASTERIDE	0	1 (1.4%)	1 (0.6%)
FLUORIDE NOS	0	1 (1.4%)	1 (0.6%)
FLUOXETINE	0	1 (1.4%)	1 (0.6%)
HYDROCODONE BITARTRATE	0	1 (1.4%)	1 (0.6%)
ISOMETHEPTENE	0	1 (1.4%)	1 (0.6%)
MINOCYCLINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.6%)
NABUMETONE	0	1 (1.4%)	1 (0.6%)
NAPROXEN SODIUM	0	1 (1.4%)	1 (0.6%)
OMEPRAZOLE	0	1 (1.4%)	1 (0.6%)
SERTRALINE HYDROCHLORIDE	0	1 (1.4%)	1 (0.6%)
TOLNAFTATE	0	1 (1.4%)	1 (0.6%)

The N’s in the denominator relate to patients entering Taper Phase or Follow-up Phase

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Table 13.14.1

Number (%) of Patients who missed more than 3 consecutive days of Study Medication by Visit

Intention-To-Treat Population

Age Group : Children

	Treatment Groups					
	Paroxetine (N = 49)		Placebo (N = 47)		Total (N = 96)	
	Missed > 3 Consecutive Days		Missed > 3 Consecutive Days		Missed > 3 Consecutive Days	
Visit	No	Yes	No	Yes	No	Yes
Week 1	49 (100.0%)	0 (0%)	47 (100.0%)	0 (0%)	96 (100.0%)	0 (0%)
Week 2	43 (91.5%)	4 (8.5%)	47 (100.0%)	0 (0%)	90 (95.7%)	4 (4.3%)
Week 3	41 (93.2%)	3 (6.8%)	46 (97.9%)	1 (2.1%)	87 (95.6%)	4 (4.4%)
Week 4	37 (100.0%)	0 (0%)	46 (100.0%)	0 (0%)	83 (100.0%)	0 (0%)
Week 6	33 (97.1%)	1 (2.9%)	42 (97.7%)	1 (2.3%)	75 (97.4%)	2 (2.6%)
Week 8	29 (96.7%)	1 (3.3%)	40 (97.6%)	1 (2.4%)	69 (97.2%)	2 (2.8%)
Overall	41 (83.7%)	8 (16.3%)	44 (93.6%)	3 (6.4%)	85 (88.5%)	11 (11.5%)

Note: Percentages are out of number of patients in each treatment group who have this study medication information on the relevant CRF page

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Table 13.14.1

Number (%) of Patients who missed more than 3 consecutive days of Study Medication by Visit

Intention-To-Treat Population

Age Group : Adolescents

	Treatment Groups					
	Paroxetine (N = 52)		Placebo (N = 55)		Total (N = 107)	
	Missed > 3 Consecutive Days		Missed > 3 Consecutive Days		Missed > 3 Consecutive Days	
Visit	No	Yes	No	Yes	No	Yes
Week 1	51 (98.1%)	1 (1.9%)	50 (94.3%)	3 (5.7%)	101 (96.2%)	4 (3.8%)
Week 2	50 (98.0%)	1 (2.0%)	48 (96.0%)	2 (4.0%)	98 (97.0%)	3 (3.0%)
Week 3	49 (96.1%)	2 (3.9%)	46 (97.9%)	1 (2.1%)	95 (96.9%)	3 (3.1%)
Week 4	50 (100.0%)	0 (0%)	45 (97.8%)	1 (2.2%)	95 (99.0%)	1 (1.0%)
Week 6	40 (90.9%)	4 (9.1%)	41 (95.3%)	2 (4.7%)	81 (93.1%)	6 (6.9%)
Week 8	36 (90.0%)	4 (10.0%)	38 (95.0%)	2 (5.0%)	74 (92.5%)	6 (7.5%)
Overall	40 (76.9%)	12 (23.1%)	45 (83.3%)	9 (16.7%)	85 (80.2%)	21 (19.8%)

Note: Percentages are out of number of patients in each treatment group who have this study medication information on the relevant CRF page

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Table 13.14.1

Number (%) of Patients who missed more than 3 consecutive days of Study Medication by Visit

Intention-To-Treat Population

Age Group : Total

	Treatment Groups					
	Paroxetine (N = 101)		Placebo (N = 102)		Total (N = 203)	
	Missed > 3 Consecutive Days		Missed > 3 Consecutive Days		Missed > 3 Consecutive Days	
Visit	No	Yes	No	Yes	No	Yes
Week 1	100 (99.0%)	1 (1.0%)	97 (97.0%)	3 (3.0%)	197 (98.0%)	4 (2.0%)
Week 2	93 (94.9%)	5 (5.1%)	95 (97.9%)	2 (2.1%)	188 (96.4%)	7 (3.6%)
Week 3	90 (94.7%)	5 (5.3%)	92 (97.9%)	2 (2.1%)	182 (96.3%)	7 (3.7%)
Week 4	87 (100.0%)	0 (0%)	91 (98.9%)	1 (1.1%)	178 (99.4%)	1 (0.6%)
Week 6	73 (93.6%)	5 (6.4%)	83 (96.5%)	3 (3.5%)	156 (95.1%)	8 (4.9%)
Week 8	65 (92.9%)	5 (7.1%)	78 (96.3%)	3 (3.7%)	143 (94.7%)	8 (5.3%)
Overall	81 (80.2%)	20 (19.8%)	89 (88.1%)	12 (11.9%)	170 (84.2%)	32 (15.8%)

Note: Percentages are out of number of patients in each treatment group who have this study medication information on the relevant CRF page

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Table 13.14.2

Tablet Accountability (number (%) of patients) at Each Visit

Intention-To-Treat Population

Age Group : Children

	Treatment Group					
	Paroxetine (N = 49)		Placebo (N = 47)		Total (N = 96)	
	Account*	Non-account	Account*	Non-account	Account*	Non-account
Week 1	39 (79.6%)	10 (20.4%)	40 (85.1%)	7 (14.9%)	79 (82.3%)	17 (17.7%)
Week 2	37 (75.5%)	12 (24.5%)	42 (89.4%)	5 (10.6%)	79 (82.3%)	17 (17.7%)
Week 3	36 (81.8%)	8 (18.2%)	37 (78.7%)	10 (21.3%)	73 (80.2%)	18 (19.8%)
Week 4	30 (81.1%)	7 (18.9%)	37 (78.7%)	10 (21.3%)	67 (79.8%)	17 (20.2%)
Week 6	26 (72.2%)	10 (27.8%)	40 (88.9%)	5 (11.1%)	66 (81.5%)	15 (18.5%)
Week 8	23 (76.7%)	7 (23.3%)	35 (83.3%)	7 (16.7%)	58 (80.6%)	14 (19.4%)

* 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

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Table 13.14.2

Tablet Accountability (number (%) of patients) at Each Visit

Intention-To-Treat Population

Age Group : Adolescents

	Treatment Group					
	Paroxetine (N = 52)		Placebo (N = 55)		Total (N = 107)	
	Account*	Non-account	Account*	Non-account	Account*	Non-account
Week 1	43 (82.7%)	9 (17.3%)	45 (81.8%)	10 (18.2%)	88 (82.2%)	19 (17.8%)
Week 2	42 (80.8%)	10 (19.2%)	42 (80.8%)	10 (19.2%)	84 (80.8%)	20 (19.2%)
Week 3	41 (80.4%)	10 (19.6%)	40 (81.6%)	9 (18.4%)	81 (81.0%)	19 (19.0%)
Week 4	40 (80.0%)	10 (20.0%)	36 (76.6%)	11 (23.4%)	76 (78.4%)	21 (21.6%)
Week 6	35 (74.5%)	12 (25.5%)	40 (93.0%)	3 (7.0%)	75 (83.3%)	15 (16.7%)
Week 8	31 (77.5%)	9 (22.5%)	35 (85.4%)	6 (14.6%)	66 (81.5%)	15 (18.5%)

* 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

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Table 13.14.2

Tablet Accountability (number (%) of patients) at Each Visit

Intention-To-Treat Population

Age Group : Total

	Treatment Group					
	Paroxetine (N = 101)		Placebo (N = 102)		Total (N = 203)	
	Account*	Non-account	Account*	Non-account	Account*	Non-account
Week 1	82 (81.2%)	19 (18.8%)	85 (83.3%)	17 (16.7%)	167 (82.3%)	36 (17.7%)
Week 2	79 (78.2%)	22 (21.8%)	84 (84.8%)	15 (15.2%)	163 (81.5%)	37 (18.5%)
Week 3	77 (81.1%)	18 (18.9%)	77 (80.2%)	19 (19.8%)	154 (80.6%)	37 (19.4%)
Week 4	70 (80.5%)	17 (19.5%)	73 (77.7%)	21 (22.3%)	143 (79.0%)	38 (21.0%)
Week 6	61 (73.5%)	22 (26.5%)	80 (90.9%)	8 (9.1%)	141 (82.5%)	30 (17.5%)
Week 8	54 (77.1%)	16 (22.9%)	70 (84.3%)	13 (15.7%)	124 (81.0%)	29 (19.0%)

* 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

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Table 13.14.3

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	49	100.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	49	100.0
Week 2	24	49.0	25	51.0	0.0	0.0	0.0	0.0	0.0	0.0	49	100.0
Week 3	9	20.0	23	51.1	13	28.9	0.0	0.0	0.0	0.0	45	100.0
Week 4	7	18.9	14	37.8	11	29.7	5	13.5	0.0	0.0	37	100.0
Week 6	6	16.7	11	30.6	13	36.1	3	8.3	3	8.3	36	100.0
Week 8	4	13.3	11	36.7	8	26.7	6	20.0	1	3.3	30	100.0

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Table 13.14.3

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	52	100.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	52	100.0
Week 2	15	28.8	37	71.2	0.0	0.0	0.0	0.0	0.0	0.0	52	100.0
Week 3	4	7.8	32	62.7	15	29.4	0.0	0.0	0.0	0.0	51	100.0
Week 4	0.0	0.0	23	46.0	21	42.0	6	12.0	0.0	0.0	50	100.0
Week 6	0.0	0.0	20	42.6	16	34.0	7	14.9	4	8.5	47	100.0
Week 8	0.0	0.0	15	37.5	14	35.0	8	20.0	3	7.5	40	100.0

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Table 13.14.3

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	101	100.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	101	100.0
Week 2	39	38.6	62	61.4	0.0	0.0	0.0	0.0	0.0	0.0	101	100.0
Week 3	13	13.5	55	57.3	28	29.2	0.0	0.0	0.0	0.0	96	100.0
Week 4	7	8.0	37	42.5	32	36.8	11	12.6	0.0	0.0	87	100.0
Week 6	6	7.2	31	37.3	29	34.9	10	12.0	7	8.4	83	100.0
Week 8	4	5.7	26	37.1	22	31.4	14	20.0	4	5.7	70	100.0

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Table 13.14.3

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	47	100.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	47	100.0
Week 2	20	42.6	27	57.4	0.0	0.0	0.0	0.0	0.0	0.0	47	100.0
Week 3	12	25.5	23	48.9	12	25.5	0.0	0.0	0.0	0.0	47	100.0
Week 4	11	23.4	15	31.9	12	25.5	9	19.1	0.0	0.0	47	100.0
Week 6	10	22.2	11	24.4	12	26.7	6	13.3	6	13.3	45	100.0
Week 8	10	23.8	9	21.4	13	31.0	3	7.1	7	16.7	42	100.0

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Table 13.14.3

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	55	100.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	55	100.0
Week 2	15	29.4	36	70.6	0.0	0.0	0.0	0.0	0.0	0.0	51	100.0
Week 3	4	8.2	25	51.0	20	40.8	0.0	0.0	0.0	0.0	49	100.0
Week 4	2	4.3	18	38.3	15	31.9	12	25.5	0.0	0.0	47	100.0
Week 6	2	4.7	10	23.3	15	34.9	10	23.3	6	14.0	43	100.0
Week 8	1	2.4	10	24.4	15	36.6	7	17.1	8	19.5	41	100.0

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Table 13.14.3

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	102	100.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	102	100.0
Week 2	35	35.7	63	64.3	0.0	0.0	0.0	0.0	0.0	0.0	98	100.0
Week 3	16	16.7	48	50.0	32	33.3	0.0	0.0	0.0	0.0	96	100.0
Week 4	13	13.8	33	35.1	27	28.7	21	22.3	0.0	0.0	94	100.0
Week 6	12	13.6	21	23.9	27	30.7	16	18.2	12	13.6	88	100.0
Week 8	11	13.3	19	22.9	28	33.7	10	12.0	15	18.1	83	100.0

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Table 13.14.4

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
5 (10.2%)	20 (40.8%)	13 (26.5%)	8 (16.3%)	3 (6.1%)	49 (100.0%)

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Table 13.14.4

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
0 (0.0%)	16 (30.8%)	21 (40.4%)	10 (19.2%)	5 (9.6%)	52 (100.0%)

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Table 13.14.4

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
5 (5.0%)	36 (35.6%)	34 (33.7%)	18 (17.8%)	8 (7.9%)	101 (100.0%)

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Table 13.14.4

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
8 (17.0%)	11 (23.4%)	15 (31.9%)	4 (8.5%)	9 (19.1%)	47 (100.0%)

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Table 13.14.4

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
5 (9.1%)	13 (23.6%)	17 (30.9%)	11 (20.0%)	9 (16.4%)	55 (100.0%)

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Table 13.14.4

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
13 (12.7%)	24 (23.5%)	32 (31.4%)	15 (14.7%)	18 (17.6%)	102 (100.0%)

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Table 13.14.5

Overall Duration of Exposure to Study Medication(Excluding Taper Medication)

Intention-To-Treat Population

Age Group: Children

Days	Paroxetine (N=49)	Placebo (N=47)	Total (N=96)
		Treatment Group	
>= 1	49 (100.0%)	47 (100.0%)	96 (100.0%)
> 7	49 (100.0%)	47 (100.0%)	96 (100.0%)
> 14	45 (91.8%)	47 (100.0%)	92 (95.8%)
> 21	40 (81.6%)	47 (100.0%)	87 (90.6%)
> 28	38 (77.6%)	46 (97.9%)	84 (87.5%)
> 42	33 (67.3%)	42 (89.4%)	75 (78.1%)
> 56	19 (38.8%)	20 (42.6%)	39 (40.6%)
Overall Mean	45.0	55.0	49.9
Minimum	9	22	9
Maximum	65	68	68

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Table 13.14.5

Overall Duration of Exposure to Study Medication(Excluding Taper Medication)

Intention-To-Treat Population

Age Group: Adolescents

Days	Paroxetine (N=52)	Placebo (N=55)	Total (N=107)
	----------Treatment Group----------		
>= 1	52 (100.0%)	55 (100.0%)	107 (100.0%)
> 7	52 (100.0%)	52 (94.5%)	104 (97.2%)
> 14	51 (98.1%)	51 (92.7%)	102 (95.3%)
> 21	50 (96.2%)	49 (89.1%)	99 (92.5%)
> 28	49 (94.2%)	46 (83.6%)	95 (88.8%)
> 42	42 (80.8%)	43 (78.2%)	85 (79.4%)
> 56	22 (42.3%)	20 (36.4%)	42 (39.3%)
Overall Mean	52.7	48.2	50.4
Minimum	10	2	2
Maximum	69	68	69

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Table 13.14.5

Overall Duration of Exposure to Study Medication(Excluding Taper Medication)

Intention-To-Treat Population

Age Group: Total

Days	Paroxetine (N=101)	Placebo (N=102)	Total (N=203)
	----------Treatment Group----------		
>= 1	101 (100.0%)	102 (100.0%)	203 (100.0%)
> 7	101 (100.0%)	99 (97.1%)	200 (98.5%)
> 14	96 (95.0%)	98 (96.1%)	194 (95.6%)
> 21	90 (89.1%)	96 (94.1%)	186 (91.6%)
> 28	87 (86.1%)	92 (90.2%)	179 (88.2%)
> 42	75 (74.3%)	85 (83.3%)	160 (78.8%)
> 56	41 (40.6%)	40 (39.2%)	81 (39.9%)
Overall Mean	49.0	51.4	50.2
Minimum	9	2	2
Maximum	69	68	69

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Table 13.14.6

Mean Daily Dosage of Paroxetine by Visit and Overall

Intention-To-Treat Population

Age Group : Children

Visit	N	Mean	Std Dev
Week 1	49	10.0	0.00
Week 2	49	15.1	5.05
Week 3	45	20.9	7.01
Week 4	37	23.8	9.53
Week 6	36	26.1	11.28
Week 8	30	26.3	10.66
Patient Mean	49	18.9	6.02

Table 13.14.6

Mean Daily Dosage of Paroxetine by Visit and Overall

Intention-To-Treat Population

Age Group : Adolescents

Visit	N	Mean	Std Dev
Week 1	52	10.0	0.00
Week 2	52	17.1	4.57
Week 3	51	22.2	5.77
Week 4	50	26.6	6.88
Week 6	47	28.9	9.61
Week 8	40	29.8	9.47
Patient Mean	52	21.8	5.01

Table 13.14.6

Mean Daily Dosage of Paroxetine by Visit and Overall

Intention-To-Treat Population

Age Group : Total

Visit	N	Mean	Std Dev
Week 1	101	10.0	0.00
Week 2	101	16.1	4.89
Week 3	96	21.6	6.38
Week 4	87	25.4	8.18
Week 6	83	27.7	10.40
Week 8	70	28.3	10.07
Patient Mean	101	20.4	5.69

12 Source Tables: Efficacy Results

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Table 14.1.1b

Summary Statistics for CDRS-R Total Score

Intention-To-Treat Population

		Paroxetine (N=101)			Placebo (N=102)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Screening	N	49	52	101	47	55	102
	MEAN	62.3	65.0	63.7	62.7	64.7	63.8
	STDDEV	10.44	9.41	9.96	9.02	9.59	9.34
	MEDIAN	60.0	64.5	62.0	62.0	62.0	62.0
	MIN	46	48	46	45	45	45
	MAX	88	85	88	86	89	89
	MISSING	0	0	0	0	0	0
Baseline	N	49	52	101	47	55	102
	MEAN	58.4	62.9	60.7	61.3	63.7	62.6
	STDDEV	8.29	9.87	9.37	9.23	8.66	8.96
	MEDIAN	57.0	62.5	59.0	61.0	63.0	62.0
	MIN	45	44	44	45	46	45
	MAX	85	84	85	85	89	89
	MISSING	0	0	0	0	0	0
Week 1	N	45	52	97	47	53	100
	MEAN	48.9	53.8	51.6	51.7	57.8	55.0
	STDDEV	12.25	12.47	12.55	13.38	12.80	13.36
	MEDIAN	50.0	53.0	52.0	52.0	57.0	56.0
	MIN	20	30	20	30	20	20
	MAX	76	83	83	89	88	89
	MISSING	4	0	4	0	2	2
Week 2	N	44	46	90	43	48	91
	MEAN	44.0	49.1	46.6	45.3	53.5	49.6
	STDDEV	12.04	11.97	12.21	14.93	12.62	14.28
	MEDIAN	43.0	47.5	46.0	45.0	52.5	50.0
	MIN	20	23	20	19	24	19
	MAX	67	70	70	88	88	88
	MISSING	3	5	8	4	3	7
Week 3	N	41	48	89	41	45	86
	MEAN	41.3	44.9	43.2	39.1	46.8	43.1
	STDDEV	14.51	12.41	13.46	13.64	12.75	13.66
	MEDIAN	41.0	44.0	43.0	39.0	48.0	41.0
	MIN	18	19	18	19	18	18
	MAX	68	85	85	65	78	78
	MISSING	2	3	5	6	5	11
Week 4	N	38	47	85	45	46	91

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 CDRS-R Total Score

Intention-To-Treat Population

		Paroxetine (N=101)			Placebo (N=102)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 4	MEAN	38.2	39.9	39.1	37.1	41.8	39.5
	STDDEV	11.96	11.87	11.87	13.17	12.29	12.88
	MEDIAN	37.0	39.0	38.0	36.0	39.0	37.0
	MIN	18	19	18	18	20	18
	MAX	69	67	69	70	78	78
	MISSING	1	2	3	1	1	2
Week 6	N	30	43	73	42	42	84
	MEAN	37.0	38.3	37.8	33.7	40.9	37.3
	STDDEV	12.86	11.98	12.28	11.64	11.50	12.05
	MEDIAN	33.5	38.0	36.0	33.0	40.0	37.0
	MIN	18	18	18	17	21	17
	MAX	70	68	70	75	70	75
	MISSING	3	2	5	2	1	3
Week 8	N	29	39	68	42	38	80
	MEAN	33.7	34.3	34.1	34.0	36.4	35.1
	STDDEV	11.79	11.09	11.31	12.15	11.94	12.04
	MEDIAN	31.0	33.0	32.5	32.5	35.5	34.0
	MIN	18	19	18	18	18	18
	MAX	63	71	71	75	65	75
	MISSING	1	3	4	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 14.1.1c

Summary Statistics for CDRS-R Total Score

Per-Protocol Population

		Paroxetine (N=74)			Placebo (N=83)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Screening	N	39	35	74	41	42	83
	MEAN	63.6	63.7	63.7	62.0	64.7	63.4
	STDDEV	10.52	8.39	9.51	8.67	9.36	9.08
	MEDIAN	61.0	63.0	62.0	62.0	64.0	63.0
	MIN	46	51	46	45	45	45
	MAX	88	80	88	86	89	89
	MISSING	0	0	0	0	0	0
Baseline	N	39	35	74	41	42	83
	MEAN	59.2	62.4	60.7	60.6	63.5	62.0
	STDDEV	8.76	9.38	9.14	9.01	8.53	8.83
	MEDIAN	57.0	60.0	58.0	59.0	62.0	61.0
	MIN	45	46	45	45	46	45
	MAX	85	81	85	82	89	89
	MISSING	0	0	0	0	0	0
Week 1	N	35	35	70	41	42	83
	MEAN	48.7	52.5	50.6	50.8	56.0	53.4
	STDDEV	13.31	10.17	11.91	13.73	11.94	13.05
	MEDIAN	49.0	53.0	52.0	51.0	57.0	54.0
	MIN	20	34	20	30	20	20
	MAX	76	74	76	89	85	89
	MISSING	4	0	4	0	0	0
Week 2	N	37	33	70	37	42	79
	MEAN	44.4	47.5	45.8	44.2	53.4	49.1
	STDDEV	11.78	11.88	11.85	15.38	12.92	14.77
	MEDIAN	43.0	47.0	45.5	42.0	52.5	49.0
	MIN	20	23	20	19	24	19
	MAX	67	70	70	88	88	88
	MISSING	2	2	4	4	0	4
Week 3	N	37	33	70	36	37	73
	MEAN	41.7	45.9	43.7	38.3	47.2	42.8
	STDDEV	14.38	13.15	13.87	13.82	13.42	14.24
	MEDIAN	41.0	47.0	42.5	37.5	48.0	41.0
	MIN	18	19	18	19	18	18
	MAX	68	85	85	65	78	78
	MISSING	0	2	2	5	4	9
Week 4	N	34	31	65	39	39	78

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 14.1.1c

Summary Statistics for CDRS-R Total Score

Per-Protocol Population

		Paroxetine (N=74)			Placebo (N=83)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Week 4	MEAN	39.0	39.7	39.3	36.1	42.8	39.4
	STDDEV	12.19	12.50	12.25	12.76	12.76	13.12
	MEDIAN	37.5	39.0	38.0	36.0	39.0	37.0
	MIN	18	19	18	18	20	18
	MAX	69	67	69	70	78	78
	MISSING	0	2	2	1	0	1
Week 6	N	26	28	54	37	37	74
	MEAN	37.7	39.8	38.8	32.8	41.3	37.1
	STDDEV	13.61	12.96	13.19	11.72	11.87	12.46
	MEDIAN	33.5	38.0	38.0	30.0	40.0	35.5
	MIN	18	18	18	17	21	17
	MAX	70	68	70	75	70	75
	MISSING	3	1	4	2	0	2
Week 8	N	27	27	54	38	34	72
	MEAN	33.9	34.4	34.2	33.6	37.0	35.2
	STDDEV	12.15	12.03	11.98	12.10	12.27	12.22
	MEDIAN	31.0	31.0	31.0	31.5	36.0	34.0
	MIN	18	19	18	18	18	18
	MAX	63	71	71	75	65	75
	MISSING	0	2	2	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 14.1.2b

Summary of Analysis for change from Baseline in CDRS-R Total score
Adjusted for Baseline Score, Age, 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	60.74	9.37	101	62.58	8.96	102				
Change From Baseline to:										
Week 1	-9.78	1.13	97	-8.14	1.20	100				
Week 2	-15.35	1.17	90	-14.03	1.24	91				
Week 3	-19.68	1.34	89	-21.08	1.47	86				
Week 4	-23.20	1.30	85	-23.72	1.36	91				
Week 6	-24.32	1.39	73	-24.77	1.40	84				
Week 8	-27.31	1.45	68	-26.47	1.47	80	-0.84	-4.54	2.87	0.655
Week 8 LOCF Endpoint	-22.58	1.47	101	-23.38	1.60	100	0.80	-3.09	4.69	0.684

* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
+ Note that for Baseline, raw means not Least Square means are presented
Note: 70% LOCF Endpoint was not created - 70 percent of patients in each trt group still in study at last trt visit

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Table 14.1.2b

Summary of Analysis for change from Baseline in CDRS-R Total score
Adjusted for Baseline Score,Gender and Comorbidity
Intention-To-Treat Population
Age Group : Children

	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	58.43	8.29	49	61.30	9.23	47				
Change From Baseline to:										
Week 1	-9.89	1.67	45	-10.42	1.71	47				
Week 2	-16.01	1.78	44	-17.44	1.89	43				
Week 3	-19.91	2.02	41	-24.33	2.17	41				
Week 4	-22.07	1.97	38	-24.62	1.97	45				
Week 6	-23.14	2.03	30	-27.00	1.92	42				
Week 8	-25.06	2.25	29	-25.46	2.13	42	0.41	-5.23	6.05	0.885
Week 8 LOCF Endpoint	-19.04	2.03	49	-24.31	2.19	47	5.27	-0.08	10.63	0.054

* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
+ Note that for Baseline, raw means not Least Square means are presented
Note: 70% LOCF Endpoint was not created - 70 percent of patients in each trt group still in study at last trt visit

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Table 14.1.2b

Summary of Analysis for change from Baseline in CDRS-R Total score
Adjusted for Baseline Score,Gender and Comorbidity
Intention-To-Treat Population
Age Group : Adolescents

	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	62.92	9.87	52	63.67	8.66	55				
Change From Baseline to:										
Week 1	-9.29	1.56	52	-5.66	1.72	53				
Week 2	-14.49	1.56	46	-10.61	1.66	48				
Week 3	-18.95	1.77	48	-17.68	2.02	45				
Week 4	-23.91	1.75	47	-22.76	1.94	46				
Week 6	-24.62	1.85	43	-22.41	2.03	42				
Week 8	-29.00	1.88	39	-27.60	2.08	38	-1.40	-6.46	3.66	0.582
Week 8 LOCF Endpoint	-25.62	2.10	52	-23.07	2.32	53	-2.55	-8.23	3.13	0.375

* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
+ Note that for Baseline, raw means not Least Square means are presented
Note: 70% LOCF Endpoint was not created - 70 percent of patients in each trt group still in study at last trt visit

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Table 14.1.2c

Summary of Analysis for change from Baseline in CDRS-R Total score
Adjusted for Baseline Score, Age, 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	60.69	9.14	74	62.04	8.83	83				
Change From Baseline to:										
Week 1	-11.26	1.31	70	-10.11	1.30	83				
Week 2	-15.78	1.39	70	-14.43	1.40	79				
Week 3	-18.83	1.60	70	-21.08	1.70	73				
Week 4	-22.88	1.55	65	-24.12	1.55	78				
Week 6	-22.45	1.64	54	-24.74	1.54	74				
Week 8	-26.22	1.71	54	-26.07	1.60	72	-0.15	-4.25	3.95	0.942
Week 8 LOCF Endpoint	-22.40	1.71	74	-24.08	1.75	83	1.68	-2.59	5.96	0.437

* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
+ Note that for Baseline, raw means not Least Square means are presented
Note: 70% LOCF Endpoint was not created - 70 percent of patients in each trt group still in study at last trt visit

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Table 14.1.2c

Summary of Analysis for change from Baseline in CDRS-R Total score
Adjusted for Baseline Score,Gender and Comorbidity
Per-Protocol Population
Age Group : Children

	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	59.15	8.76	39	60.59	9.01	41				
Change From Baseline to:										
Week 1	-10.76	1.90	35	-11.12	1.96	41				
Week 2	-16.07	1.87	37	-18.15	2.05	37				
Week 3	-19.83	2.06	37	-25.52	2.36	36				
Week 4	-21.44	2.04	34	-25.80	2.16	39				
Week 6	-22.82	2.13	26	-28.43	2.09	37				
Week 8	-24.78	2.30	27	-26.00	2.21	38	1.21	-4.64	7.07	0.680
Week 8 LOCF Endpoint	-20.77	2.16	39	-25.09	2.35	41	4.32	-1.40	10.05	0.137

* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
+ Note that for Baseline, raw means not Least Square means are presented
Note: 70% LOCF Endpoint was not created - 70 percent of patients in each trt group still in study at last trt visit

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Table 14.1.2c

Summary of Analysis for change from Baseline in CDRS-R Total score
Adjusted for Baseline Score,Gender and Comorbidity
Per-Protocol Population
Age Group : Adolescents

	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	62.40	9.38	35	63.45	8.53	42				
Change From Baseline to:										
Week 1	-11.43	1.79	35	-8.55	1.74	42				
Week 2	-15.61	2.07	33	-10.82	1.93	42				
Week 3	-17.67	2.46	33	-16.31	2.47	37				
Week 4	-24.62	2.39	31	-22.49	2.28	39				
Week 6	-21.52	2.52	28	-21.24	2.28	37				
Week 8	-27.78	2.63	27	-26.63	2.41	34	-1.15	-7.18	4.89	0.705
Week 8 LOCF Endpoint	-24.34	2.74	35	-23.47	2.66	42	-0.87	-7.46	5.72	0.793

* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
+ Note that for Baseline, raw means not Least Square means are presented
Note: 70% LOCF Endpoint was not created - 70 percent of patients in each trt group still in study at last trt visit

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Table 14.1.2.1

Summary of Analysis for Change from Baseline in CDRS-R Total score
Covariate Significance, Week 8 LOCF
Intention-To-Treat Population

	DF	Sum of Squares*	Mean Square	F-statistic	P-value
Term in model					
Baseline Score	1	5005.55	5005.55	26.34	<0.001
Age Group	1	1.84	1.84	0.01	0.922
Gender	1	553.29	553.29	2.91	0.090
Comorbidity	1	121.82	121.82	0.64	0.424

*Type III Sums of Squares

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Table 14.2.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 101)						Placebo (N = 102)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit	Severity												
Baseline	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Normal, not at all ill (1)	0	0	0	0	0	0	0	0	0	0	0	0
	Borderline mentally ill (2)	0	0	0	0	0	0	0	0	0	0	0	0
	Mildly ill (3)	0	0	2	3.8	2	2.0	2	4.3	0	0	2	2.0
	Moderately ill (4)	36	73.5	34	65.4	70	69.3	33	70.2	34	61.8	67	65.7
	Markedly ill (5)	12	24.5	14	26.9	26	25.7	9	19.1	20	36.4	29	28.4
	Severely ill (6)	1	2.0	2	3.8	3	3.0	3	6.4	1	1.8	4	3.9
	Among the most extremely ill patients (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	49	100.0	52	100.0	101	100.0	47	100.0	55	100.0	102	100.0
Week 1	Severity												
	Not assessed (0)	0	0	0	0	0	0	0	0	1	1.9	1	1.0
	Normal, not at all ill (1)	1	2.2	0	0	1	1.0	0	0	1	1.9	1	1.0
	Borderline mentally ill (2)	2	4.4	0	0	2	2.1	0	0	0	0	0	0
	Mildly ill (3)	4	8.9	10	19.2	14	14.4	9	19.1	3	5.6	12	11.9
	Moderately ill (4)	31	68.9	31	59.6	62	63.9	31	66.0	36	66.7	67	66.3
	Markedly ill (5)	6	13.3	10	19.2	16	16.5	5	10.6	10	18.5	15	14.9
	Severely ill (6)	1	2.2	1	1.9	2	2.1	1	2.1	3	5.6	4	4.0
	Among the most extremely ill patients (7)	0	0	0	0	0	0	1	2.1	0	0	1	1.0

(CONTINUED)

Table 14.2.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 101)						Placebo (N = 102)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit	Total												
Week 1		45	100.0	52	100.0	97	100.0	47	100.0	54	100.0	101	100.0
Week 2	Severity												
	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Normal, not at all ill (1)	1	2.3	1	2.2	2	2.2	1	2.3	1	2.1	2	2.2
	Borderline mentally ill (2)	3	6.8	5	10.9	8	8.9	6	14.0	2	4.2	8	8.8
	Mildly ill (3)	13	29.5	10	21.7	23	25.6	8	18.6	4	8.3	12	13.2
	Moderately ill (4)	24	54.5	25	54.3	49	54.4	25	58.1	32	66.7	57	62.6
	Markedly ill (5)	3	6.8	5	10.9	8	8.9	1	2.3	8	16.7	9	9.9
	Severely ill (6)	0	0	0	0	0	0	1	2.3	1	2.1	2	2.2
	Among the most extremely ill patients (7)	0	0	0	0	0	0	1	2.3	0	0	1	1.1
	Total	44	100.0	46	100.0	90	100.0	43	100.0	48	100.0	91	100.0
Week 3	Severity												
	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Normal, not at all ill (1)	3	7.3	1	2.1	4	4.5	6	14.6	2	4.4	8	9.3
	Borderline mentally ill (2)	5	12.2	4	8.3	9	10.1	3	7.3	1	2.2	4	4.7
	Mildly ill (3)	10	24.4	14	29.2	24	27.0	6	14.6	13	28.9	19	22.1
	Moderately ill (4)	19	46.3	25	52.1	44	49.4	23	56.1	25	55.6	48	55.8
	Markedly ill (5)	3	7.3	3	6.3	6	6.7	3	7.3	4	8.9	7	8.1

(CONTINUED)

Table 14.2.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 101)						Placebo (N = 102)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit	Severity												
Week 3	Severely ill (6)	1	2.4	1	2.1	2	2.2	0	0	0	0	0	0
	Among the most extremely ill patients (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	41	100.0	48	100.0	89	100.0	41	100.0	45	100.0	86	100.0
Week 4	Severity												
	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Normal, not at all ill (1)	2	5.3	4	8.5	6	7.1	7	15.6	3	6.5	10	11.0
	Borderline mentally ill (2)	6	15.8	6	12.8	12	14.1	5	11.1	6	13.0	11	12.1
	Mildly ill (3)	12	31.6	19	40.4	31	36.5	8	17.8	13	28.3	21	23.1
	Moderately ill (4)	15	39.5	17	36.2	32	37.6	23	51.1	23	50.0	46	50.5
	Markedly ill (5)	3	7.9	1	2.1	4	4.7	2	4.4	1	2.2	3	3.3
	Severely ill (6)	0	0	0	0	0	0	0	0	0	0	0	0
	Among the most extremely ill patients (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	38	100.0	47	100.0	85	100.0	45	100.0	46	100.0	91	100.0
Week 6	Severity												
	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Normal, not at all ill (1)	2	6.7	2	4.7	4	5.5	7	16.3	2	4.8	9	10.6
	Borderline mentally ill (2)	11	36.7	8	18.6	19	26.0	7	16.3	8	19.0	15	17.6
	Mildly ill (3)	7	23.3	19	44.2	26	35.6	15	34.9	15	35.7	30	35.3

(CONTINUED)

Table 14.2.1

Number and Percentage of Patients in Each Category of CGI Severity of Illness Score

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 101)						Placebo (N = 102)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit	Severity												
Week 6	Moderately ill (4)	8	26.7	12	27.9	20	27.4	13	30.2	15	35.7	28	32.9
	Markedly ill (5)	2	6.7	2	4.7	4	5.5	1	2.3	2	4.8	3	3.5
	Severely ill (6)	0	0	0	0	0	0	0	0	0	0	0	0
	Among the most extremely ill patients (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	30	100.0	43	100.0	73	100.0	43	100.0	42	100.0	85	100.0
Week 8	Severity												
	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Normal, not at all ill (1)	6	20.7	7	17.9	13	19.1	6	14.3	7	18.4	13	16.3
	Borderline mentally ill (2)	11	37.9	12	30.8	23	33.8	8	19.0	8	21.1	16	20.0
	Mildly ill (3)	4	13.8	11	28.2	15	22.1	9	21.4	11	28.9	20	25.0
	Moderately ill (4)	6	20.7	8	20.5	14	20.6	17	40.5	12	31.6	29	36.3
	Markedly ill (5)	2	6.9	1	2.6	3	4.4	2	4.8	0	0	2	2.5
	Severely ill (6)	0	0	0	0	0	0	0	0	0	0	0	0
	Among the most extremely ill patients (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	29	100.0	39	100.0	68	100.0	42	100.0	38	100.0	80	100.0

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Table 14.2.2

Number and Percentage of Patients by Change in CGI Severity of Illness from Baseline

Intention-To-Treat Population

		Paroxetine (N = 101)						Placebo (N = 102)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Change from Baseline to:	Change in Severity												
Week 1	-4	1	2.2	0	0	1	1.0	0	0	1	1.9	1	1.0
	-3	1	2.2	0	0	1	1.0	1	2.1	0	0	1	1.0
	-2	1	2.2	1	1.9	2	2.1	1	2.1	2	3.7	3	3.0
	-1	8	17.8	14	26.9	22	22.7	9	19.1	5	9.3	14	13.9
	0	34	75.6	35	67.3	69	71.1	35	74.5	43	79.6	78	77.2
	1	0	0	2	3.8	2	2.1	0	0	2	3.7	2	2.0
	2	0	0	0	0	0	0	1	2.1	0	0	1	1.0
	Missing	0	0	0	0	0	0	0	0	1	1.9	1	1.0
	Total	45	100.0	52	100.0	97	100.0	47	100.0	54	100.0	101	100.0
Week 2	Change in Severity												
	-4	1	2.3	0	0	1	1.1	1	2.3	1	2.1	2	2.2
	-3	0	0	1	2.2	1	1.1	1	2.3	1	2.1	2	2.2
	-2	6	13.6	9	19.6	15	16.7	6	14.0	2	4.2	8	8.8
	-1	15	34.1	13	28.3	28	31.1	12	27.9	10	20.8	22	24.2
	0	22	50.0	21	45.7	43	47.8	22	51.2	32	66.7	54	59.3
	1	0	0	2	4.3	2	2.2	0	0	2	4.2	2	2.2
	2	0	0	0	0	0	0	1	2.3	0	0	1	1.1
	Total	44	100.0	46	100.0	90	100.0	43	100.0	48	100.0	91	100.0

(CONTINUED)

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Table 14.2.2

Number and Percentage of Patients by Change in CGI Severity of Illness from Baseline

Intention-To-Treat Population

		Paroxetine (N = 101)						Placebo (N = 102)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Change from Baseline to:	Change in Severity												
Week 3	-4	2	4.9	0	0	2	2.2	1	2.4	2	4.4	3	3.5
	-3	2	4.9	2	4.2	4	4.5	6	14.6	0	0	6	7.0
	-2	6	14.6	9	18.8	15	16.9	4	9.8	5	11.1	9	10.5
	-1	11	26.8	16	33.3	27	30.3	7	17.1	15	33.3	22	25.6
	0	18	43.9	17	35.4	35	39.3	23	56.1	22	48.9	45	52.3
	1	2	4.9	3	6.3	5	5.6	0	0	1	2.2	1	1.2
	2	0	0	1	2.1	1	1.1	0	0	0	0	0	0
	Total	41	100.0	48	100.0	89	100.0	41	100.0	45	100.0	86	100.0
Week 4	Change in Severity												
	-5	0	0	0	0	0	0	1	2.2	0	0	1	1.1
	-4	0	0	1	2.1	1	1.2	2	4.4	3	6.5	5	5.5
	-3	5	13.2	6	12.8	11	12.9	5	11.1	1	2.2	6	6.6
	-2	5	13.2	9	19.1	14	16.5	4	8.9	11	23.9	15	16.5
	-1	12	31.6	20	42.6	32	37.6	13	28.9	14	30.4	27	29.7
	0	15	39.5	9	19.1	24	28.2	20	44.4	16	34.8	36	39.6
	1	1	2.6	2	4.3	3	3.5	0	0	1	2.2	1	1.1
	Total	38	100.0	47	100.0	85	100.0	45	100.0	46	100.0	91	100.0

(CONTINUED)

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Table 14.2.2

Number and Percentage of Patients by Change in CGI Severity of Illness from Baseline

Intention-To-Treat Population

		Paroxetine (N = 101)						Placebo (N = 102)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Change from Baseline to:	Change in Severity												
Week 6	-5	0	0	1	2.3	1	1.4	0	0	0	0	0	0
	-4	1	3.3	0	0	1	1.4	1	2.3	0	0	1	1.2
	-3	4	13.3	3	7.0	7	9.6	10	23.3	5	11.9	15	17.6
	-2	8	26.7	14	32.6	22	30.1	5	11.6	13	31.0	18	21.2
	-1	8	26.7	14	32.6	22	30.1	14	32.6	11	26.2	25	29.4
	0	9	30.0	11	25.6	20	27.4	13	30.2	12	28.6	25	29.4
	1	0	0	0	0	0	0	0	0	1	2.4	1	1.2
	Total	30	100.0	43	100.0	73	100.0	43	100.0	42	100.0	85	100.0
Week 8	Change in Severity												
	-5	0	0	1	2.6	1	1.5	0	0	0	0	0	0
	-4	1	3.4	2	5.1	3	4.4	2	4.8	4	10.5	6	7.5
	-3	8	27.6	8	20.5	16	23.5	7	16.7	7	18.4	14	17.5
	-2	8	27.6	11	28.2	19	27.9	7	16.7	8	21.1	15	18.8
	-1	5	17.2	11	28.2	16	23.5	7	16.7	11	28.9	18	22.5
	0	7	24.1	6	15.4	13	19.1	19	45.2	8	21.1	27	33.8
	Total	29	100.0	39	100.0	68	100.0	42	100.0	38	100.0	80	100.0

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Table 14.2.3

Summary of Analysis of Change from Baseline for CGI Severity of Illness Score

Intention-To-Treat Population
Age Group : Children

	Paroxetine					Placebo					Treatment Comparisons	
	Mean	Median	Minimum	Maximum	N	Mean	Median	Minimum	Maximum	N	Median Difference	p-value*
Baseline	4.3	4.0	4	6	49	4.3	4.0	3	6	47		
Change from baseline to:												
Week 1	-0.4	0.0	-4	0	45	-0.3	0.0	-3	2	47		
Week 2	-0.7	-0.5	-4	0	44	-0.7	0.0	-4	2	43		
Week 3	-0.9	-1.0	-4	1	41	-0.9	0.0	-4	0	41		
Week 4	-0.9	-1.0	-3	1	38	-1.1	-1.0	-5	0	45		
Week 6	-1.3	-1.0	-4	0	30	-1.3	-1.0	-4	0	43		
Week 8	-1.7	-2.0	-4	0	29	-1.2	-1.0	-4	0	42	0	0.092
Week 8 LOCF Endpoint	-1.0	-1.0	-4	1	49	-1.1	-1.0	-4	0	47	0	0.780

* P-value from Wilcoxon Rank Sum Test
Note: 70% LOCF Endpoint was not created - 70 percent of patients in each trt group still in study at last trt visit

Table 14.2.3

Summary of Analysis of Change from Baseline for CGI Severity of Illness Score

Intention-To-Treat Population
Age Group : Adolescents

	Paroxetine					Placebo					Treatment Comparisons	
	Mean	Median	Minimum	Maximum	N	Mean	Median	Minimum	Maximum	N	Median Difference	p-value*
Baseline	4.3	4.0	3	6	52	4.4	4.0	4	6	55		
Change from baseline to:												
Week 1	-0.3	0.0	-2	1	52	-0.2	0.0	-4	1	53		
Week 2	-0.7	-0.5	-3	1	46	-0.4	0.0	-4	1	48		
Week 3	-0.7	-1.0	-3	2	48	-0.7	0.0	-4	1	45		
Week 4	-1.2	-1.0	-4	1	47	-1.1	-1.0	-4	1	46		
Week 6	-1.3	-1.0	-5	0	43	-1.2	-1.0	-3	1	42		
Week 8	-1.8	-2.0	-5	0	39	-1.7	-1.5	-4	0	38	0	0.691
Week 8 LOCF Endpoint	-1.3	-1.0	-5	2	52	-1.2	-1.0	-4	1	53	0	0.485

* P-value from Wilcoxon Rank Sum Test
Note: 70% LOCF Endpoint was not created - 70 percent of patients in each trt group still in study at last trt visit

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Table 14.3.1

Number and Percentage of Patients in Each Category Of CGI Global Improvement

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 101)						Placebo (N = 102)					
		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	1	1.9	1	1.0
	Very much improved (1)	1	2.2	1	1.9	2	2.1	0	0	1	1.9	1	1.0
	Much Improved (2)	6	13.3	3	5.8	9	9.3	8	17.0	1	1.9	9	8.9
	Minimally improved (3)	17	37.8	23	44.2	40	41.2	15	31.9	12	22.2	27	26.7
	No change (4)	20	44.4	21	40.4	41	42.3	23	48.9	33	61.1	56	55.4
	Minimally worse (5)	1	2.2	4	7.7	5	5.2	1	2.1	4	7.4	5	5.0
	Much worse (6)	0	0	0	0	0	0	0	0	2	3.7	2	2.0
	Very much worse (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	45	100.0	52	100.0	97	100.0	47	100.0	54	100.0	101	100.0
Week 2	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Very much improved (1)	1	2.3	3	6.5	4	4.4	4	9.3	1	2.1	5	5.5
	Much Improved (2)	13	29.5	8	17.4	21	23.3	9	20.9	3	6.3	12	13.2
	Minimally improved (3)	18	40.9	21	45.7	39	43.3	16	37.2	22	45.8	38	41.8
	No change (4)	9	20.5	10	21.7	19	21.1	13	30.2	20	41.7	33	36.3
	Minimally worse (5)	3	6.8	4	8.7	7	7.8	1	2.3	1	2.1	2	2.2
	Much worse (6)	0	0	0	0	0	0	0	0	1	2.1	1	1.1
	Very much worse (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	44	100.0	46	100.0	90	100.0	43	100.0	48	100.0	91	100.0
Week 3	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0

(CONTINUED)

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Table 14.3.1

Number and Percentage of Patients in Each Category Of CGI Global Improvement

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 101)						Placebo (N = 102)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
Week 3	Very much improved (1)	2	4.9	3	6.3	5	5.6	8	19.5	2	4.4	10	11.6
	Much Improved (2)	17	41.5	13	27.1	30	33.7	6	14.6	12	26.7	18	20.9
	Minimally improved (3)	12	29.3	20	41.7	32	36.0	17	41.5	17	37.8	34	39.5
	No change (4)	5	12.2	9	18.8	14	15.7	10	24.4	12	26.7	22	25.6
	Minimally worse (5)	4	9.8	2	4.2	6	6.7	0	0	2	4.4	2	2.3
	Much worse (6)	1	2.4	0	0	1	1.1	0	0	0	0	0	0
	Very much worse (7)	0	0	1	2.1	1	1.1	0	0	0	0	0	0
	Total	41	100.0	48	100.0	89	100.0	41	100.0	45	100.0	86	100.0
Week 4	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Very much improved (1)	3	7.9	5	10.6	8	9.4	10	22.2	5	10.9	15	16.5
	Much Improved (2)	14	36.8	16	34.0	30	35.3	9	20.0	12	26.1	21	23.1
	Minimally improved (3)	13	34.2	16	34.0	29	34.1	16	35.6	21	45.7	37	40.7
	No change (4)	4	10.5	8	17.0	12	14.1	8	17.8	7	15.2	15	16.5
	Minimally worse (5)	1	2.6	2	4.3	3	3.5	2	4.4	1	2.2	3	3.3
	Much worse (6)	3	7.9	0	0	3	3.5	0	0	0	0	0	0
	Very much worse (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	38	100.0	47	100.0	85	100.0	45	100.0	46	100.0	91	100.0
Week 6	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Very much improved (1)	7	23.3	7	16.3	14	19.2	8	18.6	5	11.9	13	15.3

(CONTINUED)

Table 14.3.1

Number and Percentage of Patients in Each Category Of CGI Global Improvement

Intention-To-Treat Population

		Treatment Group											
		Paroxetine (N = 101)						Placebo (N = 102)					
		Children		Adolescents		Total		Children		Adolescents		Total	
		n	%	n	%	n	%	n	%	n	%	n	%
Visit													
Week 6	Much Improved (2)	10	33.3	19	44.2	29	39.7	16	37.2	17	40.5	33	38.8
	Minimally improved (3)	8	26.7	10	23.3	18	24.7	13	30.2	12	28.6	25	29.4
	No change (4)	3	10.0	6	14.0	9	12.3	4	9.3	5	11.9	9	10.6
	Minimally worse (5)	2	6.7	1	2.3	3	4.1	2	4.7	3	7.1	5	5.9
	Much worse (6)	0	0	0	0	0	0	0	0	0	0	0	0
	Very much worse (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	30	100.0	43	100.0	73	100.0	43	100.0	42	100.0	85	100.0
Week 8	Not assessed (0)	0	0	0	0	0	0	0	0	0	0	0	0
	Very much improved (1)	9	31.0	12	30.8	21	30.9	7	16.7	10	26.3	17	21.3
	Much Improved (2)	11	37.9	14	35.9	25	36.8	15	35.7	12	31.6	27	33.8
	Minimally improved (3)	5	17.2	11	28.2	16	23.5	11	26.2	11	28.9	22	27.5
	No change (4)	4	13.8	1	2.6	5	7.4	7	16.7	4	10.5	11	13.8
	Minimally worse (5)	0	0	0	0	0	0	2	4.8	1	2.6	3	3.8
	Much worse (6)	0	0	1	2.6	1	1.5	0	0	0	0	0	0
	Very much worse (7)	0	0	0	0	0	0	0	0	0	0	0	0
	Total	29	100.0	39	100.0	68	100.0	42	100.0	38	100.0	80	100.0

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Table 14.3.2

Summary of Analysis for CGI Global Improvement - Proportion of Responders
Adjusted for Baseline Score, Age, 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	11	11.3	97	10	10.0	100				
Week 2	25	27.8	90	17	18.7	91				
Week 3	35	39.3	89	28	32.6	86				
Week 4	38	44.7	85	36	39.6	91				
Week 6	43	58.9	73	46	54.1	85				
Week 8	46	67.6	68	44	55.0	80	1.85	0.92	3.73	0.084
Week 8 LOCF Endpoint	49	48.5	101	46	46.0	100	1.18	0.67	2.08	0.563

