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SmithKline Beecham

Paroxetine Hydrochloride (Paxil®)

BRL 29060

A Multicenter Study to Assess the Pharmacokinetics of Paroxetine Following Repeat Dose Administration in Children and Adolescents with Obsessive-Compulsive Disorder (OCD) and/or Depression

715

Final Clinical Pharmacology Report

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Protocol Phase: IIa

Date of First Enrollment: 15 August 2000

Date Last Subject Completed: 27 September 2001

Protocol Number: 715

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

Title

A Multicenter Study to Assess the Pharmacokinetics of Paroxetine Following Repeat Dose Administration in Children and Adolescents with Obsessive-Compulsive Disorder (OCD) and/or Depression

Investigator(s) and Center(s)

Twelve (12) Centers in the United States.

Publication

None as of February 2002.

Study Dates

15 August 2000 to 27 September 2001.

Objective(s)

BRL 29060 (paroxetine hydrochloride; Paxil®) is used in the treatment of OCD and depression, conditions which occur in the pediatric, as well as in the adult, population. Since current information about the disposition of paroxetine in the pediatric population is limited, this study descriptively assessed the pharmacokinetics of paroxetine under steady state conditions in children and adolescents administered repeat oral doses of paroxetine hydrochloride. The specific study objectives were: 1) to determine the steady state pharmacokinetic profile of paroxetine following repeat oral doses of paroxetine hydrochloride to children and adolescents and 2) to assess the safety and tolerability of paroxetine following repeat oral doses of paroxetine hydrochloride to children and adolescents.

Study Design

This was a multicenter, open-label, repeat dose, dose-rising study in children and adolescents with OCD and/or depression. Each patient received paroxetine hydrochloride orally according to the following schedule:

Days 1-14 (-2/+3):	10 mg once daily
Days 15-28 (-2/+3):	20 mg once daily
Days 29-42 (-2/+3):	30 mg once daily
Days 43-49 (-2/+3):	Dose-tapering (20 mg once daily)
Days 50-56 (+3):	Dose tapering (10 mg once daily)

Pharmacokinetic sampling for measurement of plasma paroxetine concentrations was conducted over an approximately 24 hour period following the final dose at each dosing level in the dose rising stage. There were follow-up visits at the end of the taper dosing period and at 14 (± three) days following the final dose of paroxetine hydrochloride. Patients completing this study were allowed to enroll in a six month, open-label extension study administrated under a separate protocol at the investigator's discretion. The taper dosing period was optional and the 14 day follow-up visit was not required for patients entering the open-label extension dosing study.

Study Population

Approximately 30 children ages seven to 11 years, inclusive, and approximately 30 adolescents ages 12 to 17 years, inclusive, who currently met DSM-IV criteria for OCD and/or depression (MDD) were enrolled in this study. Each age group was to be enrolled such that a ratio no greater than 2:1 was achieved based upon gender if possible.

Treatment and Administration

BRL 29060 (paroxetine hydrochloride, Paxil®) oral tablets, 10 mg (Batch number U00001) were taken once daily in doses of 10 mg, 20 mg or 30 mg, depending upon the phase of the study.

Evaluation Criteria

Safety Parameters

The safety and tolerability of protocol-specified treatments were assessed by vital signs, 12-lead ECGs, clinical laboratory tests and clinical monitoring.

Pharmacokinetic Parameters

Serial blood samples were collected over a 24 hour dosing interval after the final dose at each dose level. Plasma concentrations of paroxetine were quantitated using a method based on LC/MS/MS with on-line solid-phase extraction. Paroxetine Cmax, Tmax, AUC(0-24), CL/F and C(24) were derived using non-compartmental pharmacokinetic analysis, and their relationships with dose, age, weight, gender and CYP2D6 genotype were explored.