* 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
Note: 70% LOCF Endpoint was not created - 70 percent of patients in each trt group still in study at last trt visit

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Table 14.3.2

Summary of Analysis for CGI Global Improvement - Proportion of Responders
Adjusted for Baseline Score,Gender and Comorbidity
Intention-To-Treat Population
Age Group : Children

	Paroxetine			Placebo			Treatment Comparisons *			
	n	%	N	n	%	N	Odds Ratio	Lower 95% CI Limit	Upper 95% CI Limit	p-value
Week 1	7	15.6	45	8	17.0	47				
Week 2	14	31.8	44	13	30.2	43				
Week 3	19	46.3	41	14	34.1	41				
Week 4	17	44.7	38	19	42.2	45				
Week 6	17	56.7	30	24	55.8	43				
Week 8	20	69.0	29	22	52.4	42	2.38	0.82	6.91	0.109
Week 8 LOCF Endpoint	22	44.9	49	22	46.8	47	0.97	0.43	2.20	0.950

* 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
Note: 70% LOCF Endpoint was not created - 70 percent of patients in each trt group still in study at last trt visit

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Table 14.3.2

Summary of Analysis for CGI Global Improvement - Proportion of Responders
Adjusted for Baseline Score,Gender and Comorbidity
Intention-To-Treat Population
Age Group : Adolescents

	Paroxetine			Placebo			Treatment Comparisons *			
	n	%	N	n	%	N	Odds Ratio	Lower 95% CI Limit	Upper 95% CI Limit	p-value
Week 1	4	7.7	52	2	3.8	53				
Week 2	11	23.9	46	4	8.3	48				
Week 3	16	33.3	48	14	31.1	45				
Week 4	21	44.7	47	17	37.0	46				
Week 6	26	60.5	43	22	52.4	42				
Week 8	26	66.7	39	22	57.9	38	1.53	0.59	3.96	0.381
Week 8 LOCF Endpoint	27	51.9	52	24	45.3	53	1.46	0.65	3.24	0.358

* 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
Note: 70% LOCF Endpoint was not created - 70 percent of patients in each trt group still in study at last trt visit

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Table 14.4.1

Summary Statistics for GAF Score

Intention-To-Treat Population

		Paroxetine (N=101)			Placebo (N=102)		
Visit	Statistic	Children	Adolescents	Total	Children	Adolescents	Total
Baseline	N	49	52	101	47	55	102
	MEAN	53.2	53.6	53.4	52.3	52.3	52.3
	MEDIAN	55.0	55.0	55.0	52.0	53.0	52.5
	STDDEV	7.34	8.24	7.78	5.78	5.43	5.57
	MIN	35	35	35	40	40	40
	MAX	71	77	77	70	61	70
	MISSING	0	0	0	0	0	0
Week 4	N	37	44	81	42	44	86
	MEAN	62.8	63.6	63.3	62.1	61.0	61.5
	MEDIAN	60.0	60.5	60.0	59.5	60.0	60.0
	STDDEV	9.42	11.64	10.63	10.30	8.43	9.35
	MIN	50	45	45	50	50	50
	MAX	88	95	95	90	90	90
	MISSING	2	5	7	4	3	7
Week 6	N	30	43	73	43	42	85
	MEAN	66.1	64.3	65.0	64.8	62.6	63.7
	MEDIAN	65.0	61.0	63.0	65.0	61.0	61.0
	STDDEV	10.10	10.23	10.14	11.72	8.48	10.25
	MIN	40	45	40	48	50	48
	MAX	83	95	95	91	80	91
	MISSING	3	2	5	1	1	2
Week 8	N	29	39	68	41	38	79
	MEAN	68.8	68.3	68.5	65.9	65.9	65.9
	MEDIAN	65.0	68.0	65.0	62.0	63.5	62.0
	STDDEV	12.15	12.51	12.27	12.10	10.44	11.26
	MIN	40	45	40	50	51	50
	MAX	90	95	95	91	92	92
	MISSING	1	3	4	1	0	1

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 14.4.2

Summary of Analysis for change from Baseline in GAF score
Adjusted for Baseline Score, Age, 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	53.41	7.78	101	52.28	5.57	102				
Change From Baseline to:										
Week 4	10.23	1.11	81	9.14	1.16	86				
Week 6	11.84	1.20	73	10.66	1.20	85				
Week 8	15.22	1.49	68	12.86	1.50	79	2.36	-1.44	6.16	0.221
Week 8 LOCF Endpoint	11.95	1.35	92	10.62	1.42	95	1.33	-2.19	4.86	0.456

* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
\+ Note that for Baseline, raw means not Least Square means 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 not created - 70 percent of patients in each trt group still in study at last trt visit

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Table 14.4.2

Summary of Analysis for change from Baseline in GAF score
Adjusted for Baseline Score,Gender and Comorbidity
Intention-To-Treat Population
Age Group : Children

	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	53.18	7.34	49	52.28	5.78	47				
Change From Baseline to:										
Week 4	10.16	1.69	37	10.10	1.72	42				
Week 6	12.93	2.08	30	11.89	1.95	43				
Week 8	15.86	2.41	29	13.28	2.29	41	2.58	-3.44	8.61	0.395
Week 8 LOCF Endpoint	11.02	2.14	43	11.85	2.19	46	-0.82	-6.33	4.68	0.767

* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
+ Note that for Baseline, raw means not Least Square means 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 not created - 70 percent of patients in each trt group still in study at last trt visit

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Table 14.4.2

Summary of Analysis for change from Baseline in GAF score
Adjusted for Baseline Score,Gender and Comorbidity
Intention-To-Treat Population
Age Group : Adolescents

	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	53.62	8.24	52	52.29	5.43	55				
Change From Baseline to:										
Week 4	10.28	1.48	44	8.18	1.61	44				
Week 6	10.74	1.42	43	9.37	1.54	42				
Week 8	14.71	1.88	39	12.61	2.07	38	2.10	-2.96	7.15	0.411
Week 8 LOCF Endpoint	12.85	1.72	49	9.59	1.88	49	3.26	-1.40	7.92	0.168

* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
+ Note that for Baseline, raw means not Least Square means 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 not created - 70 percent of patients in each trt group still in study at last trt visit

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Table 14.5.1

Summary Statistics for KADS Total Score

Intention-To-Treat Population

Visit	Statistic	Treatment Group: Paroxetine (N=53)	Placebo (N=55)	Total (N=108)
Baseline	N	52	55	107
	MEAN	17.6	18.1	17.9
	MEDIAN	17.0	17.0	17.0
	STDDEV	6.17	7.43	6.82
	MINIMUM	4	1	1
	MAXIMUM	33	34	34
	MISSING	1	0	1
Week 1	N	53	53	106
	MEAN	13.7	15.2	14.5
	MEDIAN	12.0	13.0	13.0
	STDDEV	6.06	8.20	7.22
	MINIMUM	1	2	1
	MAXIMUM	28	34	34
	MISSING	0	2	2
Week 2	N	47	46	93
	MEAN	12.6	12.9	12.7
	MEDIAN	10.0	11.0	11.0
	STDDEV	6.66	8.23	7.44
	MINIMUM	4	0	0
	MAXIMUM	25	31	31
	MISSING	5	5	10
Week 3	N	48	43	91
	MEAN	12.1	11.7	11.9
	MEDIAN	10.5	9.0	10.0
	STDDEV	6.53	7.48	6.96
	MINIMUM	1	2	1
	MAXIMUM	28	32	32
	MISSING	4	7	11
Week 4	N	47	45	92
	MEAN	9.4	9.6	9.5
	MEDIAN	7.0	7.0	7.0

KADS assessed in patients >= 12 years

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 14.5.1

Summary Statistics for KADS Total Score

Intention-To-Treat Population

Visit	Statistic	Treatment Group Paroxetine (N=53)	Placebo (N=55)	Total (N=108)
Week 4	STDDEV	5.89	7.13	6.49
	MINIMUM	2	0	0
	MAXIMUM	24	25	25
	MISSING	3	2	5
Week 6	N	42	41	83
	MEAN	9.9	8.7	9.3
	MEDIAN	7.5	8.0	8.0
	STDDEV	6.19	6.43	6.30
	MINIMUM	1	0	0
	MAXIMUM	25	26	26
	MISSING	4	2	6
Week 8	N	38	38	76
	MEAN	8.8	9.1	8.9
	MEDIAN	7.0	6.5	7.0
	STDDEV	6.17	7.38	6.76
	MINIMUM	1	0	0
	MAXIMUM	22	31	31
	MISSING	4	0	4

KADS assessed in patients >= 12 years
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 14.5.2

Summary of Analysis for change from Baseline in KADS Total Score
Adjusted for Baseline Score, 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	17.63	6.17	52	18.11	7.43	55				
Change From Baseline to:										
Week 1	-4.49	0.76	52	-3.60	0.83	53				
Week 2	-5.90	0.93	46	-5.72	1.01	46				
Week 3	-5.97	0.92	48	-6.89	1.07	43				
Week 4	-7.97	0.89	46	-8.22	0.99	45				
Week 6	-6.99	0.95	41	-8.26	1.03	41				
Week 8	-8.27	1.07	37	-8.23	1.14	38	-0.04	-2.84	2.76	0.977
Week 8 LOCF Endpoint	-8.04	0.99	52	-7.22	1.09	53	-0.82	-3.50	1.85	0.542

KADS assessed in patients >= 12 years
* Difference in adjusted least square means are shown (Paroxetine minus Placebo)
+ Note that for Baseline, raw means not Least Square means are presented
Note: 70% LOCF Endpoint was not created - 70 percent of patients in each trt group still in study at last trt visit

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=101)	Treatment Group: Placebo (N=102)
TOTAL	TOTAL	15 (14.9%)	16 (15.7%)
Body as a Whole	TOTAL	8 (7.9%)	10 (9.8%)
	HEADACHE	3 (3.0%)	5 (4.9%)
	INFECTION	2 (2.0%)	1 (1.0%)
	TRAUMA	1 (1.0%)	2 (2.0%)
	PAIN	1 (1.0%)	1 (1.0%)
	ABSCESS	1 (1.0%)	0
	ABDOMINAL PAIN	0	3 (2.9%)
	BACK PAIN	0	1 (1.0%)
Digestive System	TOTAL	3 (3.0%)	2 (2.0%)
	NAUSEA	1 (1.0%)	1 (1.0%)
	DECREASED APPETITE	1 (1.0%)	0
	VOMITING	1 (1.0%)	0
	GASTROINTESTINAL DISORDER	0	1 (1.0%)
Endocrine System	TOTAL	2 (2.0%)	0
	THYROID DISORDER	2 (2.0%)	0
Respiratory System	TOTAL	2 (2.0%)	3 (2.9%)
	PHARYNGITIS	1 (1.0%)	1 (1.0%)
	SINUSITIS	1 (1.0%)	1 (1.0%)
	RESPIRATORY DISORDER	0	1 (1.0%)
Hemic and Lymphatic System	TOTAL	1 (1.0%)	0
	PURPURA	1 (1.0%)	0
Nervous System	TOTAL	0	1 (1.0%)
	INSOMNIA	0	1 (1.0%)
Special Senses	TOTAL	0	1 (1.0%)
	OTITIS MEDIA	0	1 (1.0%)
Urogenital System	TOTAL	0	1 (1.0%)
	ALBUMINURIA	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=55)
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

Body System	Preferred Term	Treatment Group: Paroxetine (N=48)	Treatment Group: Placebo (N=47)
TOTAL	TOTAL	1 (2.1%)	0
Urogenital System	TOTAL	1 (2.1%)	0
	DYSMENORRHEA	1 (2.1%)	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 : Children
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=49)	 Placebo (N=47)
TOTAL	TOTAL	34 (69.4%)	30 (63.8%)
Body as a Whole	TOTAL	22 (44.9%)	17 (36.2%)
	HEADACHE	10 (20.4%)	7 (14.9%)
	INFECTION	5 (10.2%)	5 (10.6%)
	TRAUMA	5 (10.2%)	5 (10.6%)
	ABDOMINAL PAIN	4 (8.2%)	2 (4.3%)
	ASTHENIA	3 (6.1%)	4 (8.5%)
	FEVER	3 (6.1%)	3 (6.4%)
	PAIN	1 (2.0%)	2 (4.3%)
	ALLERGIC REACTION	0	1 (2.1%)
Digestive System	TOTAL	16 (32.7%)	13 (27.7%)
	NAUSEA	6 (12.2%)	3 (6.4%)
	DYSPEPSIA	3 (6.1%)	2 (4.3%)
	VOMITING	3 (6.1%)	1 (2.1%)
	DECREASED APPETITE	2 (4.1%)	2 (4.3%)
	DIARRHEA	2 (4.1%)	1 (2.1%)
	DRY MOUTH	2 (4.1%)	0
	ULCERATIVE STOMATITIS	1 (2.0%)	1 (2.1%)
	CONSTIPATION	1 (2.0%)	0
	INCREASED APPETITE	1 (2.0%)	0
	MELENA	1 (2.0%)	0
	GASTROENTERITIS	0	1 (2.1%)
	TOOTH CARIES	0	1 (2.1%)
	TOOTH DISORDER	0	1 (2.1%)
Respiratory System	TOTAL	15 (30.6%)	15 (31.9%)
	RESPIRATORY DISORDER	5 (10.2%)	8 (17.0%)
	COUGH INCREASED	3 (6.1%)	3 (6.4%)
	RHINITIS	3 (6.1%)	3 (6.4%)
	SINUSITIS	3 (6.1%)	2 (4.3%)
	EPISTAXIS	2 (4.1%)	0
	PHARYNGITIS	1 (2.0%)	4 (8.5%)
	PNEUMONIA	1 (2.0%)	0
	YAWN	1 (2.0%)	0
	ASTHMA	0	1 (2.1%)
	BRONCHITIS	0	1 (2.1%)
Nervous System	TOTAL	12 (24.5%)	4 (8.5%)
	INSOMNIA	3 (6.1%)	0
	DEPRESSION	2 (4.1%)	1 (2.1%)
	DIZZINESS	2 (4.1%)	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 : Children
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=49)	Treatment Group: Placebo (N=47)
Nervous System	NERVOUSNESS	2 (4.1%)	1 (2.1%)
	AGITATION	2 (4.1%)	0
	ABNORMAL DREAMS	1 (2.0%)	0
	CONCENTRATION IMPAIRED	1 (2.0%)	0
	EMOTIONAL LABILITY	1 (2.0%)	0
	HOSTILITY	1 (2.0%)	0
	HYPERKINESIA	1 (2.0%)	0
	MYOCLONUS	1 (2.0%)	0
	TREMOR	1 (2.0%)	0
	SOMNOLENCE	0	2 (4.3%)
	ANXIETY	0	1 (2.1%)
Skin and Appendages	TOTAL	4 (8.2%)	4 (8.5%)
	FUNGAL DERMATITIS	1 (2.0%)	1 (2.1%)
	HERPES SIMPLEX	1 (2.0%)	0
	SWEATING	1 (2.0%)	0
	URTICARIA	1 (2.0%)	0
	HERPES ZOSTER	0	1 (2.1%)
	PRURITUS	0	1 (2.1%)
	RASH	0	1 (2.1%)
Urogenital System	TOTAL	4 (8.2%)	4 (8.5%)
	HAEMATURIA	1 (2.0%)	0
	URINARY FREQUENCY	1 (2.0%)	0
	URINARY RETENTION	1 (2.0%)	0
	URINATION IMPAIRED	1 (2.0%)	0
	ALBUMINURIA	0	3 (6.4%)
	URINARY TRACT INFECTION	0	1 (2.1%)
Cardiovascular System	TOTAL	2 (4.1%)	1 (2.1%)
	CARDIAC DISORDERS	1 (2.0%)	0
	VASODILATATION	1 (2.0%)	0
	MIGRAINE	0	1 (2.1%)
Hemic and Lymphatic System	TOTAL	2 (4.1%)	1 (2.1%)
	ANEMIA	1 (2.0%)	0
	ERYTHROCYTES ABNORMAL	1 (2.0%)	0
	PURPURA	1 (2.0%)	0
	LEUKOPENIA	0	1 (2.1%)
Musculoskeletal System	TOTAL	1 (2.0%)	0
	ARTHRALGIA	1 (2.0%)	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=49)	Placebo (N=47)
Special Senses	TOTAL	1 (2.0%)	2 (4.3%)
	ABNORMAL VISION	1 (2.0%)	0
	OTITIS EXTERNA	0	1 (2.1%)
	OTITIS MEDIA	0	1 (2.1%)
Metabolic and Nutritional Disorders	TOTAL	0	3 (6.4%)
	HYPONATREMIA	0	1 (2.1%)
	KETOSIS	0	1 (2.1%)
	THIRST	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 : Children
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=26)	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 : Children
Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=23)	Placebo (N=18)
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=52)	Treatment Group: Placebo (N=55)
TOTAL	TOTAL	37 (71.2%)	32 (58.2%)
Nervous System	TOTAL	23 (44.2%)	14 (25.5%)
	SOMNOLENCE	10 (19.2%)	5 (9.1%)
	INSOMNIA	8 (15.4%)	7 (12.7%)
	NERVOUSNESS	4 (7.7%)	3 (5.5%)
	DIZZINESS	3 (5.8%)	0
	HYPERKINESIA	2 (3.8%)	1 (1.8%)
	TREMOR	2 (3.8%)	0
	ANXIETY	1 (1.9%)	1 (1.8%)
	ABNORMAL DREAMS	1 (1.9%)	0
	AGITATION	1 (1.9%)	0
	CONCENTRATION IMPAIRED	1 (1.9%)	0
	CONFUSION	1 (1.9%)	0
	MYOCLONUS	1 (1.9%)	0
	EMOTIONAL LABILITY	0	2 (3.6%)
	WITHDRAWAL SYNDROME	0	1 (1.8%)
Body as a Whole	TOTAL	21 (40.4%)	19 (34.5%)
	HEADACHE	10 (19.2%)	13 (23.6%)
	TRAUMA	8 (15.4%)	3 (5.5%)
	ASTHENIA	4 (7.7%)	5 (9.1%)
	FEVER	4 (7.7%)	1 (1.8%)
	INFECTION	2 (3.8%)	1 (1.8%)
	PAIN	2 (3.8%)	0
	ALLERGIC REACTION	1 (1.9%)	2 (3.6%)
	BACK PAIN	1 (1.9%)	0
	ABDOMINAL PAIN	0	1 (1.8%)
Respiratory System	TOTAL	15 (28.8%)	8 (14.5%)
	PHARYNGITIS	7 (13.5%)	2 (3.6%)
	RESPIRATORY DISORDER	6 (11.5%)	3 (5.5%)
	SINUSITIS	3 (5.8%)	2 (3.6%)
	COUGH INCREASED	3 (5.8%)	0
	ASTHMA	2 (3.8%)	0
	RHINITIS	2 (3.8%)	0
	EPISTAXIS	1 (1.9%)	0
	YAWN	1 (1.9%)	0
	LARYNX DISORDER	0	1 (1.8%)
Digestive System	TOTAL	13 (25.0%)	12 (21.8%)
	NAUSEA	7 (13.5%)	6 (10.9%)
	DYSPEPSIA	3 (5.8%)	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 : Adolescents
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=52)	Placebo (N=55)
Digestive System	VOMITING	3 (5.8%)	1 (1.8%)
	DECREASED APPETITE	2 (3.8%)	2 (3.6%)
	DIARRHEA	2 (3.8%)	1 (1.8%)
	DRY MOUTH	1 (1.9%)	1 (1.8%)
	TOOTH DISORDER	1 (1.9%)	0
	CONSTIPATION	0	1 (1.8%)
	GASTRITIS	0	1 (1.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.8%)
Skin and Appendages	TOTAL	6 (11.5%)	1 (1.8%)
	CONTACT DERMATITIS	3 (5.8%)	0
	SWEATING	3 (5.8%)	0
	RASH	1 (1.9%)	0
	SKIN HYPERTROPHY	1 (1.9%)	0
	URTICARIA	1 (1.9%)	0
	FUNGAL DERMATITIS	0	1 (1.8%)
Special Senses	TOTAL	6 (11.5%)	2 (3.6%)
	OTITIS MEDIA	4 (7.7%)	1 (1.8%)
	CONJUNCTIVITIS	1 (1.9%)	0
	MYDRIASIS	1 (1.9%)	0
	EAR PAIN	0	1 (1.8%)
Urogenital System	TOTAL	5 (9.6%)	1 (1.8%)
	CYSTITIS	2 (3.8%)	0
	PYELONEPHRITIS	1 (1.9%)	0
	PYURIA	1 (1.9%)	0
	URINARY TRACT INFECTION	1 (1.9%)	0
	URINATION IMPAIRED	1 (1.9%)	0
	URINARY FREQUENCY	0	1 (1.8%)
Cardiovascular System	TOTAL	2 (3.8%)	1 (1.8%)
	VASODILATATION	2 (3.8%)	0
	MIGRAINE	0	1 (1.8%)
Hemic and Lymphatic System	TOTAL	1 (1.9%)	1 (1.8%)
	PURPURA	1 (1.9%)	0
	LEUKOPENIA	0	1 (1.8%)
Metabolic and Nutritional Disorders	TOTAL	1 (1.9%)	0
	WEIGHT LOSS	1 (1.9%)	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=52)	 Placebo (N=55)
Musculoskeletal System	TOTAL	1 (1.9%)	1 (1.8%)
	MYALGIA	1 (1.9%)	0
	ARTHRALGIA	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 : Adolescents
Male Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=27)	Placebo (N=26)
TOTAL	TOTAL	1 (3.7%)	0
Urogenital System	TOTAL	1 (3.7%)	0
	IMPOTENCE	1 (3.7%)	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 : Adolescents
Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=29)
Body System	Preferred Term		
TOTAL	TOTAL	1 (4.0%)	1 (3.4%)
Urogenital System	TOTAL	1 (4.0%)	1 (3.4%)
	MENSTRUAL DISORDER	1 (4.0%)	0
	DYSMENORRHEA	0	1 (3.4%)

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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=101)	Treatment Group: Placebo (N=102)
TOTAL	TOTAL	71 (70.3%)	62 (60.8%)
Body as a Whole	TOTAL	43 (42.6%)	36 (35.3%)
	HEADACHE	20 (19.8%)	20 (19.6%)
	TRAUMA	13 (12.9%)	8 (7.8%)
	ASTHENIA	7 (6.9%)	9 (8.8%)
	INFECTION	7 (6.9%)	6 (5.9%)
	FEVER	7 (6.9%)	4 (3.9%)
	ABDOMINAL PAIN	4 (4.0%)	3 (2.9%)
	PAIN	3 (3.0%)	2 (2.0%)
	ALLERGIC REACTION	1 (1.0%)	3 (2.9%)
	BACK PAIN	1 (1.0%)	0
Nervous System	TOTAL	35 (34.7%)	18 (17.6%)
	INSOMNIA	11 (10.9%)	7 (6.9%)
	SOMNOLENCE	10 (9.9%)	7 (6.9%)
	NERVOUSNESS	6 (5.9%)	4 (3.9%)
	DIZZINESS	5 (5.0%)	1 (1.0%)
	HYPERKINESIA	3 (3.0%)	1 (1.0%)
	AGITATION	3 (3.0%)	0
	TREMOR	3 (3.0%)	0
	DEPRESSION	2 (2.0%)	1 (1.0%)
	ABNORMAL DREAMS	2 (2.0%)	0
	CONCENTRATION IMPAIRED	2 (2.0%)	0
	MYOCLONUS	2 (2.0%)	0
	ANXIETY	1 (1.0%)	2 (2.0%)
	EMOTIONAL LABILITY	1 (1.0%)	2 (2.0%)
	CONFUSION	1 (1.0%)	0
	HOSTILITY	1 (1.0%)	0
	WITHDRAWAL SYNDROME	0	1 (1.0%)
Respiratory System	TOTAL	30 (29.7%)	23 (22.5%)
	RESPIRATORY DISORDER	11 (10.9%)	11 (10.8%)
	PHARYNGITIS	8 (7.9%)	6 (5.9%)
	SINUSITIS	6 (5.9%)	4 (3.9%)
	COUGH INCREASED	6 (5.9%)	3 (2.9%)
	RHINITIS	5 (5.0%)	3 (2.9%)
	EPISTAXIS	3 (3.0%)	0
	ASTHMA	2 (2.0%)	1 (1.0%)
	YAWN	2 (2.0%)	0
	PNEUMONIA	1 (1.0%)	0
	BRONCHITIS	0	1 (1.0%)
	LARYNX DISORDER	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
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=101)	Treatment Group: Placebo (N=102)
Digestive System	TOTAL	29 (28.7%)	25 (24.5%)
	NAUSEA	13 (12.9%)	9 (8.8%)
	DYSPEPSIA	6 (5.9%)	3 (2.9%)
	VOMITING	6 (5.9%)	2 (2.0%)
	DECREASED APPETITE	4 (4.0%)	4 (3.9%)
	DIARRHEA	4 (4.0%)	2 (2.0%)
	DRY MOUTH	3 (3.0%)	1 (1.0%)
	CONSTIPATION	1 (1.0%)	1 (1.0%)
	TOOTH DISORDER	1 (1.0%)	1 (1.0%)
	ULCERATIVE STOMATITIS	1 (1.0%)	1 (1.0%)
	INCREASED APPETITE	1 (1.0%)	0
	MELENA	1 (1.0%)	0
	GASTRITIS	0	1 (1.0%)
	GASTROENTERITIS	0	1 (1.0%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.0%)
	TOOTH CARIES	0	1 (1.0%)
Skin and Appendages	TOTAL	10 (9.9%)	5 (4.9%)
	SWEATING	4 (4.0%)	0
	CONTACT DERMATITIS	3 (3.0%)	0
	URTICARIA	2 (2.0%)	0
	FUNGAL DERMATITIS	1 (1.0%)	2 (2.0%)
	RASH	1 (1.0%)	1 (1.0%)
	HERPES SIMPLEX	1 (1.0%)	0
	SKIN HYPERTROPHY	1 (1.0%)	0
	HERPES ZOSTER	0	1 (1.0%)
	PRURITUS	0	1 (1.0%)
Urogenital System	TOTAL	9 (8.9%)	5 (4.9%)
	CYSTITIS	2 (2.0%)	0
	URINATION IMPAIRED	2 (2.0%)	0
	URINARY FREQUENCY	1 (1.0%)	1 (1.0%)
	URINARY TRACT INFECTION	1 (1.0%)	1 (1.0%)
	HAEMATURIA	1 (1.0%)	0
	PYELONEPHRITIS	1 (1.0%)	0
	PYURIA	1 (1.0%)	0
	URINARY RETENTION	1 (1.0%)	0
	ALBUMINURIA	0	3 (2.9%)
Special Senses	TOTAL	7 (6.9%)	4 (3.9%)
	OTITIS MEDIA	4 (4.0%)	2 (2.0%)
	ABNORMAL VISION	1 (1.0%)	0
	CONJUNCTIVITIS	1 (1.0%)	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
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=101)	Placebo (N=102)
Special Senses	MYDRIASIS	1 (1.0%)	0
	EAR PAIN	0	1 (1.0%)
	OTITIS EXTERNA	0	1 (1.0%)
Cardiovascular System	TOTAL	4 (4.0%)	2 (2.0%)
	VASODILATATION	3 (3.0%)	0
	CARDIAC DISORDERS	1 (1.0%)	0
	MIGRAINE	0	2 (2.0%)
Hemic and Lymphatic System	TOTAL	3 (3.0%)	2 (2.0%)
	PURPURA	2 (2.0%)	0
	ANEMIA	1 (1.0%)	0
	ERYTHROCYTES ABNORMAL	1 (1.0%)	0
	LEUKOPENIA	0	2 (2.0%)
Musculoskeletal System	TOTAL	2 (2.0%)	1 (1.0%)
	ARTHRALGIA	1 (1.0%)	1 (1.0%)
	MYALGIA	1 (1.0%)	0
Metabolic and Nutritional Disorders	TOTAL	1 (1.0%)	3 (2.9%)
	WEIGHT LOSS	1 (1.0%)	0
	HYPONATREMIA	0	1 (1.0%)
	KETOSIS	0	1 (1.0%)
	THIRST	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

Body System	Preferred Term	Treatment Group Paroxetine (N=53)	Placebo (N=55)
TOTAL	TOTAL	1 (1.9%)	0
Urogenital System	TOTAL	1 (1.9%)	0
	IMPOTENCE	1 (1.9%)	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

		Treatment Group	
		Paroxetine (N=48)	Placebo (N=47)
Body System	Preferred Term		
TOTAL	TOTAL	1 (2.1%)	1 (2.1%)
Urogenital System	TOTAL	1 (2.1%)	1 (2.1%)
	MENSTRUAL DISORDER	1 (2.1%)	0
	DYSMENORRHEA	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 : Children
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=49)	 Placebo (N=47)
TOTAL	34 (69.4%)	30 (63.8%)
HEADACHE	10 (20.4%)	7 (14.9%)
NAUSEA	6 (12.2%)	3 (6.4%)
RESPIRATORY DISORDER	5 (10.2%)	8 (17.0%)
INFECTION	5 (10.2%)	5 (10.6%)
TRAUMA	5 (10.2%)	5 (10.6%)
ABDOMINAL PAIN	4 (8.2%)	2 (4.3%)
ASTHENIA	3 (6.1%)	4 (8.5%)
COUGH INCREASED	3 (6.1%)	3 (6.4%)
FEVER	3 (6.1%)	3 (6.4%)
RHINITIS	3 (6.1%)	3 (6.4%)
DYSPEPSIA	3 (6.1%)	2 (4.3%)
SINUSITIS	3 (6.1%)	2 (4.3%)
VOMITING	3 (6.1%)	1 (2.1%)
INSOMNIA	3 (6.1%)	0
DECREASED APPETITE	2 (4.1%)	2 (4.3%)
DEPRESSION	2 (4.1%)	1 (2.1%)
DIARRHEA	2 (4.1%)	1 (2.1%)
DIZZINESS	2 (4.1%)	1 (2.1%)
NERVOUSNESS	2 (4.1%)	1 (2.1%)
AGITATION	2 (4.1%)	0
DRY MOUTH	2 (4.1%)	0
EPISTAXIS	2 (4.1%)	0
PHARYNGITIS	1 (2.0%)	4 (8.5%)
PAIN	1 (2.0%)	2 (4.3%)
FUNGAL DERMATITIS	1 (2.0%)	1 (2.1%)
ULCERATIVE STOMATITIS	1 (2.0%)	1 (2.1%)
ABNORMAL DREAMS	1 (2.0%)	0
ABNORMAL VISION	1 (2.0%)	0
ANEMIA	1 (2.0%)	0
ARTHRALGIA	1 (2.0%)	0
CARDIAC DISORDERS	1 (2.0%)	0
CONCENTRATION IMPAIRED	1 (2.0%)	0
CONSTIPATION	1 (2.0%)	0
EMOTIONAL LABILITY	1 (2.0%)	0
ERYTHROCYTES ABNORMAL	1 (2.0%)	0
HAEMATURIA	1 (2.0%)	0
HERPES SIMPLEX	1 (2.0%)	0
HOSTILITY	1 (2.0%)	0
HYPERKINESIA	1 (2.0%)	0
INCREASED APPETITE	1 (2.0%)	0
MELENA	1 (2.0%)	0
MYOCLONUS	1 (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 : Children
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=49)	Treatment Group: Placebo (N=47)
PNEUMONIA	1 (2.0%)	0
PURPURA	1 (2.0%)	0
SWEATING	1 (2.0%)	0
TREMOR	1 (2.0%)	0
URINARY FREQUENCY	1 (2.0%)	0
URINARY RETENTION	1 (2.0%)	0
URINATION IMPAIRED	1 (2.0%)	0
URTICARIA	1 (2.0%)	0
VASODILATATION	1 (2.0%)	0
YAWN	1 (2.0%)	0
ALBUMINURIA	0	3 (6.4%)
SOMNOLENCE	0	2 (4.3%)
ALLERGIC REACTION	0	1 (2.1%)
ANXIETY	0	1 (2.1%)
ASTHMA	0	1 (2.1%)
BRONCHITIS	0	1 (2.1%)
GASTROENTERITIS	0	1 (2.1%)
HERPES ZOSTER	0	1 (2.1%)
HYPONATREMIA	0	1 (2.1%)
KETOSIS	0	1 (2.1%)
LEUKOPENIA	0	1 (2.1%)
MIGRAINE	0	1 (2.1%)
OTITIS EXTERNA	0	1 (2.1%)
OTITIS MEDIA	0	1 (2.1%)
PRURITUS	0	1 (2.1%)
RASH	0	1 (2.1%)
THIRST	0	1 (2.1%)
TOOTH CARIES	0	1 (2.1%)
TOOTH DISORDER	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 : Children
Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=26)	 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 : Children
Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=23)	 Placebo (N=18)
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=52)	 Placebo (N=55)
TOTAL	37 (71.2%)	32 (58.2%)
HEADACHE	10 (19.2%)	13 (23.6%)
SOMNOLENCE	10 (19.2%)	5 (9.1%)
INSOMNIA	8 (15.4%)	7 (12.7%)
TRAUMA	8 (15.4%)	3 (5.5%)
NAUSEA	7 (13.5%)	6 (10.9%)
PHARYNGITIS	7 (13.5%)	2 (3.6%)
RESPIRATORY DISORDER	6 (11.5%)	3 (5.5%)
ASTHENIA	4 (7.7%)	5 (9.1%)
NERVOUSNESS	4 (7.7%)	3 (5.5%)
FEVER	4 (7.7%)	1 (1.8%)
OTITIS MEDIA	4 (7.7%)	1 (1.8%)
SINUSITIS	3 (5.8%)	2 (3.6%)
DYSPEPSIA	3 (5.8%)	1 (1.8%)
VOMITING	3 (5.8%)	1 (1.8%)
CONTACT DERMATITIS	3 (5.8%)	0
COUGH INCREASED	3 (5.8%)	0
DIZZINESS	3 (5.8%)	0
SWEATING	3 (5.8%)	0
DECREASED APPETITE	2 (3.8%)	2 (3.6%)
DIARRHEA	2 (3.8%)	1 (1.8%)
HYPERKINESIA	2 (3.8%)	1 (1.8%)
INFECTION	2 (3.8%)	1 (1.8%)
ASTHMA	2 (3.8%)	0
CYSTITIS	2 (3.8%)	0
PAIN	2 (3.8%)	0
RHINITIS	2 (3.8%)	0
TREMOR	2 (3.8%)	0
VASODILATATION	2 (3.8%)	0
ALLERGIC REACTION	1 (1.9%)	2 (3.6%)
ANXIETY	1 (1.9%)	1 (1.8%)
DRY MOUTH	1 (1.9%)	1 (1.8%)
ABNORMAL DREAMS	1 (1.9%)	0
AGITATION	1 (1.9%)	0
BACK PAIN	1 (1.9%)	0
CONCENTRATION IMPAIRED	1 (1.9%)	0
CONFUSION	1 (1.9%)	0
CONJUNCTIVITIS	1 (1.9%)	0
EPISTAXIS	1 (1.9%)	0
MYALGIA	1 (1.9%)	0
MYDRIASIS	1 (1.9%)	0
MYOCLONUS	1 (1.9%)	0
PURPURA	1 (1.9%)	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=52)	 Placebo (N=55)
PYELONEPHRITIS	1 (1.9%)	0
PYURIA	1 (1.9%)	0
RASH	1 (1.9%)	0
SKIN HYPERTROPHY	1 (1.9%)	0
TOOTH DISORDER	1 (1.9%)	0
URINARY TRACT INFECTION	1 (1.9%)	0
URINATION IMPAIRED	1 (1.9%)	0
URTICARIA	1 (1.9%)	0
WEIGHT LOSS	1 (1.9%)	0
YAWN	1 (1.9%)	0
EMOTIONAL LABILITY	0	2 (3.6%)
ABDOMINAL PAIN	0	1 (1.8%)
ARTHRALGIA	0	1 (1.8%)
CONSTIPATION	0	1 (1.8%)
EAR PAIN	0	1 (1.8%)
FUNGAL DERMATITIS	0	1 (1.8%)
GASTRITIS	0	1 (1.8%)
LARYNX DISORDER	0	1 (1.8%)
LEUKOPENIA	0	1 (1.8%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.8%)
MIGRAINE	0	1 (1.8%)
URINARY FREQUENCY	0	1 (1.8%)
WITHDRAWAL SYNDROME	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 : Adolescents
Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=27)	Treatment Group: Placebo (N=26)
TOTAL	1 (3.7%)	0
IMPOTENCE	1 (3.7%)	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 : Adolescents
Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=25)	 Placebo (N=29)
TOTAL	1 (4.0%)	1 (3.4%)
MENSTRUAL DISORDER	1 (4.0%)	0
DYSMENORRHEA	0	1 (3.4%)

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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 : Total
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=101)	 Placebo (N=102)
TOTAL	71 (70.3%)	62 (60.8%)
HEADACHE	20 (19.8%)	20 (19.6%)
NAUSEA	13 (12.9%)	9 (8.8%)
TRAUMA	13 (12.9%)	8 (7.8%)
RESPIRATORY DISORDER	11 (10.9%)	11 (10.8%)
INSOMNIA	11 (10.9%)	7 (6.9%)
SOMNOLENCE	10 (9.9%)	7 (6.9%)
PHARYNGITIS	8 (7.9%)	6 (5.9%)
ASTHENIA	7 (6.9%)	9 (8.8%)
INFECTION	7 (6.9%)	6 (5.9%)
FEVER	7 (6.9%)	4 (3.9%)
NERVOUSNESS	6 (5.9%)	4 (3.9%)
SINUSITIS	6 (5.9%)	4 (3.9%)
COUGH INCREASED	6 (5.9%)	3 (2.9%)
DYSPEPSIA	6 (5.9%)	3 (2.9%)
VOMITING	6 (5.9%)	2 (2.0%)
RHINITIS	5 (5.0%)	3 (2.9%)
DIZZINESS	5 (5.0%)	1 (1.0%)
DECREASED APPETITE	4 (4.0%)	4 (3.9%)
ABDOMINAL PAIN	4 (4.0%)	3 (2.9%)
DIARRHEA	4 (4.0%)	2 (2.0%)
OTITIS MEDIA	4 (4.0%)	2 (2.0%)
SWEATING	4 (4.0%)	0
PAIN	3 (3.0%)	2 (2.0%)
DRY MOUTH	3 (3.0%)	1 (1.0%)
HYPERKINESIA	3 (3.0%)	1 (1.0%)
AGITATION	3 (3.0%)	0
CONTACT DERMATITIS	3 (3.0%)	0
EPISTAXIS	3 (3.0%)	0
TREMOR	3 (3.0%)	0
VASODILATATION	3 (3.0%)	0
ASTHMA	2 (2.0%)	1 (1.0%)
DEPRESSION	2 (2.0%)	1 (1.0%)
ABNORMAL DREAMS	2 (2.0%)	0
CONCENTRATION IMPAIRED	2 (2.0%)	0
CYSTITIS	2 (2.0%)	0
MYOCLONUS	2 (2.0%)	0
PURPURA	2 (2.0%)	0
URINATION IMPAIRED	2 (2.0%)	0
URTICARIA	2 (2.0%)	0
YAWN	2 (2.0%)	0
ALLERGIC REACTION	1 (1.0%)	3 (2.9%)
ANXIETY	1 (1.0%)	2 (2.0%)

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Table 15.1.1.1X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase
by Descending Order
Intention-To-Treat Population
Age Group : Total
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=101)	 Placebo (N=102)
EMOTIONAL LABILITY	1 (1.0%)	2 (2.0%)
FUNGAL DERMATITIS	1 (1.0%)	2 (2.0%)
ARTHRALGIA	1 (1.0%)	1 (1.0%)
CONSTIPATION	1 (1.0%)	1 (1.0%)
RASH	1 (1.0%)	1 (1.0%)
TOOTH DISORDER	1 (1.0%)	1 (1.0%)
ULCERATIVE STOMATITIS	1 (1.0%)	1 (1.0%)
URINARY FREQUENCY	1 (1.0%)	1 (1.0%)
URINARY TRACT INFECTION	1 (1.0%)	1 (1.0%)
ABNORMAL VISION	1 (1.0%)	0
ANEMIA	1 (1.0%)	0
BACK PAIN	1 (1.0%)	0
CARDIAC DISORDERS	1 (1.0%)	0
CONFUSION	1 (1.0%)	0
CONJUNCTIVITIS	1 (1.0%)	0
ERYTHROCYTES ABNORMAL	1 (1.0%)	0
HAEMATURIA	1 (1.0%)	0
HERPES SIMPLEX	1 (1.0%)	0
HOSTILITY	1 (1.0%)	0
INCREASED APPETITE	1 (1.0%)	0
MELENA	1 (1.0%)	0
MYALGIA	1 (1.0%)	0
MYDRIASIS	1 (1.0%)	0
PNEUMONIA	1 (1.0%)	0
PYELONEPHRITIS	1 (1.0%)	0
PYURIA	1 (1.0%)	0
SKIN HYPERTROPHY	1 (1.0%)	0
URINARY RETENTION	1 (1.0%)	0
WEIGHT LOSS	1 (1.0%)	0
ALBUMINURIA	0	3 (2.9%)
LEUKOPENIA	0	2 (2.0%)
MIGRAINE	0	2 (2.0%)
BRONCHITIS	0	1 (1.0%)
EAR PAIN	0	1 (1.0%)
GASTRITIS	0	1 (1.0%)
GASTROENTERITIS	0	1 (1.0%)
HERPES ZOSTER	0	1 (1.0%)
HYPONATREMIA	0	1 (1.0%)
KETOSIS	0	1 (1.0%)
LARYNX DISORDER	0	1 (1.0%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.0%)
OTITIS EXTERNA	0	1 (1.0%)
PRURITUS	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=101)	 Placebo (N=102)
THIRST	0	1 (1.0%)
TOOTH CARIES	0	1 (1.0%)
WITHDRAWAL SYNDROME	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)	Treatment Group: Placebo (N=55)
TOTAL	1 (1.9%)	0
IMPOTENCE	1 (1.9%)	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=48)	 Placebo (N=47)
TOTAL	1 (2.1%)	1 (2.1%)
MENSTRUAL DISORDER	1 (2.1%)	0
DYSMENORRHEA	0	1 (2.1%)

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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=24)	 Placebo (N=26)
TOTAL	TOTAL	6 (25.0%)	5 (19.2%)
Body as a Whole	TOTAL	2 (8.3%)	0
	ALLERGIC REACTION	1 (4.2%)	0
	INFECTION	1 (4.2%)	0
Digestive System	TOTAL	1 (4.2%)	1 (3.8%)
	CONSTIPATION	1 (4.2%)	0
	DIARRHEA	0	1 (3.8%)
Hemic and Lymphatic System	TOTAL	1 (4.2%)	0
	THROMBOCYTHEMIA	1 (4.2%)	0
Nervous System	TOTAL	1 (4.2%)	1 (3.8%)
	DEPRESSION	1 (4.2%)	0
	NERVOUSNESS	1 (4.2%)	0
	ANXIETY	0	1 (3.8%)
	HYPERKINESIA	0	1 (3.8%)
Respiratory System	TOTAL	1 (4.2%)	2 (7.7%)
	PHARYNGITIS	1 (4.2%)	0
	RESPIRATORY DISORDER	0	1 (3.8%)
	RHINITIS	0	1 (3.8%)
Cardiovascular System	TOTAL	0	1 (3.8%)
	PALPITATION	0	1 (3.8%)
	TACHYCARDIA	0	1 (3.8%)
Musculoskeletal System	TOTAL	0	1 (3.8%)
	MYALGIA	0	1 (3.8%)
Urogenital System	TOTAL	0	1 (3.8%)
	HAEMATURIA	0	1 (3.8%)

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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=10)	Placebo (N=17)
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=14)	Placebo (N=9)
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=31)	Placebo (N=36)
TOTAL	TOTAL	2 (6.5%)	5 (13.9%)
Nervous System	TOTAL	1 (3.2%)	1 (2.8%)
	EMOTIONAL LABILITY	1 (3.2%)	0
	SOMNOLENCE	0	1 (2.8%)
	WITHDRAWAL SYNDROME	0	1 (2.8%)
Special Senses	TOTAL	1 (3.2%)	0
	OTITIS MEDIA	1 (3.2%)	0
Body as a Whole	TOTAL	0	2 (5.6%)
	ASTHENIA	0	1 (2.8%)
	HEADACHE	0	1 (2.8%)
Cardiovascular System	TOTAL	0	1 (2.8%)
	SYNCOPE	0	1 (2.8%)
Digestive System	TOTAL	0	1 (2.8%)
	NAUSEA	0	1 (2.8%)
Respiratory System	TOTAL	0	2 (5.6%)
	BRONCHITIS	0	1 (2.8%)
	COUGH INCREASED	0	1 (2.8%)

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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=17)	Placebo (N=17)
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=14)	Placebo (N=19)
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=55)	 Placebo (N=62)
TOTAL	TOTAL	8 (14.5%)	10 (16.1%)
Body as a Whole	TOTAL	2 (3.6%)	2 (3.2%)
	ALLERGIC REACTION	1 (1.8%)	0
	INFECTION	1 (1.8%)	0
	ASTHENIA	0	1 (1.6%)
	HEADACHE	0	1 (1.6%)
Nervous System	TOTAL	2 (3.6%)	2 (3.2%)
	DEPRESSION	1 (1.8%)	0
	EMOTIONAL LABILITY	1 (1.8%)	0
	NERVOUSNESS	1 (1.8%)	0
	ANXIETY	0	1 (1.6%)
	HYPERKINESIA	0	1 (1.6%)
	SOMNOLENCE	0	1 (1.6%)
	WITHDRAWAL SYNDROME	0	1 (1.6%)
Digestive System	TOTAL	1 (1.8%)	2 (3.2%)
	CONSTIPATION	1 (1.8%)	0
	DIARRHEA	0	1 (1.6%)
	NAUSEA	0	1 (1.6%)
Hemic and Lymphatic System	TOTAL	1 (1.8%)	0
	THROMBOCYTHEMIA	1 (1.8%)	0
Respiratory System	TOTAL	1 (1.8%)	4 (6.5%)
	PHARYNGITIS	1 (1.8%)	0
	BRONCHITIS	0	1 (1.6%)
	COUGH INCREASED	0	1 (1.6%)
	RESPIRATORY DISORDER	0	1 (1.6%)
	RHINITIS	0	1 (1.6%)
Special Senses	TOTAL	1 (1.8%)	0
	OTITIS MEDIA	1 (1.8%)	0
Cardiovascular System	TOTAL	0	2 (3.2%)
	PALPITATION	0	1 (1.6%)
	SYNCOPE	0	1 (1.6%)
	TACHYCARDIA	0	1 (1.6%)
Musculoskeletal System	TOTAL	0	1 (1.6%)
	MYALGIA	0	1 (1.6%)

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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=55)	Placebo (N=62)
Urogenital System	TOTAL	0	1 (1.6%)
	HAEMATURIA	0	1 (1.6%)

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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=27)	Placebo (N=34)
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=28)	Placebo (N=28)
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=24)	 Placebo (N=26)
TOTAL	6 (25.0%)	5 (19.2%)
ALLERGIC REACTION	1 (4.2%)	0
CONSTIPATION	1 (4.2%)	0
DEPRESSION	1 (4.2%)	0
INFECTION	1 (4.2%)	0
NERVOUSNESS	1 (4.2%)	0
PHARYNGITIS	1 (4.2%)	0
THROMBOCYTHEMIA	1 (4.2%)	0
ANXIETY	0	1 (3.8%)
DIARRHEA	0	1 (3.8%)
HAEMATURIA	0	1 (3.8%)
HYPERKINESIA	0	1 (3.8%)
MYALGIA	0	1 (3.8%)
PALPITATION	0	1 (3.8%)
RESPIRATORY DISORDER	0	1 (3.8%)
RHINITIS	0	1 (3.8%)
TACHYCARDIA	0	1 (3.8%)

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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=10)	Treatment Group: Placebo (N=17)
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=14)	 Placebo (N=9)
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=31)	 Placebo (N=36)
TOTAL	2 (6.5%)	5 (13.9%)
EMOTIONAL LABILITY	1 (3.2%)	0
OTITIS MEDIA	1 (3.2%)	0
ASTHENIA	0	1 (2.8%)
BRONCHITIS	0	1 (2.8%)
COUGH INCREASED	0	1 (2.8%)
HEADACHE	0	1 (2.8%)
NAUSEA	0	1 (2.8%)
SOMNOLENCE	0	1 (2.8%)
SYNCOPE	0	1 (2.8%)
WITHDRAWAL SYNDROME	0	1 (2.8%)

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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=17)	 Placebo (N=17)
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=14)	Treatment Group: Placebo (N=19)
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=55)	 Placebo (N=62)
TOTAL	8 (14.5%)	10 (16.1%)
ALLERGIC REACTION	1 (1.8%)	0
CONSTIPATION	1 (1.8%)	0
DEPRESSION	1 (1.8%)	0
EMOTIONAL LABILITY	1 (1.8%)	0
INFECTION	1 (1.8%)	0
NERVOUSNESS	1 (1.8%)	0
OTITIS MEDIA	1 (1.8%)	0
PHARYNGITIS	1 (1.8%)	0
THROMBOCYTHEMIA	1 (1.8%)	0
ANXIETY	0	1 (1.6%)
ASTHENIA	0	1 (1.6%)
BRONCHITIS	0	1 (1.6%)
COUGH INCREASED	0	1 (1.6%)
DIARRHEA	0	1 (1.6%)
HAEMATURIA	0	1 (1.6%)
HEADACHE	0	1 (1.6%)
HYPERKINESIA	0	1 (1.6%)
MYALGIA	0	1 (1.6%)
NAUSEA	0	1 (1.6%)
PALPITATION	0	1 (1.6%)
RESPIRATORY DISORDER	0	1 (1.6%)
RHINITIS	0	1 (1.6%)
SOMNOLENCE	0	1 (1.6%)
SYNCOPE	0	1 (1.6%)
TACHYCARDIA	0	1 (1.6%)
WITHDRAWAL SYNDROME	0	1 (1.6%)

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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=27)	 Placebo (N=34)
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=28)	 Placebo (N=28)
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=101)	Treatment Group: Placebo (N=102)
TOTAL	TOTAL	72 (71.3%)	63 (61.8%)
Body as a Whole	TOTAL	43 (42.6%)	37 (36.3%)
	HEADACHE	20 (19.8%)	20 (19.6%)
	TRAUMA	13 (12.9%)	8 (7.8%)
	INFECTION	8 (7.9%)	6 (5.9%)
	ASTHENIA	7 (6.9%)	10 (9.8%)
	FEVER	7 (6.9%)	4 (3.9%)
	ABDOMINAL PAIN	4 (4.0%)	3 (2.9%)
	PAIN	3 (3.0%)	2 (2.0%)
	ALLERGIC REACTION	2 (2.0%)	3 (2.9%)
	BACK PAIN	1 (1.0%)	0
Nervous System	TOTAL	36 (35.6%)	19 (18.6%)
	INSOMNIA	11 (10.9%)	7 (6.9%)
	SOMNOLENCE	10 (9.9%)	8 (7.8%)
	NERVOUSNESS	7 (6.9%)	4 (3.9%)
	DIZZINESS	5 (5.0%)	1 (1.0%)
	HYPERKINESIA	3 (3.0%)	2 (2.0%)
	DEPRESSION	3 (3.0%)	1 (1.0%)
	AGITATION	3 (3.0%)	0
	TREMOR	3 (3.0%)	0
	EMOTIONAL LABILITY	2 (2.0%)	2 (2.0%)
	ABNORMAL DREAMS	2 (2.0%)	0
	CONCENTRATION IMPAIRED	2 (2.0%)	0
	MYOCLONUS	2 (2.0%)	0
	ANXIETY	1 (1.0%)	3 (2.9%)
	CONFUSION	1 (1.0%)	0
	HOSTILITY	1 (1.0%)	0
	WITHDRAWAL SYNDROME	0	2 (2.0%)
Respiratory System	TOTAL	31 (30.7%)	25 (24.5%)
	RESPIRATORY DISORDER	11 (10.9%)	11 (10.8%)
	PHARYNGITIS	9 (8.9%)	6 (5.9%)
	COUGH INCREASED	6 (5.9%)	4 (3.9%)
	SINUSITIS	6 (5.9%)	4 (3.9%)
	RHINITIS	5 (5.0%)	3 (2.9%)
	EPISTAXIS	3 (3.0%)	0
	ASTHMA	2 (2.0%)	1 (1.0%)
	YAWN	2 (2.0%)	0
	PNEUMONIA	1 (1.0%)	0
	BRONCHITIS	0	2 (2.0%)
	LARYNX 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=101)	Treatment Group: Placebo (N=102)
Digestive System	TOTAL	29 (28.7%)	25 (24.5%)
	NAUSEA	13 (12.9%)	10 (9.8%)
	DYSPEPSIA	6 (5.9%)	3 (2.9%)
	VOMITING	6 (5.9%)	2 (2.0%)
	DECREASED APPETITE	4 (4.0%)	4 (3.9%)
	DIARRHEA	4 (4.0%)	2 (2.0%)
	DRY MOUTH	3 (3.0%)	1 (1.0%)
	CONSTIPATION	2 (2.0%)	1 (1.0%)
	TOOTH DISORDER	1 (1.0%)	1 (1.0%)
	ULCERATIVE STOMATITIS	1 (1.0%)	1 (1.0%)
	INCREASED APPETITE	1 (1.0%)	0
	MELENA	1 (1.0%)	0
	GASTRITIS	0	1 (1.0%)
	GASTROENTERITIS	0	1 (1.0%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.0%)
	TOOTH CARIES	0	1 (1.0%)
Skin and Appendages	TOTAL	10 (9.9%)	5 (4.9%)
	SWEATING	4 (4.0%)	0
	CONTACT DERMATITIS	3 (3.0%)	0
	URTICARIA	2 (2.0%)	0
	FUNGAL DERMATITIS	1 (1.0%)	2 (2.0%)
	RASH	1 (1.0%)	1 (1.0%)
	HERPES SIMPLEX	1 (1.0%)	0
	SKIN HYPERTROPHY	1 (1.0%)	0
	HERPES ZOSTER	0	1 (1.0%)
	PRURITUS	0	1 (1.0%)
Urogenital System	TOTAL	9 (8.9%)	5 (4.9%)
	CYSTITIS	2 (2.0%)	0
	URINATION IMPAIRED	2 (2.0%)	0
	HAEMATURIA	1 (1.0%)	1 (1.0%)
	URINARY FREQUENCY	1 (1.0%)	1 (1.0%)
	URINARY TRACT INFECTION	1 (1.0%)	1 (1.0%)
	PYELONEPHRITIS	1 (1.0%)	0
	PYURIA	1 (1.0%)	0
	URINARY RETENTION	1 (1.0%)	0
	ALBUMINURIA	0	3 (2.9%)
Special Senses	TOTAL	8 (7.9%)	4 (3.9%)
	OTITIS MEDIA	5 (5.0%)	2 (2.0%)
	ABNORMAL VISION	1 (1.0%)	0
	CONJUNCTIVITIS	1 (1.0%)	0
	MYDRIASIS	1 (1.0%)	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=101)	Treatment Group: Placebo (N=102)
Special Senses	EAR PAIN	0	1 (1.0%)
	OTITIS EXTERNA	0	1 (1.0%)
Cardiovascular System	TOTAL	4 (4.0%)	4 (3.9%)
	VASODILATATION	3 (3.0%)	0
	CARDIAC DISORDERS	1 (1.0%)	0
	MIGRAINE	0	2 (2.0%)
	PALPITATION	0	1 (1.0%)
	SYNCOPE	0	1 (1.0%)
	TACHYCARDIA	0	1 (1.0%)
Hemic and Lymphatic System	TOTAL	4 (4.0%)	2 (2.0%)
	PURPURA	2 (2.0%)	0
	ANEMIA	1 (1.0%)	0
	ERYTHROCYTES ABNORMAL	1 (1.0%)	0
	THROMBOCYTHEMIA	1 (1.0%)	0
	LEUKOPENIA	0	2 (2.0%)
Musculoskeletal System	TOTAL	2 (2.0%)	2 (2.0%)
	ARTHRALGIA	1 (1.0%)	1 (1.0%)
	MYALGIA	1 (1.0%)	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (1.0%)	3 (2.9%)
	WEIGHT LOSS	1 (1.0%)	0
	HYPONATREMIA	0	1 (1.0%)
	KETOSIS	0	1 (1.0%)
	THIRST	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

Body System	Preferred Term	Treatment Group: Paroxetine (N=53)	Treatment Group: Placebo (N=55)
TOTAL	TOTAL	1 (1.9%)	0
Urogenital System	TOTAL	1 (1.9%)	0
	IMPOTENCE	1 (1.9%)	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=48)	 Placebo (N=47)
TOTAL	TOTAL	1 (2.1%)	1 (2.1%)
Urogenital System	TOTAL	1 (2.1%)	1 (2.1%)
	MENSTRUAL DISORDER	1 (2.1%)	0
	DYSMENORRHEA	0	1 (2.1%)

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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=101)	Treatment Group: Placebo (N=102)
TOTAL	72 (71.3%)	63 (61.8%)
HEADACHE	20 (19.8%)	20 (19.6%)
NAUSEA	13 (12.9%)	10 (9.8%)
TRAUMA	13 (12.9%)	8 (7.8%)
RESPIRATORY DISORDER	11 (10.9%)	11 (10.8%)
INSOMNIA	11 (10.9%)	7 (6.9%)
SOMNOLENCE	10 (9.9%)	8 (7.8%)
PHARYNGITIS	9 (8.9%)	6 (5.9%)
INFECTION	8 (7.9%)	6 (5.9%)
ASTHENIA	7 (6.9%)	10 (9.8%)
FEVER	7 (6.9%)	4 (3.9%)
NERVOUSNESS	7 (6.9%)	4 (3.9%)
COUGH INCREASED	6 (5.9%)	4 (3.9%)
SINUSITIS	6 (5.9%)	4 (3.9%)
DYSPEPSIA	6 (5.9%)	3 (2.9%)
VOMITING	6 (5.9%)	2 (2.0%)
RHINITIS	5 (5.0%)	3 (2.9%)
OTITIS MEDIA	5 (5.0%)	2 (2.0%)
DIZZINESS	5 (5.0%)	1 (1.0%)
DECREASED APPETITE	4 (4.0%)	4 (3.9%)
ABDOMINAL PAIN	4 (4.0%)	3 (2.9%)
DIARRHEA	4 (4.0%)	2 (2.0%)
SWEATING	4 (4.0%)	0
HYPERKINESIA	3 (3.0%)	2 (2.0%)
PAIN	3 (3.0%)	2 (2.0%)
DEPRESSION	3 (3.0%)	1 (1.0%)
DRY MOUTH	3 (3.0%)	1 (1.0%)
AGITATION	3 (3.0%)	0
CONTACT DERMATITIS	3 (3.0%)	0
EPISTAXIS	3 (3.0%)	0
TREMOR	3 (3.0%)	0
VASODILATATION	3 (3.0%)	0
ALLERGIC REACTION	2 (2.0%)	3 (2.9%)
EMOTIONAL LABILITY	2 (2.0%)	2 (2.0%)
ASTHMA	2 (2.0%)	1 (1.0%)
CONSTIPATION	2 (2.0%)	1 (1.0%)
ABNORMAL DREAMS	2 (2.0%)	0
CONCENTRATION IMPAIRED	2 (2.0%)	0
CYSTITIS	2 (2.0%)	0
MYOCLONUS	2 (2.0%)	0
PURPURA	2 (2.0%)	0
URINATION IMPAIRED	2 (2.0%)	0
URTICARIA	2 (2.0%)	0
YAWN	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=101)	Treatment Group: Placebo (N=102)
ANXIETY	1 (1.0%)	3 (2.9%)
FUNGAL DERMATITIS	1 (1.0%)	2 (2.0%)
ARTHRALGIA	1 (1.0%)	1 (1.0%)
HAEMATURIA	1 (1.0%)	1 (1.0%)
MYALGIA	1 (1.0%)	1 (1.0%)
RASH	1 (1.0%)	1 (1.0%)
TOOTH DISORDER	1 (1.0%)	1 (1.0%)
ULCERATIVE STOMATITIS	1 (1.0%)	1 (1.0%)
URINARY FREQUENCY	1 (1.0%)	1 (1.0%)
URINARY TRACT INFECTION	1 (1.0%)	1 (1.0%)
ABNORMAL VISION	1 (1.0%)	0
ANEMIA	1 (1.0%)	0
BACK PAIN	1 (1.0%)	0
CARDIAC DISORDERS	1 (1.0%)	0
CONFUSION	1 (1.0%)	0
CONJUNCTIVITIS	1 (1.0%)	0
ERYTHROCYTES ABNORMAL	1 (1.0%)	0
HERPES SIMPLEX	1 (1.0%)	0
HOSTILITY	1 (1.0%)	0
INCREASED APPETITE	1 (1.0%)	0
MELENA	1 (1.0%)	0
MYDRIASIS	1 (1.0%)	0
PNEUMONIA	1 (1.0%)	0
PYELONEPHRITIS	1 (1.0%)	0
PYURIA	1 (1.0%)	0
SKIN HYPERTROPHY	1 (1.0%)	0
THROMBOCYTHEMIA	1 (1.0%)	0
URINARY RETENTION	1 (1.0%)	0
WEIGHT LOSS	1 (1.0%)	0
ALBUMINURIA	0	3 (2.9%)
BRONCHITIS	0	2 (2.0%)
LEUKOPENIA	0	2 (2.0%)
MIGRAINE	0	2 (2.0%)
WITHDRAWAL SYNDROME	0	2 (2.0%)
EAR PAIN	0	1 (1.0%)
GASTRITIS	0	1 (1.0%)
GASTROENTERITIS	0	1 (1.0%)
HERPES ZOSTER	0	1 (1.0%)
HYPONATREMIA	0	1 (1.0%)
KETOSIS	0	1 (1.0%)
LARYNX DISORDER	0	1 (1.0%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.0%)
OTITIS EXTERNA	0	1 (1.0%)
PALPITATION	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=101)	Treatment Group: Placebo (N=102)
PRURITUS	0	1 (1.0%)
SYNCOPE	0	1 (1.0%)
TACHYCARDIA	0	1 (1.0%)
THIRST	0	1 (1.0%)
TOOTH CARIES	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=55)
TOTAL	1 (1.9%)	0
IMPOTENCE	1 (1.9%)	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=48)	Treatment Group: Placebo (N=47)
TOTAL	1 (2.1%)	1 (2.1%)
MENSTRUAL DISORDER	1 (2.1%)	0
DYSMENORRHEA	0	1 (2.1%)

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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=46)	 Placebo (N=30)
TOTAL	TOTAL	9 (19.6%)	3 (10.0%)
Nervous System	TOTAL	7 (15.2%)	2 (6.7%)
	EMOTIONAL LABILITY	2 (4.3%)	1 (3.3%)
	DEPRESSION	2 (4.3%)	0
	DIZZINESS	2 (4.3%)	0
	MANIC DEPRESSIVE REACTION	1 (2.2%)	0
	NERVOUSNESS	1 (2.2%)	0
	PSYCHOSIS	1 (2.2%)	0
	SOMNOLENCE	1 (2.2%)	0
	TREMOR	1 (2.2%)	0
	AGITATION	0	1 (3.3%)
Body as a Whole	TOTAL	2 (4.3%)	0
	HEADACHE	1 (2.2%)	0
	TRAUMA	1 (2.2%)	0
Skin and Appendages	TOTAL	2 (4.3%)	0
	RASH	1 (2.2%)	0
	SWEATING	1 (2.2%)	0
Cardiovascular System	TOTAL	1 (2.2%)	0
	HYPERTENSION	1 (2.2%)	0
	TACHYCARDIA	1 (2.2%)	0
Digestive System	TOTAL	1 (2.2%)	1 (3.3%)
	NAUSEA	1 (2.2%)	1 (3.3%)
Hemic and Lymphatic System	TOTAL	1 (2.2%)	0
	ANEMIA	1 (2.2%)	0
Musculoskeletal System	TOTAL	1 (2.2%)	0
	ARTHRALGIA	1 (2.2%)	0
Respiratory System	TOTAL	1 (2.2%)	0
	RESPIRATORY DISORDER	1 (2.2%)	0
Special Senses	TOTAL	1 (2.2%)	0
	ABNORMAL VISION	1 (2.2%)	0
Urogenital System	TOTAL	0	1 (3.3%)
	GLYCOSURIA	0	1 (3.3%)

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-up Phase
By Body System
Intention-To-Treat Population Entering The Follow-Up Phase
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=17)
Body System	Preferred Term		
TOTAL	TOTAL	0	1 (5.9%)
Urogenital System	TOTAL	0	1 (5.9%)
	ABNORMAL EJACULATION	0	1 (5.9%)

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Table 15.1.1.4

Number (%) of Patients With Emergent Adverse Experiences During the Follow-up Phase
By Body System
Intention-To-Treat Population Entering The Follow-Up Phase
Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=21)	Placebo (N=13)
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=46)	 Placebo (N=30)
TOTAL	9 (19.6%)	3 (10.0%)
EMOTIONAL LABILITY	2 (4.3%)	1 (3.3%)
DEPRESSION	2 (4.3%)	0
DIZZINESS	2 (4.3%)	0
NAUSEA	1 (2.2%)	1 (3.3%)
ABNORMAL VISION	1 (2.2%)	0
ANEMIA	1 (2.2%)	0
ARTHRALGIA	1 (2.2%)	0
HEADACHE	1 (2.2%)	0
HYPERTENSION	1 (2.2%)	0
MANIC DEPRESSIVE REACTION	1 (2.2%)	0
NERVOUSNESS	1 (2.2%)	0
PSYCHOSIS	1 (2.2%)	0
RASH	1 (2.2%)	0
RESPIRATORY DISORDER	1 (2.2%)	0
SOMNOLENCE	1 (2.2%)	0
SWEATING	1 (2.2%)	0
TACHYCARDIA	1 (2.2%)	0
TRAUMA	1 (2.2%)	0
TREMOR	1 (2.2%)	0
AGITATION	0	1 (3.3%)
GLYCOSURIA	0	1 (3.3%)

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-up Phase
by Descending Order
Intention-To-Treat Population Entering The Follow-Up Phase
Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=25)	 Placebo (N=17)
TOTAL	0	1 (5.9%)
ABNORMAL EJACULATION	0	1 (5.9%)

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Table 15.1.1.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-up Phase
by Descending Order
Intention-To-Treat Population Entering The Follow-Up Phase
Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=21)	 Placebo (N=13)
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=83)	Treatment Group Placebo (N=73)
TOTAL	TOTAL	16 (19.3%)	13 (17.8%)
Nervous System	TOTAL	8 (9.6%)	4 (5.5%)
	EMOTIONAL LABILITY	3 (3.6%)	1 (1.4%)
	DEPRESSION	3 (3.6%)	0
	DIZZINESS	2 (2.4%)	0
	NERVOUSNESS	2 (2.4%)	0
	SOMNOLENCE	1 (1.2%)	1 (1.4%)
	MANIC DEPRESSIVE REACTION	1 (1.2%)	0
	PSYCHOSIS	1 (1.2%)	0
	TREMOR	1 (1.2%)	0
	AGITATION	0	1 (1.4%)
	ANXIETY	0	1 (1.4%)
	HYPERKINESIA	0	1 (1.4%)
	WITHDRAWAL SYNDROME	0	1 (1.4%)
Body as a Whole	TOTAL	4 (4.8%)	2 (2.7%)
	HEADACHE	1 (1.2%)	1 (1.4%)
	ALLERGIC REACTION	1 (1.2%)	0
	INFECTION	1 (1.2%)	0
	TRAUMA	1 (1.2%)	0
	ASTHENIA	0	1 (1.4%)
Digestive System	TOTAL	2 (2.4%)	3 (4.1%)
	NAUSEA	1 (1.2%)	2 (2.7%)
	CONSTIPATION	1 (1.2%)	0
	DIARRHEA	0	1 (1.4%)
Hemic and Lymphatic System	TOTAL	2 (2.4%)	0
	ANEMIA	1 (1.2%)	0
	THROMBOCYTHEMIA	1 (1.2%)	0
Respiratory System	TOTAL	2 (2.4%)	4 (5.5%)
	RESPIRATORY DISORDER	1 (1.2%)	1 (1.4%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
By Body System
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=83)	Placebo (N=73)
Respiratory System	PHARYNGITIS	1 (1.2%)	0
	BRONCHITIS	0	1 (1.4%)
	COUGH INCREASED	0	1 (1.4%)
	RHINITIS	0	1 (1.4%)
Skin and Appendages	TOTAL	2 (2.4%)	0
	RASH	1 (1.2%)	0
	SWEATING	1 (1.2%)	0
Special Senses	TOTAL	2 (2.4%)	0
	ABNORMAL VISION	1 (1.2%)	0
	OTITIS MEDIA	1 (1.2%)	0
Cardiovascular System	TOTAL	1 (1.2%)	2 (2.7%)
	TACHYCARDIA	1 (1.2%)	1 (1.4%)
	HYPERTENSION	1 (1.2%)	0
	PALPITATION	0	1 (1.4%)
	SYNCOPE	0	1 (1.4%)
Musculoskeletal System	TOTAL	1 (1.2%)	1 (1.4%)
	ARTHRALGIA	1 (1.2%)	0
	MYALGIA	0	1 (1.4%)
Urogenital System	TOTAL	0	2 (2.7%)
	GLYCOSURIA	0	1 (1.4%)
	HAEMATURIA	0	1 (1.4%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
By Body System
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=43)	Placebo (N=41)
Body System	Preferred Term		
TOTAL	TOTAL	0	1 (2.4%)
Urogenital System	TOTAL	0	1 (2.4%)
	ABNORMAL EJACULATION	0	1 (2.4%)

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Table 15.1.1.5

Number (%) of Patients With Emergent Adverse Experiences During the Taper Phase or Follow-Up Phase
By Body System
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=40)	Placebo (N=32)
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=83)	Treatment Group: Placebo (N=73)
TOTAL	16 (19.3%)	13 (17.8%)
EMOTIONAL LABILITY	3 (3.6%)	1 (1.4%)
DEPRESSION	3 (3.6%)	0
DIZZINESS	2 (2.4%)	0
NERVOUSNESS	2 (2.4%)	0
NAUSEA	1 (1.2%)	2 (2.7%)
HEADACHE	1 (1.2%)	1 (1.4%)
RESPIRATORY DISORDER	1 (1.2%)	1 (1.4%)
SOMNOLENCE	1 (1.2%)	1 (1.4%)
TACHYCARDIA	1 (1.2%)	1 (1.4%)
ABNORMAL VISION	1 (1.2%)	0
ALLERGIC REACTION	1 (1.2%)	0
ANEMIA	1 (1.2%)	0
ARTHRALGIA	1 (1.2%)	0
CONSTIPATION	1 (1.2%)	0
HYPERTENSION	1 (1.2%)	0
INFECTION	1 (1.2%)	0
MANIC DEPRESSIVE REACTION	1 (1.2%)	0
OTITIS MEDIA	1 (1.2%)	0
PHARYNGITIS	1 (1.2%)	0
PSYCHOSIS	1 (1.2%)	0
RASH	1 (1.2%)	0
SWEATING	1 (1.2%)	0
THROMBOCYTHEMIA	1 (1.2%)	0
TRAUMA	1 (1.2%)	0
TREMOR	1 (1.2%)	0
AGITATION	0	1 (1.4%)
ANXIETY	0	1 (1.4%)
ASTHENIA	0	1 (1.4%)
BRONCHITIS	0	1 (1.4%)
COUGH INCREASED	0	1 (1.4%)
DIARRHEA	0	1 (1.4%)
GLYCOSURIA	0	1 (1.4%)
HAEMATURIA	0	1 (1.4%)

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Table 15.1.1.5.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase Or Follow-Up Phase By Descending Order
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=83)	Treatment Group: Placebo (N=73)
HYPERKINESIA	0	1 (1.4%)
MYALGIA	0	1 (1.4%)
PALPITATION	0	1 (1.4%)
RHINITIS	0	1 (1.4%)
SYNCOPE	0	1 (1.4%)
WITHDRAWAL SYNDROME	0	1 (1.4%)

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Table 15.1.1.5.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase Or Follow-Up Phase By Descending Order
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=41)
TOTAL	0	1 (2.4%)
ABNORMAL EJACULATION	0	1 (2.4%)

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Table 15.1.1.5.X

Number (%) of Patients With Emergent Adverse Experiences Occurring in 1% or More of the Population During the Taper Phase Or Follow-Up Phase By Descending Order
Intention-To-Treat Population Entering The Taper Phase Or Follow-Up Phase
Female Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=40)	Treatment Group: Placebo (N=32)
TOTAL	0	0

Table 15.1.2: Safety Narrative for Patients who had Serious Non-Fatal Adverse Experiences

Patients With Serious Adverse Event (s) Leading to Withdrawal

PID: 701.154.25768

Protocol: 29060/701

AEGIS number: 2000019407-1

Study medication: PLACEBO

Verbatim [preferred term]: SUICIDALITY [SUICIDE ATTEMPT] (coded as Emotional Lability)

Serious Adverse Event Leading to Withdrawal: SUICIDALITY [SUICIDE ATTEMPT] (coded as Emotional Lability)

Case reference number 2000019407-1 is a clinical trial report from the double-blind study 29060/701 for major depressive disorder (MDD). This report refers to a 13-year-old white male (patient identification number 701.154.25768).

The patient had no significant medical or surgical history recorded, nor was he taking any concurrent medications. Psychiatric history (measured by K-SADS-PL interview) includes current MDD with an onset of July 1999, attention deficit disorder with an onset in January 1992, and oppositional defiant disorder with an onset in January 1998.

The patient began therapy with study medication on 21-Jun-2000. On 26-Jun-2000, 5 days later, the patient stole his parent's car and "wrecked it," and was hospitalized due to suicidal ideation. On 30-Jun-2000, the event was reported as resolved, and the patient was discharged from the hospital. It was reported that the patient was placed in a juvenile detention center. Treatment with study medication was stopped due to this event, and the patient was withdrawn from the study. The patient received the last dose of study medication on 25-Jun-2000 (Day 5).

The investigator reported the suicide attempt as moderately severe and unrelated to treatment with study medication.

Patients With Serious Adverse Event (s)

PID: 701.162.25786

Protocol: 29060/701

AEGIS number: 2000018462-1

Study medication: PRE-TREATMENT

Verbatim [preferred term]: DEPRESSION [DEPRESSION]

Case reference number 2000018462-1 is a clinical trial report from double-blind study 29060/701 for major depressive disorder (MDD). This report refers to an 11-year-old white female (patient identification number 701.162.25786).

The patient had no significant medical history or concomitant medication use. Psychiatric history (measured by K-SADS-PL) includes a current history of MDD with an onset in May 1998.

On 06-Jun-2000, prior to being randomized to study medication, the patient was hospitalized with severe depression. The patient began receiving prescription Paxil® (paroxetine) 10 mg once daily. On 09-Jun-2000, the event was reported as resolved, and the patient was discharged from the hospital.

The investigator reported the patient's depression as unrelated to treatment with study medication, as the patient had not started treatment with study medication.

On 03 June 2000, prior to hospitalization for depression, severe emotional lability (suicidal ideation) was also reported. No treatment was given for this non-serious event, and no relationship to this pre-study event was provided. The patient did not enter the study.

Patients With Serious Adverse Event (s)

PID: 701.163.25718

Protocol: 29060/701

AEGIS number: 2000018455-1

Study medication: PAROXETINE (INVESTIGATOR BROKE BLIND)

Verbatim [preferred term]: OVERDOSE {INTENTIONAL}{SYMPTOMATIC} [SUICIDE ATTEMPT] (coded as Emotional Lability); HYPERTENSION [HYPERTENSION]

Case reference number 2000018455-1 is a clinical trial report from double-blind study 29060/701 for major depressive disorder (MDD). This report refers to a 16-year-old white female (patient identification number 701.163.25718).

The patient's current medical history included trace leukocytes on urine dipstick and an allergy to bee stings. There was no reported use of concomitant medication. Psychiatric history (measured by K-SADS-PL interview) includes a current history of MDD with an onset in December 1998. No other psychiatric disorders were identified.

The patient received the first dose of study medication on 05 May 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to the highest dose of 50 mg on 01 June 2000. On 14-Jun-2000, the patient received the last dose of study medication. She withdrew from the study that day due to lack of efficacy.

The patient claimed to have ingested 100 tablets of the taper study medication at 9:30 PM on 15 June 2000, after a fight with her mother. At 4:30 AM the next morning (16 June 2000), the patient informed her mother, who then brought the patient to an emergency room. The patient reportedly felt "shaky" since 1:00 AM. The emergency room doctor stated that the patient "looked okay," but was "slightly tachycardic" with a pulse of 100. The patient was also slightly diaphoretic, with a blood pressure of 140/104. The emergency room physician contacted a poison control center, which advised against lavaging as "too much time had passed." The blind was not initially broken by the emergency room doctor. A urine drug screen was administered, which was found to be negative for approximately 700 compounds including paroxetine and other

PID: 701.163.25718 (continued)

"antidepressants." The drug screen was positive for caffeine. The patient was referred to an inpatient psychiatric unit. However, the psychiatric unit would not admit the patient until she was "medically stable," and insisted that the blind be broken prior to her admission. At 10:05 AM, the investigator broke the blind, and the study medication was determined to be active paroxetine 10 mg. Investigator was asked to explain why the patient did not test positive for paroxetine, but no further information was provided. At 10:10 AM, the patient's blood pressure came down to 122/80, but she was dizzy on standing and had blurred vision. The patient remained in the emergency room for several hours until she was completely asymptomatic. The patient was later admitted to the inpatient psychiatry unit.

The investigator reported the overdose and hypertension to be serious or a significant hazard, contraindication, side effect or precaution, and to be related to treatment with the study medication.

No explanation as to why the patient did not test positive for paroxetine on Day 40 after the patient had reportedly having taken one gram of paroxetine. The possibility that the patient did not actually ingest 100 tablets of paroxetine can not be discounted. Furthermore, the serum concentration of paroxetine had been 9.05 g/mL for the Week 4 PK sample.

In addition to and previous to the events described above, several other non-serious adverse events were reported. On 13 May 2000 (Day 9), the patient experienced moderately severe insomnia, which resolved without treatment in 9 days. Beginning 01 June 2000 (Day 28), the patient experienced mild sinusitis and increased cough. Both of these events continued beyond the end of the study.

Patients With Laboratory Values of Potential Clinical Concern

PID: 701.180.25639

Protocol: 29060/701

AEGIS number: 2000018664-1

Study medication: PAROXETINE

Verbatim [preferred term]: OVERDOSE {INTENTIONAL} [SUICIDE ATTEMPT] (coded as Emotional Lability; ARM LACERATIONS [INJURY] (coded as Trauma)

Serious Adverse Event Leading to Withdrawal: OVERDOSE {INTENTIONAL} [SUICIDE ATTEMPT] (coded as Emotional Lability; ARM LACERATIONS [INJURY] (coded as Trauma)

Laboratory Value of Potential Clinical Concern: Decreased hematocrit

Case reference number 2000018664-1 is a clinical trial report from double-blind study 29060/701 for major depressive disorder (MDD). This report refers to a 15-year-old white female (patient identification number 701.180.25639).

The patient's previous medical history included sinus headaches. The patient’s current/active medical history includes migraines, allergies to Ginseng gum and Joy dish soap, and insomnia. Concomitant medications included Motrin® (ibuprofen) and Excedrin® (acetylsalicylic acid/paracetamol/caffeine) for headache/migraine headache. Psychiatric history (measured by K-SADS-PL interview) included current MDD with an onset in April 1997. No other psychiatric disorders were identified.

PID: 701.180.25639 (continued)

The patient began receiving treatment with study medication on 28-Apr-2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to the highest dose of 30 mg on 18 May 2000. On 17-Jun-2000 (Day 51), the patient received the last dose of study medication. On 19-Jun-2000 (Day 53), two days after the last dose, the patient took 12 Extra Strength Tylenol® (paracetamol) and half a bottle of Tylenol Cold® tablets (chlorpheniramine/pseudoephedrine HCl/dextromethorphan/acetaminophen), and she also cut open her arm. The patient was hospitalized, placed in an intensive care unit, and underwent a stomach lavage. The patient was expected to be transferred to a psychiatric hospital. The patient was found to have low potassium and hemoglobin values. Treatment included prescription Paxil® (paroxetine/dose unknown), trazodone, and an iron supplement. The patient was considered withdrawn from the study because of this event. The overdose was reported to have resolved on 19-Jun-2000, and the arm lacerations was reported to have resolved in Jul-2000. The investigator reported the overdose and severe arm lacerations as unrelated to treatment with study medication, and probably associated with the condition under the study.

In addition to the serious adverse events described above, numerous other non-serious events were reported during the study. The patient experienced mild dry mouth and mild hyperkinesias on Day 3, mild increased cough and mild pharyngitis on Day 4, moderate fatigue on Day 8 and mild fatigue on Day 21, mild fever on Day 4, mild weight loss on Day 14, mild increased epistaxis on Day 15, and moderately severe dizziness and mild tremor on Day 35. No treatment was given for any except headache (Day 8). Fever, increased cough and pharyngitis were considered to be unrelated to treatment with study medication; all other events were considered to be possibly related to treatment with study medication.

Screening laboratory assessments were performed at Screening (Day –8). All laboratory values were within normal limits with the exception of slightly decreased hemoglobin of 116 G/L (normal: 120 – 160 G/L), a slightly decreased alkaline phosphatase of 58 IU/L (normal: 60 – 350 IU/L), and hematocrit of 34.9% (normal: 36 – 49%). The hematocrit value met the level of potential clinical concern. No follow-up laboratory assessments were provided.

Patients With Serious Adverse Event (s)

Patients With Serious Adverse Event (s) Leading to Withdrawal

PID: 701.182.25818

Protocol: 29060/701

AEGIS number: 2000035010-1

Study medication: PAROXETINE

Verbatim [preferred term]: EXACERBATION OF DEPRESSIVE SYMPTOMS [DEPRESSION]

Serious Adverse Event leading to Withdrawal: EXACERBATION OF DEPRESSIVE SYMPTOMS [DEPRESSION]

Case reference number 2000035010-1 is a clinical trial report from double-blind study 29060/701 for major depressive disorder (MDD). This report refers to a 9-year-old white male (patient identification number 701.182.25818).

The patient had no significant medical history. Psychiatric history (measured by K-SADS-PL interview) includes previous and current history of MDD with an onset in January 2000. No other psychiatric disorders were identified. Prior medication included paracetamol (Children's Tylenol®) for flu (Day –12). There was no reported use of concomitant medication.

The patient began receiving treatment with study medication at a dose of 10 mg/day, on 21-Nov-2000. On 30-Nov-2000, the patient took the last dose of study medication. On 02-Dec-2000, 2 days after the last dose, the patient was admitted to the hospital for an exacerbation of depressive symptoms. On 11-Dec-2000, the event was reported as resolved.

The investigator reported the severe exacerbation of depressive symptoms as unrelated to treatment with study medication, and associated with the patient's history of depression. The event resulted in withdrawal of the patient from the study.

Patients With Serious Adverse Event (s)

PID: 701.183.27620

Protocol: 29060/701

AEGIS number: 2000028504-1

Study medication: PAROXETINE

Verbatim [preferred term]: SUICIDAL IDEATION [SUICIDE ATTEMPT] (coded as Emotional Lability)

Case reference number 2000028504-1 is a clinical trial report from a double-blind study 29060/701 for major depressive disorder (MDD). This report refers to a 11-year-old white female (patient identification number 701.183.27620).

The patient had no significant medical history with the exception of myopia. Psychiatric history (measured by K-SADS-PL interview) included a current history of MDD with an onset in November 1999. No other psychiatric disorders were identified. There was no recorded use of concomitant medication.

The patient began treatment with study medication on 06-Sep-2000. The patient began treatment at a dose of 10 mg/day and was titrated up to the highest dose of 20 mg on 13 September 2000. The last dose of blinded study medication was taken on 21 September 2000.

On 25-Sep-2000 (Day 20), 19 days after the first dose, and 4 days after the last dose of study medication, the patient's mother called the investigator site to report that her daughter was admitted to the hospital for suicidal ideation. The patient had stated to her mother that she wanted to hang herself from the ceiling fan. The patient's mother thought that daughter was "attention seeking." No action was reportedly taken in regard to this event, but the patient was lost to follow-up. At the time of this report, the event was ongoing.

The investigator reported this severe event to be unrelated to treatment with study medication, and associated with the patient becoming more depressed.

Patients With Serious Adverse Event (s) Leading to Withdrawal

PID: 701.185.25963

Protocol: 29060/701

AEGIS number: 2000032572-1

Study medication: PAROXETINE

Verbatim [preferred term]: ACUTE EXACERBATION OF MAJOR DEPRESSIVE DISORDER [DEPRESSION AGGRAVATED] (coded as Depression)

Serious Adverse Event Leading to Withdrawal: ACUTE EXACERBATION OF MAJOR DEPRESSIVE DISORDER [DEPRESSION AGGRAVATED] (coded as Depression)

Case reference number 2000032572-1 is a clinical trial report from double-blind study 29060/701 for major depressive disorder (MDD). This report refers to an 11-year-old black male (patient identification number 701.185.25963).

The patient's previous surgical history included tonsillectomy. The patient's current/active medical history included asthma, recurrent headaches, allergies to ibuprofen and milk, and mild bilateral gynecomastia. Psychiatric history (measured by K-SADS-PL interview) included previous and current history of MDD with an onset in February 1998, enuresis with an onset in January 1997, and encopresis with an onset in January 1997. Concomitant medications included Tylenol® (paracetamol) for right leg pain and headache, and Albuterol® (salbutamol) for asthma.

The patient began receiving treatment with study medication on 10-Oct-2000. The patient began treatment at a dose of 10 mg/day and was titrated up to the highest dose of 30 mg on 24 October 2000. The patient received the last dose of study medication on 06 November 2000 (Day 28). No reason was given for cessation of medication.

PID: 701.185.25963 (continued)

On 08-Nov-2000 (Day 30), two days later, the patient held a knife to his wrist and threatened to harm himself. The patient was hospitalized with an acute exacerbation of major depressive disorder. The patient was treated with Wellbutrin® (amfebutamone hydrochloride), and was discharged in stable condition.

The event was reported to be resolved on 13-Nov-2000. The patient was withdrawn from the study due to the event.

The investigator reported the moderately severe acute exacerbation of major depressive disorder as unrelated to treatment with study medication, and probably associated with conduct disorder.

In addition to the depressive event described above, the patient experienced a non-serious event of mild right leg pain, beginning 28 October 2000, which resolved with treatment (Tylenol®) in one day.

Patients With Serious Adverse Event (s) Leading to Withdrawal

PID: 701.185.25965

Protocol: 29060/701

AEGIS number: 2000032158-1

Study medication: PAROXETINE

Verbatim [preferred term]: EXACERBATION OF SYMPTOMS OF MAJOR DEPRESSIVE DISORDER [DEPRESSION AGGRAVATED] (coded as Depression)

Serious Adverse Event Leading to Withdrawal: EXACERBATION OF SYMPTOMS OF MAJOR DEPRESSIVE DISORDER [DEPRESSION AGGRAVATED] (coded as Depression)

Case reference number 2000032158-1 is a clinical trial report from double-blind study 29060/701 for major depressive disorder (MDD). This report refers to a 10-year-old black female (patient identification number 701.185.25965).

The patient's previous medical history included tonsillitis. The patient's current medical history included asthma, and allergies to penicillin, tomatoes, and orange juice. Psychiatric history (measured by K-SADS-PL interview) includes a previous and current history of MDD with an onset in January 2000. No other psychiatric disorders were identified. Concomitant medications included Albuterol® (salbutamol) for asthma.

The patient received the first dose of study medication on 14-Oct-2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to the highest dose of 30 mg on 27 October 2000. The last dose of study medication was taken on 02 November 2000 (Day 20).

On 02-Nov-2000 (Day 20), 19 days after the first dose, the patient was hospitalized after a 5-day history of extreme uncontrolled aggression. The patient

PID: 701.185.25965 (continued)

had been getting "out of control," with acts of aggression and violence. The patient tried to smother herself with pillows in the hospital examination room.

The patient was diagnosed with exacerbation of symptoms of major depressive disorder. Treatment with study medication was stopped due to this event, and the patient was withdrawn from the study. On 08-Nov-2000, the event resolved. The patient was treated with olanzapine (Zyprexa®) for aggressive behavior on Day 20, and with paroxetine (Paxil®) for depression on Day 21.

The investigator reported the moderately severe exacerbation of symptoms of major depressive disorder as not related to treatment with study medication, and associated with the patient's psychosocial history.

On 02 November 2000 (Week 3), the patient's pulse rate of 62 bpm reached the level of potential clinical concern. The pulse rate was 90 bpm at Week 4 and otherwise within normal limits (normal limits: 65-115 bpm) throughout the study with a range of values from 62 bpm (Week 3) to 92 bpm (Baseline). Systolic and diastolic blood pressure were within normal range throughout the study.

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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=104)	 Placebo (N=102)
TOTAL	TOTAL	6 (5.8%)	1 (1.0%)
Nervous System	TOTAL	6 (5.8%)	1 (1.0%)
	EMOTIONAL LABILITY	3 (2.9%)	1 (1.0%)
	DEPRESSION	3 (2.9%)	0
Body as a Whole	TOTAL	1 (1.0%)	0
	TRAUMA	1 (1.0%)	0
Cardiovascular System	TOTAL	1 (1.0%)	0
	HYPERTENSION	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

Body System	Preferred Term	Treatment Group: Paroxetine (N=54)	Treatment Group: Placebo (N=55)
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=50)	Placebo (N=47)
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
Gender Non Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group: Paroxetine (N=49)	Treatment Group: Placebo (N=47)
TOTAL	TOTAL	27 (55.1%)	29 (61.7%)
Body as a Whole	TOTAL	15 (30.6%)	15 (31.9%)
	HEADACHE	6 (12.2%)	4 (8.5%)
	ASTHENIA	3 (6.1%)	4 (8.5%)
	TRAUMA	3 (6.1%)	4 (8.5%)
	ABDOMINAL PAIN	3 (6.1%)	1 (2.1%)
	INFECTION	2 (4.1%)	3 (6.4%)
	FEVER	1 (2.0%)	3 (6.4%)
	PAIN	1 (2.0%)	2 (4.3%)
Digestive System	TOTAL	15 (30.6%)	11 (23.4%)
	NAUSEA	6 (12.2%)	3 (6.4%)
	DYSPEPSIA	3 (6.1%)	2 (4.3%)
	VOMITING	3 (6.1%)	0
	DRY MOUTH	2 (4.1%)	0
	DECREASED APPETITE	1 (2.0%)	2 (4.3%)
	DIARRHEA	1 (2.0%)	1 (2.1%)
	CONSTIPATION	1 (2.0%)	0
	INCREASED APPETITE	1 (2.0%)	0
	MELENA	1 (2.0%)	0
	ULCERATIVE STOMATITIS	1 (2.0%)	0
	GASTROENTERITIS	0	1 (2.1%)
	TOOTH CARIES	0	1 (2.1%)
	TOOTH DISORDER	0	1 (2.1%)
Respiratory System	TOTAL	10 (20.4%)	14 (29.8%)
	RESPIRATORY DISORDER	5 (10.2%)	7 (14.9%)
	RHINITIS	3 (6.1%)	3 (6.4%)
	COUGH INCREASED	2 (4.1%)	1 (2.1%)
	SINUSITIS	2 (4.1%)	0
	EPISTAXIS	1 (2.0%)	0
	YAWN	1 (2.0%)	0
	PHARYNGITIS	0	4 (8.5%)
	ASTHMA	0	1 (2.1%)
Nervous System	TOTAL	7 (14.3%)	3 (6.4%)
	INSOMNIA	3 (6.1%)	0
	DIZZINESS	2 (4.1%)	1 (2.1%)
	CONCENTRATION IMPAIRED	1 (2.0%)	0
	EMOTIONAL LABILITY	1 (2.0%)	0
	HYPERKINESIA	1 (2.0%)	0
	MYOCLONUS	1 (2.0%)	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
Gender Non Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group: Paroxetine (N=49)	Treatment Group: Placebo (N=47)
Nervous System	TREMOR	1 (2.0%)	0
	SOMNOLENCE	0	2 (4.3%)
Urogenital System	TOTAL	4 (8.2%)	3 (6.4%)
	HAEMATURIA	1 (2.0%)	0
	URINARY FREQUENCY	1 (2.0%)	0
	URINARY RETENTION	1 (2.0%)	0
	URINATION IMPAIRED	1 (2.0%)	0
	ALBUMINURIA	0	3 (6.4%)
Skin and Appendages	TOTAL	2 (4.1%)	4 (8.5%)
	FUNGAL DERMATITIS	1 (2.0%)	1 (2.1%)
	HERPES SIMPLEX	1 (2.0%)	0
	HERPES ZOSTER	0	1 (2.1%)
	PRURITUS	0	1 (2.1%)
	RASH	0	1 (2.1%)
Cardiovascular System	TOTAL	1 (2.0%)	0
	CARDIAC DISORDERS	1 (2.0%)	0
Hemic and Lymphatic System	TOTAL	1 (2.0%)	0
	ERYTHROCYTES ABNORMAL	1 (2.0%)	0
Metabolic and Nutritional Disorders	TOTAL	0	3 (6.4%)
	HYPONATREMIA	0	1 (2.1%)
	KETOSIS	0	1 (2.1%)
	THIRST	0	1 (2.1%)
Special Senses	TOTAL	0	2 (4.3%)
	OTITIS EXTERNA	0	1 (2.1%)
	OTITIS MEDIA	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 : Children
Gender Non Specific Adverse Experiences
Intensity : Moderate

Body System	Preferred Term	Treatment Group Paroxetine (N=49)	 Placebo (N=47)
TOTAL	TOTAL	19 (38.8%)	11 (23.4%)
Body as a Whole	TOTAL	8 (16.3%)	7 (14.9%)
	HEADACHE	4 (8.2%)	4 (8.5%)
	INFECTION	3 (6.1%)	2 (4.3%)
	FEVER	2 (4.1%)	0
	TRAUMA	1 (2.0%)	2 (4.3%)
	ABDOMINAL PAIN	1 (2.0%)	1 (2.1%)
	ALLERGIC REACTION	0	1 (2.1%)
Nervous System	TOTAL	5 (10.2%)	1 (2.1%)
	DEPRESSION	2 (4.1%)	1 (2.1%)
	AGITATION	2 (4.1%)	0
	NERVOUSNESS	1 (2.0%)	1 (2.1%)
	ABNORMAL DREAMS	1 (2.0%)	0
	ANXIETY	0	1 (2.1%)
Respiratory System	TOTAL	5 (10.2%)	4 (8.5%)
	COUGH INCREASED	1 (2.0%)	2 (4.3%)
	SINUSITIS	1 (2.0%)	2 (4.3%)
	EPISTAXIS	1 (2.0%)	0
	PHARYNGITIS	1 (2.0%)	0
	PNEUMONIA	1 (2.0%)	0
	BRONCHITIS	0	1 (2.1%)
	RESPIRATORY DISORDER	0	1 (2.1%)
Digestive System	TOTAL	3 (6.1%)	2 (4.3%)
	DIARRHEA	2 (4.1%)	0
	DECREASED APPETITE	1 (2.0%)	0
	ULCERATIVE STOMATITIS	0	1 (2.1%)
	VOMITING	0	1 (2.1%)
Skin and Appendages	TOTAL	3 (6.1%)	0
	HERPES SIMPLEX	1 (2.0%)	0
	SWEATING	1 (2.0%)	0
	URTICARIA	1 (2.0%)	0
Hemic and Lymphatic System	TOTAL	2 (4.1%)	1 (2.1%)
	ANEMIA	1 (2.0%)	0
	PURPURA	1 (2.0%)	0
	LEUKOPENIA	0	1 (2.1%)
Cardiovascular System	TOTAL	1 (2.0%)	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 : Children
Gender Non Specific Adverse Experiences
Intensity : Moderate

Body System	Preferred Term	Treatment Group: Paroxetine (N=49)	Treatment Group: Placebo (N=47)
Cardiovascular System	VASODILATATION	1 (2.0%)	0
	MIGRAINE	0	1 (2.1%)
Musculoskeletal System	TOTAL	1 (2.0%)	0
	ARTHRALGIA	1 (2.0%)	0
Special Senses	TOTAL	1 (2.0%)	0
	ABNORMAL VISION	1 (2.0%)	0
Urogenital System	TOTAL	0	1 (2.1%)
	URINARY TRACT INFECTION	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 : Children
Gender Non Specific Adverse Experiences
Intensity : Severe

Body System	Preferred Term	Treatment Group: Paroxetine (N=49)	Treatment Group: Placebo (N=47)
TOTAL	TOTAL	4 (8.2%)	1 (2.1%)
Body as a Whole	TOTAL	2 (4.1%)	0
	TRAUMA	2 (4.1%)	0
Nervous System	TOTAL	2 (4.1%)	0
	HOSTILITY	1 (2.0%)	0
	NERVOUSNESS	1 (2.0%)	0
Cardiovascular System	TOTAL	0	1 (2.1%)
	MIGRAINE	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 : Children
Male Specific Adverse Experiences
Intensity : Mild

		Treatment Group	
		Paroxetine (N=26)	Placebo (N=29)
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
Male Specific Adverse Experiences
Intensity : Moderate

		Treatment Group	
		Paroxetine (N=26)	Placebo (N=29)
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
Male Specific Adverse Experiences
Intensity : Severe

		Treatment Group	
		Paroxetine (N=26)	Placebo (N=29)
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
Female Specific Adverse Experiences
Intensity : Mild

		Treatment Group	
		Paroxetine (N=23)	Placebo (N=18)
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
Female Specific Adverse Experiences
Intensity : Moderate

		Treatment Group	
		Paroxetine (N=23)	Placebo (N=18)
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
Female Specific Adverse Experiences
Intensity : Severe

		Treatment Group	
		Paroxetine (N=23)	Placebo (N=18)
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
Gender Non Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group: Paroxetine (N=52)	Treatment Group: Placebo (N=55)
TOTAL	TOTAL	30 (57.7%)	28 (50.9%)
Body as a Whole	TOTAL	16 (30.8%)	14 (25.5%)
	TRAUMA	6 (11.5%)	1 (1.8%)
	HEADACHE	4 (7.7%)	8 (14.5%)
	FEVER	4 (7.7%)	1 (1.8%)
	ASTHENIA	3 (5.8%)	3 (5.5%)
	INFECTION	2 (3.8%)	0
	PAIN	2 (3.8%)	0
	ALLERGIC REACTION	1 (1.9%)	2 (3.6%)
	BACK PAIN	1 (1.9%)	0
	ABDOMINAL PAIN	0	1 (1.8%)
Nervous System	TOTAL	12 (23.1%)	9 (16.4%)
	SOMNOLENCE	5 (9.6%)	4 (7.3%)
	NERVOUSNESS	3 (5.8%)	2 (3.6%)
	INSOMNIA	3 (5.8%)	1 (1.8%)
	HYPERKINESIA	2 (3.8%)	0
	TREMOR	2 (3.8%)	0
	ABNORMAL DREAMS	1 (1.9%)	0
	DIZZINESS	1 (1.9%)	0
	MYOCLONUS	1 (1.9%)	0
	ANXIETY	0	1 (1.8%)
	EMOTIONAL LABILITY	0	1 (1.8%)
	WITHDRAWAL SYNDROME	0	1 (1.8%)
Respiratory System	TOTAL	11 (21.2%)	5 (9.1%)
	RESPIRATORY DISORDER	5 (9.6%)	2 (3.6%)
	PHARYNGITIS	4 (7.7%)	0
	SINUSITIS	3 (5.8%)	2 (3.6%)
	COUGH INCREASED	2 (3.8%)	0
	RHINITIS	2 (3.8%)	0
	EPISTAXIS	1 (1.9%)	0
	YAWN	1 (1.9%)	0
	LARYNX DISORDER	0	1 (1.8%)
Digestive System	TOTAL	10 (19.2%)	11 (20.0%)
	NAUSEA	5 (9.6%)	6 (10.9%)
	DIARRHEA	2 (3.8%)	1 (1.8%)
	DYSPEPSIA	2 (3.8%)	1 (1.8%)
	VOMITING	2 (3.8%)	0
	DRY MOUTH	1 (1.9%)	1 (1.8%)
	TOOTH DISORDER	1 (1.9%)	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System. Intention-To Treat Population
Age Group : Adolescents
Gender Non Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group: Paroxetine (N=52)	Treatment Group: Placebo (N=55)
Digestive System	DECREASED APPETITE	0	2 (3.6%)
	CONSTIPATION	0	1 (1.8%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.8%)
Special Senses	TOTAL	4 (7.7%)	0
	OTITIS MEDIA	2 (3.8%)	0
	CONJUNCTIVITIS	1 (1.9%)	0
	MYDRIASIS	1 (1.9%)	0
Skin and Appendages	TOTAL	3 (5.8%)	1 (1.8%)
	CONTACT DERMATITIS	2 (3.8%)	0
	SKIN HYPERTROPHY	1 (1.9%)	0
	SWEATING	1 (1.9%)	0
	FUNGAL DERMATITIS	0	1 (1.8%)
Cardiovascular System	TOTAL	1 (1.9%)	0
	VASODILATATION	1 (1.9%)	0
Metabolic and Nutritional Disorders	TOTAL	1 (1.9%)	0
	WEIGHT LOSS	1 (1.9%)	0
Musculoskeletal System	TOTAL	1 (1.9%)	0
	MYALGIA	1 (1.9%)	0
Urogenital System	TOTAL	1 (1.9%)	1 (1.8%)
	PYURIA	1 (1.9%)	0
	URINARY FREQUENCY	0	1 (1.8%)
Hemic and Lymphatic System	TOTAL	0	1 (1.8%)
	LEUKOPENIA	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 : Adolescents
Gender Non Specific Adverse Experiences
Intensity : Moderate