Subject Disposition and Key Demographic Data

Sixty-two (62) children (7-11 years) and adolescents (12-17 years) with either OCD and/or MDD were enrolled and dosed with paroxetine during this study. There were a total of twenty-one (21) withdrawals, which were either due to adverse events (6), lost to follow-up (4), protocol deviations (7) or other reasons (4). Demographic data for all enrolled patients are summarized below:

		Age (years)	Height (cm)	Weight (kg)
Children	**Mean**	10	142.9	42.1
n = 27	**SD**	1.1	9.63	13.62
74% Male, 26% Female	**Range**	8-11	125.5-164.0	25.9-76.5
Adolescents	**Mean**	14	164.5	68.2
n = 35	**SD**	1.8	12.41	22.96
57% Male, 43% Female	**Range**	12-17	129.0-190.5	30.1-141.0
Pooled	**Mean**	12	155.1	56.8
n = 62	**SD**	2.8	15.53	23.31
65% Male, 35% Female	**Range**	8-17	125.5-190.5	25.9-141.0

Children: 85% White; 7% Black; 7% Other; **Adolescents**: 83% White; 11% Black; 6% Other; **Pooled**: 84% White; 10% Black; 6% Other

Safety Results

There were no deaths during this study. There were two (2) serious adverse events [manic reaction (1) and drug level increased (1)] and six (6) withdrawals due to adverse events (AEs) [manic reaction –1, drug level increased (overdose) – 1, asthma (exacerbation) - 1, rash - 1, manic reaction and hyperkinesia – 1 and dizziness and hyperkinesia], which included the two (2) serious AEs. Summary details for the treatment-emergent AEs reported during this study are listed by patient and treatment group in the table below:

	Children					**Adolescents**				
	Paroxetine Dose (mg UID)					**Paroxetine Dose (mg UID)**				
	10	20	30	20T	10T	10	20	30	20T	10T
Total Number of AEs	53	41	25	11	2	72	41	29	6	3
Most frequent AE = Headache	8	4	2	0	0	11	10	4	0	1
Number of Patients with AEs	18	12	11	5	2	25	20	15	4	2
Number of Patients Exposed	27	25	25	13	7	35	33	30	16	5

T = Taper.

There were no clinically significant changes in vital signs (height, weight, heart rate, blood pressure) or ECG intervals. Only one (1) safety laboratory value of potential clinical concern was considered clinically significant during this study. This increased AST (97 IU/L) was considered an AE by the investigator, but was asymptomatic, considered probably unrelated to paroxetine and resolved in approximately two weeks.

Pharmacokinetics

Of the 62 pediatric patients (27 children and 35 adolescents) entered into the study, a total of 59 (25 children and 34 adolescents) completed the first period of dosing (10 mg/day) and provided plasma samples for pharmacokinetic analysis. Most of these patients (23 children and 28 adolescents) went on to complete the dose-rising phase and provided samples at all three dose levels (10, 20 and 30 mg/day). However, pharmacokinetic data at 20 mg/day from one patient were excluded from further analysis due to a dosing error, and data from three others were deemed uninterpretable due to internal data inconsistencies. The most important steady state pharmacokinetic parameters - Cmax, AUC(0-24) and CL/F (before and after normalization for weight) - are summarized by dose and age-group below.