Body System	Preferred Term	Treatment Group: Paroxetine (N=52)	Treatment Group: Placebo (N=55)
TOTAL	TOTAL	25 (48.1%)	19 (34.5%)
Nervous System	TOTAL	16 (30.8%)	10 (18.2%)
	INSOMNIA	5 (9.6%)	6 (10.9%)
	SOMNOLENCE	5 (9.6%)	3 (5.5%)
	DIZZINESS	2 (3.8%)	0
	NERVOUSNESS	1 (1.9%)	1 (1.8%)
	AGITATION	1 (1.9%)	0
	ANXIETY	1 (1.9%)	0
	CONCENTRATION IMPAIRED	1 (1.9%)	0
	CONFUSION	1 (1.9%)	0
	HYPERKINESIA	0	1 (1.8%)
Body as a Whole	TOTAL	9 (17.3%)	9 (16.4%)
	HEADACHE	7 (13.5%)	7 (12.7%)
	ASTHENIA	2 (3.8%)	2 (3.6%)
	TRAUMA	2 (3.8%)	1 (1.8%)
	INFECTION	0	1 (1.8%)
Respiratory System	TOTAL	6 (11.5%)	3 (5.5%)
	PHARYNGITIS	3 (5.8%)	2 (3.6%)
	ASTHMA	2 (3.8%)	0
	RESPIRATORY DISORDER	1 (1.9%)	1 (1.8%)
	COUGH INCREASED	1 (1.9%)	0
Digestive System	TOTAL	5 (9.6%)	3 (5.5%)
	NAUSEA	2 (3.8%)	1 (1.8%)
	DECREASED APPETITE	2 (3.8%)	0
	VOMITING	1 (1.9%)	1 (1.8%)
	DYSPEPSIA	1 (1.9%)	0
	GASTRITIS	0	1 (1.8%)
Urogenital System	TOTAL	4 (7.7%)	0
	CYSTITIS	1 (1.9%)	0
	PYELONEPHRITIS	1 (1.9%)	0
	URINARY TRACT INFECTION	1 (1.9%)	0
	URINATION IMPAIRED	1 (1.9%)	0
Skin and Appendages	TOTAL	3 (5.8%)	0
	SWEATING	2 (3.8%)	0
	CONTACT DERMATITIS	1 (1.9%)	0
	RASH	1 (1.9%)	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System. Intention-To Treat Population
Age Group : Adolescents
Gender Non Specific Adverse Experiences
Intensity : Moderate

Body System	Preferred Term	Treatment Group Paroxetine (N=52)	 Placebo (N=55)
Special Senses	TOTAL	2 (3.8%)	2 (3.6%)
	OTITIS MEDIA	2 (3.8%)	1 (1.8%)
	EAR PAIN	0	1 (1.8%)
Cardiovascular System	TOTAL	1 (1.9%)	1 (1.8%)
	VASODILATATION	1 (1.9%)	0
	MIGRAINE	0	1 (1.8%)
Hemic and Lymphatic System	TOTAL	1 (1.9%)	0
	PURPURA	1 (1.9%)	0
Musculoskeletal System	TOTAL	0	1 (1.8%)
	ARTHRALGIA	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 : Adolescents
Gender Non Specific Adverse Experiences
Intensity : Severe

Body System	Preferred Term	Treatment Group: Paroxetine (N=52)	Treatment Group: Placebo (N=55)
TOTAL	TOTAL	4 (7.7%)	3 (5.5%)
Body as a Whole	TOTAL	2 (3.8%)	1 (1.8%)
	TRAUMA	1 (1.9%)	1 (1.8%)
	HEADACHE	1 (1.9%)	0
Skin and Appendages	TOTAL	1 (1.9%)	0
	URTICARIA	1 (1.9%)	0
Urogenital System	TOTAL	1 (1.9%)	0
	CYSTITIS	1 (1.9%)	0
Cardiovascular System	TOTAL	0	1 (1.8%)
	MIGRAINE	0	1 (1.8%)
Nervous System	TOTAL	0	1 (1.8%)
	EMOTIONAL LABILITY	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 : Adolescents
Male Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group Paroxetine (N=27)	Placebo (N=26)
TOTAL	TOTAL	1 (3.7%)	0
Urogenital System	TOTAL	1 (3.7%)	0
	IMPOTENCE	1 (3.7%)	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 : Adolescents
Male Specific Adverse Experiences
Intensity : Moderate

		Treatment Group	
		Paroxetine (N=27)	Placebo (N=26)
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
Male Specific Adverse Experiences
Intensity : Severe

		Treatment Group	
		Paroxetine (N=27)	Placebo (N=26)
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
Female Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group Paroxetine (N=25)	Placebo (N=29)
TOTAL	TOTAL	1 (4.0%)	1 (3.4%)
Urogenital System	TOTAL	1 (4.0%)	1 (3.4%)
	MENSTRUAL DISORDER	1 (4.0%)	0
	DYSMENORRHEA	0	1 (3.4%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System. Intention-To Treat Population
Age Group : Adolescents
Female Specific Adverse Experiences
Intensity : Moderate

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=29)
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
Female Specific Adverse Experiences
Intensity : Severe

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=29)
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
Gender Non Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group: Paroxetine (N=101)	Treatment Group: Placebo (N=102)
TOTAL	TOTAL	57 (56.4%)	57 (55.9%)
Body as a Whole	TOTAL	31 (30.7%)	29 (28.4%)
	HEADACHE	10 (9.9%)	12 (11.8%)
	TRAUMA	9 (8.9%)	5 (4.9%)
	ASTHENIA	6 (5.9%)	7 (6.9%)
	FEVER	5 (5.0%)	4 (3.9%)
	INFECTION	4 (4.0%)	3 (2.9%)
	ABDOMINAL PAIN	3 (3.0%)	2 (2.0%)
	PAIN	3 (3.0%)	2 (2.0%)
	ALLERGIC REACTION	1 (1.0%)	2 (2.0%)
	BACK PAIN	1 (1.0%)	0
Digestive System	TOTAL	25 (24.8%)	22 (21.6%)
	NAUSEA	11 (10.9%)	9 (8.8%)
	DYSPEPSIA	5 (5.0%)	3 (2.9%)
	VOMITING	5 (5.0%)	0
	DIARRHEA	3 (3.0%)	2 (2.0%)
	DRY MOUTH	3 (3.0%)	1 (1.0%)
	DECREASED APPETITE	1 (1.0%)	4 (3.9%)
	CONSTIPATION	1 (1.0%)	1 (1.0%)
	TOOTH DISORDER	1 (1.0%)	1 (1.0%)
	INCREASED APPETITE	1 (1.0%)	0
	MELENA	1 (1.0%)	0
	ULCERATIVE STOMATITIS	1 (1.0%)	0
	GASTROENTERITIS	0	1 (1.0%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.0%)
	TOOTH CARIES	0	1 (1.0%)
Respiratory System	TOTAL	21 (20.8%)	19 (18.6%)
	RESPIRATORY DISORDER	10 (9.9%)	9 (8.8%)
	RHINITIS	5 (5.0%)	3 (2.9%)
	SINUSITIS	5 (5.0%)	2 (2.0%)
	PHARYNGITIS	4 (4.0%)	4 (3.9%)
	COUGH INCREASED	4 (4.0%)	1 (1.0%)
	EPISTAXIS	2 (2.0%)	0
	YAWN	2 (2.0%)	0
	ASTHMA	0	1 (1.0%)
	LARYNX DISORDER	0	1 (1.0%)
Nervous System	TOTAL	19 (18.8%)	12 (11.8%)
	INSOMNIA	6 (5.9%)	1 (1.0%)
	SOMNOLENCE	5 (5.0%)	6 (5.9%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System. Intention-To Treat Population
Age Group : Total
Gender Non Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group: Paroxetine (N=101)	Treatment Group: Placebo (N=102)
Nervous System	NERVOUSNESS	3 (3.0%)	2 (2.0%)
	DIZZINESS	3 (3.0%)	1 (1.0%)
	HYPERKINESIA	3 (3.0%)	0
	TREMOR	3 (3.0%)	0
	MYOCLONUS	2 (2.0%)	0
	EMOTIONAL LABILITY	1 (1.0%)	1 (1.0%)
	ABNORMAL DREAMS	1 (1.0%)	0
	CONCENTRATION IMPAIRED	1 (1.0%)	0
	ANXIETY	0	1 (1.0%)
	WITHDRAWAL SYNDROME	0	1 (1.0%)
Skin and Appendages	TOTAL	5 (5.0%)	5 (4.9%)
	CONTACT DERMATITIS	2 (2.0%)	0
	FUNGAL DERMATITIS	1 (1.0%)	2 (2.0%)
	HERPES SIMPLEX	1 (1.0%)	0
	SKIN HYPERTROPHY	1 (1.0%)	0
	SWEATING	1 (1.0%)	0
	HERPES ZOSTER	0	1 (1.0%)
	PRURITUS	0	1 (1.0%)
	RASH	0	1 (1.0%)
Urogenital System	TOTAL	5 (5.0%)	4 (3.9%)
	URINARY FREQUENCY	1 (1.0%)	1 (1.0%)
	HAEMATURIA	1 (1.0%)	0
	PYURIA	1 (1.0%)	0
	URINARY RETENTION	1 (1.0%)	0
	URINATION IMPAIRED	1 (1.0%)	0
	ALBUMINURIA	0	3 (2.9%)
Special Senses	TOTAL	4 (4.0%)	2 (2.0%)
	OTITIS MEDIA	2 (2.0%)	1 (1.0%)
	CONJUNCTIVITIS	1 (1.0%)	0
	MYDRIASIS	1 (1.0%)	0
	OTITIS EXTERNA	0	1 (1.0%)
Cardiovascular System	TOTAL	2 (2.0%)	0
	CARDIAC DISORDERS	1 (1.0%)	0
	VASODILATATION	1 (1.0%)	0
Hemic and Lymphatic System	TOTAL	1 (1.0%)	1 (1.0%)
	ERYTHROCYTES ABNORMAL	1 (1.0%)	0
	LEUKOPENIA	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
Gender Non Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group Paroxetine (N=101)	Placebo (N=102)
Metabolic and Nutritional Disorders	TOTAL	1 (1.0%)	3 (2.9%)
	WEIGHT LOSS	1 (1.0%)	0
	HYPONATREMIA	0	1 (1.0%)
	KETOSIS	0	1 (1.0%)
	THIRST	0	1 (1.0%)
Musculoskeletal System	TOTAL	1 (1.0%)	0
	MYALGIA	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
Gender Non Specific Adverse Experiences
Intensity : Moderate

Body System	Preferred Term	Treatment Group: Paroxetine (N=101)	Treatment Group: Placebo (N=102)
TOTAL	TOTAL	44 (43.6%)	30 (29.4%)
Nervous System	TOTAL	21 (20.8%)	11 (10.8%)
	INSOMNIA	5 (5.0%)	6 (5.9%)
	SOMNOLENCE	5 (5.0%)	3 (2.9%)
	AGITATION	3 (3.0%)	0
	NERVOUSNESS	2 (2.0%)	2 (2.0%)
	DEPRESSION	2 (2.0%)	1 (1.0%)
	DIZZINESS	2 (2.0%)	0
	ANXIETY	1 (1.0%)	1 (1.0%)
	ABNORMAL DREAMS	1 (1.0%)	0
	CONCENTRATION IMPAIRED	1 (1.0%)	0
	CONFUSION	1 (1.0%)	0
	HYPERKINESIA	0	1 (1.0%)
Body as a Whole	TOTAL	17 (16.8%)	16 (15.7%)
	HEADACHE	11 (10.9%)	11 (10.8%)
	INFECTION	3 (3.0%)	3 (2.9%)
	TRAUMA	3 (3.0%)	3 (2.9%)
	ASTHENIA	2 (2.0%)	2 (2.0%)
	FEVER	2 (2.0%)	0
	ABDOMINAL PAIN	1 (1.0%)	1 (1.0%)
	ALLERGIC REACTION	0	1 (1.0%)
Respiratory System	TOTAL	11 (10.9%)	7 (6.9%)
	PHARYNGITIS	4 (4.0%)	2 (2.0%)
	COUGH INCREASED	2 (2.0%)	2 (2.0%)
	ASTHMA	2 (2.0%)	0
	RESPIRATORY DISORDER	1 (1.0%)	2 (2.0%)
	SINUSITIS	1 (1.0%)	2 (2.0%)
	EPISTAXIS	1 (1.0%)	0
	PNEUMONIA	1 (1.0%)	0
	BRONCHITIS	0	1 (1.0%)
Digestive System	TOTAL	8 (7.9%)	5 (4.9%)
	DECREASED APPETITE	3 (3.0%)	0
	NAUSEA	2 (2.0%)	1 (1.0%)
	DIARRHEA	2 (2.0%)	0
	VOMITING	1 (1.0%)	2 (2.0%)
	DYSPEPSIA	1 (1.0%)	0
	GASTRITIS	0	1 (1.0%)
	ULCERATIVE STOMATITIS	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
Gender Non Specific Adverse Experiences
Intensity : Moderate

Body System	Preferred Term	Treatment Group: Paroxetine (N=101)	Treatment Group: Placebo (N=102)
Skin and Appendages	TOTAL	6 (5.9%)	0
	SWEATING	3 (3.0%)	0
	CONTACT DERMATITIS	1 (1.0%)	0
	HERPES SIMPLEX	1 (1.0%)	0
	RASH	1 (1.0%)	0
	URTICARIA	1 (1.0%)	0
Urogenital System	TOTAL	4 (4.0%)	1 (1.0%)
	URINARY TRACT INFECTION	1 (1.0%)	1 (1.0%)
	CYSTITIS	1 (1.0%)	0
	PYELONEPHRITIS	1 (1.0%)	0
	URINATION IMPAIRED	1 (1.0%)	0
Hemic and Lymphatic System	TOTAL	3 (3.0%)	1 (1.0%)
	PURPURA	2 (2.0%)	0
	ANEMIA	1 (1.0%)	0
	LEUKOPENIA	0	1 (1.0%)
Special Senses	TOTAL	3 (3.0%)	2 (2.0%)
	OTITIS MEDIA	2 (2.0%)	1 (1.0%)
	ABNORMAL VISION	1 (1.0%)	0
	EAR PAIN	0	1 (1.0%)
Cardiovascular System	TOTAL	2 (2.0%)	2 (2.0%)
	VASODILATATION	2 (2.0%)	0
	MIGRAINE	0	2 (2.0%)
Musculoskeletal System	TOTAL	1 (1.0%)	1 (1.0%)
	ARTHRALGIA	1 (1.0%)	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
Gender Non Specific Adverse Experiences
Intensity : Severe

Body System	Preferred Term	Treatment Group: Paroxetine (N=101)	Treatment Group: Placebo (N=102)
TOTAL	TOTAL	8 (7.9%)	4 (3.9%)
Body as a Whole	TOTAL	4 (4.0%)	1 (1.0%)
	TRAUMA	3 (3.0%)	1 (1.0%)
	HEADACHE	1 (1.0%)	0
Nervous System	TOTAL	2 (2.0%)	1 (1.0%)
	HOSTILITY	1 (1.0%)	0
	NERVOUSNESS	1 (1.0%)	0
	EMOTIONAL LABILITY	0	1 (1.0%)
Skin and Appendages	TOTAL	1 (1.0%)	0
	URTICARIA	1 (1.0%)	0
Urogenital System	TOTAL	1 (1.0%)	0
	CYSTITIS	1 (1.0%)	0
Cardiovascular System	TOTAL	0	2 (2.0%)
	MIGRAINE	0	2 (2.0%)

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System. Intention-To Treat Population
Age Group : Total
Male Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group: Paroxetine (N=53)	Treatment Group: Placebo (N=55)
TOTAL	TOTAL	1 (1.9%)	0
Urogenital System	TOTAL	1 (1.9%)	0
	IMPOTENCE	1 (1.9%)	0

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Table 15.1.3.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Intensity
By Body System. Intention-To Treat Population
Age Group : Total
Male Specific Adverse Experiences
Intensity : Moderate

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=55)
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
Male Specific Adverse Experiences
Intensity : Severe

		Treatment Group	
		Paroxetine (N=53)	Placebo (N=55)
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
Female Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group Paroxetine (N=48)	Placebo (N=47)
TOTAL	TOTAL	1 (2.1%)	1 (2.1%)
Urogenital System	TOTAL	1 (2.1%)	1 (2.1%)
	MENSTRUAL DISORDER	1 (2.1%)	0
	DYSMENORRHEA	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 : Total
Female Specific Adverse Experiences
Intensity : Moderate

		Treatment Group	
		Paroxetine (N=48)	Placebo (N=47)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

BRL 29060 - 701

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
Female Specific Adverse Experiences
Intensity : Severe

		Treatment Group	
		Paroxetine (N=48)	Placebo (N=47)
Body System	Preferred Term		
TOTAL	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
Gender Non Specific Adverse Experiences
Intensity : Mild

Preferred Term	Treatment Group Paroxetine (N=49)	 Placebo (N=47)
TOTAL	27 (55.1%)	29 (61.7%)
HEADACHE	6 (12.2%)	4 (8.5%)
NAUSEA	6 (12.2%)	3 (6.4%)
RESPIRATORY DISORDER	5 (10.2%)	7 (14.9%)
ASTHENIA	3 (6.1%)	4 (8.5%)
TRAUMA	3 (6.1%)	4 (8.5%)
RHINITIS	3 (6.1%)	3 (6.4%)
DYSPEPSIA	3 (6.1%)	2 (4.3%)
ABDOMINAL PAIN	3 (6.1%)	1 (2.1%)
INSOMNIA	3 (6.1%)	0
VOMITING	3 (6.1%)	0
INFECTION	2 (4.1%)	3 (6.4%)
COUGH INCREASED	2 (4.1%)	1 (2.1%)
DIZZINESS	2 (4.1%)	1 (2.1%)
DRY MOUTH	2 (4.1%)	0
SINUSITIS	2 (4.1%)	0
FEVER	1 (2.0%)	3 (6.4%)
DECREASED APPETITE	1 (2.0%)	2 (4.3%)
PAIN	1 (2.0%)	2 (4.3%)
DIARRHEA	1 (2.0%)	1 (2.1%)
FUNGAL DERMATITIS	1 (2.0%)	1 (2.1%)
CARDIAC DISORDERS	1 (2.0%)	0
CONCENTRATION IMPAIRED	1 (2.0%)	0
CONSTIPATION	1 (2.0%)	0
EMOTIONAL LABILITY	1 (2.0%)	0
EPISTAXIS	1 (2.0%)	0
ERYTHROCYTES ABNORMAL	1 (2.0%)	0
HAEMATURIA	1 (2.0%)	0
HERPES SIMPLEX	1 (2.0%)	0
HYPERKINESIA	1 (2.0%)	0
INCREASED APPETITE	1 (2.0%)	0
MELENA	1 (2.0%)	0
MYOCLONUS	1 (2.0%)	0
TREMOR	1 (2.0%)	0
ULCERATIVE STOMATITIS	1 (2.0%)	0
URINARY FREQUENCY	1 (2.0%)	0
URINARY RETENTION	1 (2.0%)	0
URINATION IMPAIRED	1 (2.0%)	0
YAWN	1 (2.0%)	0
PHARYNGITIS	0	4 (8.5%)
ALBUMINURIA	0	3 (6.4%)
SOMNOLENCE	0	2 (4.3%)
ASTHMA	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 : Children
Gender Non Specific Adverse Experiences
Intensity : Mild

Preferred Term	Treatment Group: Paroxetine (N=49)	Treatment Group: Placebo (N=47)
GASTROENTERITIS	0	1 (2.1%)
HERPES ZOSTER	0	1 (2.1%)
HYPONATREMIA	0	1 (2.1%)
KETOSIS	0	1 (2.1%)
OTITIS EXTERNA	0	1 (2.1%)
OTITIS MEDIA	0	1 (2.1%)
PRURITUS	0	1 (2.1%)
RASH	0	1 (2.1%)
THIRST	0	1 (2.1%)
TOOTH CARIES	0	1 (2.1%)
TOOTH DISORDER	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 : Children
Gender Non Specific Adverse Experiences
Intensity : Moderate

Preferred Term	Treatment Group Paroxetine (N=49)	 Placebo (N=47)
TOTAL	19 (38.8%)	11 (23.4%)
HEADACHE	4 (8.2%)	4 (8.5%)
INFECTION	3 (6.1%)	2 (4.3%)
DEPRESSION	2 (4.1%)	1 (2.1%)
AGITATION	2 (4.1%)	0
DIARRHEA	2 (4.1%)	0
FEVER	2 (4.1%)	0
COUGH INCREASED	1 (2.0%)	2 (4.3%)
SINUSITIS	1 (2.0%)	2 (4.3%)
TRAUMA	1 (2.0%)	2 (4.3%)
ABDOMINAL PAIN	1 (2.0%)	1 (2.1%)
NERVOUSNESS	1 (2.0%)	1 (2.1%)
ABNORMAL DREAMS	1 (2.0%)	0
ABNORMAL VISION	1 (2.0%)	0
ANEMIA	1 (2.0%)	0
ARTHRALGIA	1 (2.0%)	0
DECREASED APPETITE	1 (2.0%)	0
EPISTAXIS	1 (2.0%)	0
HERPES SIMPLEX	1 (2.0%)	0
PHARYNGITIS	1 (2.0%)	0
PNEUMONIA	1 (2.0%)	0
PURPURA	1 (2.0%)	0
SWEATING	1 (2.0%)	0
URTICARIA	1 (2.0%)	0
VASODILATATION	1 (2.0%)	0
ALLERGIC REACTION	0	1 (2.1%)
ANXIETY	0	1 (2.1%)
BRONCHITIS	0	1 (2.1%)
LEUKOPENIA	0	1 (2.1%)
MIGRAINE	0	1 (2.1%)
RESPIRATORY DISORDER	0	1 (2.1%)
ULCERATIVE STOMATITIS	0	1 (2.1%)
URINARY TRACT INFECTION	0	1 (2.1%)
VOMITING	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 : Children
Gender Non Specific Adverse Experiences
Intensity : Severe

Preferred Term	Treatment Group Paroxetine (N=49)	 Placebo (N=47)
TOTAL	4 (8.2%)	1 (2.1%)
TRAUMA	2 (4.1%)	0
HOSTILITY	1 (2.0%)	0
NERVOUSNESS	1 (2.0%)	0
MIGRAINE	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 : Children
Male Specific Adverse Experiences
Intensity : Mild

Preferred Term	Treatment Group Paroxetine (N=26)	 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 : Children
Male Specific Adverse Experiences
Intensity : Moderate

Preferred Term	Treatment Group Paroxetine (N=26)	 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 : Children
Male Specific Adverse Experiences
Intensity : Severe

Preferred Term	Treatment Group Paroxetine (N=26)	 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 : Children
Female Specific Adverse Experiences
Intensity : Mild

Preferred Term	Treatment Group Paroxetine (N=23)	 Placebo (N=18)
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
Female Specific Adverse Experiences
Intensity : Moderate

Preferred Term	Treatment Group Paroxetine (N=23)	 Placebo (N=18)
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
Female Specific Adverse Experiences
Intensity : Severe

Preferred Term	Treatment Group Paroxetine (N=23)	 Placebo (N=18)
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
Gender Non Specific Adverse Experiences
Intensity : Mild

Preferred Term	Treatment Group: Paroxetine (N=52)	Treatment Group: Placebo (N=55)
TOTAL	30 (57.7%)	28 (50.9%)
TRAUMA	6 (11.5%)	1 (1.8%)
NAUSEA	5 (9.6%)	6 (10.9%)
SOMNOLENCE	5 (9.6%)	4 (7.3%)
RESPIRATORY DISORDER	5 (9.6%)	2 (3.6%)
HEADACHE	4 (7.7%)	8 (14.5%)
FEVER	4 (7.7%)	1 (1.8%)
PHARYNGITIS	4 (7.7%)	0
ASTHENIA	3 (5.8%)	3 (5.5%)
NERVOUSNESS	3 (5.8%)	2 (3.6%)
SINUSITIS	3 (5.8%)	2 (3.6%)
INSOMNIA	3 (5.8%)	1 (1.8%)
DIARRHEA	2 (3.8%)	1 (1.8%)
DYSPEPSIA	2 (3.8%)	1 (1.8%)
CONTACT DERMATITIS	2 (3.8%)	0
COUGH INCREASED	2 (3.8%)	0
HYPERKINESIA	2 (3.8%)	0
INFECTION	2 (3.8%)	0
OTITIS MEDIA	2 (3.8%)	0
PAIN	2 (3.8%)	0
RHINITIS	2 (3.8%)	0
TREMOR	2 (3.8%)	0
VOMITING	2 (3.8%)	0
ALLERGIC REACTION	1 (1.9%)	2 (3.6%)
DRY MOUTH	1 (1.9%)	1 (1.8%)
ABNORMAL DREAMS	1 (1.9%)	0
BACK PAIN	1 (1.9%)	0
CONJUNCTIVITIS	1 (1.9%)	0
DIZZINESS	1 (1.9%)	0
EPISTAXIS	1 (1.9%)	0
MYALGIA	1 (1.9%)	0
MYDRIASIS	1 (1.9%)	0
MYOCLONUS	1 (1.9%)	0
PYURIA	1 (1.9%)	0
SKIN HYPERTROPHY	1 (1.9%)	0
SWEATING	1 (1.9%)	0
TOOTH DISORDER	1 (1.9%)	0
VASODILATATION	1 (1.9%)	0
WEIGHT LOSS	1 (1.9%)	0
YAWN	1 (1.9%)	0
DECREASED APPETITE	0	2 (3.6%)
ABDOMINAL PAIN	0	1 (1.8%)
ANXIETY	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 : Adolescents
Gender Non Specific Adverse Experiences
Intensity : Mild

Preferred Term	Treatment Group Paroxetine (N=52)	 Placebo (N=55)
CONSTIPATION	0	1 (1.8%)
EMOTIONAL LABILITY	0	1 (1.8%)
FUNGAL DERMATITIS	0	1 (1.8%)
LARYNX DISORDER	0	1 (1.8%)
LEUKOPENIA	0	1 (1.8%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.8%)
URINARY FREQUENCY	0	1 (1.8%)
WITHDRAWAL SYNDROME	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 : Adolescents

Gender Non Specific Adverse Experiences

Intensity : Moderate

Preferred Term	Treatment Group: Paroxetine (N=52)	Treatment Group: Placebo (N=55)
TOTAL	25 (48.1%)	19 (34.5%)
HEADACHE	7 (13.5%)	7 (12.7%)
INSOMNIA	5 (9.6%)	6 (10.9%)
SOMNOLENCE	5 (9.6%)	3 (5.5%)
PHARYNGITIS	3 (5.8%)	2 (3.6%)
ASTHENIA	2 (3.8%)	2 (3.6%)
NAUSEA	2 (3.8%)	1 (1.8%)
OTITIS MEDIA	2 (3.8%)	1 (1.8%)
TRAUMA	2 (3.8%)	1 (1.8%)
ASTHMA	2 (3.8%)	0
DECREASED APPETITE	2 (3.8%)	0
DIZZINESS	2 (3.8%)	0
SWEATING	2 (3.8%)	0
NERVOUSNESS	1 (1.9%)	1 (1.8%)
RESPIRATORY DISORDER	1 (1.9%)	1 (1.8%)
VOMITING	1 (1.9%)	1 (1.8%)
AGITATION	1 (1.9%)	0
ANXIETY	1 (1.9%)	0
CONCENTRATION IMPAIRED	1 (1.9%)	0
CONFUSION	1 (1.9%)	0
CONTACT DERMATITIS	1 (1.9%)	0
COUGH INCREASED	1 (1.9%)	0
CYSTITIS	1 (1.9%)	0
DYSPEPSIA	1 (1.9%)	0
PURPURA	1 (1.9%)	0
PYELONEPHRITIS	1 (1.9%)	0
RASH	1 (1.9%)	0
URINARY TRACT INFECTION	1 (1.9%)	0
URINATION IMPAIRED	1 (1.9%)	0
VASODILATATION	1 (1.9%)	0
ARTHRALGIA	0	1 (1.8%)
EAR PAIN	0	1 (1.8%)
GASTRITIS	0	1 (1.8%)
HYPERKINESIA	0	1 (1.8%)
INFECTION	0	1 (1.8%)
MIGRAINE	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 : Adolescents
Gender Non Specific Adverse Experiences
Intensity : Severe

Preferred Term	Treatment Group Paroxetine (N=52)	 Placebo (N=55)
TOTAL	4 (7.7%)	3 (5.5%)
TRAUMA	1 (1.9%)	1 (1.8%)
CYSTITIS	1 (1.9%)	0
HEADACHE	1 (1.9%)	0
URTICARIA	1 (1.9%)	0
EMOTIONAL LABILITY	0	1 (1.8%)
MIGRAINE	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 : Adolescents

Male Specific Adverse Experiences

Intensity : Mild

Preferred Term	Treatment Group Paroxetine (N=27)	Placebo (N=26)
TOTAL	1 (3.7%)	0
IMPOTENCE	1 (3.7%)	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 : Adolescents
Male Specific Adverse Experiences
Intensity : Moderate

Preferred Term	Treatment Group Paroxetine (N=27)	 Placebo (N=26)
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
Male Specific Adverse Experiences
Intensity : Severe

Preferred Term	Treatment Group Paroxetine (N=27)	 Placebo (N=26)
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
Female Specific Adverse Experiences
Intensity : Mild

Preferred Term	Treatment Group Paroxetine (N=25)	 Placebo (N=29)
TOTAL	1 (4.0%)	1 (3.4%)
MENSTRUAL DISORDER	1 (4.0%)	0
DYSMENORRHEA	0	1 (3.4%)

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase
by Intensity by Descending Order. Intention-To-Treat Population
Age Group : Adolescents
Female Specific Adverse Experiences
Intensity : Moderate

Preferred Term	Treatment Group Paroxetine (N=25)	 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
Female Specific Adverse Experiences
Intensity : Severe

Preferred Term	Treatment Group Paroxetine (N=25)	 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 : Total
Gender Non Specific Adverse Experiences
Intensity : Mild

Preferred Term	Treatment Group Paroxetine (N=101)	 Placebo (N=102)
TOTAL	57 (56.4%)	57 (55.9%)
NAUSEA	11 (10.9%)	9 (8.8%)
HEADACHE	10 (9.9%)	12 (11.8%)
RESPIRATORY DISORDER	10 (9.9%)	9 (8.8%)
TRAUMA	9 (8.9%)	5 (4.9%)
ASTHENIA	6 (5.9%)	7 (6.9%)
INSOMNIA	6 (5.9%)	1 (1.0%)
SOMNOLENCE	5 (5.0%)	6 (5.9%)
FEVER	5 (5.0%)	4 (3.9%)
DYSPEPSIA	5 (5.0%)	3 (2.9%)
RHINITIS	5 (5.0%)	3 (2.9%)
SINUSITIS	5 (5.0%)	2 (2.0%)
VOMITING	5 (5.0%)	0
PHARYNGITIS	4 (4.0%)	4 (3.9%)
INFECTION	4 (4.0%)	3 (2.9%)
COUGH INCREASED	4 (4.0%)	1 (1.0%)
ABDOMINAL PAIN	3 (3.0%)	2 (2.0%)
DIARRHEA	3 (3.0%)	2 (2.0%)
NERVOUSNESS	3 (3.0%)	2 (2.0%)
PAIN	3 (3.0%)	2 (2.0%)
DIZZINESS	3 (3.0%)	1 (1.0%)
DRY MOUTH	3 (3.0%)	1 (1.0%)
HYPERKINESIA	3 (3.0%)	0
TREMOR	3 (3.0%)	0
OTITIS MEDIA	2 (2.0%)	1 (1.0%)
CONTACT DERMATITIS	2 (2.0%)	0
EPISTAXIS	2 (2.0%)	0
MYOCLONUS	2 (2.0%)	0
YAWN	2 (2.0%)	0
DECREASED APPETITE	1 (1.0%)	4 (3.9%)
ALLERGIC REACTION	1 (1.0%)	2 (2.0%)
FUNGAL DERMATITIS	1 (1.0%)	2 (2.0%)
CONSTIPATION	1 (1.0%)	1 (1.0%)
EMOTIONAL LABILITY	1 (1.0%)	1 (1.0%)
TOOTH DISORDER	1 (1.0%)	1 (1.0%)
URINARY FREQUENCY	1 (1.0%)	1 (1.0%)
ABNORMAL DREAMS	1 (1.0%)	0
BACK PAIN	1 (1.0%)	0
CARDIAC DISORDERS	1 (1.0%)	0
CONCENTRATION IMPAIRED	1 (1.0%)	0
CONJUNCTIVITIS	1 (1.0%)	0
ERYTHROCYTES ABNORMAL	1 (1.0%)	0
HAEMATURIA	1 (1.0%)	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
Gender Non Specific Adverse Experiences
Intensity : Mild

Preferred Term	Treatment Group Paroxetine (N=101)	 Placebo (N=102)
HERPES SIMPLEX	1 (1.0%)	0
INCREASED APPETITE	1 (1.0%)	0
MELENA	1 (1.0%)	0
MYALGIA	1 (1.0%)	0
MYDRIASIS	1 (1.0%)	0
PYURIA	1 (1.0%)	0
SKIN HYPERTROPHY	1 (1.0%)	0
SWEATING	1 (1.0%)	0
ULCERATIVE STOMATITIS	1 (1.0%)	0
URINARY RETENTION	1 (1.0%)	0
URINATION IMPAIRED	1 (1.0%)	0
VASODILATATION	1 (1.0%)	0
WEIGHT LOSS	1 (1.0%)	0
ALBUMINURIA	0	3 (2.9%)
ANXIETY	0	1 (1.0%)
ASTHMA	0	1 (1.0%)
GASTROENTERITIS	0	1 (1.0%)
HERPES ZOSTER	0	1 (1.0%)
HYPONATREMIA	0	1 (1.0%)
KETOSIS	0	1 (1.0%)
LARYNX DISORDER	0	1 (1.0%)
LEUKOPENIA	0	1 (1.0%)
LIVER FUNCTION TESTS ABNORMAL	0	1 (1.0%)
OTITIS EXTERNA	0	1 (1.0%)
PRURITUS	0	1 (1.0%)
RASH	0	1 (1.0%)
THIRST	0	1 (1.0%)
TOOTH CARIES	0	1 (1.0%)
WITHDRAWAL SYNDROME	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
Gender Non Specific Adverse Experiences
Intensity : Moderate

Preferred Term	Treatment Group Paroxetine (N=101)	 Placebo (N=102)
TOTAL	44 (43.6%)	30 (29.4%)
HEADACHE	11 (10.9%)	11 (10.8%)
INSOMNIA	5 (5.0%)	6 (5.9%)
SOMNOLENCE	5 (5.0%)	3 (2.9%)
PHARYNGITIS	4 (4.0%)	2 (2.0%)
INFECTION	3 (3.0%)	3 (2.9%)
TRAUMA	3 (3.0%)	3 (2.9%)
AGITATION	3 (3.0%)	0
DECREASED APPETITE	3 (3.0%)	0
SWEATING	3 (3.0%)	0
ASTHENIA	2 (2.0%)	2 (2.0%)
COUGH INCREASED	2 (2.0%)	2 (2.0%)
NERVOUSNESS	2 (2.0%)	2 (2.0%)
DEPRESSION	2 (2.0%)	1 (1.0%)
NAUSEA	2 (2.0%)	1 (1.0%)
OTITIS MEDIA	2 (2.0%)	1 (1.0%)
ASTHMA	2 (2.0%)	0
DIARRHEA	2 (2.0%)	0
DIZZINESS	2 (2.0%)	0
FEVER	2 (2.0%)	0
PURPURA	2 (2.0%)	0
VASODILATATION	2 (2.0%)	0
RESPIRATORY DISORDER	1 (1.0%)	2 (2.0%)
SINUSITIS	1 (1.0%)	2 (2.0%)
VOMITING	1 (1.0%)	2 (2.0%)
ABDOMINAL PAIN	1 (1.0%)	1 (1.0%)
ANXIETY	1 (1.0%)	1 (1.0%)
ARTHRALGIA	1 (1.0%)	1 (1.0%)
URINARY TRACT INFECTION	1 (1.0%)	1 (1.0%)
ABNORMAL DREAMS	1 (1.0%)	0
ABNORMAL VISION	1 (1.0%)	0
ANEMIA	1 (1.0%)	0
CONCENTRATION IMPAIRED	1 (1.0%)	0
CONFUSION	1 (1.0%)	0
CONTACT DERMATITIS	1 (1.0%)	0
CYSTITIS	1 (1.0%)	0
DYSPEPSIA	1 (1.0%)	0
EPISTAXIS	1 (1.0%)	0
HERPES SIMPLEX	1 (1.0%)	0
PNEUMONIA	1 (1.0%)	0
PYELONEPHRITIS	1 (1.0%)	0
RASH	1 (1.0%)	0
URINATION IMPAIRED	1 (1.0%)	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
Gender Non Specific Adverse Experiences
Intensity : Moderate

Preferred Term	Treatment Group Paroxetine (N=101)	 Placebo (N=102)
URTICARIA	1 (1.0%)	0
MIGRAINE	0	2 (2.0%)
ALLERGIC REACTION	0	1 (1.0%)
BRONCHITIS	0	1 (1.0%)
EAR PAIN	0	1 (1.0%)
GASTRITIS	0	1 (1.0%)
HYPERKINESIA	0	1 (1.0%)
LEUKOPENIA	0	1 (1.0%)
ULCERATIVE STOMATITIS	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
Gender Non Specific Adverse Experiences
Intensity : Severe

Preferred Term	Treatment Group Paroxetine (N=101)	 Placebo (N=102)
TOTAL	8 (7.9%)	4 (3.9%)
TRAUMA	3 (3.0%)	1 (1.0%)
CYSTITIS	1 (1.0%)	0
HEADACHE	1 (1.0%)	0
HOSTILITY	1 (1.0%)	0
NERVOUSNESS	1 (1.0%)	0
URTICARIA	1 (1.0%)	0
MIGRAINE	0	2 (2.0%)
EMOTIONAL LABILITY	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
Male Specific Adverse Experiences
Intensity : Mild

Preferred Term	Treatment Group Paroxetine (N=53)	 Placebo (N=55)
TOTAL	1 (1.9%)	0
IMPOTENCE	1 (1.9%)	0

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Table 15.1.3.1.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Treatment Phase
by Intensity by Descending Order. Intention-To-Treat Population
Age Group : Total
Male Specific Adverse Experiences
Intensity : Moderate

Preferred Term	Treatment Group Paroxetine (N=53)	 Placebo (N=55)
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
Male Specific Adverse Experiences
Intensity : Severe

Preferred Term	Treatment Group Paroxetine (N=53)	 Placebo (N=55)
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
Female Specific Adverse Experiences
Intensity : Mild

Preferred Term	Treatment Group Paroxetine (N=48)	 Placebo (N=47)
TOTAL	1 (2.1%)	1 (2.1%)
MENSTRUAL DISORDER	1 (2.1%)	0
DYSMENORRHEA	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 : Total
Female Specific Adverse Experiences
Intensity : Moderate

Preferred Term	Treatment Group Paroxetine (N=48)	 Placebo (N=47)
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
Female Specific Adverse Experiences
Intensity : Severe

Preferred Term	Treatment Group Paroxetine (N=48)	 Placebo (N=47)
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
Gender Non Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group Paroxetine (N=24)	Placebo (N=26)
TOTAL	TOTAL	2 (8.3%)	3 (11.5%)
Digestive System	TOTAL	1 (4.2%)	0
	CONSTIPATION	1 (4.2%)	0
Hemic and Lymphatic System	TOTAL	1 (4.2%)	0
	THROMBOCYTHEMIA	1 (4.2%)	0
Cardiovascular System	TOTAL	0	1 (3.8%)
	PALPITATION	0	1 (3.8%)
	TACHYCARDIA	0	1 (3.8%)
Musculoskeletal System	TOTAL	0	1 (3.8%)
	MYALGIA	0	1 (3.8%)
Nervous System	TOTAL	0	1 (3.8%)
	ANXIETY	0	1 (3.8%)
Respiratory System	TOTAL	0	1 (3.8%)
	RESPIRATORY DISORDER	0	1 (3.8%)
Urogenital System	TOTAL	0	1 (3.8%)
	HAEMATURIA	0	1 (3.8%)

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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
Gender Non Specific Adverse Experiences
Intensity : Moderate

Body System	Preferred Term	Treatment Group Paroxetine (N=24)	Placebo (N=26)
TOTAL	TOTAL	4 (16.7%)	3 (11.5%)
Body as a Whole	TOTAL	2 (8.3%)	0
	ALLERGIC REACTION	1 (4.2%)	0
	INFECTION	1 (4.2%)	0
Nervous System	TOTAL	1 (4.2%)	1 (3.8%)
	DEPRESSION	1 (4.2%)	0
	NERVOUSNESS	1 (4.2%)	0
	HYPERKINESIA	0	1 (3.8%)
Respiratory System	TOTAL	1 (4.2%)	1 (3.8%)
	PHARYNGITIS	1 (4.2%)	0
	RHINITIS	0	1 (3.8%)
Digestive System	TOTAL	0	1 (3.8%)
	DIARRHEA	0	1 (3.8%)

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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
Gender Non Specific Adverse Experiences
Intensity : Severe

		Treatment Group	
		Paroxetine (N=24)	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
Male Specific Adverse Experiences
Intensity : Mild

		Treatment Group	
		Paroxetine (N=10)	Placebo (N=17)
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
Male Specific Adverse Experiences
Intensity : Moderate

		Treatment Group	
		Paroxetine (N=10)	Placebo (N=17)
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
Male Specific Adverse Experiences
Intensity : Severe

		Treatment Group	
		Paroxetine (N=10)	Placebo (N=17)
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
Female Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group Paroxetine (N=14)	Placebo (N=9)
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
Female Specific Adverse Experiences
Intensity : Moderate

		Treatment Group	
		Paroxetine (N=14)	Placebo (N=9)
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
Female Specific Adverse Experiences
Intensity : Severe

		Treatment Group	
		Paroxetine (N=14)	Placebo (N=9)
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
Gender Non Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group Paroxetine (N=31)	Placebo (N=36)
TOTAL	TOTAL	1 (3.2%)	4 (11.1%)
Special Senses	TOTAL	1 (3.2%)	0
	OTITIS MEDIA	1 (3.2%)	0
Body as a Whole	TOTAL	0	2 (5.6%)
	ASTHENIA	0	1 (2.8%)
	HEADACHE	0	1 (2.8%)
Cardiovascular System	TOTAL	0	1 (2.8%)
	SYNCOPE	0	1 (2.8%)
Digestive System	TOTAL	0	1 (2.8%)
	NAUSEA	0	1 (2.8%)
Nervous System	TOTAL	0	1 (2.8%)
	SOMNOLENCE	0	1 (2.8%)
	WITHDRAWAL SYNDROME	0	1 (2.8%)
Respiratory System	TOTAL	0	1 (2.8%)
	COUGH INCREASED	0	1 (2.8%)

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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
Gender Non Specific Adverse Experiences
Intensity : Moderate

Body System	Preferred Term	Treatment Group Paroxetine (N=31)	Placebo (N=36)
TOTAL	TOTAL	0	1 (2.8%)
Respiratory System	TOTAL	0	1 (2.8%)
	BRONCHITIS	0	1 (2.8%)

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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
Gender Non Specific Adverse Experiences
Intensity : Severe

Body System	Preferred Term	Treatment Group Paroxetine (N=31)	Placebo (N=36)
TOTAL	TOTAL	1 (3.2%)	0
Nervous System	TOTAL	1 (3.2%)	0
	EMOTIONAL LABILITY	1 (3.2%)	0

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Table 15.1.3.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Intensity
By Body System. Intention-To-Treat Population Entering The Taper Phase
Age Group : Adolescents
Male Specific Adverse Experiences
Intensity : Mild

		Treatment Group	
		Paroxetine (N=17)	Placebo (N=17)
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
Male Specific Adverse Experiences
Intensity : Moderate

		Treatment Group	
		Paroxetine (N=17)	Placebo (N=17)
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
Male Specific Adverse Experiences
Intensity : Severe

		Treatment Group	
		Paroxetine (N=17)	Placebo (N=17)
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
Female Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group Paroxetine (N=14)	Treatment Group Placebo (N=19)
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
Female Specific Adverse Experiences
Intensity : Moderate

		Treatment Group	
		Paroxetine (N=14)	Placebo (N=19)
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
Female Specific Adverse Experiences
Intensity : Severe

		Treatment Group	
		Paroxetine (N=14)	Placebo (N=19)
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
Gender Non Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group Paroxetine (N=55)	Placebo (N=62)
TOTAL	TOTAL	3 (5.5%)	7 (11.3%)
Digestive System	TOTAL	1 (1.8%)	1 (1.6%)
	CONSTIPATION	1 (1.8%)	0
	NAUSEA	0	1 (1.6%)
Hemic and Lymphatic System	TOTAL	1 (1.8%)	0
	THROMBOCYTHEMIA	1 (1.8%)	0
Special Senses	TOTAL	1 (1.8%)	0
	OTITIS MEDIA	1 (1.8%)	0
Body as a Whole	TOTAL	0	2 (3.2%)
	ASTHENIA	0	1 (1.6%)
	HEADACHE	0	1 (1.6%)
Cardiovascular System	TOTAL	0	2 (3.2%)
	PALPITATION	0	1 (1.6%)
	SYNCOPE	0	1 (1.6%)
	TACHYCARDIA	0	1 (1.6%)
Musculoskeletal System	TOTAL	0	1 (1.6%)
	MYALGIA	0	1 (1.6%)
Nervous System	TOTAL	0	2 (3.2%)
	ANXIETY	0	1 (1.6%)
	SOMNOLENCE	0	1 (1.6%)
	WITHDRAWAL SYNDROME	0	1 (1.6%)
Respiratory System	TOTAL	0	2 (3.2%)
	COUGH INCREASED	0	1 (1.6%)
	RESPIRATORY DISORDER	0	1 (1.6%)
Urogenital System	TOTAL	0	1 (1.6%)
	HAEMATURIA	0	1 (1.6%)

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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
Gender Non Specific Adverse Experiences
Intensity : Moderate

Body System	Preferred Term	Treatment Group Paroxetine (N=55)	Placebo (N=62)
TOTAL	TOTAL	4 (7.3%)	4 (6.5%)
Body as a Whole	TOTAL	2 (3.6%)	0
	ALLERGIC REACTION	1 (1.8%)	0
	INFECTION	1 (1.8%)	0
Nervous System	TOTAL	1 (1.8%)	1 (1.6%)
	DEPRESSION	1 (1.8%)	0
	NERVOUSNESS	1 (1.8%)	0
	HYPERKINESIA	0	1 (1.6%)
Respiratory System	TOTAL	1 (1.8%)	2 (3.2%)
	PHARYNGITIS	1 (1.8%)	0
	BRONCHITIS	0	1 (1.6%)
	RHINITIS	0	1 (1.6%)
Digestive System	TOTAL	0	1 (1.6%)
	DIARRHEA	0	1 (1.6%)

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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
Gender Non Specific Adverse Experiences
Intensity : Severe

Body System	Preferred Term	Treatment Group Paroxetine (N=55)	Placebo (N=62)
TOTAL	TOTAL	1 (1.8%)	0
Nervous System	TOTAL	1 (1.8%)	0
	EMOTIONAL LABILITY	1 (1.8%)	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
Male Specific Adverse Experiences
Intensity : Mild

		Treatment Group	
		Paroxetine (N=27)	Placebo (N=34)
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
Male Specific Adverse Experiences
Intensity : Moderate

		Treatment Group	
		Paroxetine (N=27)	Placebo (N=34)
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
Male Specific Adverse Experiences
Intensity : Severe

		Treatment Group	
		Paroxetine (N=27)	Placebo (N=34)
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
Female Specific Adverse Experiences
Intensity : Mild

		Treatment Group	
		Paroxetine (N=28)	Placebo (N=28)
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
Female Specific Adverse Experiences
Intensity : Moderate

		Treatment Group	
		Paroxetine (N=28)	Placebo (N=28)
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
Female Specific Adverse Experiences
Intensity : Severe

		Treatment Group	
		Paroxetine (N=28)	Placebo (N=28)
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

Gender Non Specific Adverse Experiences

Intensity : Mild

Preferred Term	Treatment Group: Paroxetine (N=24)	Treatment Group: Placebo (N=26)
TOTAL	2 (8.3%)	3 (11.5%)
CONSTIPATION	1 (4.2%)	0
THROMBOCYTHEMIA	1 (4.2%)	0
ANXIETY	0	1 (3.8%)
HAEMATURIA	0	1 (3.8%)
MYALGIA	0	1 (3.8%)
PALPITATION	0	1 (3.8%)
RESPIRATORY DISORDER	0	1 (3.8%)
TACHYCARDIA	0	1 (3.8%)

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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

Gender Non Specific Adverse Experiences

Intensity : Moderate

Preferred Term	Treatment Group Paroxetine (N=24)	 Placebo (N=26)
TOTAL	4 (16.7%)	3 (11.5%)
ALLERGIC REACTION	1 (4.2%)	0
DEPRESSION	1 (4.2%)	0
INFECTION	1 (4.2%)	0
NERVOUSNESS	1 (4.2%)	0
PHARYNGITIS	1 (4.2%)	0
DIARRHEA	0	1 (3.8%)
HYPERKINESIA	0	1 (3.8%)
RHINITIS	0	1 (3.8%)

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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

Gender Non Specific Adverse Experiences

Intensity : Severe

Preferred Term	Treatment Group: Paroxetine (N=24)	Treatment Group: Placebo (N=26)
TOTAL	0	0

BRL 29060 - 701

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

Male Specific Adverse Experiences

Intensity : Mild

Preferred Term	Treatment Group: Paroxetine (N=10)	Treatment Group: Placebo (N=17)
TOTAL	0	0

BRL 29060 - 701

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

Male Specific Adverse Experiences

Intensity : Moderate

Preferred Term	Treatment Group: Paroxetine (N=10)	Treatment Group: Placebo (N=17)
TOTAL	0	0

BRL 29060 - 701

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

Male Specific Adverse Experiences

Intensity : Severe

Preferred Term	Treatment Group: Paroxetine (N=10)	Treatment Group: Placebo (N=17)
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

Female Specific Adverse Experiences

Intensity : Mild

Preferred Term	Treatment Group: Paroxetine (N=14)	Treatment Group: Placebo (N=9)
TOTAL	0	0

BRL 29060 - 701

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

Female Specific Adverse Experiences

Intensity : Moderate

Preferred Term	Treatment Group: Paroxetine (N=14)	Treatment Group: Placebo (N=9)
TOTAL	0	0

BRL 29060 - 701

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

Female Specific Adverse Experiences

Intensity : Severe

Preferred Term	Treatment Group: Paroxetine (N=14)	Treatment Group: Placebo (N=9)
TOTAL	0	0

BRL 29060 - 701

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
Gender Non Specific Adverse Experiences
Intensity : Mild

Preferred Term	Treatment Group Paroxetine (N=31)	 Placebo (N=36)
TOTAL	1 (3.2%)	4 (11.1%)
OTITIS MEDIA	1 (3.2%)	0
ASTHENIA	0	1 (2.8%)
COUGH INCREASED	0	1 (2.8%)
HEADACHE	0	1 (2.8%)
NAUSEA	0	1 (2.8%)
SOMNOLENCE	0	1 (2.8%)
SYNCOPE	0	1 (2.8%)
WITHDRAWAL SYNDROME	0	1 (2.8%)

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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

Gender Non Specific Adverse Experiences

Intensity : Moderate

Preferred Term	Treatment Group Paroxetine (N=31)	Placebo (N=36)
TOTAL	0	1 (2.8%)
BRONCHITIS	0	1 (2.8%)

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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

Gender Non Specific Adverse Experiences

Intensity : Severe

Preferred Term	Treatment Group: Paroxetine (N=31)	Treatment Group: Placebo (N=36)
TOTAL	1 (3.2%)	0
EMOTIONAL LABILITY	1 (3.2%)	0

BRL 29060 - 701

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

Male Specific Adverse Experiences

Intensity : Mild

Preferred Term	Treatment Group: Paroxetine (N=17)	Treatment Group: Placebo (N=17)
TOTAL	0	0

BRL 29060 - 701

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

Male Specific Adverse Experiences

Intensity : Moderate

Preferred Term	Treatment Group: Paroxetine (N=17)	Treatment Group: Placebo (N=17)
TOTAL	0	0

BRL 29060 - 701

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

Male Specific Adverse Experiences

Intensity : Severe

Preferred Term	Treatment Group: Paroxetine (N=17)	Treatment Group: Placebo (N=17)
TOTAL	0	0

BRL 29060 - 701

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

Female Specific Adverse Experiences

Intensity : Mild

Preferred Term	Treatment Group: Paroxetine (N=14)	Treatment Group: Placebo (N=19)
TOTAL	0	0

BRL 29060 - 701

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

Female Specific Adverse Experiences

Intensity : Moderate

Preferred Term	Treatment Group: Paroxetine (N=14)	Treatment Group: Placebo (N=19)
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

Female Specific Adverse Experiences

Intensity : Severe

Preferred Term	Treatment Group: Paroxetine (N=14)	Treatment Group: Placebo (N=19)
TOTAL	0	0

BRL 29060 - 701

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

Gender Non Specific Adverse Experiences

Intensity : Mild

Preferred Term	Treatment Group Paroxetine (N=55)	 Placebo (N=62)
TOTAL	3 (5.5%)	7 (11.3%)
CONSTIPATION	1 (1.8%)	0
OTITIS MEDIA	1 (1.8%)	0
THROMBOCYTHEMIA	1 (1.8%)	0
ANXIETY	0	1 (1.6%)
ASTHENIA	0	1 (1.6%)
COUGH INCREASED	0	1 (1.6%)
HAEMATURIA	0	1 (1.6%)
HEADACHE	0	1 (1.6%)
MYALGIA	0	1 (1.6%)
NAUSEA	0	1 (1.6%)
PALPITATION	0	1 (1.6%)
RESPIRATORY DISORDER	0	1 (1.6%)
SOMNOLENCE	0	1 (1.6%)
SYNCOPE	0	1 (1.6%)
TACHYCARDIA	0	1 (1.6%)
WITHDRAWAL SYNDROME	0	1 (1.6%)

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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

Gender Non Specific Adverse Experiences

Intensity : Moderate

Preferred Term	Treatment Group Paroxetine (N=55)	 Placebo (N=62)
TOTAL	4 (7.3%)	4 (6.5%)
ALLERGIC REACTION	1 (1.8%)	0
DEPRESSION	1 (1.8%)	0
INFECTION	1 (1.8%)	0
NERVOUSNESS	1 (1.8%)	0
PHARYNGITIS	1 (1.8%)	0
BRONCHITIS	0	1 (1.6%)
DIARRHEA	0	1 (1.6%)
HYPERKINESIA	0	1 (1.6%)
RHINITIS	0	1 (1.6%)

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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

Gender Non Specific Adverse Experiences

Intensity : Severe

Preferred Term	Treatment Group Paroxetine (N=55)	Placebo (N=62)
TOTAL	1 (1.8%)	0
EMOTIONAL LABILITY	1 (1.8%)	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

Male Specific Adverse Experiences

Intensity : Mild

Preferred Term	Treatment Group: Paroxetine (N=27)	Treatment Group: Placebo (N=34)
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

Male Specific Adverse Experiences

Intensity : Moderate

Preferred Term	Treatment Group: Paroxetine (N=27)	Treatment Group: Placebo (N=34)
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

Male Specific Adverse Experiences

Intensity : Severe

Preferred Term	Treatment Group: Paroxetine (N=27)	Treatment Group: Placebo (N=34)
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

Female Specific Adverse Experiences

Intensity : Mild

Preferred Term	Treatment Group: Paroxetine (N=28)	Treatment Group: Placebo (N=28)
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

Female Specific Adverse Experiences

Intensity : Moderate

Preferred Term	Treatment Group: Paroxetine (N=28)	Treatment Group: Placebo (N=28)
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

Female Specific Adverse Experiences

Intensity : Severe

Preferred Term	Treatment Group: Paroxetine (N=28)	Treatment Group: Placebo (N=28)
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

Gender Non Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group Paroxetine (N=101)	 Placebo (N=102)
TOTAL	TOTAL	57 (56.4%)	59 (57.8%)
Body as a Whole	TOTAL	31 (30.7%)	30 (29.4%)
	HEADACHE	10 (9.9%)	12 (11.8%)
	TRAUMA	9 (8.9%)	5 (4.9%)
	ASTHENIA	6 (5.9%)	8 (7.8%)
	FEVER	5 (5.0%)	4 (3.9%)
	INFECTION	4 (4.0%)	3 (2.9%)
	ABDOMINAL PAIN	3 (3.0%)	2 (2.0%)
	PAIN	3 (3.0%)	2 (2.0%)
	ALLERGIC REACTION	1 (1.0%)	2 (2.0%)
	BACK PAIN	1 (1.0%)	0
Digestive System	TOTAL	25 (24.8%)	22 (21.6%)
	NAUSEA	11 (10.9%)	10 (9.8%)
	DYSPEPSIA	5 (5.0%)	3 (2.9%)
	VOMITING	5 (5.0%)	0
	DIARRHEA	3 (3.0%)	2 (2.0%)
	DRY MOUTH	3 (3.0%)	1 (1.0%)
	CONSTIPATION	2 (2.0%)	1 (1.0%)
	DECREASED APPETITE	1 (1.0%)	4 (3.9%)
	TOOTH DISORDER	1 (1.0%)	1 (1.0%)
	INCREASED APPETITE	1 (1.0%)	0
	MELENA	1 (1.0%)	0
	ULCERATIVE STOMATITIS	1 (1.0%)	0
	GASTROENTERITIS	0	1 (1.0%)
	LIVER FUNCTION TESTS ABNORMAL	0	1 (1.0%)
	TOOTH CARIES	0	1 (1.0%)
Respiratory System	TOTAL	21 (20.8%)	20 (19.6%)
	RESPIRATORY DISORDER	10 (9.9%)	9 (8.8%)
	RHINITIS	5 (5.0%)	3 (2.9%)
	SINUSITIS	5 (5.0%)	2 (2.0%)
	PHARYNGITIS	4 (4.0%)	4 (3.9%)
	COUGH INCREASED	4 (4.0%)	2 (2.0%)
	EPISTAXIS	2 (2.0%)	0
	YAWN	2 (2.0%)	0
	ASTHMA	0	1 (1.0%)
	LARYNX DISORDER	0	1 (1.0%)
Nervous System	TOTAL	19 (18.8%)	14 (13.7%)
	INSOMNIA	6 (5.9%)	1 (1.0%)
	SOMNOLENCE	5 (5.0%)	7 (6.9%)

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Table 15.1.3.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase or Taper Phase by Intensity
By Body System. Intention-To-Treat Population

Gender Non Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group: Paroxetine (N=101)	Treatment Group: Placebo (N=102)
Nervous System	NERVOUSNESS	3 (3.0%)	2 (2.0%)
	DIZZINESS	3 (3.0%)	1 (1.0%)
	HYPERKINESIA	3 (3.0%)	0
	TREMOR	3 (3.0%)	0
	MYOCLONUS	2 (2.0%)	0
	EMOTIONAL LABILITY	1 (1.0%)	1 (1.0%)
	ABNORMAL DREAMS	1 (1.0%)	0
	CONCENTRATION IMPAIRED	1 (1.0%)	0
	ANXIETY	0	2 (2.0%)
	WITHDRAWAL SYNDROME	0	2 (2.0%)
Skin and Appendages	TOTAL	5 (5.0%)	5 (4.9%)
	CONTACT DERMATITIS	2 (2.0%)	0
	FUNGAL DERMATITIS	1 (1.0%)	2 (2.0%)
	HERPES SIMPLEX	1 (1.0%)	0
	SKIN HYPERTROPHY	1 (1.0%)	0
	SWEATING	1 (1.0%)	0
	HERPES ZOSTER	0	1 (1.0%)
	PRURITUS	0	1 (1.0%)
	RASH	0	1 (1.0%)
Special Senses	TOTAL	5 (5.0%)	2 (2.0%)
	OTITIS MEDIA	3 (3.0%)	1 (1.0%)
	CONJUNCTIVITIS	1 (1.0%)	0
	MYDRIASIS	1 (1.0%)	0
	OTITIS EXTERNA	0	1 (1.0%)
Urogenital System	TOTAL	5 (5.0%)	4 (3.9%)
	HAEMATURIA	1 (1.0%)	1 (1.0%)
	URINARY FREQUENCY	1 (1.0%)	1 (1.0%)
	PYURIA	1 (1.0%)	0
	URINARY RETENTION	1 (1.0%)	0
	URINATION IMPAIRED	1 (1.0%)	0
	ALBUMINURIA	0	3 (2.9%)
Cardiovascular System	TOTAL	2 (2.0%)	2 (2.0%)
	CARDIAC DISORDERS	1 (1.0%)	0
	VASODILATATION	1 (1.0%)	0
	PALPITATION	0	1 (1.0%)
	SYNCOPE	0	1 (1.0%)
	TACHYCARDIA	0	1 (1.0%)
Hemic and Lymphatic System	TOTAL	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

Gender Non Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group Paroxetine (N=101)	Placebo (N=102)
Hemic and Lymphatic System	ERYTHROCYTES ABNORMAL	1 (1.0%)	0
	THROMBOCYTHEMIA	1 (1.0%)	0
	LEUKOPENIA	0	1 (1.0%)
Metabolic and Nutritional Disorders	TOTAL	1 (1.0%)	3 (2.9%)
	WEIGHT LOSS	1 (1.0%)	0
	HYPONATREMIA	0	1 (1.0%)
	KETOSIS	0	1 (1.0%)
	THIRST	0	1 (1.0%)
Musculoskeletal System	TOTAL	1 (1.0%)	1 (1.0%)
	MYALGIA	1 (1.0%)	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

Gender Non Specific Adverse Experiences
Intensity : Moderate

Body System	Preferred Term	Treatment Group: Paroxetine (N=101)	Treatment Group: Placebo (N=102)
TOTAL	TOTAL	45 (44.6%)	30 (29.4%)
Nervous System	TOTAL	22 (21.8%)	12 (11.8%)
	INSOMNIA	5 (5.0%)	6 (5.9%)
	SOMNOLENCE	5 (5.0%)	3 (2.9%)
	NERVOUSNESS	3 (3.0%)	2 (2.0%)
	DEPRESSION	3 (3.0%)	1 (1.0%)
	AGITATION	3 (3.0%)	0
	DIZZINESS	2 (2.0%)	0
	ANXIETY	1 (1.0%)	1 (1.0%)
	ABNORMAL DREAMS	1 (1.0%)	0
	CONCENTRATION IMPAIRED	1 (1.0%)	0
	CONFUSION	1 (1.0%)	0
	HYPERKINESIA	0	2 (2.0%)
Body as a Whole	TOTAL	18 (17.8%)	16 (15.7%)
	HEADACHE	11 (10.9%)	11 (10.8%)
	INFECTION	4 (4.0%)	3 (2.9%)
	TRAUMA	3 (3.0%)	3 (2.9%)
	ASTHENIA	2 (2.0%)	2 (2.0%)
	FEVER	2 (2.0%)	0
	ABDOMINAL PAIN	1 (1.0%)	1 (1.0%)
	ALLERGIC REACTION	1 (1.0%)	1 (1.0%)
Respiratory System	TOTAL	12 (11.9%)	8 (7.8%)
	PHARYNGITIS	5 (5.0%)	2 (2.0%)
	COUGH INCREASED	2 (2.0%)	2 (2.0%)
	ASTHMA	2 (2.0%)	0
	RESPIRATORY DISORDER	1 (1.0%)	2 (2.0%)
	SINUSITIS	1 (1.0%)	2 (2.0%)
	EPISTAXIS	1 (1.0%)	0
	PNEUMONIA	1 (1.0%)	0
	BRONCHITIS	0	2 (2.0%)
	RHINITIS	0	1 (1.0%)
Digestive System	TOTAL	8 (7.9%)	6 (5.9%)
	DECREASED APPETITE	3 (3.0%)	0
	DIARRHEA	2 (2.0%)	1 (1.0%)
	NAUSEA	2 (2.0%)	1 (1.0%)
	VOMITING	1 (1.0%)	2 (2.0%)
	DYSPEPSIA	1 (1.0%)	0
	GASTRITIS	0	1 (1.0%)
	ULCERATIVE STOMATITIS	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

Gender Non Specific Adverse Experiences
Intensity : Moderate

Body System	Preferred Term	Treatment Group: Paroxetine (N=101)	Treatment Group: Placebo (N=102)
Skin and Appendages	TOTAL	6 (5.9%)	0
	SWEATING	3 (3.0%)	0
	CONTACT DERMATITIS	1 (1.0%)	0
	HERPES SIMPLEX	1 (1.0%)	0
	RASH	1 (1.0%)	0
	URTICARIA	1 (1.0%)	0
Urogenital System	TOTAL	4 (4.0%)	1 (1.0%)
	URINARY TRACT INFECTION	1 (1.0%)	1 (1.0%)
	CYSTITIS	1 (1.0%)	0
	PYELONEPHRITIS	1 (1.0%)	0
	URINATION IMPAIRED	1 (1.0%)	0
Hemic and Lymphatic System	TOTAL	3 (3.0%)	1 (1.0%)
	PURPURA	2 (2.0%)	0
	ANEMIA	1 (1.0%)	0
	LEUKOPENIA	0	1 (1.0%)
Special Senses	TOTAL	3 (3.0%)	2 (2.0%)
	OTITIS MEDIA	2 (2.0%)	1 (1.0%)
	ABNORMAL VISION	1 (1.0%)	0
	EAR PAIN	0	1 (1.0%)
Cardiovascular System	TOTAL	2 (2.0%)	2 (2.0%)
	VASODILATATION	2 (2.0%)	0
	MIGRAINE	0	2 (2.0%)
Musculoskeletal System	TOTAL	1 (1.0%)	1 (1.0%)
	ARTHRALGIA	1 (1.0%)	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

Gender Non Specific Adverse Experiences
Intensity : Severe

Body System	Preferred Term	Treatment Group Paroxetine (N=101)	 Placebo (N=102)
TOTAL	TOTAL	9 (8.9%)	4 (3.9%)
Body as a Whole	TOTAL	4 (4.0%)	1 (1.0%)
	TRAUMA	3 (3.0%)	1 (1.0%)
	HEADACHE	1 (1.0%)	0
Nervous System	TOTAL	3 (3.0%)	1 (1.0%)
	EMOTIONAL LABILITY	1 (1.0%)	1 (1.0%)
	HOSTILITY	1 (1.0%)	0
	NERVOUSNESS	1 (1.0%)	0
Skin and Appendages	TOTAL	1 (1.0%)	0
	URTICARIA	1 (1.0%)	0
Urogenital System	TOTAL	1 (1.0%)	0
	CYSTITIS	1 (1.0%)	0
Cardiovascular System	TOTAL	0	2 (2.0%)
	MIGRAINE	0	2 (2.0%)

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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

Male Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group: Paroxetine (N=53)	Treatment Group: Placebo (N=55)
TOTAL	TOTAL	1 (1.9%)	0
Urogenital System	TOTAL	1 (1.9%)	0
	IMPOTENCE	1 (1.9%)	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

Male Specific Adverse Experiences
Intensity : Moderate

Body System	Preferred Term	Treatment Group: Paroxetine (N=53)	Treatment Group: Placebo (N=55)
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

Male Specific Adverse Experiences
Intensity : Severe

Body System	Preferred Term	Treatment Group: Paroxetine (N=53)	Treatment Group: Placebo (N=55)
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

Female Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group Paroxetine (N=48)	 Placebo (N=47)
TOTAL	TOTAL	1 (2.1%)	1 (2.1%)
Urogenital System	TOTAL	1 (2.1%)	1 (2.1%)
	MENSTRUAL DISORDER	1 (2.1%)	0
	DYSMENORRHEA	0	1 (2.1%)

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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

Female Specific Adverse Experiences
Intensity : Moderate

Body System	Preferred Term	Treatment Group: Paroxetine (N=48)	Treatment Group: Placebo (N=47)
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

Female Specific Adverse Experiences
Intensity : Severe

Body System	Preferred Term	Treatment Group Paroxetine (N=48)	Placebo (N=47)
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

Gender Non Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group: Paroxetine (N=46)	Treatment Group: Placebo (N=30)
TOTAL	TOTAL	6 (13.0%)	1 (3.3%)
Nervous System	TOTAL	3 (6.5%)	0
	DIZZINESS	1 (2.2%)	0
	EMOTIONAL LABILITY	1 (2.2%)	0
	PSYCHOSIS	1 (2.2%)	0
	SOMNOLENCE	1 (2.2%)	0
Body as a Whole	TOTAL	1 (2.2%)	0
	HEADACHE	1 (2.2%)	0
Digestive System	TOTAL	1 (2.2%)	1 (3.3%)
	NAUSEA	1 (2.2%)	1 (3.3%)
Musculoskeletal System	TOTAL	1 (2.2%)	0
	ARTHRALGIA	1 (2.2%)	0
Respiratory System	TOTAL	1 (2.2%)	0
	RESPIRATORY DISORDER	1 (2.2%)	0
Skin and Appendages	TOTAL	1 (2.2%)	0
	RASH	1 (2.2%)	0
Urogenital System	TOTAL	0	1 (3.3%)
	GLYCOSURIA	0	1 (3.3%)

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Table 15.1.3.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Intensity
By Body System. Intention-To Treat Population Entering The Follow-Up Phase

Gender Non Specific Adverse Experiences
Intensity : Moderate

Body System	Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=30)
TOTAL	TOTAL	6 (13.0%)	2 (6.7%)
Nervous System	TOTAL	5 (10.9%)	2 (6.7%)
	DEPRESSION	2 (4.3%)	0
	DIZZINESS	1 (2.2%)	0
	MANIC DEPRESSIVE REACTION	1 (2.2%)	0
	NERVOUSNESS	1 (2.2%)	0
	TREMOR	1 (2.2%)	0
	AGITATION	0	1 (3.3%)
	EMOTIONAL LABILITY	0	1 (3.3%)
Cardiovascular System	TOTAL	1 (2.2%)	0
	HYPERTENSION	1 (2.2%)	0
	TACHYCARDIA	1 (2.2%)	0
Hemic and Lymphatic System	TOTAL	1 (2.2%)	0
	ANEMIA	1 (2.2%)	0
Skin and Appendages	TOTAL	1 (2.2%)	0
	SWEATING	1 (2.2%)	0
Special Senses	TOTAL	1 (2.2%)	0
	ABNORMAL VISION	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

Gender Non Specific Adverse Experiences
Intensity : Severe

Body System	Preferred Term	Treatment Group Paroxetine (N=46)	Placebo (N=30)
TOTAL	TOTAL	3 (6.5%)	0
Nervous System	TOTAL	2 (4.3%)	0
	DEPRESSION	1 (2.2%)	0
	EMOTIONAL LABILITY	1 (2.2%)	0
Body as a Whole	TOTAL	1 (2.2%)	0
	TRAUMA	1 (2.2%)	0
Cardiovascular System	TOTAL	1 (2.2%)	0
	HYPERTENSION	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

Male Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group Paroxetine (N=25)	Placebo (N=17)
TOTAL	TOTAL	0	1 (5.9%)
Urogenital System	TOTAL	0	1 (5.9%)
	ABNORMAL EJACULATION	0	1 (5.9%)

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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

Male Specific Adverse Experiences
Intensity : Moderate

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=17)
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

Male Specific Adverse Experiences
Intensity : Severe

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=17)
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

Female Specific Adverse Experiences
Intensity : Mild

Body System	Preferred Term	Treatment Group Paroxetine (N=21)	Placebo (N=13)
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

Female Specific Adverse Experiences
Intensity : Moderate

Body System	Preferred Term	Treatment Group: Paroxetine (N=21)	Treatment Group: Placebo (N=13)
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

Female Specific Adverse Experiences
Intensity : Severe

Body System	Preferred Term	Treatment Group Paroxetine (N=21)	Placebo (N=13)
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

Gender Non Specific Adverse Experiences
Intensity : Mild

Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=30)
TOTAL	6 (13.0%)	1 (3.3%)
NAUSEA	1 (2.2%)	1 (3.3%)
ARTHRALGIA	1 (2.2%)	0
DIZZINESS	1 (2.2%)	0
EMOTIONAL LABILITY	1 (2.2%)	0
HEADACHE	1 (2.2%)	0
PSYCHOSIS	1 (2.2%)	0
RASH	1 (2.2%)	0
RESPIRATORY DISORDER	1 (2.2%)	0
SOMNOLENCE	1 (2.2%)	0
GLYCOSURIA	0	1 (3.3%)

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-up Phase by Intensity by Descending Order. Intention-To-Treat Population Entering The Follow-Up Phase

Gender Non Specific Adverse Experiences
Intensity : Moderate

Preferred Term	Treatment Group Paroxetine (N=46)	 Placebo (N=30)
TOTAL	6 (13.0%)	2 (6.7%)
DEPRESSION	2 (4.3%)	0
ABNORMAL VISION	1 (2.2%)	0
ANEMIA	1 (2.2%)	0
DIZZINESS	1 (2.2%)	0
HYPERTENSION	1 (2.2%)	0
MANIC DEPRESSIVE REACTION	1 (2.2%)	0
NERVOUSNESS	1 (2.2%)	0
SWEATING	1 (2.2%)	0
TACHYCARDIA	1 (2.2%)	0
TREMOR	1 (2.2%)	0
AGITATION	0	1 (3.3%)
EMOTIONAL LABILITY	0	1 (3.3%)

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Table 15.1.3.4.X

Number (%) of Patients with Emergent Adverse Experiences Occurring in 1% or More of the Population During the Follow-up Phase by Intensity by Descending Order. Intention-To-Treat Population Entering The Follow-Up Phase

Gender Non Specific Adverse Experiences
Intensity : Severe

Preferred Term	Treatment Group: Paroxetine (N=46)	Treatment Group: Placebo (N=30)
TOTAL	3 (6.5%)	0
DEPRESSION	1 (2.2%)	0
EMOTIONAL LABILITY	1 (2.2%)	0
HYPERTENSION	1 (2.2%)	0
TRAUMA	1 (2.2%)	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

Male Specific Adverse Experiences
Intensity : Mild

Preferred Term	Treatment Group Paroxetine (N=25)	 Placebo (N=17)
TOTAL	0	1 (5.9%)
ABNORMAL EJACULATION	0	1 (5.9%)

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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

Male Specific Adverse Experiences
Intensity : Moderate

Preferred Term	Treatment Group: Paroxetine (N=25)	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

Male Specific Adverse Experiences
Intensity : Severe

Preferred Term	Treatment Group: Paroxetine (N=25)	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

Female Specific Adverse Experiences
Intensity : Mild

Preferred Term	Treatment Group: Paroxetine (N=21)	Treatment Group: Placebo (N=13)
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

Female Specific Adverse Experiences
Intensity : Moderate

Preferred Term	Treatment Group: Paroxetine (N=21)	Treatment Group: Placebo (N=13)
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

Female Specific Adverse Experiences
Intensity : Severe

Preferred Term	Treatment Group: Paroxetine (N=21)	Treatment Group: Placebo (N=13)
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=49)	Treatment Group: Placebo (N=47)
TOTAL	TOTAL	21 (42.9%)	13 (27.7%)
Digestive System	TOTAL	12 (24.5%)	6 (12.8%)
	NAUSEA	5 (10.2%)	3 (6.4%)
	DYSPEPSIA	3 (6.1%)	1 (2.1%)
	DECREASED APPETITE	2 (4.1%)	1 (2.1%)
	DIARRHEA	2 (4.1%)	1 (2.1%)
	DRY MOUTH	2 (4.1%)	0
	CONSTIPATION	1 (2.0%)	0
	INCREASED APPETITE	1 (2.0%)	0
	VOMITING	1 (2.0%)	0
Body as a Whole	TOTAL	8 (16.3%)	7 (14.9%)
	HEADACHE	5 (10.2%)	4 (8.5%)
	ABDOMINAL PAIN	3 (6.1%)	1 (2.1%)
	ASTHENIA	2 (4.1%)	3 (6.4%)
Nervous System	TOTAL	8 (16.3%)	3 (6.4%)
	INSOMNIA	3 (6.1%)	0
	DIZZINESS	2 (4.1%)	1 (2.1%)
	AGITATION	2 (4.1%)	0
	ABNORMAL DREAMS	1 (2.0%)	0
	CONCENTRATION IMPAIRED	1 (2.0%)	0
	HOSTILITY	1 (2.0%)	0
	HYPERKINESIA	1 (2.0%)	0
	NERVOUSNESS	1 (2.0%)	0
	TREMOR	1 (2.0%)	0
	SOMNOLENCE	0	2 (4.3%)
Respiratory System	TOTAL	5 (10.2%)	0
	EPISTAXIS	2 (4.1%)	0
	COUGH INCREASED	1 (2.0%)	0
	RESPIRATORY DISORDER	1 (2.0%)	0
	RHINITIS	1 (2.0%)	0
	YAWN	1 (2.0%)	0
Urogenital System	TOTAL	3 (6.1%)	0
	URINARY FREQUENCY	1 (2.0%)	0
	URINARY RETENTION	1 (2.0%)	0
	URINATION IMPAIRED	1 (2.0%)	0
Skin and Appendages	TOTAL	2 (4.1%)	2 (4.3%)
	HERPES SIMPLEX	1 (2.0%)	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=49)	Treatment Group: Placebo (N=47)
Skin and Appendages	SWEATING	1 (2.0%)	0
	PRURITUS	0	1 (2.1%)
	RASH	0	1 (2.1%)
Cardiovascular System	TOTAL	1 (2.0%)	0
	VASODILATATION	1 (2.0%)	0
Special Senses	TOTAL	1 (2.0%)	0
	ABNORMAL VISION	1 (2.0%)	0
Hemic and Lymphatic System	TOTAL	0	1 (2.1%)
	LEUKOPENIA	0	1 (2.1%)
Metabolic and Nutritional Disorders	TOTAL	0	2 (4.3%)
	HYPONATREMIA	0	1 (2.1%)
	THIRST	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 : Children
Male Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=26)	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 : Children
Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=23)	Placebo (N=18)
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=52)	 Placebo (N=55)
TOTAL	TOTAL	27 (51.9%)	23 (41.8%)
Nervous System	TOTAL	22 (42.3%)	12 (21.8%)
	SOMNOLENCE	10 (19.2%)	5 (9.1%)
	INSOMNIA	7 (13.5%)	6 (10.9%)
	NERVOUSNESS	4 (7.7%)	3 (5.5%)
	DIZZINESS	3 (5.8%)	0
	HYPERKINESIA	2 (3.8%)	1 (1.8%)
	TREMOR	2 (3.8%)	0
	ANXIETY	1 (1.9%)	1 (1.8%)
	ABNORMAL DREAMS	1 (1.9%)	0
	AGITATION	1 (1.9%)	0
	CONCENTRATION IMPAIRED	1 (1.9%)	0
	CONFUSION	1 (1.9%)	0
	MYOCLONUS	1 (1.9%)	0
	EMOTIONAL LABILITY	0	1 (1.8%)
	WITHDRAWAL SYNDROME	0	1 (1.8%)
Digestive System	TOTAL	9 (17.3%)	9 (16.4%)
	NAUSEA	6 (11.5%)	6 (10.9%)
	DECREASED APPETITE	2 (3.8%)	2 (3.6%)
	DRY MOUTH	1 (1.9%)	1 (1.8%)
	DYSPEPSIA	1 (1.9%)	1 (1.8%)
	DIARRHEA	1 (1.9%)	0
	CONSTIPATION	0	1 (1.8%)
Body as a Whole	TOTAL	8 (15.4%)	11 (20.0%)
	HEADACHE	6 (11.5%)	8 (14.5%)
	ASTHENIA	3 (5.8%)	4 (7.3%)
	TRAUMA	2 (3.8%)	0
	ABDOMINAL PAIN	0	1 (1.8%)
Respiratory System	TOTAL	3 (5.8%)	0
	COUGH INCREASED	1 (1.9%)	0
	RHINITIS	1 (1.9%)	0
	SINUSITIS	1 (1.9%)	0
	YAWN	1 (1.9%)	0
Skin and Appendages	TOTAL	3 (5.8%)	0
	SWEATING	3 (5.8%)	0
Cardiovascular System	TOTAL	2 (3.8%)	0
	VASODILATATION	2 (3.8%)	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=52)	Treatment Group: Placebo (N=55)
Metabolic and Nutritional Disorders	TOTAL	1 (1.9%)	0
	WEIGHT LOSS	1 (1.9%)	0
Special Senses	TOTAL	1 (1.9%)	0
	MYDRIASIS	1 (1.9%)	0
Urogenital System	TOTAL	1 (1.9%)	1 (1.8%)
	CYSTITIS	1 (1.9%)	0
	URINATION IMPAIRED	1 (1.9%)	0
	URINARY FREQUENCY	0	1 (1.8%)
Hemic and Lymphatic System	TOTAL	0	1 (1.8%)
	LEUKOPENIA	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 : Adolescents
Male Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=27)	Treatment Group: Placebo (N=26)
TOTAL	TOTAL	1 (3.7%)	0
Urogenital System	TOTAL	1 (3.7%)	0
	IMPOTENCE	1 (3.7%)	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 : Adolescents
Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=25)	 Placebo (N=29)
TOTAL	TOTAL	1 (4.0%)	0
Urogenital System	TOTAL	1 (4.0%)	0
	MENSTRUAL DISORDER	1 (4.0%)	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=101)	Treatment Group: Placebo (N=102)
TOTAL	TOTAL	48 (47.5%)	36 (35.3%)
Nervous System	TOTAL	30 (29.7%)	15 (14.7%)
	SOMNOLENCE	10 (9.9%)	7 (6.9%)
	INSOMNIA	10 (9.9%)	6 (5.9%)
	NERVOUSNESS	5 (5.0%)	3 (2.9%)
	DIZZINESS	5 (5.0%)	1 (1.0%)
	HYPERKINESIA	3 (3.0%)	1 (1.0%)
	AGITATION	3 (3.0%)	0
	TREMOR	3 (3.0%)	0
	ABNORMAL DREAMS	2 (2.0%)	0
	CONCENTRATION IMPAIRED	2 (2.0%)	0
	ANXIETY	1 (1.0%)	1 (1.0%)
	CONFUSION	1 (1.0%)	0
	HOSTILITY	1 (1.0%)	0
	MYOCLONUS	1 (1.0%)	0
	EMOTIONAL LABILITY	0	1 (1.0%)
	WITHDRAWAL SYNDROME	0	1 (1.0%)
Digestive System	TOTAL	21 (20.8%)	15 (14.7%)
	NAUSEA	11 (10.9%)	9 (8.8%)
	DECREASED APPETITE	4 (4.0%)	3 (2.9%)
	DYSPEPSIA	4 (4.0%)	2 (2.0%)
	DIARRHEA	3 (3.0%)	1 (1.0%)
	DRY MOUTH	3 (3.0%)	1 (1.0%)
	CONSTIPATION	1 (1.0%)	1 (1.0%)
	INCREASED APPETITE	1 (1.0%)	0
	VOMITING	1 (1.0%)	0
Body as a Whole	TOTAL	16 (15.8%)	18 (17.6%)
	HEADACHE	11 (10.9%)	12 (11.8%)
	ASTHENIA	5 (5.0%)	7 (6.9%)
	ABDOMINAL PAIN	3 (3.0%)	2 (2.0%)
	TRAUMA	2 (2.0%)	0
Respiratory System	TOTAL	8 (7.9%)	0
	COUGH INCREASED	2 (2.0%)	0
	EPISTAXIS	2 (2.0%)	0
	RHINITIS	2 (2.0%)	0
	YAWN	2 (2.0%)	0
	RESPIRATORY DISORDER	1 (1.0%)	0
	SINUSITIS	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=101)	Treatment Group: Placebo (N=102)
Skin and Appendages	TOTAL	5 (5.0%)	2 (2.0%)
	SWEATING	4 (4.0%)	0
	HERPES SIMPLEX	1 (1.0%)	0
	PRURITUS	0	1 (1.0%)
	RASH	0	1 (1.0%)
Urogenital System	TOTAL	4 (4.0%)	1 (1.0%)
	URINATION IMPAIRED	2 (2.0%)	0
	URINARY FREQUENCY	1 (1.0%)	1 (1.0%)
	CYSTITIS	1 (1.0%)	0
	URINARY RETENTION	1 (1.0%)	0
Cardiovascular System	TOTAL	3 (3.0%)	0
	VASODILATATION	3 (3.0%)	0
Special Senses	TOTAL	2 (2.0%)	0
	ABNORMAL VISION	1 (1.0%)	0
	MYDRIASIS	1 (1.0%)	0
Metabolic and Nutritional Disorders	TOTAL	1 (1.0%)	2 (2.0%)
	WEIGHT LOSS	1 (1.0%)	0
	HYPONATREMIA	0	1 (1.0%)
	THIRST	0	1 (1.0%)
Hemic and Lymphatic System	TOTAL	0	2 (2.0%)
	LEUKOPENIA	0	2 (2.0%)

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Table 15.1.4.1

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Total
Male Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=53)	Treatment Group: Placebo (N=55)
TOTAL	TOTAL	1 (1.9%)	0
Urogenital System	TOTAL	1 (1.9%)	0
	IMPOTENCE	1 (1.9%)	0

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Table 15.1.4.1

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Total
Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=48)	Treatment Group: Placebo (N=47)
TOTAL	TOTAL	1 (2.1%)	0
Urogenital System	TOTAL	1 (2.1%)	0
	MENSTRUAL DISORDER	1 (2.1%)	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 : Children
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=49)	 Placebo (N=47)
TOTAL	21 (42.9%)	13 (27.7%)
HEADACHE	5 (10.2%)	4 (8.5%)
NAUSEA	5 (10.2%)	3 (6.4%)
ABDOMINAL PAIN	3 (6.1%)	1 (2.1%)
DYSPEPSIA	3 (6.1%)	1 (2.1%)
INSOMNIA	3 (6.1%)	0
ASTHENIA	2 (4.1%)	3 (6.4%)
DECREASED APPETITE	2 (4.1%)	1 (2.1%)
DIARRHEA	2 (4.1%)	1 (2.1%)
DIZZINESS	2 (4.1%)	1 (2.1%)
AGITATION	2 (4.1%)	0
DRY MOUTH	2 (4.1%)	0
EPISTAXIS	2 (4.1%)	0
ABNORMAL DREAMS	1 (2.0%)	0
ABNORMAL VISION	1 (2.0%)	0
CONCENTRATION IMPAIRED	1 (2.0%)	0
CONSTIPATION	1 (2.0%)	0
COUGH INCREASED	1 (2.0%)	0
HERPES SIMPLEX	1 (2.0%)	0
HOSTILITY	1 (2.0%)	0
HYPERKINESIA	1 (2.0%)	0
INCREASED APPETITE	1 (2.0%)	0
NERVOUSNESS	1 (2.0%)	0
RESPIRATORY DISORDER	1 (2.0%)	0
RHINITIS	1 (2.0%)	0
SWEATING	1 (2.0%)	0
TREMOR	1 (2.0%)	0
URINARY FREQUENCY	1 (2.0%)	0
URINARY RETENTION	1 (2.0%)	0
URINATION IMPAIRED	1 (2.0%)	0
VASODILATATION	1 (2.0%)	0
VOMITING	1 (2.0%)	0
YAWN	1 (2.0%)	0
SOMNOLENCE	0	2 (4.3%)
HYPONATREMIA	0	1 (2.1%)
LEUKOPENIA	0	1 (2.1%)
PRURITUS	0	1 (2.1%)
RASH	0	1 (2.1%)
THIRST	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 : Children
Male Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=26)	 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 : Children
Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=23)	 Placebo (N=18)
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=52)	 Placebo (N=55)
TOTAL	27 (51.9%)	23 (41.8%)
SOMNOLENCE	10 (19.2%)	5 (9.1%)
INSOMNIA	7 (13.5%)	6 (10.9%)
HEADACHE	6 (11.5%)	8 (14.5%)
NAUSEA	6 (11.5%)	6 (10.9%)
NERVOUSNESS	4 (7.7%)	3 (5.5%)
ASTHENIA	3 (5.8%)	4 (7.3%)
DIZZINESS	3 (5.8%)	0
SWEATING	3 (5.8%)	0
DECREASED APPETITE	2 (3.8%)	2 (3.6%)
HYPERKINESIA	2 (3.8%)	1 (1.8%)
TRAUMA	2 (3.8%)	0
TREMOR	2 (3.8%)	0
VASODILATATION	2 (3.8%)	0
ANXIETY	1 (1.9%)	1 (1.8%)
DRY MOUTH	1 (1.9%)	1 (1.8%)
DYSPEPSIA	1 (1.9%)	1 (1.8%)
ABNORMAL DREAMS	1 (1.9%)	0
AGITATION	1 (1.9%)	0
CONCENTRATION IMPAIRED	1 (1.9%)	0
CONFUSION	1 (1.9%)	0
COUGH INCREASED	1 (1.9%)	0
CYSTITIS	1 (1.9%)	0
DIARRHEA	1 (1.9%)	0
MYDRIASIS	1 (1.9%)	0
MYOCLONUS	1 (1.9%)	0
RHINITIS	1 (1.9%)	0
SINUSITIS	1 (1.9%)	0
URINATION IMPAIRED	1 (1.9%)	0
WEIGHT LOSS	1 (1.9%)	0
YAWN	1 (1.9%)	0
ABDOMINAL PAIN	0	1 (1.8%)
CONSTIPATION	0	1 (1.8%)
EMOTIONAL LABILITY	0	1 (1.8%)
LEUKOPENIA	0	1 (1.8%)
URINARY FREQUENCY	0	1 (1.8%)
WITHDRAWAL SYNDROME	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 : Adolescents
Male Specific Adverse Experiences

Preferred Term	Treatment Group: Paroxetine (N=27)	Treatment Group: Placebo (N=26)
TOTAL	1 (3.7%)	0
IMPOTENCE	1 (3.7%)	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=25)	 Placebo (N=29)
TOTAL	1 (4.0%)	0
MENSTRUAL DISORDER	1 (4.0%)	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=101)	 Placebo (N=102)
TOTAL	48 (47.5%)	36 (35.3%)
HEADACHE	11 (10.9%)	12 (11.8%)
NAUSEA	11 (10.9%)	9 (8.8%)
SOMNOLENCE	10 (9.9%)	7 (6.9%)
INSOMNIA	10 (9.9%)	6 (5.9%)
ASTHENIA	5 (5.0%)	7 (6.9%)
NERVOUSNESS	5 (5.0%)	3 (2.9%)
DIZZINESS	5 (5.0%)	1 (1.0%)
DECREASED APPETITE	4 (4.0%)	3 (2.9%)
DYSPEPSIA	4 (4.0%)	2 (2.0%)
SWEATING	4 (4.0%)	0
ABDOMINAL PAIN	3 (3.0%)	2 (2.0%)
DIARRHEA	3 (3.0%)	1 (1.0%)
DRY MOUTH	3 (3.0%)	1 (1.0%)
HYPERKINESIA	3 (3.0%)	1 (1.0%)
AGITATION	3 (3.0%)	0
TREMOR	3 (3.0%)	0
VASODILATATION	3 (3.0%)	0
ABNORMAL DREAMS	2 (2.0%)	0
CONCENTRATION IMPAIRED	2 (2.0%)	0
COUGH INCREASED	2 (2.0%)	0
EPISTAXIS	2 (2.0%)	0
RHINITIS	2 (2.0%)	0
TRAUMA	2 (2.0%)	0
URINATION IMPAIRED	2 (2.0%)	0
YAWN	2 (2.0%)	0
ANXIETY	1 (1.0%)	1 (1.0%)
CONSTIPATION	1 (1.0%)	1 (1.0%)
URINARY FREQUENCY	1 (1.0%)	1 (1.0%)
ABNORMAL VISION	1 (1.0%)	0
CONFUSION	1 (1.0%)	0
CYSTITIS	1 (1.0%)	0
HERPES SIMPLEX	1 (1.0%)	0
HOSTILITY	1 (1.0%)	0
INCREASED APPETITE	1 (1.0%)	0
MYDRIASIS	1 (1.0%)	0
MYOCLONUS	1 (1.0%)	0
RESPIRATORY DISORDER	1 (1.0%)	0
SINUSITIS	1 (1.0%)	0
URINARY RETENTION	1 (1.0%)	0
VOMITING	1 (1.0%)	0
WEIGHT LOSS	1 (1.0%)	0
LEUKOPENIA	0	2 (2.0%)

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Table 15.1.4.1.X

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Treatment Phase by Descending Order
Intention-To-Treat Population
Age Group : Total
Gender Non Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=101)	 Placebo (N=102)
EMOTIONAL LABILITY	0	1 (1.0%)
HYPONATREMIA	0	1 (1.0%)
PRURITUS	0	1 (1.0%)
RASH	0	1 (1.0%)
THIRST	0	1 (1.0%)
WITHDRAWAL SYNDROME	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=55)
TOTAL	1 (1.9%)	0
IMPOTENCE	1 (1.9%)	0

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Table 15.1.4.1.X

Number (%) of Patients with Related or Possibly Related Emergent Adverse Experiences Occurring in 1% or More of the Population
During the Treatment Phase by Descending Order
Intention-To-Treat Population
Age Group : Total
Female Specific Adverse Experiences

Preferred Term	Treatment Group Paroxetine (N=48)	 Placebo (N=47)
TOTAL	1 (2.1%)	0
MENSTRUAL DISORDER	1 (2.1%)	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=24)	 Placebo (N=26)
TOTAL	TOTAL	2 (8.3%)	2 (7.7%)
Digestive System	TOTAL	1 (4.2%)	1 (3.8%)
	CONSTIPATION	1 (4.2%)	0
	DIARRHEA	0	1 (3.8%)
Nervous System	TOTAL	1 (4.2%)	1 (3.8%)
	DEPRESSION	1 (4.2%)	0
	NERVOUSNESS	1 (4.2%)	0
	ANXIETY	0	1 (3.8%)
	HYPERKINESIA	0	1 (3.8%)
Cardiovascular System	TOTAL	0	1 (3.8%)
	PALPITATION	0	1 (3.8%)
	TACHYCARDIA	0	1 (3.8%)

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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=10)	Placebo (N=17)
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=14)	Placebo (N=9)
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

		Treatment Group	
		Paroxetine (N=31)	Placebo (N=36)
Body System	Preferred Term		
TOTAL	TOTAL	1 (3.2%)	2 (5.6%)
Nervous System	TOTAL	1 (3.2%)	1 (2.8%)
	EMOTIONAL LABILITY	1 (3.2%)	0
	SOMNOLENCE	0	1 (2.8%)
	WITHDRAWAL SYNDROME	0	1 (2.8%)
Body as a Whole	TOTAL	0	2 (5.6%)
	ASTHENIA	0	1 (2.8%)
	HEADACHE	0	1 (2.8%)
Digestive System	TOTAL	0	1 (2.8%)
	NAUSEA	0	1 (2.8%)

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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=17)	Placebo (N=17)
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=14)	Placebo (N=19)
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=55)	Treatment Group: Placebo (N=62)
TOTAL	TOTAL	3 (5.5%)	4 (6.5%)
Nervous System	TOTAL	2 (3.6%)	2 (3.2%)
	DEPRESSION	1 (1.8%)	0
	EMOTIONAL LABILITY	1 (1.8%)	0
	NERVOUSNESS	1 (1.8%)	0
	ANXIETY	0	1 (1.6%)
	HYPERKINESIA	0	1 (1.6%)
	SOMNOLENCE	0	1 (1.6%)
	WITHDRAWAL SYNDROME	0	1 (1.6%)
Digestive System	TOTAL	1 (1.8%)	2 (3.2%)
	CONSTIPATION	1 (1.8%)	0
	DIARRHEA	0	1 (1.6%)
	NAUSEA	0	1 (1.6%)
Body as a Whole	TOTAL	0	2 (3.2%)
	ASTHENIA	0	1 (1.6%)
	HEADACHE	0	1 (1.6%)
Cardiovascular System	TOTAL	0	1 (1.6%)
	PALPITATION	0	1 (1.6%)
	TACHYCARDIA	0	1 (1.6%)

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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=27)	Placebo (N=34)
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=28)	Placebo (N=28)
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=101)	Treatment Group: Placebo (N=102)
TOTAL	TOTAL	48 (47.5%)	37 (36.3%)
Nervous System	TOTAL	31 (30.7%)	16 (15.7%)
	SOMNOLENCE	10 (9.9%)	8 (7.8%)
	INSOMNIA	10 (9.9%)	6 (5.9%)
	NERVOUSNESS	6 (5.9%)	3 (2.9%)
	DIZZINESS	5 (5.0%)	1 (1.0%)
	HYPERKINESIA	3 (3.0%)	2 (2.0%)
	AGITATION	3 (3.0%)	0
	TREMOR	3 (3.0%)	0
	ABNORMAL DREAMS	2 (2.0%)	0
	CONCENTRATION IMPAIRED	2 (2.0%)	0
	ANXIETY	1 (1.0%)	2 (2.0%)
	EMOTIONAL LABILITY	1 (1.0%)	1 (1.0%)
	CONFUSION	1 (1.0%)	0
	DEPRESSION	1 (1.0%)	0
	HOSTILITY	1 (1.0%)	0
	MYOCLONUS	1 (1.0%)	0
	WITHDRAWAL SYNDROME	0	2 (2.0%)
Digestive System	TOTAL	21 (20.8%)	15 (14.7%)
	NAUSEA	11 (10.9%)	10 (9.8%)
	DECREASED APPETITE	4 (4.0%)	3 (2.9%)
	DYSPEPSIA	4 (4.0%)	2 (2.0%)
	DIARRHEA	3 (3.0%)	1 (1.0%)
	DRY MOUTH	3 (3.0%)	1 (1.0%)
	CONSTIPATION	2 (2.0%)	1 (1.0%)
	INCREASED APPETITE	1 (1.0%)	0
	VOMITING	1 (1.0%)	0
Body as a Whole	TOTAL	16 (15.8%)	19 (18.6%)
	HEADACHE	11 (10.9%)	12 (11.8%)
	ASTHENIA	5 (5.0%)	8 (7.8%)
	ABDOMINAL PAIN	3 (3.0%)	2 (2.0%)
	TRAUMA	2 (2.0%)	0
Respiratory System	TOTAL	8 (7.9%)	0
	COUGH INCREASED	2 (2.0%)	0
	EPISTAXIS	2 (2.0%)	0
	RHINITIS	2 (2.0%)	0
	YAWN	2 (2.0%)	0
	RESPIRATORY DISORDER	1 (1.0%)	0
	SINUSITIS	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=101)	Treatment Group: Placebo (N=102)
Skin and Appendages	TOTAL	5 (5.0%)	2 (2.0%)
	SWEATING	4 (4.0%)	0
	HERPES SIMPLEX	1 (1.0%)	0
	PRURITUS	0	1 (1.0%)
	RASH	0	1 (1.0%)
Urogenital System	TOTAL	4 (4.0%)	1 (1.0%)
	URINATION IMPAIRED	2 (2.0%)	0
	URINARY FREQUENCY	1 (1.0%)	1 (1.0%)
	CYSTITIS	1 (1.0%)	0
	URINARY RETENTION	1 (1.0%)	0
Cardiovascular System	TOTAL	3 (3.0%)	1 (1.0%)
	VASODILATATION	3 (3.0%)	0
	PALPITATION	0	1 (1.0%)
	TACHYCARDIA	0	1 (1.0%)
Special Senses	TOTAL	2 (2.0%)	0
	ABNORMAL VISION	1 (1.0%)	0
	MYDRIASIS	1 (1.0%)	0
Metabolic and Nutritional Disorders	TOTAL	1 (1.0%)	2 (2.0%)
	WEIGHT LOSS	1 (1.0%)	0
	HYPONATREMIA	0	1 (1.0%)
	THIRST	0	1 (1.0%)
Hemic and Lymphatic System	TOTAL	0	2 (2.0%)
	LEUKOPENIA	0	2 (2.0%)

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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=55)
Body System	Preferred Term		
TOTAL	TOTAL	1 (1.9%)	0
Urogenital System	TOTAL	1 (1.9%)	0
	IMPOTENCE	1 (1.9%)	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

Body System	Preferred Term	Treatment Group: Paroxetine (N=48)	Treatment Group: Placebo (N=47)
TOTAL	TOTAL	1 (2.1%)	0
Urogenital System	TOTAL	1 (2.1%)	0
	MENSTRUAL DISORDER	1 (2.1%)	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=46)	Treatment Group: Placebo (N=30)
TOTAL	TOTAL	3 (6.5%)	1 (3.3%)
Nervous System	TOTAL	3 (6.5%)	0
	DIZZINESS	2 (4.3%)	0
	MANIC DEPRESSIVE REACTION	1 (2.2%)	0
	NERVOUSNESS	1 (2.2%)	0
	SOMNOLENCE	1 (2.2%)	0
	TREMOR	1 (2.2%)	0
Body as a Whole	TOTAL	1 (2.2%)	0
	HEADACHE	1 (2.2%)	0
Cardiovascular System	TOTAL	1 (2.2%)	0
	HYPERTENSION	1 (2.2%)	0
	TACHYCARDIA	1 (2.2%)	0
Digestive System	TOTAL	1 (2.2%)	1 (3.3%)
	NAUSEA	1 (2.2%)	1 (3.3%)
Skin and Appendages	TOTAL	1 (2.2%)	0
	SWEATING	1 (2.2%)	0
Special Senses	TOTAL	1 (2.2%)	0
	ABNORMAL VISION	1 (2.2%)	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

Body System	Preferred Term	Treatment Group: Paroxetine (N=25)	Treatment Group: Placebo (N=17)
TOTAL	TOTAL	0	1 (5.9%)
Urogenital System	TOTAL	0	1 (5.9%)
	ABNORMAL EJACULATION	0	1 (5.9%)

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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=21)	Placebo (N=13)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

Table 15.1.5: Safety Narrative for Patients who were withdrawn due to Adverse Experiences

Patients With Non-Serious Adverse Events Leading to Withdrawal

PID: 701.148.27660

Treatment Group: Paroxetine

Adverse Event: Hostility (Increased Aggression)

This 9-year-old Hispanic male was a participant in the trial of BRL-29060/701, which was conducted in children and adolescents with major depressive disorder (MDD).