Paroxetine steady state pharmacokinetic parameter [units]		**Children**			**Adolescents**		
		10 mg [n=23]	**20 mg** [n=23]	**30 mg** [n=21]	**10 mg** [n=33]	**20 mg** [n=29]	**30 mg** [n=27]
Cmax	Mean	19.5	58.6	129.0	12.0	42.7	94.0
[ng/mL]	SD	18.2	34.5	106.9	13.0	30.0	51.4
	Minimum	1.3	19.4	28.3	0.3	10.7	28.5
	Maximum	90.9	142.4	552.6	62.8	129.9	262.9
	Geom. mean	**14.0**	**50.0**	**105.5**	**6.6**	**35.0**	**82.4**
	CVb	**109%**	**63%**	**68%**	**191%**	**70%**	**56%**
AUC(0-24)	Mean	285	899	2081	189	733	1631
[ng.h/mL]	SD	291	552	1737	227	581	1040
	Minimum	14	295	529	4	150	501
	Maximum	1424	2633	9018	1134	2628	5485
	Geom. mean	**188**	**772**	**1711**	**94**	**570**	**1395**
	CVb	**131%**	**60%**	**66%**	**227%**	**82%**	**60%**
CL/F	Mean	93.3	29.8	20.6	273.3	44.4	24.8
[L/h]	SD	144.1	15.9	12.4	495.8	32.3	13.2
	Minimum	7.0	7.6	3.3	8.8	7.6	5.5
	Maximum	708.7	67.9	56.7	2597.4	133.8	59.8
	Geom. mean	**53.2**	**25.9**	**17.5**	**106.6**	**35.1**	**21.5**
	CVb	**131%**	**60%**	**66%**	**227%**	**82%**	**60%**
CL/F (weight-normalized)	Mean	2.22	0.73	0.50	3.63	0.65	0.36
	SD	3.66	0.37	0.33	5.79	0.38	0.16
	Minimum	0.26	0.20	0.12	0.16	0.09	0.12
[(L/h)/kg]	Maximum	18.36	1.76	1.47	29.58	1.52	0.78
	Geom. mean	**1.31**	**0.64**	**0.42**	**1.64**	**0.54**	**0.33**
	CVb	**117%**	**58%**	**66%**	**202%**	**76%**	**53%**

At corresponding doses, median Tmax values in the two age-groups were similar (3-5 hours), suggesting comparable rates of absorption. No pharmacokinetic differences due to gender were evident in the Cmax, AUC(0-24) or CL/F data in either age-group at any of the three dose levels.

The Cmax and AUC(0-24) data confirm that, at each dose level, paroxetine steady state systemic exposure was higher in children (8-11 years) than in adolescents (12-17 years). However, for both parameters, the differences diminished with increasing dose; geometric mean values in children were approximately 100% higher at 10 mg but less than 30% higher at 30 mg. Mean Cmax and AUC(0-24) values increased disproportionately with dose in both groups, but this was accompanied by a marked reduction in variability (CVb), most notably between the 10 and 20 mg dose levels. Expressed in terms of clearance, geometric mean CL/F (un-normalized) at 10 mg in children was approximately 50% lower than in adolescents, but only 25% lower at 20 mg and 20% lower at 30 mg. Within each group, geometric mean CL/F fell more than two-fold between 10 and 20 mg, but by less than 40% between 20 and 30 mg.

As suggested by the groupwise (mean) data, Cmax and AUC(0-24) tended to fall with increasing age, while CL/F tended to rise. Variability was, however, considerable. Mirroring the effect of age, AUC(0-24) and Cmax also tended to fall with increasing weight, while CL/F again tended to rise. However, weight-normalized CL/F values at each dose level appeared to remain relatively constant across the age range studied.

Because the combined effects of age, weight and dose on the pharmacokinetics of paroxetine in the pediatric population are evidently rather complex, a covariate analysis was performed. Strong associations ($P \leq 0.001$) were observed between weight and Cmax, AUC(0-24) and un-normalized

CL/F, but no statistically significant association was observed between weight and weight-normalized CL/F. After adjusting for weight, no significant effect was found for any of these parameters when age was added to the model. However, significant interactions ($P<0.05$) between weight and dose were observed for Cmax, AUC(0-24) and un-normalized CL/F, due to small differences between the 10 mg dose level and the two higher doses in the degree of change with increasing weight.

CYP2D6 genotyping was performed for 53 of the 59 patients providing pharmacokinetic data, enabling their baseline phenotypes to be predicted. As expected, the EM phenotype predominated. No PMs were identified among the younger group, but three of the adolescents were predicted to possess this phenotype. Although one of these had the highest Cmax and AUC(0-24) and the lowest clearance in this age-group, parameter values in the other two putative PM patients were less readily distinguishable from the EM patients.