The patient entered the study with no significant previous medical conditions reported, but with a surgical history of inguinal hernia repair. Current medical history includes asthma, allergic rhinitis, nickel allergy, stomach rash, non-specific sinusitis, and stomach aches. Psychiatric history (measured by K-SADS-PL interview) includes current history of MDD, onset May 2000, with no other psychiatric disorders identified.

Prior medications for asthma, which were continued into the study, were budesonide inhalation (Pulmicort®), oral montelukast sodium (Singulair®), salbutamol inhalation (Albuterol®), and salmeterol hydronaphthoate inhalation (Serevent®). Loratadine (Claritin®) for allergies was also continued into the study. Other concomitant medications include paracetamol (Tylenol®), given for headache on Day 23, and brompheniramine maleate/phenylephrine HCl/phenylpropanolamine HCl (Dimetapp®), given as needed for allergies, beginning on Day 6.

The patient was randomized to the paroxetine regimen and took the first dose of paroxetine on 18 November 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to the highest dose of 20 mg on 02 December 2000. On 19 November (Day 2), while at a dose level of 10 mg, the patient experienced severe hostility (increased aggression) that lasted for 32 days. No treatment was given for this non-serious event that the investigator considered to be possibly related to treatment with study medication. This event resulted in the withdrawal of the patient from the study. The patient discontinued study medication on 17 December 2000 (Day 30).

PID: 701.148.27660 (continued)

The patient was also reported to have experienced mild tremor (shaky feeling) with onset on 20 November 2000 (Day 3) and a duration of 9 days, moderately severe purpura (bruised right cheek) with onset 22 November 2000 (Day 5) and continuing at study end, moderately severe headache with onset 09 December 2000 (Day 22) and a duration of 1 day, two episodes of melena on Day 22 with a duration of 1 day, and mild tremor of right hand with onset on 11 December (Day 24) and a duration of 9 days. The tremor (shaky feeling) was considered to be possibly related to treatment with study medication, and headache and melena were considered to be probably unrelated to treatment with study medication. Hand tremor and purpura were considered to be unrelated to treatment with study medication.

Patients With Non-Serious Adverse Events Leading to Withdrawal

PID: 701.149.27665

Treatment Group: Paroxetine

Adverse event: Epistaxis (Nose Bleed)

This 9-year-old white female was a participant in the trial of BRL-29060/701, which was conducted in children and adolescents with major depressive disorder (MDD).

The patient entered the study with no significant previous medical history reported, but a previous surgical history of bilateral inguinal hernia repair and umbilical hernia repair. Current medical history includes asthma and allergy to penicillin. Psychiatric history (measured by K-SADS-PL interview) includes current MDD with an onset of July 2000. No other psychiatric disorders were identified.

No previous or concomitant medications were reported.

The patient was randomized to the paroxetine regimen and took the first dose of paroxetine on 05 October 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to the highest dose of 30 mg/day on 20 October 2000. On 20 October 2000 (Day 16), while at a dose level of 30 mg, the patient experienced moderately severe epistaxis that resolved within 4 days. No treatment was given for this non-serious event that was considered by the investigator to be related to treatment with study medication. This event resulted in withdrawal of the patient from study. The patient discontinued study medication on 21 October 2000 (Day 17).

The patient also experienced a mild infection (scabies) on 05 October 2000 (Day 1) that resolved within 22 days, reportedly without treatment. The investigator considered the scabies to be unrelated to treatment with study medication.

The patient was started on buspirone HCl (BuSpar®) for major depressive disorder beginning 6 days after withdrawal from the study.

Patients With Non-Serious Adverse Events Leading to Withdrawal

PID: 701.161.25653

Treatment Group: Paroxetine

Adverse event: Agitation/Nervousness (Agitation, Irritability)

This 8-year-old white male was a participant in the trial of BRL-29060/701, which was conducted in children and adolescents with major depressive disorder (MDD).

The patient entered the study with a previous surgical history of tonsillectomy, adenoidectomy and repair of a communicating hydrocele. Previous and current medical conditions include asthma, obesity, recurrent ear infections and corrective lenses. Psychiatric history (measured by K-SADS-PL interview) includes previous and current MDD with an onset of January 1993, overanxious disorder with an onset of January 1994, and generalized anxiety disorder with an onset of January 1994.

Concomitant medication included salbuterol inhalation (Albuterol®) for asthma, paroxetine (Paxil®) for major depressive disorder (beginning Day 47), and risperidone (Risperdal®) for agitation (beginning Day 47).

The patient was randomized to the paroxetine regimen and took the first dose of paroxetine on 29 June 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to the highest dose of 50 mg/day on 01 August 2000. On 14 August 2000, while at a dose level of 50 mg, the patient experienced moderately severe agitation and irritability that continued beyond the end of the study. The patient was treated with risperidone (Risperdal®) beginning 14 August 2000 (Day 47). This non-serious event was considered by the investigator to be possibly related to treatment with study medication. These events resulted in withdrawal of the patient from the study. The patient discontinued study medication on 14 August 2000 (Day 47).

No other adverse events were reported.

The patient was started on prescription paroxetine (Paxil®) for major depressive disorder on 14 August 2000 (Day 47).

Patients With Non-Serious Adverse Events Leading to Withdrawal

PID: 701.182.25816

Treatment Group: Paroxetine

Adverse event: Depression (Exacerbation of Depressive Symptoms)

This 8-year-old white female was a participant in the trial of BRL-29060/701, which was conducted in children and adolescents with major depressive disorder (MDD).

The patient entered the study with no significant previous medical or surgical history reported. Current medical history includes migraine headache. Psychiatric history (measured by K-SADS-PL interview) includes previous and current MDD with an onset of January 2000. No other psychiatric disorders were identified.

Previous medications included bismuth subsalicylate (Pepto-Bismol®) given for stomach ache 9 days before the start of study medication, and lidocaine/prilocaine (EMLA®) topical anesthetic given 7 days before the start of study medication to ease the discomfort of injection for laboratory tests. Concomitant medications included ibuprofen/pseudoephedrine HCl (Advil Cough and Sinus®) medication (Day 1) for sneezing, congestion and cough, ibuprofen (Day 34) for headache; and ibuprofen (Motrin®), prescribed as needed, for headache.

The patient was randomized to the paroxetine regimen and took the first dose of paroxetine on 08 November 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to the highest dose of 20 mg on 06 December 2000. On 05 December 2000 (Day 28), while at a dose level of 10 mg, the patient experienced a moderately severe exacerbation of depressive symptoms that continued beyond the end of the study. No treatment was given for this non-serious event that was considered by the investigator to be probably unrelated to treatment with study medication. The exacerbation of depressive symptoms resulted in withdrawal of the patient from the study. The patient discontinued study medication on 11 December 2000 (Day 34).

PID: 701.182.25816 (continued)

The patient also experienced decreased appetite (Day –6) that resolved in 10 days, increased cough, congestion, and sneezing (Day 1) that resolved in 2 days, vomiting (Day 9) that resolved in 1 day, asthenia (Day 18) that resolved in 14 days, emotional lability (Day 20) that continued throughout the study, and headache (Day 34) that resolved in 1 day. All of these events were considered to be mild in severity, and all (except decreased appetite, for which no attribution was provided, inasmuch as this event began before administration of study med) were considered to be unrelated to treatment with study medication.

On 28 November 2000 (Week 3), the patient's pulse rate decreased to 52 bpm, reaching the level of potential clinical concern. The level of clinical concern is defined as above or below the normal limits of 65-155 bpm with a corresponding significant increase or decrease in pulse rate.

The pulse rate values ranged from the low of 52 bpm (Week 3) to 122 bpm (Baseline). The diastolic blood pressure was within normal limits throughout (range 61 to 80 mmHg); the systolic blood pressure was slightly decreased to 94 mmHg (screening) and to 85 mmHg on 05 December 2000 (Week 4). The range of systolic blood pressure was 85 mmHg (Week 4) to 108 mmHg (Week 2).

Patients With Non-Serious Adverse Events Leading to Withdrawal

PID: 701.161.25650

Treatment Group: Paroxetine

Adverse event: Pyelonephritis (Pyelonephritis)

This 15-year-old white female was a participant in the trial of BRL-29060/701, which was conducted in children and adolescents with major depressive disorder (MDD).

The patient entered the study with no significant previous medical or surgical history reported. Current medical history includes periodontal abscess. Psychiatric history (measured by K-SADS-PL interview) includes previous and current MDD with an onset of March 1998, and Post-Traumatic Stress Syndrome (PTSD) with an onset of August 1998. No other psychiatric disorders were identified.

Previous medications included amfebutamone HCl (Wellbutrin®) for major depressive disorder, and paracetamol/hydrocodone bitartrate (Vicodin®) for dental surgery. Concomitant medications were given for pyelonephritis; these were promethazine HCl (Phenergan®) given on Days 57-62, and sulphamethoxazole/trimethoprim (Septra®) given on Days 57-71.

The patient was randomized to the paroxetine regimen and took the first dose of paroxetine on 10 July 2000. The patient began treatment at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to the highest dose of 40 mg/day on 09 August 2000. On 22 August 2000 (Day 44), while at a dose level of 40 mg/day, the patient experienced moderately severe pyelonephritis. Pyelonephritis was treated with Phenergan® and Septra® and resolved within 28 days. This event was considered by the investigator to be unrelated to treatment with study medication, but the patient was withdrawn from the study. The patient discontinued study medication on 12 September 2000.

The patient also experienced moderately severe insomnia (Day 9) that continued beyond the end of the study, and mild nausea (Day 24) that resolved in one day.

PID: 701.161.25650 (continued)

Neither event required treatment. Nausea was considered to be related to treatment with study medication, and insomnia was considered to be possibly related to treatment with study medication. No other adverse events were reported.

Patients With Non-Serious Adverse Events Leading to Withdrawal

PID: 701.162.25970

Treatment Group: Placebo

Adverse event: Emotional Lability (Mood Swings), Insomnia (Insomnia), Nervousness (Restlessness)

This 17-year-old white female was a participant in the trial of BRL-29060/701, which was conducted in children and adolescents with major depressive disorder (MDD).

The patient entered the study with no significant previous medical history, and with a surgical history of appendectomy and extraction of wisdom teeth. No significant current medical conditions were reported. Psychiatric history (measured by K-SADS-PL interview) includes current MDD with an onset date of January 2000. No other psychiatric disorders were identified.

Previous and current medications included the oral contraceptive desogestrel/ ethinylestradiol (Ortho-Cept 28®) for birth control.

The patient was randomized to the placebo regimen and took the first dose of study medication on 05 August 2000. The patient began receiving treatment at dose level 1 (equivalent to 10 mg/day of active medication). The last dose of study medication was taken on 11 August 2000. On 05 August 2000 (Day 1), the patient experienced severe emotional lability (mood swings) that resolved without treatment within 9 days. On Day 3, mild insomnia and moderately severe nervousness (restlessness) were reported. These events were untreated and resolved within 7 days. All three of these non-serious events resulted in withdrawal from the study. The investigator considered all to be possibly related to treatment with study medication. No other adverse events were reported.

BRL 29060 - 701

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=49)	 Placebo (N=47)
TOTAL	TOTAL	6 (12.2%)	0
Body as a Whole	TOTAL	4 (8.2%)	0
	HEADACHE	2 (4.1%)	0
	ASTHENIA	1 (2.0%)	0
	INFECTION	1 (2.0%)	0
	PAIN	1 (2.0%)	0
Nervous System	TOTAL	4 (8.2%)	0
	DEPRESSION	2 (4.1%)	0
	AGITATION	1 (2.0%)	0
	EMOTIONAL LABILITY	1 (2.0%)	0
	HOSTILITY	1 (2.0%)	0
	NERVOUSNESS	1 (2.0%)	0
	TREMOR	1 (2.0%)	0
Digestive System	TOTAL	2 (4.1%)	0
	MELENA	1 (2.0%)	0
	VOMITING	1 (2.0%)	0
Respiratory System	TOTAL	2 (4.1%)	0
	COUGH INCREASED	1 (2.0%)	0
	EPISTAXIS	1 (2.0%)	0
	RESPIRATORY DISORDER	1 (2.0%)	0
	RHINITIS	1 (2.0%)	0
Hemic and Lymphatic System	TOTAL	1 (2.0%)	0
	PURPURA	1 (2.0%)	0

BRL 29060 - 701

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=26)	Placebo (N=29)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

BRL 29060 - 701

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=23)	Placebo (N=18)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

BRL 29060 - 701

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=52)	Placebo (N=55)
Body System	Preferred Term		
TOTAL	TOTAL	2 (3.8%)	1 (1.8%)
Nervous System	TOTAL	2 (3.8%)	1 (1.8%)
	INSOMNIA	2 (3.8%)	1 (1.8%)
	EMOTIONAL LABILITY	0	1 (1.8%)
	NERVOUSNESS	0	1 (1.8%)
Digestive System	TOTAL	1 (1.9%)	0
	NAUSEA	1 (1.9%)	0
Respiratory System	TOTAL	1 (1.9%)	0
	COUGH INCREASED	1 (1.9%)	0
	SINUSITIS	1 (1.9%)	0
Urogenital System	TOTAL	1 (1.9%)	0
	PYELONEPHRITIS	1 (1.9%)	0

BRL 29060 - 701

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=27)	Placebo (N=26)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

BRL 29060 - 701

Table 15.1.5.1

Number (%) of Patients with Emergent Adverse Experiences Leading to Withdrawal During the Treatment Phase
By Body System
Intention-To-Treat Population
Age Group : Adolescents
Female Specific Adverse Experiences

		Treatment Group	
		Paroxetine (N=25)	Placebo (N=29)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

BRL 29060 - 701

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=101)	Treatment Group: Placebo (N=102)
TOTAL	TOTAL	8 (7.9%)	1 (1.0%)
Nervous System	TOTAL	6 (5.9%)	1 (1.0%)
	INSOMNIA	2 (2.0%)	1 (1.0%)
	DEPRESSION	2 (2.0%)	0
	EMOTIONAL LABILITY	1 (1.0%)	1 (1.0%)
	NERVOUSNESS	1 (1.0%)	1 (1.0%)
	AGITATION	1 (1.0%)	0
	HOSTILITY	1 (1.0%)	0
	TREMOR	1 (1.0%)	0
Body as a Whole	TOTAL	4 (4.0%)	0
	HEADACHE	2 (2.0%)	0
	ASTHENIA	1 (1.0%)	0
	INFECTION	1 (1.0%)	0
	PAIN	1 (1.0%)	0
Digestive System	TOTAL	3 (3.0%)	0
	MELENA	1 (1.0%)	0
	NAUSEA	1 (1.0%)	0
	VOMITING	1 (1.0%)	0
Respiratory System	TOTAL	3 (3.0%)	0
	COUGH INCREASED	2 (2.0%)	0
	EPISTAXIS	1 (1.0%)	0
	RESPIRATORY DISORDER	1 (1.0%)	0
	RHINITIS	1 (1.0%)	0
	SINUSITIS	1 (1.0%)	0
Hemic and Lymphatic System	TOTAL	1 (1.0%)	0
	PURPURA	1 (1.0%)	0
Urogenital System	TOTAL	1 (1.0%)	0
	PYELONEPHRITIS	1 (1.0%)	0

BRL 29060 - 701

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=55)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

BRL 29060 - 701

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=48)	Placebo (N=47)
Body System	Preferred Term		
TOTAL	TOTAL	0	0

BRL 29060 - 701

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=49)	Treatment Group: Placebo (N=47)
TOTAL	6 (12.2%)	0
DEPRESSION	2 (4.1%)	0
HEADACHE	2 (4.1%)	0
AGITATION	1 (2.0%)	0
ASTHENIA	1 (2.0%)	0
COUGH INCREASED	1 (2.0%)	0
EMOTIONAL LABILITY	1 (2.0%)	0
EPISTAXIS	1 (2.0%)	0
HOSTILITY	1 (2.0%)	0
INFECTION	1 (2.0%)	0
MELENA	1 (2.0%)	0
NERVOUSNESS	1 (2.0%)	0
PAIN	1 (2.0%)	0
PURPURA	1 (2.0%)	0
RESPIRATORY DISORDER	1 (2.0%)	0
RHINITIS	1 (2.0%)	0
TREMOR	1 (2.0%)	0
VOMITING	1 (2.0%)	0

BRL 29060 - 701

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=26)	Placebo (N=29)
TOTAL	0	0

BRL 29060 - 701

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=23)	 Placebo (N=18)
TOTAL	0	0

BRL 29060 - 701

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=52)	 Placebo (N=55)
TOTAL	2 (3.8%)	1 (1.8%)
INSOMNIA	2 (3.8%)	1 (1.8%)
COUGH INCREASED	1 (1.9%)	0
NAUSEA	1 (1.9%)	0
PYELONEPHRITIS	1 (1.9%)	0
SINUSITIS	1 (1.9%)	0
EMOTIONAL LABILITY	0	1 (1.8%)
NERVOUSNESS	0	1 (1.8%)

BRL 29060 - 701

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=27)	Placebo (N=26)
TOTAL	0	0

BRL 29060 - 701

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=25)	Placebo (N=29)
TOTAL	0	0

BRL 29060 - 701

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=101)	 Placebo (N=102)
TOTAL	8 (7.9%)	1 (1.0%)
INSOMNIA	2 (2.0%)	1 (1.0%)
COUGH INCREASED	2 (2.0%)	0
DEPRESSION	2 (2.0%)	0
HEADACHE	2 (2.0%)	0
EMOTIONAL LABILITY	1 (1.0%)	1 (1.0%)
NERVOUSNESS	1 (1.0%)	1 (1.0%)
AGITATION	1 (1.0%)	0
ASTHENIA	1 (1.0%)	0
EPISTAXIS	1 (1.0%)	0
HOSTILITY	1 (1.0%)	0
INFECTION	1 (1.0%)	0
MELENA	1 (1.0%)	0
NAUSEA	1 (1.0%)	0
PAIN	1 (1.0%)	0
PURPURA	1 (1.0%)	0
PYELONEPHRITIS	1 (1.0%)	0
RESPIRATORY DISORDER	1 (1.0%)	0
RHINITIS	1 (1.0%)	0
SINUSITIS	1 (1.0%)	0
TREMOR	1 (1.0%)	0
VOMITING	1 (1.0%)	0

BRL 29060 - 701

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)	Treatment Group: Placebo (N=55)
TOTAL	0	0

BRL 29060 - 701

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=48)	Treatment Group: Placebo (N=47)
TOTAL	0	0

BRL 29060 - 701

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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=49)	HEADACHE	4	8.2	3	6.1	2	4.1	1	2.0	0	0.0	0	0.0	0	0.0	10	20.4
	NAUSEA	4	8.2	0	0.0	1	2.0	0	0.0	0	0.0	1	2.0	0	0.0	6	12.2
	INFECTION	1	2.0	0	0.0	0	0.0	1	2.0	1	2.0	2	4.1	0	0.0	5	10.2
	RESPIRATORY DISORDER	1	2.0	2	4.1	1	2.0	0	0.0	1	2.0	0	0.0	0	0.0	5	10.2
	TRAUMA	1	2.0	0	0.0	2	4.1	0	0.0	1	2.0	1	2.0	0	0.0	5	10.2
	ABDOMINAL PAIN	0	0.0	0	0.0	2	4.1	1	2.0	0	0.0	1	2.0	0	0.0	4	8.2
	ASTHENIA	1	2.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	3	6.1
	COUGH INCREASED	1	2.0	1	2.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	3	6.1
	DYSPEPSIA	2	4.1	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.1
	FEVER	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	3	6.1
	INSOMNIA	2	4.1	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	3	6.1
	RHINITIS	1	2.0	1	2.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	3	6.1
	SINUSITIS	3	6.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.1
	VOMITING	1	2.0	0	0.0	1	2.0	0	0.0	1	2.0	0	0.0	0	0.0	3	6.1
	AGITATION	0	0.0	0	0.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	2	4.1
	DECREASED APPETITE	1	2.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	2	4.1
	DEPRESSION	0	0.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	0	0.0	2	4.1
	DIARRHEA	2	4.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.1

(CONTINUED)

BRL 29060 - 701

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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Paroxetine (N=49)	DIZZINESS	1	2.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.1
	DRY MOUTH	2	4.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.1
	EPISTAXIS	0	0.0	1	2.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	2	4.1
	NERVOUSNESS	0	0.0	0	0.0	0	0.0	1	2.0	1	2.0	0	0.0	0	0.0	2	4.1
	ABNORMAL DREAMS	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	ABNORMAL VISION	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0
	ARTHRALGIA	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	CARDIAC DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0
	CONCENTRATION IMPAIRED	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	CONSTIPATION	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	ERYTHROCYTES ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0
	FUNGAL DERMATITIS	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	HAEMATURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0
	HERPES SIMPLEX	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0
	HOSTILITY	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0

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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

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=49)	HYPERKINESIA	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	INCREASED APPETITE	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	MELENA	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	MYOCLONUS	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	PAIN	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	PHARYNGITIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	1	2.0
	PNEUMONIA	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0
	PURPURA	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	SWEATING	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0
	TREMOR	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	ULCERATIVE STOMATITIS	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	URINARY FREQUENCY	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0
	URINARY RETENTION	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0
	URINATION IMPAIRED	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	URTICARIA	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0
	VASODILATATION	0	0.0	0	0.0	0	0.0	1	2.0	0	0.0	0	0.0	0	0.0	1	2.0
	YAWN	1	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.0

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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

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=47)	RESPIRATORY DISORDER	1	2.1	1	2.1	0	0.0	4	8.5	1	2.1	1	2.1	0	0.0	8	17.0
	HEADACHE	2	4.3	0	0.0	0	0.0	3	6.4	0	0.0	2	4.3	0	0.0	7	14.9
	INFECTION	0	0.0	1	2.1	2	4.3	0	0.0	1	2.1	1	2.1	0	0.0	5	10.6
	TRAUMA	0	0.0	2	4.3	2	4.3	0	0.0	1	2.1	0	0.0	0	0.0	5	10.6
	ASTHENIA	3	6.4	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	4	8.5
	PHARYNGITIS	4	8.5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	8.5
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.4	0	0.0	3	6.4
	COUGH INCREASED	1	2.1	0	0.0	0	0.0	0	0.0	2	4.3	0	0.0	0	0.0	3	6.4
	FEVER	0	0.0	1	2.1	0	0.0	1	2.1	0	0.0	1	2.1	0	0.0	3	6.4
	NAUSEA	2	4.3	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	6.4
	RHINITIS	2	4.3	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	3	6.4
	ABDOMINAL PAIN	0	0.0	1	2.1	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	2	4.3
	DECREASED APPETITE	0	0.0	0	0.0	1	2.1	0	0.0	1	2.1	0	0.0	0	0.0	2	4.3
	DYSPEPSIA	1	2.1	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	2	4.3
	PAIN	1	2.1	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	2	4.3
	SINUSITIS	1	2.1	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	2	4.3
	SOMNOLENCE	2	4.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	4.3
	ALLERGIC REACTION	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	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 : Children
Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Placebo (N=47)	ANXIETY	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	ASTHMA	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	BRONCHITIS	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	1	2.1
	DEPRESSION	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	1	2.1
	DIARRHEA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	1	2.1
	DIZZINESS	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	1	2.1
	FUNGAL DERMATITIS	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	GASTROENTERITIS	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	HERPES ZOSTER	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	1	2.1
	HYPONATREMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	1	2.1
	KETOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	1	2.1
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	1	2.1
	MIGRAINE	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	NERVOUSNESS	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	1	2.1
	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	1	2.1
	OTITIS MEDIA	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	1	2.1
	PRURITUS	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	RASH	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	1	2.1
	THIRST	0	0.0	1	2.1	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 : Children
Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Placebo (N=47)	TOOTH CARIES	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	TOOTH DISORDER	0	0.0	0	0.0	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	ULCERATIVE STOMATITIS	1	2.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
	URINARY TRACT INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	0	0.0	1	2.1
	VOMITING	0	0.0	0	0.0	0	0.0	1	2.1	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 : Children
Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Paroxetine (N=26)	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

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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		Post Week 8		Total	
		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

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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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Paroxetine (N=23)	TOTAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Placebo (N=18)	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

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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=52)	HEADACHE	5	9.6	3	5.8	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	10	19.2
	SOMNOLENCE	2	3.8	2	3.8	2	3.8	4	7.7	0	0.0	0	0.0	0	0.0	10	19.2
	INSOMNIA	3	5.8	2	3.8	2	3.8	1	1.9	0	0.0	0	0.0	0	0.0	8	15.4
	TRAUMA	2	3.8	0	0.0	1	1.9	1	1.9	3	5.8	1	1.9	0	0.0	8	15.4
	NAUSEA	3	5.8	0	0.0	1	1.9	1	1.9	1	1.9	1	1.9	0	0.0	7	13.5
	PHARYNGITIS	1	1.9	0	0.0	2	3.8	1	1.9	1	1.9	2	3.8	0	0.0	7	13.5
	RESPIRATORY DISORDER	3	5.8	0	0.0	1	1.9	2	3.8	0	0.0	0	0.0	0	0.0	6	11.5
	ASTHENIA	2	3.8	0	0.0	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	4	7.7
	FEVER	1	1.9	1	1.9	1	1.9	0	0.0	1	1.9	0	0.0	0	0.0	4	7.7
	NERVOUSNESS	3	5.8	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	7.7
	OTITIS MEDIA	1	1.9	0	0.0	0	0.0	2	3.8	0	0.0	1	1.9	0	0.0	4	7.7
	CONTACT DERMATITIS	1	1.9	1	1.9	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	3	5.8
	COUGH INCREASED	2	3.8	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	3	5.8
	DIZZINESS	1	1.9	0	0.0	0	0.0	2	3.8	0	0.0	0	0.0	0	0.0	3	5.8
	DYSPEPSIA	1	1.9	0	0.0	0	0.0	1	1.9	1	1.9	0	0.0	0	0.0	3	5.8
	SINUSITIS	0	0.0	1	1.9	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	3	5.8
	SWEATING	0	0.0	0	0.0	2	3.8	0	0.0	1	1.9	0	0.0	0	0.0	3	5.8
	VOMITING	0	0.0	1	1.9	2	3.8	0	0.0	0	0.0	0	0.0	0	0.0	3	5.8

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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 : Adolescents
Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Post Week 8		Total	
Treatment Group	Preferred Term	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=52)	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	1	1.9	0	0.0	2	3.8
	CYSTITIS	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	2	3.8
	DECREASED APPETITE	1	1.9	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	2	3.8
	DIARRHEA	0	0.0	2	3.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8
	HYPERKINESIA	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8
	INFECTION	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	2	3.8
	PAIN	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	2	3.8
	RHINITIS	1	1.9	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	2	3.8
	TREMOR	1	1.9	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	2	3.8
	VASODILATATION	0	0.0	0	0.0	1	1.9	1	1.9	0	0.0	0	0.0	0	0.0	2	3.8
	ABNORMAL DREAMS	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9
	AGITATION	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	ALLERGIC REACTION	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	ANXIETY	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	BACK PAIN	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	CONCENTRATION IMPAIRED	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	CONFUSION	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	CONJUNCTIVITIS	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Adolescents
Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Paroxetine (N=52)	DRY MOUTH	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	EPISTAXIS	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	MYALGIA	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	MYDRIASIS	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	MYOCLONUS	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	1	1.9
	PURPURA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	1	1.9
	PYELONEPHRITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9
	PYURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	1	1.9
	RASH	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9
	SKIN HYPERTROPHY	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	1	1.9
	TOOTH DISORDER	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	URINARY TRACT INFECTION	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	URINATION IMPAIRED	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	URTICARIA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9	0	0.0	0	0.0	1	1.9
	WEIGHT LOSS	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9
	YAWN	0	0.0	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Adolescents
Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Post Week 8		Total	
Treatment Group	Preferred Term	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=55)	HEADACHE	10	18.2	1	1.8	1	1.8	1	1.8	0	0.0	0	0.0	0	0.0	13	23.6
	INSOMNIA	5	9.1	0	0.0	1	1.8	0	0.0	1	1.8	0	0.0	0	0.0	7	12.7
	NAUSEA	4	7.3	0	0.0	2	3.6	0	0.0	0	0.0	0	0.0	0	0.0	6	10.9
	ASTHENIA	3	5.5	0	0.0	1	1.8	0	0.0	1	1.8	0	0.0	0	0.0	5	9.1
	SOMNOLENCE	4	7.3	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	5	9.1
	NERVOUSNESS	2	3.6	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	5.5
	RESPIRATORY DISORDER	1	1.8	0	0.0	0	0.0	0	0.0	2	3.6	0	0.0	0	0.0	3	5.5
	TRAUMA	0	0.0	1	1.8	1	1.8	0	0.0	0	0.0	1	1.8	0	0.0	3	5.5
	ALLERGIC REACTION	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	2	3.6
	DECREASED APPETITE	1	1.8	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	2	3.6
	EMOTIONAL LABILITY	2	3.6	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	3.6
	PHARYNGITIS	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	1	1.8	0	0.0	2	3.6
	SINUSITIS	0	0.0	1	1.8	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	2	3.6
	ABDOMINAL PAIN	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	ANXIETY	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	ARTHRALGIA	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	1	1.8
	CONSTIPATION	1	1.8	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 : Adolescents
Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Placebo (N=55)	DIARRHEA	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	DRY MOUTH	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	DYSPEPSIA	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 PAIN	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	1	1.8
	FEVER	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	1	1.8
	FUNGAL DERMATITIS	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	GASTRITIS	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	HYPERKINESIA	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	1	1.8
	LARYNX DISORDER	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	1	1.8
	LIVER FUNCTION TESTS ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	0	0.0	1	1.8
	MIGRAINE	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	OTITIS MEDIA	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	URINARY FREQUENCY	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	VOMITING	0	0.0	0	0.0	1	1.8	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8
	WITHDRAWAL SYNDROME	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.8	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 : Adolescents
Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Paroxetine (N=27)	IMPOTENCE	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.7

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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
Male Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Placebo (N=26)	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

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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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Paroxetine (N=25)	MENSTRUAL DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0	1	4.0

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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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Placebo (N=29)	DYSMENORRHEA	1	3.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	3.4

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total
Gender Non Specific Adverse Experiences

Treatment Group	Preferred Term	Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=101)	HEADACHE	9	8.9	6	5.9	3	3.0	2	2.0	0	0.0	0	0.0	0	0.0	20	19.8
	NAUSEA	7	6.9	0	0.0	2	2.0	1	1.0	1	1.0	2	2.0	0	0.0	13	12.9
	TRAUMA	3	3.0	0	0.0	3	3.0	1	1.0	4	4.0	2	2.0	0	0.0	13	12.9
	INSOMNIA	5	5.0	2	2.0	2	2.0	1	1.0	1	1.0	0	0.0	0	0.0	11	10.9
	RESPIRATORY DISORDER	4	4.0	2	2.0	2	2.0	2	2.0	1	1.0	0	0.0	0	0.0	11	10.9
	SOMNOLENCE	2	2.0	2	2.0	2	2.0	4	4.0	0	0.0	0	0.0	0	0.0	10	9.9
	PHARYNGITIS	1	1.0	0	0.0	2	2.0	1	1.0	1	1.0	3	3.0	0	0.0	8	7.9
	ASTHENIA	3	3.0	0	0.0	2	2.0	2	2.0	0	0.0	0	0.0	0	0.0	7	6.9
	FEVER	2	2.0	2	2.0	1	1.0	0	0.0	1	1.0	1	1.0	0	0.0	7	6.9
	INFECTION	1	1.0	1	1.0	0	0.0	1	1.0	2	2.0	2	2.0	0	0.0	7	6.9
	COUGH INCREASED	3	3.0	1	1.0	0	0.0	1	1.0	1	1.0	0	0.0	0	0.0	6	5.9
	DYSPEPSIA	3	3.0	1	1.0	0	0.0	1	1.0	1	1.0	0	0.0	0	0.0	6	5.9
	NERVOUSNESS	3	3.0	1	1.0	0	0.0	1	1.0	1	1.0	0	0.0	0	0.0	6	5.9
	SINUSITIS	3	3.0	1	1.0	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	6	5.9
	VOMITING	1	1.0	1	1.0	3	3.0	0	0.0	1	1.0	0	0.0	0	0.0	6	5.9
	DIZZINESS	2	2.0	0	0.0	1	1.0	2	2.0	0	0.0	0	0.0	0	0.0	5	5.0
	RHINITIS	2	2.0	1	1.0	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	5	5.0
	ABDOMINAL PAIN	0	0.0	0	0.0	2	2.0	1	1.0	0	0.0	1	1.0	0	0.0	4	4.0

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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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=101)	DECREASED APPETITE	2	2.0	0	0.0	0	0.0	2	2.0	0	0.0	0	0.0	0	0.0	4	4.0
	DIARRHEA	2	2.0	2	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	4.0
	OTITIS MEDIA	1	1.0	0	0.0	0	0.0	2	2.0	0	0.0	1	1.0	0	0.0	4	4.0
	SWEATING	0	0.0	0	0.0	2	2.0	1	1.0	1	1.0	0	0.0	0	0.0	4	4.0
	AGITATION	0	0.0	0	0.0	1	1.0	1	1.0	1	1.0	0	0.0	0	0.0	3	3.0
	CONTACT DERMATITIS	1	1.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	3	3.0
	DRY MOUTH	3	3.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3.0
	EPISTAXIS	0	0.0	2	2.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	3	3.0
	HYPERKINESIA	1	1.0	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	3	3.0
	PAIN	1	1.0	0	0.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	3	3.0
	TREMOR	2	2.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	3	3.0
	VASODILATATION	0	0.0	0	0.0	1	1.0	2	2.0	0	0.0	0	0.0	0	0.0	3	3.0
	ABNORMAL DREAMS	1	1.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	2	2.0
	ASTHMA	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0	0	0.0	2	2.0
	CONCENTRATION IMPAIRED	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	CYSTITIS	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	2	2.0
	DEPRESSION	0	0.0	0	0.0	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	2	2.0
	MYOCLONUS	0	0.0	0	0.0	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	2	2.0

(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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=101)	PURPURA	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	2	2.0
	URINATION IMPAIRED	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	URTICARIA	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	2	2.0
	YAWN	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	ABNORMAL VISION	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	ALLERGIC REACTION	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	ANEMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	ANXIETY	1	1.0	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	1	1.0
	BACK PAIN	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	CARDIAC DISORDERS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	CONFUSION	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	CONJUNCTIVITIS	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	CONSTIPATION	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	ERYTHROCYTES ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Paroxetine (N=101)	FUNGAL DERMATITIS	1	1.0	0	0.0	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	1	1.0	0	0.0	1	1.0
	HERPES SIMPLEX	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	HOSTILITY	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	INCREASED APPETITE	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	MELENA	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	MYALGIA	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	MYDRIASIS	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	PNEUMONIA	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	PYELONEPHRITIS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	PYURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	RASH	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 HYPERTROPHY	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 DISORDER	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	ULCERATIVE STOMATITIS	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	URINARY FREQUENCY	0	0.0	0	0.0	0	0.0	1	1.0	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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Paroxetine (N=101)	URINARY RETENTION	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	URINARY TRACT INFECTION	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	WEIGHT LOSS	0	0.0	1	1.0	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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=102)	HEADACHE	12	11.8	1	1.0	1	1.0	4	3.9	0	0.0	2	2.0	0	0.0	20	19.6
	RESPIRATORY DISORDER	2	2.0	1	1.0	0	0.0	4	3.9	3	2.9	1	1.0	0	0.0	11	10.8
	ASTHENIA	6	5.9	0	0.0	1	1.0	0	0.0	2	2.0	0	0.0	0	0.0	9	8.8
	NAUSEA	6	5.9	1	1.0	2	2.0	0	0.0	0	0.0	0	0.0	0	0.0	9	8.8
	TRAUMA	0	0.0	3	2.9	3	2.9	0	0.0	1	1.0	1	1.0	0	0.0	8	7.8
	INSOMNIA	5	4.9	0	0.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	7	6.9
	SOMNOLENCE	6	5.9	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	7	6.9
	INFECTION	0	0.0	1	1.0	2	2.0	0	0.0	2	2.0	1	1.0	0	0.0	6	5.9
	PHARYNGITIS	4	3.9	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0	0	0.0	6	5.9
	DECREASED APPETITE	1	1.0	0	0.0	2	2.0	0	0.0	1	1.0	0	0.0	0	0.0	4	3.9
	FEVER	0	0.0	1	1.0	0	0.0	1	1.0	1	1.0	1	1.0	0	0.0	4	3.9
	NERVOUSNESS	2	2.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	4	3.9
	SINUSITIS	1	1.0	1	1.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	4	3.9
	ABDOMINAL PAIN	1	1.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	3	2.9
	ALBUMINURIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.9	0	0.0	3	2.9
	ALLERGIC REACTION	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0	1	1.0	0	0.0	3	2.9
	COUGH INCREASED	1	1.0	0	0.0	0	0.0	0	0.0	2	2.0	0	0.0	0	0.0	3	2.9
	DYSPEPSIA	2	2.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.9

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Table 15.1.6.1.X

Adverse Experiences Emergent During the Treatment Phase by the Time of First Occurrence
By Descending Order (Number (%) of Patients)
Intention-To-Treat Population
Age Group : Total
Gender Non Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Post Week 8		Total	
Treatment Group	Preferred Term	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=102)	RHINITIS	2	2.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	3	2.9
	ANXIETY	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	DIARRHEA	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0	0	0.0	2	2.0
	EMOTIONAL LABILITY	2	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	FUNGAL DERMATITIS	0	0.0	2	2.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	LEUKOPENIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0	0	0.0	2	2.0
	MIGRAINE	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	2.0
	OTITIS MEDIA	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0	0	0.0	0	0.0	2	2.0
	PAIN	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	2	2.0
	VOMITING	0	0.0	0	0.0	1	1.0	1	1.0	0	0.0	0	0.0	0	0.0	2	2.0
	ARTHRALGIA	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	ASTHMA	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	BRONCHITIS	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	CONSTIPATION	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	DEPRESSION	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	1	1.0
	DIZZINESS	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	DRY MOUTH	1	1.0	0	0.0	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	0	0.0	1	1.0	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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Placebo (N=102)	GASTRITIS	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	GASTROENTERITIS	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	HERPES ZOSTER	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0	1	1.0
	HYPERKINESIA	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	HYPONATREMIA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	KETOSIS	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	LARYNX DISORDER	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	LIVER FUNCTION TESTS ABNORMAL	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	OTITIS EXTERNA	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	0	0.0	1	1.0
	PRURITUS	0	0.0	1	1.0	0	0.0	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	1	1.0
	THIRST	0	0.0	1	1.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0
	TOOTH CARIES	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	0	0.0	0	0.0	1	1.0	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	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	1	1.0
	URINARY TRACT INFECTION	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Placebo (N=102)	WITHDRAWAL SYNDROME	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.0	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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Paroxetine (N=53)	IMPOTENCE	1	1.9	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	1.9

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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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Placebo (N=55)	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

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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		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Paroxetine (N=48)	MENSTRUAL DISORDER	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1	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 : Total
Female Specific Adverse Experiences

		Week 1		Week 2		Week 3		Week 4		Week 6		Week 8		Post Week 8		Total	
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Treatment Group	Preferred Term																
Placebo (N=47)	DYSMENORRHEA	1	2.1	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 15.1.7.1

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=101)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	57	56.4	44	43.6	8	7.9
Body as a Whole	TOTAL	30	29.7	17	16.8	4	4.0
	ABDOMINAL PAIN	3	3.0	1	1.0	0	0.0
	ALLERGIC REACTION	1	1.0	0	0.0	0	0.0
	ASTHENIA	5	5.0	2	2.0	0	0.0
	BACK PAIN	1	1.0	0	0.0	0	0.0
	FEVER	5	5.0	2	2.0	0	0.0
	HEADACHE	8	7.9	11	10.9	1	1.0
	INFECTION	4	4.0	3	3.0	0	0.0
	PAIN	3	3.0	0	0.0	0	0.0
	TRAUMA	7	6.9	3	3.0	3	3.0
Cardiovascular System	TOTAL	2	2.0	2	2.0	0	0.0
	CARDIAC DISORDERS	1	1.0	0	0.0	0	0.0
	VASODILATATION	1	1.0	2	2.0	0	0.0
Digestive System	TOTAL	24	23.8	8	7.9	0	0.0
	CONSTIPATION	1	1.0	0	0.0	0	0.0
	DECREASED APPETITE	1	1.0	3	3.0	0	0.0
	DIARRHEA	2	2.0	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=101)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DRY MOUTH	3	3.0	0	0.0	0	0.0
	DYSPEPSIA	5	5.0	1	1.0	0	0.0
	INCREASED APPETITE	1	1.0	0	0.0	0	0.0
	MELENA	1	1.0	0	0.0	0	0.0
	NAUSEA	11	10.9	2	2.0	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	5.0	1	1.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.0	3	3.0	0	0.0
	ANEMIA	0	0.0	1	1.0	0	0.0
	ERYTHROCYTES ABNORMAL	1	1.0	0	0.0	0	0.0
	PURPURA	0	0.0	2	2.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	1	1.0	0	0.0	0	0.0
	WEIGHT LOSS	1	1.0	0	0.0	0	0.0
Musculoskeletal System	TOTAL	1	1.0	1	1.0	0	0.0
	ARTHRALGIA	0	0.0	1	1.0	0	0.0
	MYALGIA	1	1.0	0	0.0	0	0.0
Nervous System	TOTAL	19	18.8	21	20.8	2	2.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System. Intention-To-Treat Population
Treatment Group : Paroxetine (N=101)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	ABNORMAL DREAMS	1	1.0	1	1.0	0	0.0
	AGITATION	0	0.0	3	3.0	0	0.0
	ANXIETY	0	0.0	1	1.0	0	0.0
	CONCENTRATION IMPAIRED	1	1.0	1	1.0	0	0.0
	CONFUSION	0	0.0	1	1.0	0	0.0
	DEPRESSION	0	0.0	2	2.0	0	0.0
	DIZZINESS	3	3.0	2	2.0	0	0.0
	EMOTIONAL LABILITY	1	1.0	0	0.0	0	0.0
	HOSTILITY	0	0.0	0	0.0	1	1.0
	HYPERKINESIA	3	3.0	0	0.0	0	0.0
	INSOMNIA	6	5.9	5	5.0	0	0.0
	MYOCLONUS	2	2.0	0	0.0	0	0.0
	NERVOUSNESS	3	3.0	2	2.0	1	1.0
	SOMNOLENCE	5	5.0	5	5.0	0	0.0
	TREMOR	3	3.0	0	0.0	0	0.0
Respiratory System	TOTAL	21	20.8	11	10.9	0	0.0
	ASTHMA	0	0.0	2	2.0	0	0.0
	COUGH INCREASED	4	4.0	2	2.0	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System. Intention-To-Treat Population
Treatment Group : Paroxetine (N=101)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	EPISTAXIS	2	2.0	1	1.0	0	0.0
	PHARYNGITIS	4	4.0	4	4.0	0	0.0
	PNEUMONIA	0	0.0	1	1.0	0	0.0
	RESPIRATORY DISORDER	10	9.9	1	1.0	0	0.0
	RHINITIS	5	5.0	0	0.0	0	0.0
	SINUSITIS	5	5.0	1	1.0	0	0.0
	YAWN	2	2.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	4	4.0	6	5.9	1	1.0
	CONTACT DERMATITIS	2	2.0	1	1.0	0	0.0
	FUNGAL DERMATITIS	1	1.0	0	0.0	0	0.0
	HERPES SIMPLEX	0	0.0	1	1.0	0	0.0
	RASH	0	0.0	1	1.0	0	0.0
	SKIN HYPERTROPHY	1	1.0	0	0.0	0	0.0
	SWEATING	1	1.0	3	3.0	0	0.0
	URTICARIA	0	0.0	1	1.0	1	1.0
Special Senses	TOTAL	4	4.0	3	3.0	0	0.0
	ABNORMAL VISION	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 : Paroxetine (N=101)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Special Senses	CONJUNCTIVITIS	1	1.0	0	0.0	0	0.0
	MYDRIASIS	1	1.0	0	0.0	0	0.0
	OTITIS MEDIA	2	2.0	2	2.0	0	0.0
Urogenital System	TOTAL	5	5.0	4	4.0	1	1.0
	CYSTITIS	0	0.0	1	1.0	1	1.0
	HAEMATURIA	1	1.0	0	0.0	0	0.0
	PYELONEPHRITIS	0	0.0	1	1.0	0	0.0
	PYURIA	1	1.0	0	0.0	0	0.0
	URINARY FREQUENCY	1	1.0	0	0.0	0	0.0
	URINARY RETENTION	1	1.0	0	0.0	0	0.0
	URINARY TRACT INFECTION	0	0.0	1	1.0	0	0.0
	URINATION IMPAIRED	1	1.0	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	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	1.9	0	0.0	0	0.0
Urogenital System	TOTAL	1	1.9	0	0.0	0	0.0
	IMPOTENCE	1	1.9	0	0.0	0	0.0

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Table 15.1.7.1

Number (%) of Patients with Emergent Adverse Experiences During the Treatment Phase by Maximum Intensity
By Body System. Intention-To-Treat Population
Treatment Group : Paroxetine (N=48)
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	2.1	0	0.0	0	0.0
Urogenital System	TOTAL	1	2.1	0	0.0	0	0.0
	MENSTRUAL DISORDER	1	2.1	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=102)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	54	52.9	29	28.4	4	3.9
Body as a Whole	TOTAL	28	27.5	16	15.7	1	1.0
	ABDOMINAL PAIN	2	2.0	1	1.0	0	0.0
	ALLERGIC REACTION	2	2.0	1	1.0	0	0.0
	ASTHENIA	7	6.9	2	2.0	0	0.0
	FEVER	4	3.9	0	0.0	0	0.0
	HEADACHE	9	8.8	11	10.8	0	0.0
	INFECTION	3	2.9	3	2.9	0	0.0
	PAIN	2	2.0	0	0.0	0	0.0
	TRAUMA	4	3.9	3	2.9	1	1.0
Cardiovascular System	TOTAL	0	0.0	0	0.0	2	2.0
	MIGRAINE	0	0.0	0	0.0	2	2.0
Digestive System	TOTAL	21	20.6	5	4.9	0	0.0
	CONSTIPATION	1	1.0	0	0.0	0	0.0
	DECREASED APPETITE	4	3.9	0	0.0	0	0.0
	DIARRHEA	2	2.0	0	0.0	0	0.0
	DRY MOUTH	1	1.0	0	0.0	0	0.0
	DYSPEPSIA	3	2.9	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=102)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	GASTRITIS	0	0.0	1	1.0	0	0.0
	GASTROENTERITIS	1	1.0	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	1.0	0	0.0	0	0.0
	NAUSEA	8	7.8	1	1.0	0	0.0
	TOOTH CARIES	1	1.0	0	0.0	0	0.0
	TOOTH DISORDER	1	1.0	0	0.0	0	0.0
	ULCERATIVE STOMATITIS	0	0.0	1	1.0	0	0.0
	VOMITING	0	0.0	2	2.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.0	1	1.0	0	0.0
	LEUKOPENIA	1	1.0	1	1.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	3	2.9	0	0.0	0	0.0
	HYPONATREMIA	1	1.0	0	0.0	0	0.0
	KETOSIS	1	1.0	0	0.0	0	0.0
	THIRST	1	1.0	0	0.0	0	0.0
Musculoskeletal System	TOTAL	0	0.0	1	1.0	0	0.0
	ARTHRALGIA	0	0.0	1	1.0	0	0.0
Nervous System	TOTAL	10	9.8	11	10.8	1	1.0
	ANXIETY	1	1.0	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=102)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	DEPRESSION	0	0.0	1	1.0	0	0.0
	DIZZINESS	1	1.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	1	1.0	0	0.0	1	1.0
	HYPERKINESIA	0	0.0	1	1.0	0	0.0
	INSOMNIA	1	1.0	6	5.9	0	0.0
	NERVOUSNESS	2	2.0	2	2.0	0	0.0
	SOMNOLENCE	4	3.9	3	2.9	0	0.0
	WITHDRAWAL SYNDROME	1	1.0	0	0.0	0	0.0
Respiratory System	TOTAL	19	18.6	7	6.9	0	0.0
	ASTHMA	1	1.0	0	0.0	0	0.0
	BRONCHITIS	0	0.0	1	1.0	0	0.0
	COUGH INCREASED	1	1.0	2	2.0	0	0.0
	LARYNX DISORDER	1	1.0	0	0.0	0	0.0
	PHARYNGITIS	4	3.9	2	2.0	0	0.0
	RESPIRATORY DISORDER	9	8.8	2	2.0	0	0.0
	RHINITIS	3	2.9	0	0.0	0	0.0
	SINUSITIS	2	2.0	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 : Placebo (N=102)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Skin and Appendages	TOTAL	5	4.9	0	0.0	0	0.0
	FUNGAL DERMATITIS	2	2.0	0	0.0	0	0.0
	HERPES ZOSTER	1	1.0	0	0.0	0	0.0
	PRURITUS	1	1.0	0	0.0	0	0.0
	RASH	1	1.0	0	0.0	0	0.0
Special Senses	TOTAL	2	2.0	2	2.0	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	1	1.0	1	1.0	0	0.0
Urogenital System	TOTAL	4	3.9	1	1.0	0	0.0
	ALBUMINURIA	3	2.9	0	0.0	0	0.0
	URINARY FREQUENCY	1	1.0	0	0.0	0	0.0
	URINARY TRACT INFECTION	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 : Placebo (N=55)
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=47)
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	1	2.1	0	0.0	0	0.0
Urogenital System	TOTAL	1	2.1	0	0.0	0	0.0
	DYSMENORRHEA	1	2.1	0	0.0	0	0.0

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Table 15.1.7.2

Number (%) of Patients with Emergent Adverse Experiences During the Taper Phase by Maximum Intensity
By Body System. Intention-To-Treat Population Entering The Taper Phase
Treatment Group : Paroxetine (N=55)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	3	5.5	4	7.3	1	1.8
Body as a Whole	TOTAL	0	0.0	2	3.6	0	0.0
	ALLERGIC REACTION	0	0.0	1	1.8	0	0.0
	INFECTION	0	0.0	1	1.8	0	0.0
Digestive System	TOTAL	1	1.8	0	0.0	0	0.0
	CONSTIPATION	1	1.8	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.8	0	0.0	0	0.0
	THROMBOCYTHEMIA	1	1.8	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	1	1.8	1	1.8
	DEPRESSION	0	0.0	1	1.8	0	0.0
	EMOTIONAL LABILITY	0	0.0	0	0.0	1	1.8
	NERVOUSNESS	0	0.0	1	1.8	0	0.0
Respiratory System	TOTAL	0	0.0	1	1.8	0	0.0
	PHARYNGITIS	0	0.0	1	1.8	0	0.0
Special Senses	TOTAL	1	1.8	0	0.0	0	0.0
	OTITIS MEDIA	1	1.8	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=27)
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=28)
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=62)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	7	11.3	4	6.5	0	0.0
Body as a Whole	TOTAL	2	3.2	0	0.0	0	0.0
	ASTHENIA	1	1.6	0	0.0	0	0.0
	HEADACHE	1	1.6	0	0.0	0	0.0
Cardiovascular System	TOTAL	2	3.2	0	0.0	0	0.0
	PALPITATION	1	1.6	0	0.0	0	0.0
	SYNCOPE	1	1.6	0	0.0	0	0.0
	TACHYCARDIA	1	1.6	0	0.0	0	0.0
Digestive System	TOTAL	1	1.6	1	1.6	0	0.0
	DIARRHEA	0	0.0	1	1.6	0	0.0
	NAUSEA	1	1.6	0	0.0	0	0.0
Musculoskeletal System	TOTAL	1	1.6	0	0.0	0	0.0
	MYALGIA	1	1.6	0	0.0	0	0.0
Nervous System	TOTAL	2	3.2	1	1.6	0	0.0
	ANXIETY	1	1.6	0	0.0	0	0.0
	HYPERKINESIA	0	0.0	1	1.6	0	0.0
	SOMNOLENCE	1	1.6	0	0.0	0	0.0
	WITHDRAWAL SYNDROME	1	1.6	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 : Placebo (N=62)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	TOTAL	2	3.2	2	3.2	0	0.0
	BRONCHITIS	0	0.0	1	1.6	0	0.0
	COUGH INCREASED	1	1.6	0	0.0	0	0.0
	RESPIRATORY DISORDER	1	1.6	0	0.0	0	0.0
	RHINITIS	0	0.0	1	1.6	0	0.0
Urogenital System	TOTAL	1	1.6	0	0.0	0	0.0
	HAEMATURIA	1	1.6	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=34)
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=28)
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=101)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	57	56.4	45	44.6	9	8.9
Body as a Whole	TOTAL	30	29.7	18	17.8	4	4.0
	ABDOMINAL PAIN	3	3.0	1	1.0	0	0.0
	ALLERGIC REACTION	1	1.0	1	1.0	0	0.0
	ASTHENIA	5	5.0	2	2.0	0	0.0
	BACK PAIN	1	1.0	0	0.0	0	0.0
	FEVER	5	5.0	2	2.0	0	0.0
	HEADACHE	8	7.9	11	10.9	1	1.0
	INFECTION	4	4.0	4	4.0	0	0.0
	PAIN	3	3.0	0	0.0	0	0.0
	TRAUMA	7	6.9	3	3.0	3	3.0
Cardiovascular System	TOTAL	2	2.0	2	2.0	0	0.0
	CARDIAC DISORDERS	1	1.0	0	0.0	0	0.0
	VASODILATATION	1	1.0	2	2.0	0	0.0
Digestive System	TOTAL	24	23.8	8	7.9	0	0.0
	CONSTIPATION	2	2.0	0	0.0	0	0.0
	DECREASED APPETITE	1	1.0	3	3.0	0	0.0
	DIARRHEA	2	2.0	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=101)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DRY MOUTH	3	3.0	0	0.0	0	0.0
	DYSPEPSIA	5	5.0	1	1.0	0	0.0
	INCREASED APPETITE	1	1.0	0	0.0	0	0.0
	MELENA	1	1.0	0	0.0	0	0.0
	NAUSEA	11	10.9	2	2.0	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	5.0	1	1.0	0	0.0
Hemic and Lymphatic System	TOTAL	2	2.0	3	3.0	0	0.0
	ANEMIA	0	0.0	1	1.0	0	0.0
	ERYTHROCYTES ABNORMAL	1	1.0	0	0.0	0	0.0
	PURPURA	0	0.0	2	2.0	0	0.0
	THROMBOCYTHEMIA	1	1.0	0	0.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	1	1.0	0	0.0	0	0.0
	WEIGHT LOSS	1	1.0	0	0.0	0	0.0
Musculoskeletal System	TOTAL	1	1.0	1	1.0	0	0.0
	ARTHRALGIA	0	0.0	1	1.0	0	0.0
	MYALGIA	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=101)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	TOTAL	19	18.8	22	21.8	3	3.0
	ABNORMAL DREAMS	1	1.0	1	1.0	0	0.0
	AGITATION	0	0.0	3	3.0	0	0.0
	ANXIETY	0	0.0	1	1.0	0	0.0
	CONCENTRATION IMPAIRED	1	1.0	1	1.0	0	0.0
	CONFUSION	0	0.0	1	1.0	0	0.0
	DEPRESSION	0	0.0	3	3.0	0	0.0
	DIZZINESS	3	3.0	2	2.0	0	0.0
	EMOTIONAL LABILITY	1	1.0	0	0.0	1	1.0
	HOSTILITY	0	0.0	0	0.0	1	1.0
	HYPERKINESIA	3	3.0	0	0.0	0	0.0
	INSOMNIA	6	5.9	5	5.0	0	0.0
	MYOCLONUS	2	2.0	0	0.0	0	0.0
	NERVOUSNESS	3	3.0	3	3.0	1	1.0
	SOMNOLENCE	5	5.0	5	5.0	0	0.0
	TREMOR	3	3.0	0	0.0	0	0.0
Respiratory System	TOTAL	21	20.8	12	11.9	0	0.0
	ASTHMA	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=101)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	COUGH INCREASED	4	4.0	2	2.0	0	0.0
	EPISTAXIS	2	2.0	1	1.0	0	0.0
	PHARYNGITIS	4	4.0	5	5.0	0	0.0
	PNEUMONIA	0	0.0	1	1.0	0	0.0
	RESPIRATORY DISORDER	10	9.9	1	1.0	0	0.0
	RHINITIS	5	5.0	0	0.0	0	0.0
	SINUSITIS	5	5.0	1	1.0	0	0.0
	YAWN	2	2.0	0	0.0	0	0.0
Skin and Appendages	TOTAL	4	4.0	6	5.9	1	1.0
	CONTACT DERMATITIS	2	2.0	1	1.0	0	0.0
	FUNGAL DERMATITIS	1	1.0	0	0.0	0	0.0
	HERPES SIMPLEX	0	0.0	1	1.0	0	0.0
	RASH	0	0.0	1	1.0	0	0.0
	SKIN HYPERTROPHY	1	1.0	0	0.0	0	0.0
	SWEATING	1	1.0	3	3.0	0	0.0
	URTICARIA	0	0.0	1	1.0	1	1.0
Special Senses	TOTAL	5	5.0	3	3.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity
By Body System. Intention-To-Treat Population
Treatment Group : Paroxetine (N=101)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Special Senses	ABNORMAL VISION	0	0.0	1	1.0	0	0.0
	CONJUNCTIVITIS	1	1.0	0	0.0	0	0.0
	MYDRIASIS	1	1.0	0	0.0	0	0.0
	OTITIS MEDIA	3	3.0	2	2.0	0	0.0
Urogenital System	TOTAL	5	5.0	4	4.0	1	1.0
	CYSTITIS	0	0.0	1	1.0	1	1.0
	HAEMATURIA	1	1.0	0	0.0	0	0.0
	PYELONEPHRITIS	0	0.0	1	1.0	0	0.0
	PYURIA	1	1.0	0	0.0	0	0.0
	URINARY FREQUENCY	1	1.0	0	0.0	0	0.0
	URINARY RETENTION	1	1.0	0	0.0	0	0.0
	URINARY TRACT INFECTION	0	0.0	1	1.0	0	0.0
	URINATION IMPAIRED	1	1.0	1	1.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity
By Body System. Intention-To-Treat Population
Treatment Group : Paroxetine (N=53)
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	1.9	0	0.0	0	0.0
Urogenital System	TOTAL	1	1.9	0	0.0	0	0.0
	IMPOTENCE	1	1.9	0	0.0	0	0.0

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Table 15.1.7.3

Number (%) of Patients with Emergent Adverse Experiences During the Treatment or Taper Phase by Maximum Intensity
By Body System. Intention-To-Treat Population
Treatment Group : Paroxetine (N=48)
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	2.1	0	0.0	0	0.0
Urogenital System	TOTAL	1	2.1	0	0.0	0	0.0
	MENSTRUAL DISORDER	1	2.1	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=102)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	56	54.9	29	28.4	4	3.9
Body as a Whole	TOTAL	29	28.4	16	15.7	1	1.0
	ABDOMINAL PAIN	2	2.0	1	1.0	0	0.0
	ALLERGIC REACTION	2	2.0	1	1.0	0	0.0
	ASTHENIA	8	7.8	2	2.0	0	0.0
	FEVER	4	3.9	0	0.0	0	0.0
	HEADACHE	9	8.8	11	10.8	0	0.0
	INFECTION	3	2.9	3	2.9	0	0.0
	PAIN	2	2.0	0	0.0	0	0.0
	TRAUMA	4	3.9	3	2.9	1	1.0
Cardiovascular System	TOTAL	2	2.0	0	0.0	2	2.0
	MIGRAINE	0	0.0	0	0.0	2	2.0
	PALPITATION	1	1.0	0	0.0	0	0.0
	SYNCOPE	1	1.0	0	0.0	0	0.0
	TACHYCARDIA	1	1.0	0	0.0	0	0.0
Digestive System	TOTAL	20	19.6	6	5.9	0	0.0
	CONSTIPATION	1	1.0	0	0.0	0	0.0
	DECREASED APPETITE	4	3.9	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=102)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Digestive System	DIARRHEA	1	1.0	1	1.0	0	0.0
	DRY MOUTH	1	1.0	0	0.0	0	0.0
	DYSPEPSIA	3	2.9	0	0.0	0	0.0
	GASTRITIS	0	0.0	1	1.0	0	0.0
	GASTROENTERITIS	1	1.0	0	0.0	0	0.0
	LIVER FUNCTION TESTS ABNORMAL	1	1.0	0	0.0	0	0.0
	NAUSEA	9	8.8	1	1.0	0	0.0
	TOOTH CARIES	1	1.0	0	0.0	0	0.0
	TOOTH DISORDER	1	1.0	0	0.0	0	0.0
	ULCERATIVE STOMATITIS	0	0.0	1	1.0	0	0.0
	VOMITING	0	0.0	2	2.0	0	0.0
Hemic and Lymphatic System	TOTAL	1	1.0	1	1.0	0	0.0
	LEUKOPENIA	1	1.0	1	1.0	0	0.0
Metabolic and Nutritional Disorders	TOTAL	3	2.9	0	0.0	0	0.0
	HYPONATREMIA	1	1.0	0	0.0	0	0.0
	KETOSIS	1	1.0	0	0.0	0	0.0
	THIRST	1	1.0	0	0.0	0	0.0
Musculoskeletal System	TOTAL	1	1.0	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=102)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Musculoskeletal System	ARTHRALGIA	0	0.0	1	1.0	0	0.0
	MYALGIA	1	1.0	0	0.0	0	0.0
Nervous System	TOTAL	12	11.8	12	11.8	1	1.0
	ANXIETY	2	2.0	1	1.0	0	0.0
	DEPRESSION	0	0.0	1	1.0	0	0.0
	DIZZINESS	1	1.0	0	0.0	0	0.0
	EMOTIONAL LABILITY	1	1.0	0	0.0	1	1.0
	HYPERKINESIA	0	0.0	2	2.0	0	0.0
	INSOMNIA	1	1.0	6	5.9	0	0.0
	NERVOUSNESS	2	2.0	2	2.0	0	0.0
	SOMNOLENCE	5	4.9	3	2.9	0	0.0
	WITHDRAWAL SYNDROME	2	2.0	0	0.0	0	0.0
Respiratory System	TOTAL	19	18.6	8	7.8	0	0.0
	ASTHMA	1	1.0	0	0.0	0	0.0
	BRONCHITIS	0	0.0	2	2.0	0	0.0
	COUGH INCREASED	2	2.0	2	2.0	0	0.0
	LARYNX DISORDER	1	1.0	0	0.0	0	0.0
	PHARYNGITIS	4	3.9	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 : Placebo (N=102)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Respiratory System	RESPIRATORY DISORDER	9	8.8	2	2.0	0	0.0
	RHINITIS	2	2.0	1	1.0	0	0.0
	SINUSITIS	2	2.0	2	2.0	0	0.0
Skin and Appendages	TOTAL	5	4.9	0	0.0	0	0.0
	FUNGAL DERMATITIS	2	2.0	0	0.0	0	0.0
	HERPES ZOSTER	1	1.0	0	0.0	0	0.0
	PRURITUS	1	1.0	0	0.0	0	0.0
	RASH	1	1.0	0	0.0	0	0.0
Special Senses	TOTAL	2	2.0	2	2.0	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	1	1.0	1	1.0	0	0.0
Urogenital System	TOTAL	4	3.9	1	1.0	0	0.0
	ALBUMINURIA	3	2.9	0	0.0	0	0.0
	HAEMATURIA	1	1.0	0	0.0	0	0.0
	URINARY FREQUENCY	1	1.0	0	0.0	0	0.0
	URINARY TRACT INFECTION	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 : Placebo (N=55)
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 : Placebo (N=47)
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	2.1	0	0.0	0	0.0
Urogenital System	TOTAL	1	2.1	0	0.0	0	0.0
	DYSMENORRHEA	1	2.1	0	0.0	0	0.0

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Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Maximum Intensity
By Body System. Intention-To-Treat Population Entering The Follow-Up Phase
Treatment Group : Paroxetine (N=46)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	6	13.0	5	10.9	3	6.5
Body as a Whole	TOTAL	1	2.2	0	0.0	1	2.2
	HEADACHE	1	2.2	0	0.0	0	0.0
	TRAUMA	0	0.0	0	0.0	1	2.2
Cardiovascular System	TOTAL	0	0.0	1	2.2	1	2.2
	HYPERTENSION	0	0.0	0	0.0	1	2.2
	TACHYCARDIA	0	0.0	1	2.2	0	0.0
Digestive System	TOTAL	1	2.2	0	0.0	0	0.0
	NAUSEA	1	2.2	0	0.0	0	0.0
Hemic and Lymphatic System	TOTAL	0	0.0	1	2.2	0	0.0
	ANEMIA	0	0.0	1	2.2	0	0.0
Musculoskeletal System	TOTAL	1	2.2	0	0.0	0	0.0
	ARTHRALGIA	1	2.2	0	0.0	0	0.0
Nervous System	TOTAL	3	6.5	4	8.7	2	4.3
	DEPRESSION	0	0.0	1	2.2	1	2.2
	DIZZINESS	1	2.2	1	2.2	0	0.0
	EMOTIONAL LABILITY	1	2.2	0	0.0	1	2.2
	MANIC DEPRESSIVE REACTION	0	0.0	1	2.2	0	0.0

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Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Maximum Intensity
By Body System. Intention-To-Treat Population Entering The Follow-Up Phase
Treatment Group : Paroxetine (N=46)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
Nervous System	NERVOUSNESS	0	0.0	1	2.2	0	0.0
	PSYCHOSIS	1	2.2	0	0.0	0	0.0
	SOMNOLENCE	1	2.2	0	0.0	0	0.0
	TREMOR	0	0.0	1	2.2	0	0.0
Respiratory System	TOTAL	1	2.2	0	0.0	0	0.0
	RESPIRATORY DISORDER	1	2.2	0	0.0	0	0.0
Skin and Appendages	TOTAL	1	2.2	1	2.2	0	0.0
	RASH	1	2.2	0	0.0	0	0.0
	SWEATING	0	0.0	1	2.2	0	0.0
Special Senses	TOTAL	0	0.0	1	2.2	0	0.0
	ABNORMAL VISION	0	0.0	1	2.2	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=25)
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=21)
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
		N	%	N	%	N	%
Body System	Preferred Term						
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Maximum Intensity
By Body System. Intention-To-Treat Population Entering The Follow-Up Phase
Treatment Group : Placebo (N=30)
Gender Non Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	3.3	2	6.7	0	0.0
Digestive System	TOTAL	1	3.3	0	0.0	0	0.0
	NAUSEA	1	3.3	0	0.0	0	0.0
Nervous System	TOTAL	0	0.0	2	6.7	0	0.0
	AGITATION	0	0.0	1	3.3	0	0.0
	EMOTIONAL LABILITY	0	0.0	1	3.3	0	0.0
Urogenital System	TOTAL	1	3.3	0	0.0	0	0.0
	GLYCOSURIA	1	3.3	0	0.0	0	0.0

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Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Maximum Intensity
By Body System. Intention-To-Treat Population Entering The Follow-Up Phase
Treatment Group : Placebo (N=17)
Male Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	1	5.9	0	0.0	0	0.0
Urogenital System	TOTAL	1	5.9	0	0.0	0	0.0
	ABNORMAL EJACULATION	1	5.9	0	0.0	0	0.0

Table 15.1.7.4

Number (%) of Patients with Emergent Adverse Experiences During the Follow-up Phase by Maximum Intensity
By Body System. Intention-To-Treat Population Entering The Follow-Up Phase
Treatment Group : Placebo (N=13)
Female Specific Adverse Experiences

		Intensity					
		Mild		Moderate		Severe	
Body System	Preferred Term	N	%	N	%	N	%
TOTAL	TOTAL	0	0.0	0	0.0	0	0.0

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Table 15.1.8

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=49)	 Placebo (N=47)
TOTAL	TOTAL	5 (10.2%)	2 (4.3%)
Digestive System	TOTAL	2 (4.1%)	0
	NAUSEA	1 (2.0%)	0
	VOMITING	1 (2.0%)	0
Nervous System	TOTAL	2 (4.1%)	1 (2.1%)
	AGITATION	1 (2.0%)	0
	DIZZINESS	1 (2.0%)	0
	SOMNOLENCE	0	1 (2.1%)
Cardiovascular System	TOTAL	1 (2.0%)	0
	VASODILATATION	1 (2.0%)	0
Skin and Appendages	TOTAL	1 (2.0%)	1 (2.1%)
	SWEATING	1 (2.0%)	0
	PRURITUS	0	1 (2.1%)
Special Senses	TOTAL	1 (2.0%)	0
	ABNORMAL VISION	1 (2.0%)	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
Male Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=26)	Treatment Group: 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 : Children
Female Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=23)	Treatment Group: Placebo (N=18)
TOTAL	TOTAL	0	0

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Table 15.1.8

Number (%) of Patients with Decreased Dose of Study Medication due to Emergent Adverse Experiences During the Treatment Phase
By Body System. Intention-To-Treat Population

Age Group : Adolescents
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=52)	Treatment Group Placebo (N=55)
TOTAL	TOTAL	4 (7.7%)	3 (5.5%)
Nervous System	TOTAL	4 (7.7%)	1 (1.8%)
	SOMNOLENCE	1 (1.9%)	1 (1.8%)
	AGITATION	1 (1.9%)	0
	HYPERKINESIA	1 (1.9%)	0
	INSOMNIA	1 (1.9%)	0
	NERVOUSNESS	1 (1.9%)	0
Urogenital System	TOTAL	1 (1.9%)	0
	URINATION IMPAIRED	1 (1.9%)	0
Body as a Whole	TOTAL	0	1 (1.8%)
	ASTHENIA	0	1 (1.8%)
Digestive System	TOTAL	0	1 (1.8%)
	NAUSEA	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 : Adolescents
Male Specific Adverse Experiences

Body System	Preferred Term	Treatment Group: Paroxetine (N=27)	Treatment Group: Placebo (N=26)
TOTAL	TOTAL	1 (3.7%)	0
Urogenital System	TOTAL	1 (3.7%)	0
	IMPOTENCE	1 (3.7%)	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=25)	Treatment Group: 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 : Total
Gender Non Specific Adverse Experiences

Body System	Preferred Term	Treatment Group Paroxetine (N=101)	 Placebo (N=102)
TOTAL	TOTAL	9 (8.9%)	5 (4.9%)
Nervous System	TOTAL	6 (5.9%)	2 (2.0%)
	AGITATION	2 (2.0%)	0
	SOMNOLENCE	1 (1.0%)	2 (2.0%)
	DIZZINESS	1 (1.0%)	0
	HYPERKINESIA	1 (1.0%)	0
	INSOMNIA	1 (1.0%)	0
	NERVOUSNESS	1 (1.0%)	0
Digestive System	TOTAL	2 (2.0%)	1 (1.0%)
	NAUSEA	1 (1.0%)	1 (1.0%)
	VOMITING	1 (1.0%)	0
Cardiovascular System	TOTAL	1 (1.0%)	0
	VASODILATATION	1 (1.0%)	0
Skin and Appendages	TOTAL	1 (1.0%)	1 (1.0%)
	SWEATING	1 (1.0%)	0
	PRURITUS	0	1 (1.0%)
Special Senses	TOTAL	1 (1.0%)	0
	ABNORMAL VISION	1 (1.0%)	0
Urogenital System	TOTAL	1 (1.0%)	0
	URINATION IMPAIRED	1 (1.0%)	0
Body as a Whole	TOTAL	0	1 (1.0%)
	ASTHENIA	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

Body System	Preferred Term	Treatment Group: Paroxetine (N=53)	Treatment Group: Placebo (N=55)
TOTAL	TOTAL	1 (1.9%)	0
Urogenital System	TOTAL	1 (1.9%)	0
	IMPOTENCE	1 (1.9%)	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

Body System	Preferred Term	Treatment Group: Paroxetine (N=48)	Treatment Group: Placebo (N=47)
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	101	108.0	108.0	11.77	88	140	102	107.7	106.0	11.73	75	145
Change from baseline to:												
Week 1	96	0.3	0.0	10.01	-29	30	99	0.2	0.0	10.36	-44	28
Week 2	88	1.5	0.0	9.04	-35	20	91	0.3	0.0	9.15	-28	33
Week 3	87	1.3	2.0	10.99	-40	28	86	-0.1	0.0	9.23	-22	22
Week 4	84	2.6	2.0	10.64	-25	23	90	0.5	0.0	10.79	-33	45
Week 6	70	0.1	0.0	9.37	-25	23	83	0.3	-1.0	11.77	-29	52
Week 8	49	2.5	2.0	10.31	-25	22	72	1.1	0.0	11.35	-39	37

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	101	68.1	69.0	8.36	50	89	102	68.1	69.0	10.05	38	96
Change from baseline to:												
Week 1	96	-0.4	-2.0	10.34	-29	47	99	0.3	0.0	8.13	-22	24
Week 2	88	0.2	0.0	10.16	-44	21	91	0.9	0.0	9.42	-30	25
Week 3	87	1.0	0.0	9.53	-37	30	86	-1.0	-1.0	8.69	-28	24
Week 4	84	1.7	0.0	9.13	-17	28	90	-0.4	0.0	9.82	-28	29
Week 6	70	0.2	0.0	11.27	-20	57	83	0.8	0.0	9.41	-16	29
Week 8	49	1.7	0.0	9.53	-18	30	72	-0.0	0.0	8.26	-26	19

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	101	81.6	80.0	12.23	48	122	102	77.9	78.0	11.87	52	110
Change from baseline to:												
Week 1	96	-3.1	-2.0	10.57	-36	22	99	1.4	1.0	10.90	-46	28
Week 2	88	-2.7	-2.0	12.06	-35	29	91	-0.3	0.0	11.23	-34	30
Week 3	87	-3.1	-2.0	13.63	-70	27	86	1.7	0.0	10.99	-24	36
Week 4	84	-1.3	0.0	11.26	-44	22	90	0.7	0.0	10.79	-26	20
Week 6	71	-0.1	0.0	12.42	-35	27	83	1.0	0.0	11.52	-33	39
Week 8	49	-0.1	0.0	11.66	-24	36	72	1.5	0.0	12.03	-41	36

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	101	153.10	156.00	16.682	116.8	185.4	102	153.08	153.35	16.512	119.4	185.4
Change from baseline to:												
Week 8	47	0.57	0.00	1.029	0.0	5.1	72	1.18	0.05	3.004	0.0	17.8

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	101	58.18	56.00	23.634	20.4	132.6	102	55.52	54.50	22.398	21.8	131.4
Change from baseline to:												
Week 8	47	0.65	0.40	2.095	-3.6	6.0	71	0.92	0.70	1.742	-2.3	8.6

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline

Table 15.2.1.1

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
Pre-Treatment 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	101	24.06	23.10	6.981	12.6	46.0	102	22.91	21.30	6.223	13.6	45.4
Change from baseline to:												
Week 8	47	0.09	0.20	0.841	-1.8	1.9	71	0.05	0.10	1.017	-5.3	1.8

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
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	101	108.0	108.0	11.77	88	140	102	107.7	106.0	11.73	75	145
Change from baseline to:												
Week 3	3	-2.7	-2.0	3.06	-6	0						
Week 4	5	-6.8	-10.0	7.82	-16	4	1	18.0	18.0		18	18
Week 6	6	4.0	4.5	3.74	0	10	5	3.0	0.0	7.21	-4	13
Week 8	43	0.0	0.0	9.61	-16	24	40	1.2	2.0	9.77	-20	22
Post Week 8	32	3.0	1.0	10.09	-14	24	29	1.8	0.0	10.00	-17	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 8')
have both assessments in the summary statistics, but N represents the number of subjects at that week.

Table 15.2.1.2

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
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	101	68.1	69.0	8.36	50	89	102	68.1	69.0	10.05	38	96
Change from baseline to:												
Week 3	3	-6.0	-8.0	9.17	-14	4						
Week 4	5	0.0	4.0	16.43	-24	18	1	0.0	0.0		0	0
Week 6	6	1.3	0.0	7.23	-6	10	5	7.8	8.0	5.76	0	16
Week 8	43	0.2	0.0	8.76	-16	18	40	1.3	2.0	10.52	-22	30
Post Week 8	32	3.6	4.0	8.71	-20	20	29	1.1	0.0	9.15	-22	20

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline
Subjects who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 8')
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
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	101	81.6	80.0	12.23	48	122	102	77.9	78.0	11.87	52	110
Change from baseline to:												
Week 3	3	-5.3	-4.0	8.08	-14	2						
Week 4	5	-10.4	-11.0	16.95	-36	10	1	22.0	22.0		22	22
Week 6	6	7.0	7.0	11.10	-5	25	5	-13.6	-4.0	16.50	-34	0
Week 8	43	-1.2	0.0	15.16	-47	30	40	1.2	0.0	11.23	-30	26
Post Week 8	32	0.3	0.0	10.52	-20	18	29	-0.9	0.0	10.62	-28	18

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 8')
have both assessments in the summary statistics, but N represents the number of subjects at that week.

Table 15.2.1.2

Summary Statistics for Baseline and Change from Baseline for Vital Signs by Visit
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	101	153.10	156.00	16.682	116.8	185.4	102	153.08	153.35	16.512	119.4	185.4
Change from baseline to:												
Week 8	23	0.57	0.00	0.905	0.0	3.0	8	0.39	0.00	0.738	0.0	2.0

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 8')
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
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	101	58.18	56.00	23.634	20.4	132.6	102	55.52	54.50	22.398	21.8	131.4
Change from baseline to:												
Week 8	23	-0.74	0.60	5.252	-16.0	6.2	7	1.33	0.00	3.334	-0.9	8.6

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline
Subjects who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 8')
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
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	101	24.06	23.10	6.981	12.6	46.0	102	22.91	21.30	6.223	13.6	45.4
Change from baseline to:												
Week 8	23	-0.42	0.20	1.940	-6.0	2.2	7	0.29	-0.20	1.116	-0.6	2.5

Note: For height, weight and BMI, the last pre-treatment assessment is taken to be Baseline
Subjects who have two assessments at the same week (e.g. taper and follow-up both in 'Post Week 8')
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

Number (%) of Patients with Vital Signs of Potential Clinical Concern during the Treatment Phase (including Taper)

Intention-To-Treat Population

Vital Signs Variable : Systolic Blood Pressure / mmHg

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	101	N/A	102	N/A
Number with Baseline and Post-Baseline Assessment	101	100.0	100	100.0
Low	23	22.8	32	32.0
Significant Decrease	1	1.0	2	2.0
Low & Significant Decrease	1	1.0	1	1.0
Low & Significant Increase	0	0.0	0	0.0
High	2	2.0	3	3.0
Significant Increase	0	0.0	1	1.0
High & Significant Increase	0	0.0	1	1.0
High & Significant Decrease	0	0.0	1	1.0

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

Number (%) of Patients with Vital Signs of Potential Clinical Concern during the Treatment Phase (including Taper)

Intention-To-Treat Population

Vital Signs Variable : Diastolic Blood Pressure / mmHg

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	101	N/A	102	N/A
Number with Baseline and Post-Baseline Assessment	101	100.0	100	100.0
Low	5	5.0	10	10.0
Significant Decrease	3	3.0	4	4.0
Low & Significant Decrease	1	1.0	2	2.0
Low & Significant Increase	0	0.0	0	0.0
High	7	6.9	8	8.0
Significant Increase	3	3.0	0	0.0
High & Significant Increase	2	2.0	0	0.0
High & Significant Decrease	0	0.0	1	1.0

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

Number (%) of Patients with Vital Signs of Potential Clinical Concern during the Treatment Phase (including Taper)

Intention-To-Treat Population

Vital Signs Variable : Heart Rate / BPM

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	101	N/A	102	N/A
Number with Baseline and Post-Baseline Assessment	101	100.0	100	100.0
Low	16	15.8	14	14.0
Significant Decrease	6	5.9	3	3.0
Low & Significant Decrease	3	3.0	2	2.0
Low & Significant Increase	0	0.0	1	1.0
High	3	3.0	0	0.0
Significant Increase	2	2.0	4	4.0
High & Significant Increase	0	0.0	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

Number (%) of Patients with Vital Signs of Potential Clinical Concern during the Treatment Phase (including Taper)

Intention-To-Treat Population

Vital Signs Variable : Weight / kg

	Treatment Group			
	Paroxetine		Placebo	
	n	%	n	%
Number with Assessment	101	N/A	102	N/A
Number with Baseline and Post-Baseline Assessment	68	100.0	85	100.0
Low	1	1.5	0	0.0
Significant Decrease	3	4.4	0	0.0
Low & Significant Decrease	1	1.5	0	0.0
Low & Significant Increase	0	0.0	0	0.0
High	29	42.6	22	25.9
Significant Increase	6	8.8	6	7.1
High & Significant Increase	3	4.4	2	2.4
High & Significant Decrease	1	1.5	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)	1 (5.9%)	2 (4.0%)	1 (2.2%)
Number of Patients with Assessment	17 (100.0%)	50 (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.

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)	2 (11.8%)	4 (8.0%)	5 (10.9%)
Number of Patients with Assessment	17 (100.0%)	50 (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:Children
Parameter:Red Blood Cell Count, Unit:10^12/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	17 (100.0%)	50 (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.

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	Paroxetine	Placebo
Number of Patients with Assessment	17 (100.0%)	50 (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.

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	17 (100.0%)	50 (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.

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	17 (100.0%)	50 (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.

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)	0 (0.0%)	5 (10.0%)	1 (2.2%)
Number of Patients with Assessment	17 (100.0%)	50 (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.

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)	2 (11.8%)	3 (6.0%)	1 (2.2%)
Number of Patients with Assessment	17 (100.0%)	50 (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.

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	17 (100.0%)	50 (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.

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
Low (Extended)	2 (11.8%)	0 (0.0%)	2 (4.3%)
Number of Patients with Assessment	17 (100.0%)	50 (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.

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	17 (100.0%)	50 (100.0%)	47 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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)	0 (0.0%)	0 (0.0%)	1 (2.1%)
Number of Patients with Assessment	17 (100.0%)	50 (100.0%)	47 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	17 (100.0%)	50 (100.0%)	47 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	17 (100.0%)	50 (100.0%)	47 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	17 (100.0%)	50 (100.0%)	47 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	17 (100.0%)	50 (100.0%)	47 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	17 (100.0%)	50 (100.0%)	47 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	17 (100.0%)	50 (100.0%)	47 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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
High (Extended)	0 (0.0%)	0 (0.0%)	1 (2.1%)
Number of Patients with Assessment	17 (100.0%)	50 (100.0%)	47 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	17 (100.0%)	50 (100.0%)	47 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	16 (100.0%)	49 (100.0%)	47 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	28 (100.0%)	54 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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)	2 (7.1%)	6 (11.1%)	4 (7.3%)
Number of Patients with Assessment	28 (100.0%)	54 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	28 (100.0%)	54 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	28 (100.0%)	54 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	28 (100.0%)	54 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	28 (100.0%)	54 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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)	0 (0.0%)	0 (0.0%)	2 (3.6%)
Number of Patients with Assessment	28 (100.0%)	54 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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
Number of Patients with Assessment	28 (100.0%)	54 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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:Monocytes Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	28 (100.0%)	54 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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
High (Extended)	1 (3.6%)	0 (0.0%)	0 (0.0%)
Low (Extended)	1 (3.6%)	1 (1.9%)	2 (3.6%)
Number of Patients with Assessment	28 (100.0%)	54 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	31 (100.0%)	53 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	31 (100.0%)	53 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	31 (100.0%)	53 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	31 (100.0%)	53 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	31 (100.0%)	53 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	31 (100.0%)	53 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	31 (100.0%)	53 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	Paroxetine	Placebo
Number of Patients with Assessment	31 (100.0%)	53 (100.0%)	55 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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
Number of Patients with Assessment	31 (100.0%)	54 (100.0%)	54 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	30 (100.0%)	54 (100.0%)	54 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	30 (100.0%)	53 (100.0%)	54 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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:Hemoglobin, Unit:G/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Low (Extended)	1 (2.2%)	2 (1.9%)	1 (1.0%)
Number of Patients with Assessment	45 (100.0%)	104 (100.0%)	101 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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)	4 (8.9%)	10 (9.6%)	9 (8.9%)
Number of Patients with Assessment	45 (100.0%)	104 (100.0%)	101 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	45 (100.0%)	104 (100.0%)	101 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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
Number of Patients with Assessment	45 (100.0%)	104 (100.0%)	101 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are 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	45 (100.0%)	104 (100.0%)	101 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are 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

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	45 (100.0%)	104 (100.0%)	101 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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)	0 (0.0%)	5 (4.8%)	3 (3.0%)
Number of Patients with Assessment	45 (100.0%)	104 (100.0%)	101 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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)	2 (4.4%)	3 (2.9%)	1 (1.0%)
Number of Patients with Assessment	45 (100.0%)	104 (100.0%)	101 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are 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:Monocytes Absolute, Unit:10^9/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	45 (100.0%)	104 (100.0%)	101 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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)	1 (2.2%)	0 (0.0%)	0 (0.0%)
Low (Extended)	3 (6.7%)	1 (1.0%)	4 (4.0%)
Number of Patients with Assessment	45 (100.0%)	104 (100.0%)	101 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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:Sodium, Unit:MMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	48 (100.0%)	103 (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.

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)	0 (0.0%)	0 (0.0%)	1 (1.0%)
Number of Patients with Assessment	48 (100.0%)	103 (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.

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	48 (100.0%)	103 (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.

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	48 (100.0%)	103 (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.

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	48 (100.0%)	103 (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.

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	48 (100.0%)	103 (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.

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	48 (100.0%)	103 (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.

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
Number of Patients with Assessment	48 (100.0%)	103 (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.

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 (0.0%)	0 (0.0%)	1 (1.0%)
Number of Patients with Assessment	48 (100.0%)	104 (100.0%)	101 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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:Free T3, Unit:PMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	47 (100.0%)	104 (100.0%)	101 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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 Free Thyroxine, Unit:PMOL/L

Flag	Treatment Group: No Therapy Dispensed	Paroxetine	Placebo
Number of Patients with Assessment	46 (100.0%)	102 (100.0%)	101 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.2

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Treatment Phase (including Taper)

Intention-To-Treat Population
Age Group : Children
Parameter : Hemoglobin Unit : G/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Low (Extended)	1 (3.2%)	0 (0.0%)
Number of Patients with Assessment	31 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	Placebo
Low (Extended)	5 (16.1%)	6 (15.8%)
Number of Patients with Assessment	31 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	31 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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
Number of Patients with Assessment	31 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	31 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	31 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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 (0.0%)	1 (2.6%)
Number of Patients with Assessment	31 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	Placebo
Number of Patients with Assessment	31 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	31 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	Placebo
Low (Extended)	2 (6.5%)	3 (7.9%)
Number of Patients with Assessment	31 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	31 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

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	Treatment Group: Placebo
High (Extended)	0 (0.0%)	1 (2.4%)
Number of Patients with Assessment	31 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

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	Placebo
Number of Patients with Assessment	31 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

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	31 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

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	31 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

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	Placebo
Number of Patients with Assessment	31 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

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	Placebo
Number of Patients with Assessment	31 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

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	31 (100.0%)	41 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.2

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	Placebo
Number of Patients with Assessment	35 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	Treatment Group: Placebo
Low (Extended)	3 (8.6%)	1 (2.6%)
Number of Patients with Assessment	35 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	35 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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
Low (Extended)	0 (0.0%)	1 (2.6%)
Number of Patients with Assessment	35 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	35 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	35 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	35 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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
Number of Patients with Assessment	35 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	35 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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
Low (Extended)	1 (2.9%)	2 (5.3%)
Number of Patients with Assessment	35 (100.0%)	38 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	Placebo
Number of Patients with Assessment	36 (100.0%)	39 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	36 (100.0%)	39 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	36 (100.0%)	39 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	Treatment Group: Placebo
Number of Patients with Assessment	36 (100.0%)	39 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	36 (100.0%)	39 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	36 (100.0%)	39 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	Treatment Group: Placebo
Number of Patients with Assessment	36 (100.0%)	39 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	36 (100.0%)	39 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	3 (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	Placebo
Number of Patients with Assessment	3 (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	3 (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	Treatment Group: Placebo
Low (Extended)	1 (1.5%)	0 (0.0%)
Number of Patients with Assessment	66 (100.0%)	76 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	Placebo
Low (Extended)	8 (12.1%)	7 (9.2%)
Number of Patients with Assessment	66 (100.0%)	76 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	66 (100.0%)	76 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	Treatment Group: Placebo
Low (Extended)	0 (0.0%)	1 (1.3%)
Number of Patients with Assessment	66 (100.0%)	76 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	66 (100.0%)	76 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	66 (100.0%)	76 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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 (0.0%)	1 (1.3%)
Number of Patients with Assessment	66 (100.0%)	76 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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
Number of Patients with Assessment	66 (100.0%)	76 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	66 (100.0%)	76 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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)	3 (4.5%)	5 (6.6%)
Number of Patients with Assessment	66 (100.0%)	76 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	67 (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	Treatment Group: Placebo
High (Extended)	0 (0.0%)	1 (1.3%)
Number of Patients with Assessment	67 (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	67 (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	67 (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	67 (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	67 (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	Placebo
Number of Patients with Assessment	67 (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	67 (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	3 (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	3 (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	3 (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 15.3.1.2.1: Laboratory Data Narratives

Patients With Laboratory Values of Potential Clinical Concern

PID 701.170.25633

Treatment Group: Paroxetine

Laboratory Remarks: Decreased Hematocrit, Decreased Hemoglobin

This 9-year old black male was a participant in the trial of BRL-20960/701, which was conducted in children and adolescents with major depressive disorder (MDD).

The patient entered the study with no significant prior medical or surgical history reported. Psychiatric history (measured by K-SADS-PL interview) includes current MDD with an onset in January 1998. No other psychiatric disorders were identified. Current medical history includes asthma, and intermittent anxiety, agitation, headache, insomnia and non-specified sinusitis.

Concomitant medications included only salbutamol (Albuterol®) for asthma.

Laboratory values assessed at screening (Visit 1; Day -8) were within normal limits, with the exception of a decreased hemoglobin level of 107 g/L (normal: 115-155 g/L) and a decreased hematocrit level of 34.6% (normal: 35.0-45.0%). Both of these laboratory values were at levels of potential clinical concern.

The patient was randomized to the paroxetine regimen on 10 August 2000. The patient was started on paroxetine at a dose of 10 mg/day and was titrated up, in 10 mg/week increments, to the target dose of 40 mg on 06 September 2000. The patient's last dose of study medication was taken on 03 October 2000 (Day 55). At week 8 (Day 55), the patient had a decreased hemoglobin level of 111 g/L and a decreased hematocrit level of 34.7%, both of which remained at levels of potential clinical concern. Absolute eosinophils were slightly increased to 0.7300 10^9/L (normal: 0.0500 – 0.5500 10^9/L), but all other laboratory values were within normal limits. No follow-up laboratory assessments were provided.

At week 8 (Day 55), moderately severe anemia (hypochromasia) and mild RBC abnormalities (ovalocytes, microcytosis) were reported as non-serious adverse events. No treatment was given, and the investigator considered the events unrelated to treatment with study medication. The events were reportedly

PID 701.170.25633 (continued)

continuing at study end. No other adverse events were reported. The patient completed the study as planned.

Patients With Laboratory Values of Potential Clinical Concern

PID 701.153.25698

Treatment Group: Placebo

Laboratory Remarks: Decreased Absolute Neutrophils

This 15-year old white male was a participant in the trial of BRL-20960/701, which was conducted in children and adolescents with major depressive disorder.

The patient entered the study with a previous medical history of anemia, chicken pox, and leukopenia. There were no significant current medical conditions reported. Psychiatric history (measured by K-SADS-PL interview) includes previous and current history of MDD with an onset in January 1993, and agoraphobia with an onset in January 1994.

No concomitant use of medication was reported.

Laboratory values assessed at screening (Visit 1; Day -23) were within normal limits, with the exception of a slightly decreased white blood count of 3.6 10^9/L (normal: 4.5 – 13.0 10^9/L), and a slightly increased sodium level of 151 mmol/L (normal: 135 – 146 mmol/L). Absolute neutrophil count of 1.81 10^9/L (normal: 1.8 – 8.0 10^9/L) was within normal limits at screening. Baseline laboratory values (Day –16) were within normal limits, with the exception of a slightly decreased white blood count of 4.4 10^9/L. Absolute neutrophil count of 2.37 10^9/L remained within normal limits at this visit.

The patient was randomized to the placebo regimen on 06 July 2000. The patient was started on placebo medication at dose level 1 (equivalent to 10 mg/day of active medication) and was titrated up, in 10 mg/week increments, to the target dose level 3 (equivalent to 30 mg of active medication) on 01 August 2000. The patient's last dose of study medication was taken on 28 August 2000 (Day 54). At week 8 (Day 54), the patient had a decreased absolute neutrophil count of 1.21 10^9/L, which was at a level of potential clinical concern. The white blood count of 3.1 10^9/L, and the absolute monocyte value of 0.12 10^9/L were below normal limits at week 8, but all other values were within normal limits. A repeat laboratory screening was performed at Day 69 which showed the absolute

PID 701.153.25698 (continued)

neutrophil level within normal range (1.83 10^9/L). Absolute monocyte level of 0.33 10^9/L was also within normal range. The white blood count of 4.3 10^9/L remained slightly below normal limits.

At week 8 (Day 54), mild leukopenia was reported as a non-serious adverse event. The leukopenia resolved within 16 days without treatment. The investigator considered the leukopenia to be possibly related to treatment with study medication. Other non-serious adverse events reported on Day 6 included moderately severe insomnia and mild nervousness. No treatment was given for either event. Insomnia resolved within 9 days and hematuria resolved within 18 days. The investigator considered these two events to be possibly related to treatment with study medication. No other adverse events were reported. The patient completed the study as planned.

Patients With Laboratory Values of Potential Clinical Concern

PID 701.164.25831

Treatment Group: Placebo

Laboratory Remarks: Decreased Absolute Neutrophils

This 9-year old black male was a participant in the trial of BRL-20960/701, which was conducted in children and adolescents with major depressive disorder (MDD).

The patient entered the study with no significant previous or current medical history reported. Psychiatric history (measured by K-SADS-PL interview) includes MDD with an onset in March 2000. No other psychiatric disorders were identified.

Concomitant medications included cetirizine HCl (Zyrtec®) for sinus congestion beginning on Day 4 and continuing, dextromethorphan hydrobromide/doxylamine succinate/paracetamol (Nyquil®) for cough and sinus congestion beginning Day 38 of the study, paracetamol (Tylenol®) for headache (Day 54), and body lotion which was used to treat dust mites (onset Day 41, treatment dispensed Day 64).

Laboratory values assessed at screening (Visit 1; Day -6) were within normal limits, with the exception of a decreased absolute neutrophil count of 1.76 10^9/L (normal: 1.8 – 8.0 10^9/L). The decreased absolute neutrophil count was at the level of potential clinical concern.

The patient was randomized to the placebo regimen on 03 August 2000. The patient's last dose of study medication was taken on 27 September 2000 (Day 56). At week 8 (Day 56), the patient's absolute neutrophil value was 1.37 10^9/L, which remained at a level of potential clinical concern. The sodium level was slightly decreased to 133 mmol/L (normal: 135 – 146 mmol/L). All other laboratory values were within normal range. All laboratory values were within normal limits by Day 70, on which date a repeat laboratory assessment was performed. Absolute neutrophil count was 2.08 10^9/L.

At week 8 (Day 56), moderately severe leukopenia and mildly decreased low sodium levels were reported as non-serious adverse events. No treatment

PID 701.164.25831 (continued)

was given for either, which resolved within 15 days. The investigator considered these events to be possibly related to treatment with study medication.

Other non-serious adverse events reported include mild sore throat and moderately severe sinusitis (Day 4, Day 38), moderate trauma on left foot from glass and mild laceration from glass (Day 13), moderately severe cough (Day 38, Day 51), allergic reaction to dust mites (Day 41), mild rash (Day 54), and mild fever and moderately severe headache (Day 54). The patient completed the study as planned.

Patients With Laboratory Values of Potential Clinical Concern

PID 701.185.25964

Treatment Group: Placebo

Laboratory Remarks: Decreased Hematocrit

This 10-year old black male was a participant in the trial of BRL-20960/701, which was conducted in children and adolescents with major depressive disorder (MDD).

The patient entered the study with a previous medical history of Attention Deficit Hyperactivity Disorder (ADHD), for which Adderall® was prescribed, and history of recurrent headaches, for which Tylenol® and ibuprofen were taken as needed. Current medical history includes continuing recurrent headaches. Psychiatric history (measured by K-SADS-PL interview) included MDD with an onset in January 1996.

Concomitant medications included paracetamol (Tylenol®) and ibuprofen for headaches, as needed.

Laboratory values assessed at screening (Visit 1; Day -7) were within normal limits, with the exception of a decreased absolute neutrophil count of 1.46 10^9/L (normal: 1.8 – 8.0 10^9/L), a slightly increased absolute eosinophil count of 0.6600 10^9/L (normal: 0.0500 – 0.5500 10^9/L) and a slightly decreased absolute monocyte count of 0.1800 10^9/L (normal: 0.200 – 1.100 10^9/L). The decreased absolute neutrophil count was at the level of potential clinical concern.

The patient was randomized to the placebo regimen on 11 October 2000. The patient was started on placebo medication at dose level 1 (equivalent to 10 mg/day active medication) and was titrated to dose level 2 (equivalent to 20 mg/day active medication) on 20 October 2000. The patient's last dose of study medication was taken on 05 December 2000. At week 8 (Day 56), the patient had a decreased hematocrit level of 33.7% (normal: 35 – 45%), which was at a level of potential clinical concern. Platelets of 413,000 10^9/L (normal: 130,000 – 400,000 10^9/L) were slightly above normal limits at week 8, but all

PID 701.185.25964 **(continued)**

other values were otherwise unremarkable. No follow-up hematologic laboratory assessments were provided.

At week 8 (Day 56), mild ketosis, and mild albuminuria were reported as non-serious adverse events. Mild hematuria was also reported as a non-serious adverse event with onset on Day 63. No treatment was given for any of these events, and the investigator considered the events unrelated to treatment with study medication. Ketosis resolved within 8 days, but albuminuria and hematuria were reportedly continuing at study end. No other adverse events were reported. The patient completed the study as planned.

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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
Low (Extended)	1 (11.1%)	0 (0.0%)
Number of Patients with Assessment	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Hematocrit, Unit : %

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Low (Extended)	1 (11.1%)	1 (33.3%)
Number of Patients with Assessment	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	9 (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 : White Blood Cell Count, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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
High (Extended)	1 (11.1%)	0 (0.0%)
Number of Patients with Assessment	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Children
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Low (Extended)	1 (11.1%)	0 (0.0%)
Number of Patients with Assessment	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	Placebo
Number of Patients with Assessment	9 (100.0%)	3 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	7 (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 : Adolescents
Parameter : Hematocrit, Unit : %

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Low (Extended)	3 (42.9%)	1 (20.0%)
Number of Patients with Assessment	7 (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 : Adolescents
Parameter : Red Blood Cell Count, Unit : 10^12/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	7 (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 : Adolescents
Parameter : White Blood Cell Count, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	7 (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 : Adolescents
Parameter : Platelets, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	7 (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 : Adolescents
Parameter : Basophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	7 (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 : Adolescents
Parameter : Eosinophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	7 (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 : Adolescents
Parameter : Lymphocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	7 (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 : Adolescents
Parameter : Monocytes Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	7 (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 : Adolescents
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	7 (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.

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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 : Adolescents
Parameter : Sodium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	7 (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 : Adolescents
Parameter : Potassium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	7 (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 : Adolescents
Parameter : Blood Urea Nitrogen, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	7 (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 : Adolescents
Parameter : Creatinine, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	7 (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 : Adolescents
Parameter : Alkaline Phosphatase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	7 (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 : Adolescents
Parameter : Aspartate Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	7 (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 : Adolescents
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	7 (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 : Adolescents
Parameter : Total Bilirubin, Unit : UMOL/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Number of Patients with Assessment	7 (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 : Adolescents
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 : Adolescents
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 : Adolescents
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 : Total
Parameter : Hemoglobin, Unit : G/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Low (Extended)	1 (6.3%)	0 (0.0%)
Number of Patients with Assessment	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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)	4 (25.0%)	2 (25.0%)
Number of Patients with Assessment	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High 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	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	Placebo
Number of Patients with Assessment	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	Placebo
Number of Patients with Assessment	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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
High (Extended)	1 (6.3%)	0 (0.0%)
Number of Patients with Assessment	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Neutrophils Absolute, Unit : 10^9/L

Flag	Treatment Group: Paroxetine	Treatment Group: Placebo
Low (Extended)	1 (6.3%)	0 (0.0%)
Number of Patients with Assessment	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Sodium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Potassium, Unit : MMOL/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	Placebo
Number of Patients with Assessment	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

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Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Aspartate Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of Clinical Concern, Follow-Up Phase

Intention-To-Treat Population Entering The Follow-Up Phase
Age Group : Total
Parameter : Alanine Aminotransferase, Unit : IU/L

Flag	Treatment Group: Paroxetine	Placebo
Number of Patients with Assessment	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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	16 (100.0%)	8 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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
Number of Patients with Assessment	2 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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
Number of Patients with Assessment	2 (100.0%)

Number of Patients with Assessment = number of patients who had a measurement for this lab parameter at any time.
Where no High or Low rows are shown for a parameter which has concern values defined,
no patients fell into these respective categories.

Table 15.3.1.3

Number (%) of Patients with Laboratory Values Flagged as of 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
Number of Patients with Assessment	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 15.3.2

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	57	2	0	59	0	0	13	0	0	13
L	n	0	0	2	2	0	4	0	0	0	2	0	2
-	n	0	0	0	0	1	1	0	0	0	0	1	1
+	%	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	97	3	0	100	0	0	100	0	0	100
L	%	0	0	50	50	0	100	0	0	0	100	0	100
-	%	0	0	0	0	100	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 : 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	0	1	0	0	1	0	0	1	0	0	1
I	n	0	1	66	3	0	70	0	0	7	0	0	7
L	n	0	0	2	1	0	3	0	0	0	0	0	0
-	n	0	0	1	0	0	1	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	100	0	0	100
I	%	0	1	94	4	0	100	0	0	100	0	0	100
L	%	0	0	67	33	0	100	0	0	0	0	0	0
-	%	0	0	100	0	0	100	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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	2	0	0	2	0	0	0	0	0	0
I	n	0	0	54	0	4	58	0	0	12	0	2	14
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	3	0	3	6	0	0	0	0	2	2
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	0	93	0	7	100	0	0	86	0	14	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	50	0	50	100	0	0	0	0	100	100

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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 : 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	1	0	0	1	0	0	0	0	0	0
I	n	0	0	60	0	6	66	0	0	6	0	2	8
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	7	0	1	8	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	91	0	9	100	0	0	75	0	25	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	88	0	13	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

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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 : 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	63	0	0	63	0	0	15	1	0	16
L	n	0	0	1	0	0	1	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	50	50	0	0	100	0	0	0	0	0	0
I	%	0	0	100	0	0	100	0	0	94	6	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 : 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	1	1	0	0	2	0	0	1	0	0	1
I	n	0	0	65	3	0	68	0	0	7	0	0	7
L	n	0	0	4	1	0	5	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	50	50	0	0	100	0	0	100	0	0	100
I	%	0	0	96	4	0	100	0	0	100	0	0	100
L	%	0	0	80	20	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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 : 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	0	58	3	0	61	0	1	11	2	0	14
L	n	0	0	3	1	0	4	0	0	1	1	0	2
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	0	95	5	0	100	0	7	79	14	0	100
L	%	0	0	75	25	0	100	0	0	50	50	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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 : 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	66	3	0	69	0	0	7	1	0	8
L	n	0	0	4	2	0	6	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	96	4	0	100	0	0	88	13	0	100
L	%	0	0	67	33	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 : 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	0	0	0	0	0	1	0	0	0	1
I	n	0	2	64	0	0	66	0	0	15	0	0	15
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	100	0	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

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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 : 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	0	2	0	0	2	0	0	0	0	0	0
I	n	0	2	70	0	0	72	0	0	8	0	0	8
L	n	0	0	1	0	0	1	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	3	97	0	0	100	0	0	100	0	0	100
L	%	0	0	100	0	0	100	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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 : 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	66	0	0	66	0	0	16	0	0	16
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	75	0	0	75	0	0	8	0	0	8
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	1	3	0	0	4	0	1	0	0	0	1
H	n	0	1	4	0	0	5	0	0	0	0	0	0
I	n	0	3	51	1	0	55	0	0	14	0	0	14
L	n	0	0	2	0	0	2	0	0	0	1	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	25	75	0	0	100	0	100	0	0	0	100
H	%	0	20	80	0	0	100	0	0	0	0	0	0
I	%	0	5	93	2	0	100	0	0	100	0	0	100
L	%	0	0	100	0	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 : 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	0	1	1	0	0	2	0	0	0	0	0	0
H	n	0	1	2	0	0	3	0	0	0	0	0	0
I	n	1	2	63	0	0	66	0	0	6	1	0	7
L	n	0	0	3	1	0	4	0	0	1	0	0	1
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	50	50	0	0	100	0	0	0	0	0	0
H	%	0	33	67	0	0	100	0	0	0	0	0	0
I	%	2	3	95	0	0	100	0	0	86	14	0	100
L	%	0	0	75	25	0	100	0	0	100	0	0	100
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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	2	0	0	2	1	0	0	0	0	1
H	n	0	0	0	0	0	0	0	0	0	0	0	0
I	n	0	1	63	0	0	64	0	0	15	0	0	15
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	100	0	0	0	0	100
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	2	98	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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	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	73	0	0	73	0	0	8	0	0	8
L	n	0	0	1	0	0	1	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	100	0	0	100	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	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 : 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	54	5	0	59	0	0	11	2	0	13
L	n	0	0	6	1	0	7	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	92	8	0	100	0	0	85	15	0	100
L	%	0	0	86	14	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	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	51	10	0	61	0	0	4	2	0	6
L	n	0	0	10	4	0	14	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	0	84	16	0	100	0	0	67	33	0	100
L	%	0	0	71	29	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 : 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	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	61	0	2	64	0	0	14	0	0	14
L	n	0	0	0	0	0	0	0	0	1	0	1	2
-	n	0	0	1	0	0	1	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	2	95	0	3	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	50	0	50	100
-	%	0	0	100	0	0	100	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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 : 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	0	0	0	0	0	0	0	0	0	0
H	n	0	0	1	0	0	1	0	0	0	0	0	0
I	n	0	0	65	0	3	68	0	0	8	0	0	8
L	n	0	0	2	0	1	3	0	0	0	0	0	0
-	n	0	0	3	0	0	3	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	96	0	4	100	0	0	100	0	0	100
L	%	0	0	67	0	33	100	0	0	0	0	0	0
-	%	0	0	100	0	0	100	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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	1	0	0	1	0	0	1	0	0	1
I	n	0	0	66	0	0	66	0	0	15	0	0	15
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	100	0	0	100
I	%	0	0	100	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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 : 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	1	0	0	1	0	0	0	0	0	0
I	n	0	1	77	1	0	79	0	0	8	0	0	8
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	97	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 : 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	2	0	0	2	0	0	0	0	0	0
I	n	0	1	64	0	0	65	0	0	16	0	0	16
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	2	98	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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	1	0	0	1	0	0	0	0	0	0
H	n	0	1	1	0	0	2	0	0	0	0	0	0
I	n	1	0	75	0	0	76	0	0	8	0	0	8
L	n	0	0	1	0	0	1	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	100	0	0	100	0	0	0	0	0	0
H	%	0	50	50	0	0	100	0	0	0	0	0	0
I	%	1	0	99	0	0	100	0	0	100	0	0	100
L	%	0	0	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 : 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	0	0	0	0	0	0	0	0	0	0
I	n	0	0	64	3	0	67	0	0	16	0	0	16
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	96	4	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 : 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	0	76	2	0	78	0	0	8	0	0	8
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	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	97	3	0	100	0	0	100	0	0	100
L	%	0	0	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

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	1	66	0	0	67	0	0	16	0	0	16
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 : 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	1	0	0	1	0	0	0	0	0	0
I	n	0	1	76	1	0	78	0	0	8	0	0	8
L	n	0	0	1	0	0	1	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	100	0	0	100	0	0	0	0	0	0
I	%	0	1	97	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 : 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	1	0	0	1	0	0	0	0	0	0
I	n	0	0	66	0	0	66	0	1	15	0	0	16
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	6	94	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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	3	0	0	5	0	0	0	0	0	0
I	n	0	0	75	0	0	75	0	0	8	0	0	8
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	40	60	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 : 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	67	0	0	67	0	0	16	0	0	16
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	1	0	0	0	1	0	0	0	0	0	0
I	n	0	2	77	0	0	79	0	0	8	0	0	8
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	100	0	0	0	100	0	0	0	0	0	0
I	%	0	3	97	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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 : 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	0	66	0	0	66	0	0	16	0	0	16
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

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	1	1	0	0	2	0	0	0	0	0	0
I	n	0	1	77	0	0	78	0	1	7	0	0	8
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	50	50	0	0	100	0	0	0	0	0	0
I	%	0	1	99	0	0	100	0	13	88	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	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	66	0	0	67	0	0	16	0	0	16
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

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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 : 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	0	0	0	0	0	0	0	0	0	0	0
I	n	0	0	80	0	0	80	0	0	8	0	0	8
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 : 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	3	0	0	3	0	0	2	0	0	2
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	100	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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 : Thyroid Stimulating Hormone Unit : MU/L
Treatment Group : Placebo

		Endpoint (incl. Taper)					
BASELINE		+	H	I	L	-	T
+	n	0	0	0	0	0	0
H	n	0	0	1	0	0	1
I	n	0	0	2	0	0	2
L	n	0	0	0	0	0	0
-	n	0	0	0	0	0	0
+	%	0	0	0	0	0	0
H	%	0	0	100	0	0	100
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

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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 : 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	3	0	0	3	0	0	2	0	0	2
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	100	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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 : Free T3 Unit : Picomoles per Litre
Treatment Group : Placebo

		Endpoint (incl. Taper)					
BASELINE		+	H	I	L	-	T
+	n	0	0	0	0	0	0
H	n	0	0	0	0	0	0
I	n	0	0	3	0	0	3
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 : 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	2	0	0	2	0	0	2	0	0	2
L	n	0	0	0	0	0	0	0	0	0	0	0	0
-	n	0	0	0	0	0	0	0	0	0	0	0	0
+	%	0	0	0	0	0	0	0	0	0	0	0	0
H	%	0	0	0	0	0	0	0	0	0	0	0	0
I	%	0	0	100	0	0	100	0	0	100	0	0	100
L	%	0	0	0	0	0	0	0	0	0	0	0	0
-	%	0	0	0	0	0	0	0	0	0	0	0	0

+: High Clinical Concern, H: Higher Than Reference Range, I: In Range,
L: Lower Than Reference Range, -: Low Clinical Concern, T: Total
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 : Total Free Thyroxine Unit : Picomoles per Litre
Treatment Group : Placebo

		Endpoint (incl. Taper)					
BASELINE		+	H	I	L	-	T
+	n	0	0	0	0	0	0
H	n	0	0	0	0	0	0
I	n	0	0	3	0	0	3
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

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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	25 (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 (12.0%)	2 (6.3%)
Trace	0 (0.0%)	1 (3.1%)
Number of Patients with Assessment	25 (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 Red Blood Cells/HPF

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	1 (4.0%)	1 (3.1%)
Many	2 (8.0%)	2 (6.3%)
Number of Patients with Assessment	25 (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 White Blood Cells/HPF

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	6 (24.0%)	2 (6.3%)
Many	1 (4.0%)	1 (3.1%)
Moderate	2 (8.0%)	0 (0.0%)
Number of Patients with Assessment	25 (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 Bacteria

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	5 (71.4%)	5 (83.3%)
Moderate	2 (28.6%)	1 (16.7%)
Number of Patients with Assessment	7 (100.0%)	6 (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	1 (4.0%)	3 (9.4%)
Trace	2 (8.0%)	1 (3.1%)
Number of Patients with Assessment	25 (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	2 (100.0%)	4 (100.0%)
Moderate	1 (50.0%)	0 (0.0%)
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

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Table 15.3.5.2

Number (%) of Patients with Abnormal Urinalysis Findings, Treatment Phase (including Taper)
Intention-To-Treat Population

Parameter : Uric Acid Crystals

Result	Treatment Group Placebo
Few	1 (100.0%)
Number of Patients with Assessment	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 701

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	5 (55.6%)	16 (76.2%)
Many	3 (33.3%)	5 (23.8%)
Moderate	1 (11.1%)	0 (0.0%)
Number of Patients with Assessment	9 (100.0%)	21 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 701

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	7 (10.8%)	8 (10.0%)
Number of Patients with Assessment	65 (100.0%)	80 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 701

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	12 (85.7%)	14 (87.5%)
Many	0 (0.0%)	1 (6.3%)
Moderate	3 (21.4%)	1 (6.3%)
Number of Patients with Assessment	14 (100.0%)	16 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 701

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	9 (64.3%)	11 (91.7%)
Moderate	5 (35.7%)	1 (8.3%)
Number of Patients with Assessment	14 (100.0%)	12 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 701

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
Positive	0 (0.0%)	1 (50.0%)
Number of Patients with Assessment	9 (100.0%)	2 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 701

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 (11.1%)	0 (0.0%)
Number of Patients with Assessment	9 (100.0%)	2 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 701

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
Many	1 (11.1%)	0 (0.0%)
Number of Patients with Assessment	9 (100.0%)	2 (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	1 (11.1%)	0 (0.0%)
Many	1 (11.1%)	0 (0.0%)
Number of Patients with Assessment	9 (100.0%)	2 (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 Protein - Dipstick

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Positive	2 (22.2%)	0 (0.0%)
Trace	1 (11.1%)	0 (0.0%)
Number of Patients with Assessment	9 (100.0%)	2 (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
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 Amorphous Sediment

Result	Treatment Group: Paroxetine	Treatment Group: Placebo
Few	3 (75.0%)	1 (100.0%)
Many	1 (25.0%)	0 (0.0%)
Number of Patients with Assessment	4 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 701

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 (5.6%)	1 (25.0%)
Number of Patients with Assessment	18 (100.0%)	4 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 701

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	4 (100.0%)	2 (100.0%)
Number of Patients with Assessment	4 (100.0%)	2 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 701

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	7 (100.0%)	1 (100.0%)
Number of Patients with Assessment	7 (100.0%)	1 (100.0%)

Number of Patients with Assessment = number of patients who had an assessment for this parameter at any time

BRL 29060 - 701

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 Yeast

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

BRL 29060 - 701

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	Units	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Hemoglobin	Grams per Litre	Baseline	101	132.74257	12.322056	133.00000	102.0000	173.0000
		Week 8	57	133.78947	11.227735	133.00000	107.0000	164.0000
		Endpoint	66	132.57576	11.282472	131.00000	107.0000	164.0000
		Endpoint Change	66	-0.78788	5.808522	-1.00000	-11.0000	16.0000
Hematocrit	Percentage	Baseline	101	39.70990	3.631983	39.50000	31.2000	52.5000
		Week 8	57	39.99123	3.147521	39.70000	32.9000	48.7000
		Endpoint	66	39.62879	3.294740	39.60000	32.9000	48.7000
		Endpoint Change	66	-0.31515	2.202393	-0.25000	-5.9000	5.7000
Red Blood Cell Count	10^12 per Litre	Baseline	101	4.63861	0.358879	4.60000	3.5000	5.5000
		Week 8	57	4.69123	0.323640	4.60000	4.1000	5.6000
		Endpoint	66	4.64848	0.333394	4.60000	4.0000	5.6000
		Endpoint Change	66	-0.03788	0.231228	0.00000	-0.6000	0.6000
White Blood Cell Count	10^9 per Litre	Baseline	101	7.04851	1.976543	6.70000	3.9000	14.9000
		Week 8	57	6.87544	1.708621	6.50000	3.9000	11.0000
		Endpoint	66	6.75606	1.721192	6.35000	3.7000	11.0000
		Endpoint Change	66	-0.31667	1.610693	-0.30000	-6.0000	3.4000
Platelets	10^9 per Litre	Baseline	101	293.99010	60.613447	290.00000	159.0000	455.0000
		Week 8	57	286.08772	63.252973	279.00000	186.0000	444.0000
		Endpoint	66	285.87879	60.656794	279.50000	186.0000	444.0000
		Endpoint Change	66	-4.69697	39.780927	-4.50000	-136.0000	166.0000
Basophils Absolute	10^9 per Litre	Baseline	101	0.02079	0.016952	0.02000	0.0000	0.1100
		Week 8	57	0.02281	0.012501	0.02000	0.0000	0.0700
		Endpoint	66	0.02273	0.012836	0.02000	0.0000	0.0700
		Endpoint Change	66	0.00167	0.021525	0.00000	-0.1000	0.0400
Eosinophils Absolute	10^9 per Litre	Baseline	101	0.27158	0.201250	0.22000	0.0000	0.9600
		Week 8	57	0.28825	0.176657	0.23000	0.0400	0.7300
		Endpoint	66	0.27409	0.174805	0.23000	0.0400	0.7300
		Endpoint Change	66	-0.02394	0.178626	-0.02000	-0.7300	0.4000
Lymphocytes Absolute	10^9 per Litre	Baseline	101	2.60386	0.793596	2.45000	1.4800	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 8 includes only assessments that are on-treatment (including taper)

BRL 29060 - 701

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	Units	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Lymphocytes Absolute	10^9 per Litre	Week 8	57	2.37035	0.643639	2.20000	1.1500	4.1700
		Endpoint	66	2.37030	0.631482	2.20500	1.1500	4.1700
		Endpoint Change	66	-0.26212	0.637320	-0.17000	-1.9800	0.8000
Monocytes Absolute	10^9 per Litre	Baseline	101	0.37653	0.182178	0.35000	0.0100	0.8900
		Week 8	57	0.35333	0.149204	0.32000	0.0800	0.7600
		Endpoint	66	0.35212	0.142208	0.32000	0.0800	0.7600
		Endpoint Change	66	-0.04500	0.170359	-0.05500	-0.5900	0.4700
Neutrophils Absolute	10^9 per Litre	Baseline	101	3.78178	1.386882	3.66000	0.9900	8.6100
		Week 8	57	3.84333	1.464859	3.57000	1.5400	8.0900
		Endpoint	66	3.73909	1.457471	3.48500	1.1700	8.0900
		Endpoint Change	66	0.00667	1.249031	-0.13500	-3.6400	3.3100
Sodium	Millimoles per Litre	Baseline	101	141.94059	2.167126	142.00000	135.0000	149.0000
		Week 8	59	141.16949	1.858369	141.00000	137.0000	146.0000
		Endpoint	67	141.13433	2.073611	141.00000	135.0000	146.0000
		Endpoint Change	67	-0.71642	2.627396	-1.00000	-8.0000	4.0000
Potassium	Millimoles per Litre	Baseline	101	4.39406	0.399955	4.30000	3.7000	5.6000
		Week 8	59	4.30678	0.378228	4.20000	3.5000	5.7000
		Endpoint	67	4.32537	0.381521	4.30000	3.5000	5.7000
		Endpoint Change	67	-0.02985	0.444500	-0.10000	-1.4000	1.8000
Blood Urea Nitrogen	Millimoles per Litre	Baseline	101	4.34409	1.024869	4.28400	2.1420	7.1400
		Week 8	59	4.30820	0.985217	4.28400	2.1420	6.4260
		Endpoint	67	4.32663	0.983636	4.28400	2.1420	6.4260
		Endpoint Change	67	0.05328	1.053281	0.00000	-3.2130	2.4990
Creatinine	Micromoles per Litre	Baseline	101	52.95248	15.837918	53.04000	26.5200	106.0800
		Week 8	59	56.63593	17.765044	53.04000	35.3600	141.4400
		Endpoint	67	55.94269	17.162662	53.04000	35.3600	141.4400
		Endpoint Change	67	2.24299	10.918578	0.00000	-26.5200	53.0400
Alkaline Phosphatase	International Units per Litre	Baseline	101	222.38614	97.821876	224.00000	56.0000	479.0000

Endpoint is the last on treatment assessment (including Taper Phase)
Note: For laboratory assessments, the last pre-treatment assessment is taken as Baseline
Week 8 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	Units	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Alkaline Phosphatase	International Units per Litre	Week 8	59	199.45763	81.732179	199.00000	69.0000	380.0000
		Endpoint	67	206.68657	83.565654	200.00000	69.0000	386.0000
		Endpoint Change	67	-15.02985	29.218078	-12.00000	-98.0000	60.0000
Aspartate Aminotransferase	International Units per Litre	Baseline	101	22.58416	6.553270	22.00000	10.0000	40.0000
		Week 8	59	21.44068	5.775308	20.00000	12.0000	38.0000
		Endpoint	67	22.00000	5.765624	21.00000	12.0000	38.0000
		Endpoint Change	67	-0.82090	5.048028	-1.00000	-19.0000	9.0000
Alanine Aminotransferase	International Units per Litre	Baseline	101	16.09901	6.956299	14.00000	6.0000	47.0000
		Week 8	59	15.94915	5.528683	15.00000	8.0000	31.0000
		Endpoint	67	16.01493	5.147793	15.00000	8.0000	31.0000
		Endpoint Change	67	-0.28358	6.087259	1.00000	-27.0000	14.0000
Total Bilirubin	Micromoles per Litre	Baseline	101	8.34683	3.787464	8.55000	3.4200	22.2300
		Week 8	59	7.88339	3.953545	6.84000	3.4200	23.9400
		Endpoint	67	7.98851	4.107324	6.84000	3.4200	23.9400
		Endpoint Change	67	-0.45940	2.894967	0.00000	-10.2600	6.8400
Thyroid Stimulating Hormone	MU L	Baseline	101	2.08911	1.098991	1.90000	0.1000	5.1000
		Week 8	1	1.10000	.	1.10000	1.1000	1.1000
		Endpoint	3	0.70000	0.360555	0.60000	0.4000	1.1000
		Endpoint Change	3	-0.76667	0.737111	-0.50000	-1.6000	-0.2000
Free T3	Picomoles per Litre	Baseline	101	5.67193	0.628553	5.71340	4.0502	7.3458
		Week 8	1	5.66720	.	5.66720	5.6672	5.6672
		Endpoint	3	5.53373	0.314603	5.66720	5.1744	5.7596
		Endpoint Change	3	-0.40553	0.077512	-0.41580	-0.4774	-0.3234
Total Free Thyroxine	Picomoles per Litre	Baseline	99	13.83818	2.083474	14.19000	10.3200	19.3500
		Week 8	1	12.90000	.	12.90000	12.9000	12.9000
		Endpoint	3	15.05000	1.970508	15.48000	12.9000	16.7700

Endpoint is the last on treatment assessment (including Taper Phase)
Note: For laboratory assessments, the last pre-treatment assessment is taken as Baseline
Week 8 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	Units	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Total Free Thyroxine	Picomoles per Litre	Endpoint Change	2	-1.93500	0.912168	-1.93500	-2.5800	-1.2900

Endpoint is the last on treatment assessment (including Taper Phase)
Note: For laboratory assessments, the last pre-treatment assessment is taken as Baseline
Week 8 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	Units	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Hemoglobin	Grams per Litre	Baseline	100	132.52000	11.140499	131.00000	111.0000	162.0000
		Week 8	70	130.35714	9.457817	129.50000	109.0000	159.0000
		Endpoint	76	130.57895	10.044253	129.50000	109.0000	159.0000
		Endpoint Change	74	-1.09459	6.540012	-1.00000	-24.0000	13.0000
Hematocrit	Percentage	Baseline	100	39.52700	3.481230	39.30000	32.7000	48.8000
		Week 8	70	38.62143	3.014116	38.40000	30.7000	47.6000
		Endpoint	76	38.67105	3.074272	38.35000	30.7000	47.6000
		Endpoint Change	74	-0.57162	2.553350	-0.60000	-9.4000	7.3000
Red Blood Cell Count	10^12 per Litre	Baseline	100	4.58300	0.391850	4.60000	3.7000	5.6000
		Week 8	70	4.51857	0.354799	4.50000	3.7000	5.3000
		Endpoint	76	4.51316	0.343062	4.40000	3.7000	5.3000
		Endpoint Change	74	-0.04054	0.263235	-0.10000	-0.8000	0.7000
White Blood Cell Count	10^9 per Litre	Baseline	100	6.73000	1.636546	6.70000	3.8000	13.2000
		Week 8	70	6.59143	1.860555	6.35000	2.5000	12.7000
		Endpoint	76	6.71842	1.699310	6.40000	4.1000	12.7000
		Endpoint Change	74	-0.09324	1.419370	-0.20000	-3.2000	5.0000
Platelets	10^9 per Litre	Baseline	100	279.42000	64.671224	277.50000	94.0000	468.0000
		Week 8	70	277.10000	54.130318	273.00000	162.0000	413.0000
		Endpoint	76	279.76316	58.375764	275.50000	150.0000	457.0000
		Endpoint Change	74	-2.22973	45.936092	-3.00000	-163.0000	167.0000
Basophils Absolute	10^9 per Litre	Baseline	100	0.02130	0.015548	0.02000	0.0000	0.1000
		Week 8	70	0.01743	0.011507	0.01500	0.0000	0.0600
		Endpoint	76	0.01763	0.011298	0.02000	0.0000	0.0600
		Endpoint Change	74	-0.00311	0.015870	0.00000	-0.0700	0.0300
Eosinophils Absolute	10^9 per Litre	Baseline	100	0.22850	0.199375	0.18000	0.0000	1.3300
		Week 8	70	0.23714	0.179776	0.18000	0.0400	1.0400
		Endpoint	76	0.22750	0.175470	0.17500	0.0300	1.0400
		Endpoint Change	74	-0.01338	0.192448	-0.03000	-0.6500	0.8800
Lymphocytes Absolute	10^9 per Litre	Baseline	100	2.35350	0.647764	2.28000	0.8000	4.8700

Endpoint is the last on treatment assessment (including Taper Phase)
Note: For laboratory assessments, the last pre-treatment assessment is taken as Baseline
Week 8 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	Units	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Lymphocytes Absolute	10^9 per Litre	Week 8	70	2.37271	0.637177	2.31500	1.1300	4.0900
		Endpoint	76	2.38329	0.631133	2.32500	1.2600	4.0900
		Endpoint Change	74	0.01797	0.484084	-0.00500	-0.9500	1.9800
Monocytes Absolute	10^9 per Litre	Baseline	100	0.34640	0.167613	0.33000	0.0000	0.8000
		Week 8	70	0.34300	0.158520	0.33500	0.0000	0.8400
		Endpoint	76	0.34513	0.158160	0.34000	0.0000	0.8400
		Endpoint Change	74	-0.00743	0.177487	-0.00500	-0.6600	0.4100
Neutrophils Absolute	10^9 per Litre	Baseline	100	3.78070	1.276932	3.80000	1.4600	8.2600
		Week 8	70	3.62229	1.417516	3.38000	1.0600	7.3900
		Endpoint	76	3.74579	1.324313	3.58000	1.5700	7.3900
		Endpoint Change	74	-0.08649	1.204700	0.01500	-2.7200	2.6500
Sodium	Millimoles per Litre	Baseline	101	141.83168	2.035040	142.00000	138.0000	147.0000
		Week 8	75	141.33333	2.183063	141.00000	133.0000	147.0000
		Endpoint	80	141.47500	1.961496	141.00000	137.0000	147.0000
		Endpoint Change	79	-0.32911	2.346419	0.00000	-6.0000	5.0000
Potassium	Millimoles per Litre	Baseline	101	4.40396	0.420219	4.40000	3.3000	6.1000
		Week 8	75	4.34133	0.391840	4.30000	3.7000	6.1000
		Endpoint	80	4.35375	0.409984	4.30000	3.7000	6.1000
		Endpoint Change	79	-0.06456	0.408574	0.00000	-1.3000	1.0000
Blood Urea Nitrogen	Millimoles per Litre	Baseline	101	4.26986	1.289082	4.28400	1.4280	8.2110
		Week 8	75	4.35540	1.179663	4.28400	2.1420	7.4970
		Endpoint	80	4.33309	1.172044	4.28400	2.1420	7.4970
		Endpoint Change	79	0.10846	1.200963	0.00000	-3.2130	2.1420
Creatinine	Micromoles per Litre	Baseline	101	54.44040	15.297679	53.04000	26.5200	132.6000
		Week 8	75	53.15787	15.276344	53.04000	26.5200	97.2400
		Endpoint	80	53.37150	15.500343	53.04000	26.5200	97.2400
		Endpoint Change	79	-0.22380	15.112077	0.00000	-79.5600	53.0400
Alkaline Phosphatase	International Units per Litre	Baseline	101	216.09901	98.298780	230.00000	49.0000	512.0000

Endpoint is the last on treatment assessment (including Taper Phase)
Note: For laboratory assessments, the last pre-treatment assessment is taken as Baseline
Week 8 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	Units	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Alkaline Phosphatase	International Units per Litre	Week 8	75	222.01333	93.874916	223.00000	58.0000	466.0000
		Endpoint	80	214.13750	95.674652	216.00000	58.0000	466.0000
		Endpoint Change	79	-9.74684	36.147301	-4.00000	-127.0000	51.0000
Aspartate Aminotransferase	International Units per Litre	Baseline	101	23.26733	6.532826	23.00000	13.0000	47.0000
		Week 8	75	24.00000	8.182050	23.00000	12.0000	53.0000
		Endpoint	80	22.96250	6.897888	22.00000	12.0000	46.0000
		Endpoint Change	79	-0.59494	4.628560	0.00000	-13.0000	18.0000
Alanine Aminotransferase	International Units per Litre	Baseline	101	16.13861	8.634848	14.00000	7.0000	59.0000
		Week 8	75	17.98667	15.921678	13.00000	6.0000	115.0000
		Endpoint	80	16.30000	10.881874	13.00000	6.0000	84.0000
		Endpoint Change	79	0.54430	7.237363	0.00000	-18.0000	33.0000
Total Bilirubin	Micromoles per Litre	Baseline	101	7.73733	4.157756	6.84000	3.4200	32.4900
		Week 8	75	8.20800	3.290452	8.55000	3.4200	20.5200
		Endpoint	80	8.18662	3.272822	7.69500	3.4200	20.5200
		Endpoint Change	79	0.90911	2.666546	0.00000	-5.1300	8.5500
Thyroid Stimulating Hormone	MU L	Baseline	100	2.42700	1.428346	2.10000	0.5000	11.7000
		Week 8	2	2.50000	1.555635	2.50000	1.4000	3.6000
		Endpoint	3	2.43333	1.106044	2.30000	1.4000	3.6000
		Endpoint Change	3	-2.33333	5.006329	0.20000	-8.1000	0.9000
Free T3	Picomoles per Litre	Baseline	100	5.56695	0.752839	5.59020	3.7422	8.0850
		Week 8	2	5.81350	0.511804	5.81350	5.4516	6.1754
		Endpoint	3	5.50807	0.640968	5.45160	4.8972	6.1754
		Endpoint Change	3	0.34907	0.299146	0.27720	0.0924	0.6776
Total Free Thyroxine	Picomoles per Litre	Baseline	100	13.94490	2.063796	14.19000	9.0300	20.6400
		Week 8	2	12.90000	0.000000	12.90000	12.9000	12.9000
		Endpoint	3	13.33000	0.744782	12.90000	12.9000	14.1900

Endpoint is the last on treatment assessment (including Taper Phase)
Note: For laboratory assessments, the last pre-treatment assessment is taken as Baseline
Week 8 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	Units	Visit	N	Mean	Std Dev	Median	Minimum	Maximum
Total Free Thyroxine	Picomoles per Litre	Endpoint Change	3	0.00000	0.000000	0.00000	0.0000	0.0000

Endpoint is the last on treatment assessment (including Taper Phase)
Note: For laboratory assessments, the last pre-treatment assessment is taken as Baseline
Week 8 includes only assessments that are on-treatment (including taper)

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Table 15.4.1

ECG Assessment

All Patients

Visit		Treatment Group: No Therapy Dispensed (N=99) n	%	Paroxetine (N=104) n	%	Placebo (N=102) n	%	Total (N=305) n	%
Screening	Abnormal	1	1.9	0		0		1	0.4
	Normal	51	96.2	104	100.0	102	100.0	257	99.2
	Unknown	1	1.9	0		0		1	0.4
	Total	53	100.0	104	100.0	102	100.0	259	100.0
Last Study Treatment ECG	Abnormal	0		0		0		0	
	Normal	0		68	100.0	76	100.0	144	100.0
	Unknown	0		0		0		0	
	N/A	0		0		0		0	
	Total	0		68	100.0	76	100.0	144	100.0
Early Withdrawals ECG	Abnormal	0		0		0		0	
	Normal	0		15	100.0	10	100.0	25	100.0
	Unknown	0		0		0		0	
	N/A	0		0		0		0	
	Total	0		15	100.0	10	100.0	25	100.0
Taper End ECG	Abnormal	0		0		0		0	
	Normal	0		2	66.7	4	100.0	6	85.7
	Unknown*	0		0		0		0	
	N/A**	0		1	33.3	0		1	14.3
	Total	0		3	100.0	4	100.0	7	100.0
Follow Up ECG	Abnormal	0		0		0		0	
	Normal	0		1	100.0	1	100.0	2	100.0
	Unknown*	0		0		0		0	
	N/A**	0		0		0		0	
	Total	0		1	100.0	1	100.0	2	100.0

* Abnormal at previous visit, but result of re-test unknown
** Not applicable, Normal at previous visit
(ECGs at timepoints other than Screening and Week 8/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 14.1bx

Mean Change From Baseline (+/- 2 Standard Errors) In CDRS-R Total Score
Intention to Treat Population

Age Group : Children

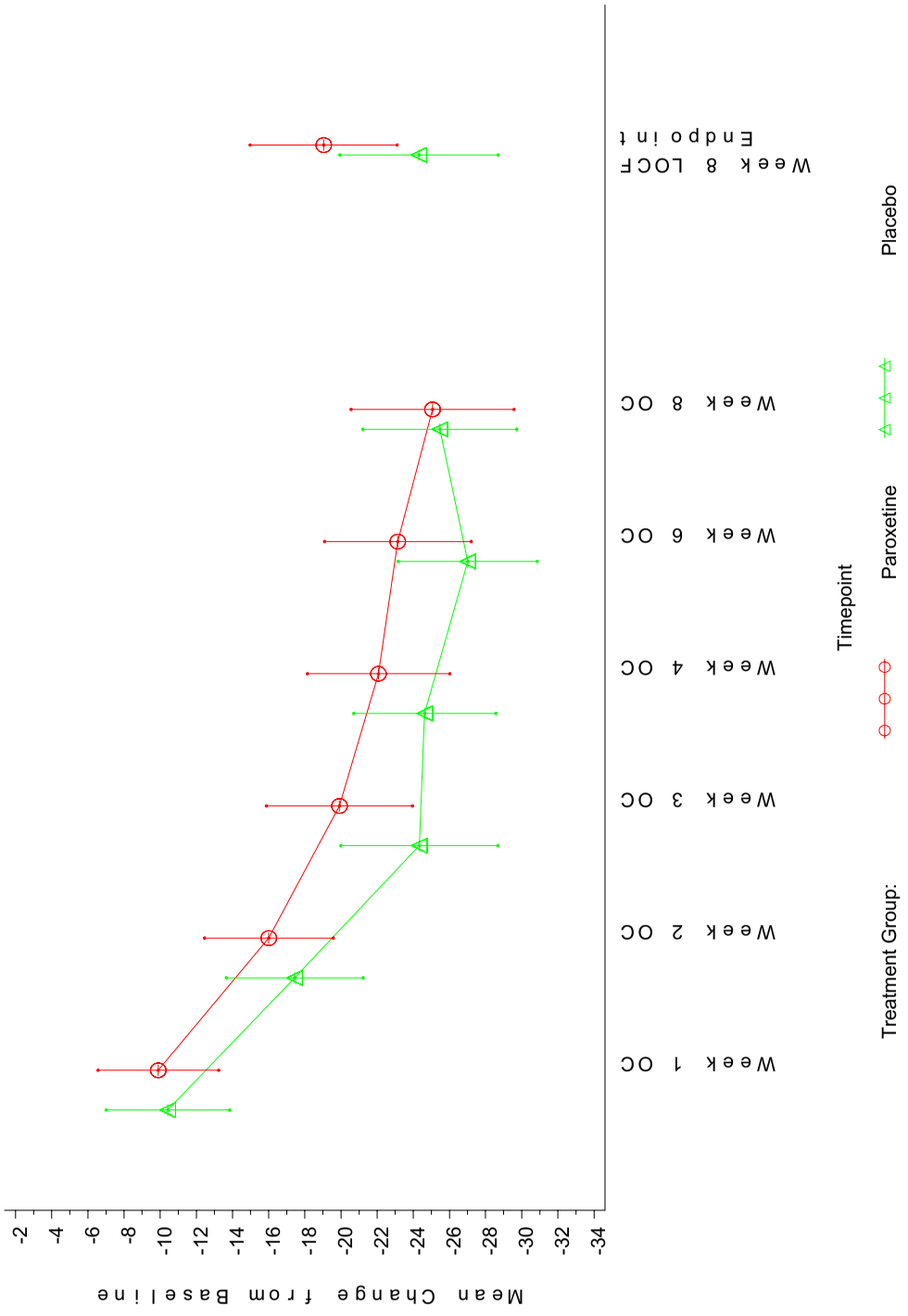

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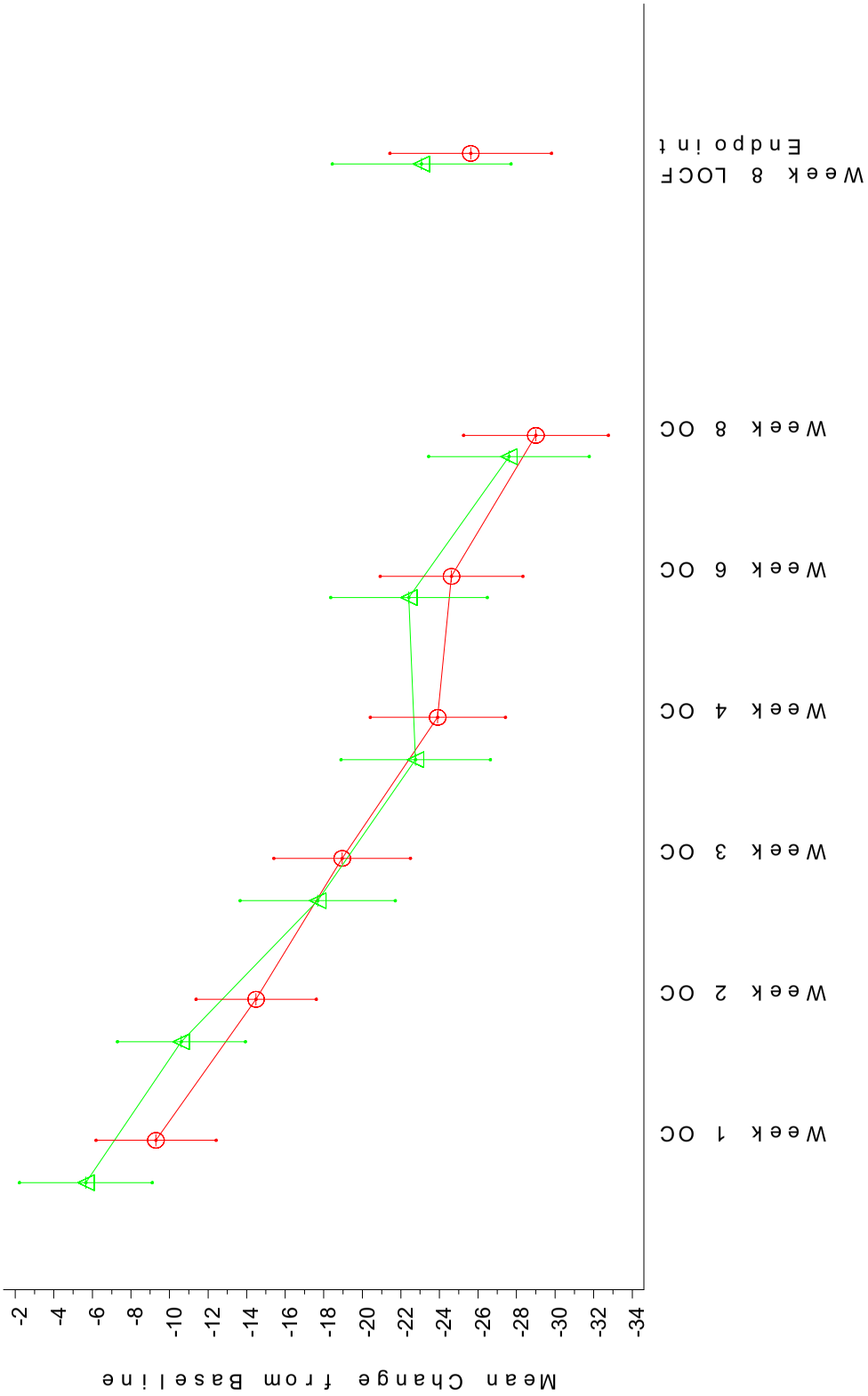
Figure 14.1by

Mean Change From Baseline (+/- 2 Standard Errors) In CDRS-R Total Score
Intention to Treat Population

Age Group : Adolescents



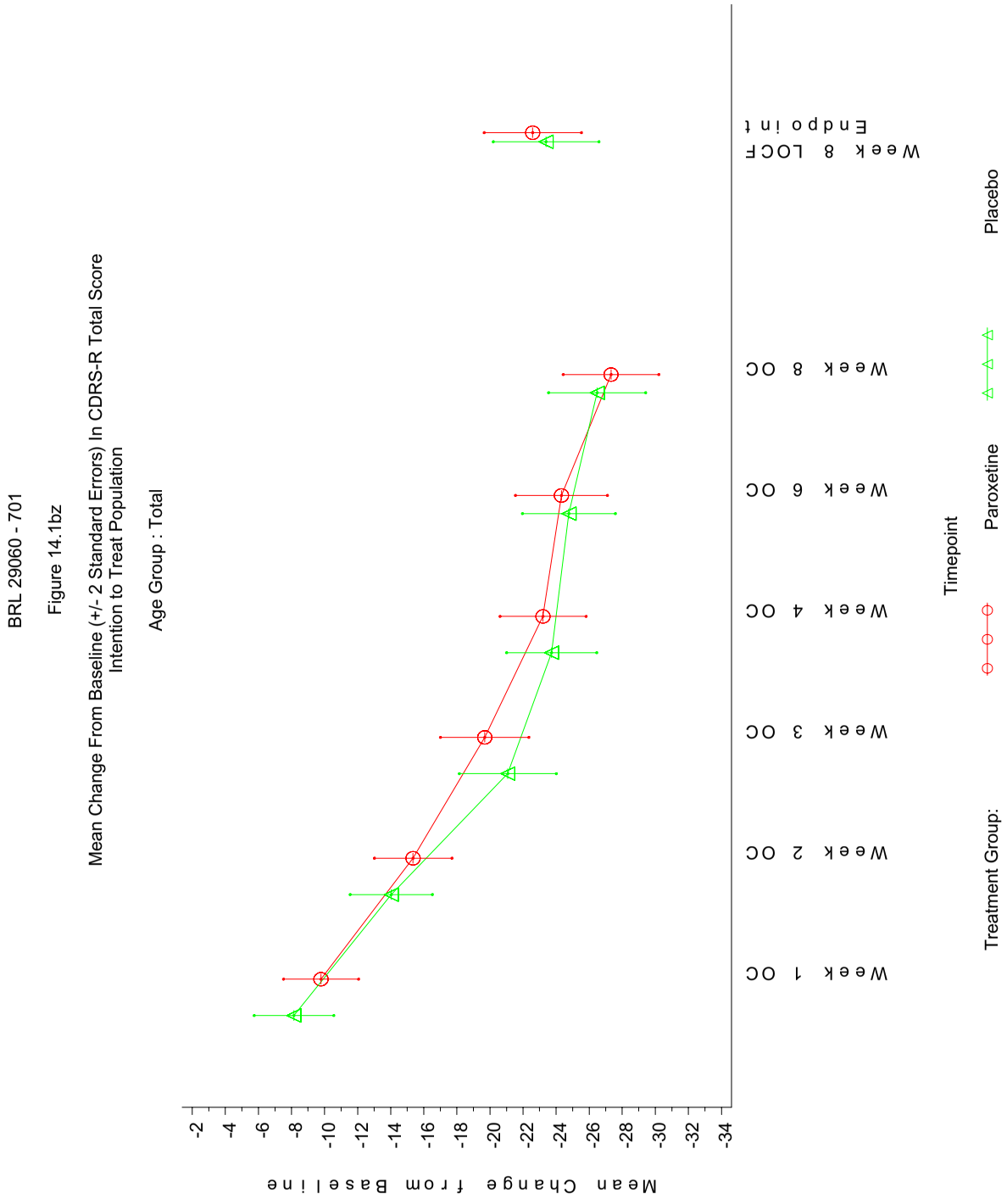

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Figure 14.1bz
Mean Change From Baseline (+/- 2 Standard Errors) In CDRS-R Total Score
Intention to Treat Population
Age Group : Total
Mean Change from Baseline
-2
-4
-6
-8
-10
-12
-14
-16
-18
-20
-22
-24
-26
-28
-30
-32
-34
Week 1 OC
Week 2 OC
Week 3 OC
Week 4 OC
Week 6 OC
Week 8 OC
Week 8 LOCF Endpoint
Timepoint
Treatment Group:
Paroxetine
Placebo

15 Errata

15 Errata

Table 16.0 Errata

Table/Listing	Error
Tables 13.3.1b, 13.3.1c, 13.3.2, Section 11; Listing 13.3.1b, Appendix B	Patients 701.165.25661 in the paroxetine group and 701.165.25662 in the placebo group completed the Week 8 visit CRF, but because the visit occurred <50 days after the first dose of study medication, the completions were slotted to Week 6. Patient 701.184.25955 in the paroxetine group was incorrectly slotted to Week 6. These patients have not been included in the Week 8 OC dataset.
Table 13.13.1, Section 11; Listing 13.13.1, Appendix B.	Prior psychoactive medications taken for MDD were classified incorrectly by therapeutic class.
Table 13.13.2.1, Section 11; Listing 13.13.2, Appendix B	Among prior psychoactive medications taken for indications other than MDD, trazodone was incorrectly classified as a TCA in the data source table; it should be in the "other" category.
Listing 15.5.1, Appendix D	Patient 701.182.25818, in the paroxetine group, is listed as having a medical procedure of hospitalization, which was consequent to an SAE of exacerbation of depressive symptoms. Hospitalization is not to be considered as a medical procedure.
Table 15.1.5.1, 15.1.5.1.X, Section 13; Listings 15.1.2, 15.1.3.3, Appendix D	Patient 701.185.25963, in the paroxetine group, stopped taking study medication on Day 28; no reason has been provided. Two days later, the patient threatened to harm himself and was hospitalized with an acute exacerbation of major depressive disorder. The SAE leading to withdrawal appears in Listing 15.1.2 as having occurred during the Taper or Follow-up Phase because it started 2 days after the last dose of study medication. The AE appears in Listing 15.1.4, Appendix D, as an AE leading to withdrawal. The demography tables also reflect the patient as having withdrawn due to an AE.

Table/Listing	Error
Listings 15.1.2, 15.1.3.3, and 15.1.4, Appendix D; Tables 15.1.5.1, 15.1.5.1.X, Section 13; Tables 13.3.1b, 13.3.3, Section 11; Listing 13.3.1b, Appendix B	Patient 701.163.25718 withdrew from the study on Day 41 due to lack of efficacy, and taper medication was dispensed. The next day, she claimed to have ingested all the taper medication, and was hospitalized with an SAE of emotional lability. The SAE is incorrectly recorded in the database as having led to withdrawal, with an action taken coded as STP (study medication stopped). Therefore the SAE is tabulated as an AE withdrawal in both the safety tables and the demography tables.
Tables 15.1.5.1, 15.1.5.1.X, Section 13; Listings 15.1.2, 15.1.3.3, Appendix D	Patient 701.182.25818 took 8 days of study medication, which was 10 mg of paroxetine per day. On Day 11, the patient experienced a moderate exacerbation of depressive symptoms and was withdrawn from the study. The following day, the depression became severe and was considered an SAE. This patient does not appear in the withdrawal table because the AE coded as leading to withdrawal started after the last dose of study medication, but is listed as having withdrawn due to an AE in Listing 15.1.4, Appendix D, and is counted as having withdrawn due to an AE in the demography tables.
Tables 15.1.1.1, 15.1.5.1.X, 15.1.1.3, 15.1.1.3.X, 15.1.1.4, 15.1.1.4.X, 15.1.1.5, 15.1.1.5.X, 15.1.3.1, 15.1.3.1.X, 15.1.3.3, 15.1.3.4, 15.1.3.4.X, 15.1.5.1, 15.1.5.1.X, 15.1.6.1.X, 15.1.7.1, 15.1.7.3, 15.1.7.4, Section 13; Listings 15.1.1, 15.1.2, 15.1.3.2¸ 15.1.3.3, 15.1.4, Appendix D.	Patient 701.154.25768, randomized to placebo, was hospitalized for emotional lability after 5 days and was withdrawn from the study. The AE was coded as occurring during the Follow-up Phase since the AE occurred 1 day after the patient's last dose of study medication. The patient is counted as having withdrawn due to an AE in the demography tables.

Table/Listing	Error
Tables 15.1.1.1, 15.1.5.1.X, 15.1.1.3, 15.1.1.3.X, 15.1.1.4, 15.1.1.4.X, 15.1.1.5, 15.1.1.5.X, 15.1.3.1, 15.1.3.1.X, 15.1.3.3, 15.1.3.4, 15.1.3.4.X, 15.1.5.1, 15.1.5.1.X, 15.1.6.1.X, 15.1.7.1, 15.1.7.3, 15.1.7.4, Section 13; Listings 15.1.1, 15.1.2, 15.1.3.2¸ 15.1.3.3, 15.1.4, Appendix D.	Patient 701.180.25639 took 51 days of study medication, which was paroxetine, and stopped medication with no reason provided. Two days later, the patient was hospitalized in intensive care for emotional lability. This patient does not appear in the withdrawal table because the AE coded as leading to withdrawal started after the last dose of study medication, but is counted as having withdrawn due to an AE in the demography tables.
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.