Conclusion

In both pediatric age-groups, paroxetine steady state systemic exposure (Cmax and AUC(0-24)) increased disproportionately with dose, but also became less variable, mirroring the behavior of paroxetine in the adult population. Cmax and AUC(0-24) were higher and clearance lower in children than in adolescents. The association of paroxetine plasma concentrations with dose and weight (age) in this study may at first appear to support a weight-based dosing recommendation in pediatric patients. However, normalization of clearance for weight did not significantly reduce the very broad between-subject pharmacokinetic variability at any dose level. Moreover, noting the similarities between the adolescent and adult exposure data, and the absence of a clear relationship of exposure to effectiveness in adult patients treated with paroxetine, the results do not warrant a weight-based dosing regimen in the pediatric patient population. Paroxetine was generally safe and well-tolerated by pediatric patients ages 8 to 17 years.

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1 Introduction

BRL 29060 (paroxetine hydrochloride; Paxil®) is used in the treatment of OCD and depression, conditions which occur in the pediatric, as well as in the adult, population. Since current information about the disposition of paroxetine in the pediatric population is limited, this study descriptively assessed the pharmacokinetics of paroxetine under steady state conditions in children and adolescents administered repeat oral doses of paroxetine hydrochloride.

1.1 Background

Paroxetine is an orally administered selective serotonin reuptake inhibitor (SSRI) used in the treatment of OCD and depression, conditions which occur in the pediatric, as well as in the adult, population. The pharmacokinetic profile of paroxetine has been fully characterized in the adult population. Paroxetine is well absorbed after oral dosing but, because of a significant first-pass effect, not all of the dose reaches the systemic circulation. Paroxetine exhibits non-linear pharmacokinetics due primarily to dose-dependent bioavailability, arising from the involvement of the saturable, polymorphic cytochrome P450 enzyme CYP2D6 in its metabolism [1]. In single dose studies, paroxetine plasma concentrations increase disproportionately with dose in most subjects, but not in all. In PM subjects (poor metabolizers who lack CYP2D6), concentrations are the highest initially but increase linearly with dose. Similarly, in repeat dose studies, although most subjects show greater than predicted paroxetine accumulation during the approach to steady state, accumulation in PMs is entirely predictable; non-linearity is confined to EMs (extensive metabolizers). Importantly, although non-linearity is also evident when increasing the daily dose at steady state, the deviations from linearity are less pronounced because CYP2D6 is already partially saturated. In all of these dosing scenarios (increasing dose level and duration), the between-subject pharmacokinetic variability progressively diminishes. These properties indicate that all subjects (EMs and PMs) have alternative, non-saturable pathways by which paroxetine is cleared from the body when CYP2D6 is absent or saturated. These linear pathways predominate at steady state, and therefore the influence of CYP2D6 status as a determinant of pharmacokinetic properties during the routine clinical use of paroxetine is much reduced. Also, because paroxetine plasma concentrations are not predictive of clinical outcome (efficacy or AEs), the same starting doses and titration regimens are suitable for EMs and PMs alike [1].

In the pediatric population, the pharmacokinetic profile of paroxetine has only previously been described across a limited range of doses [2]. Thirty depressed pediatric patients (6 to 17 years) each received a single 10 mg dose, followed by repeated once daily dosing at 10 mg, with an optional increase to 20 mg after 4 weeks. The single dose half-life (average 11.1 hours) was reported to be shorter than in adults, possibly suggesting higher paroxetine clearance, but other pharmacokinetic features mirrored the adult population. In particular, when the daily dose was doubled from 10 to 20 mg, average steady state plasma concentrations increased nearly seven-fold. Moreover, the broad between-subject variability in clearance was related to CYP2D6 activity. Finally, once steady state had been achieved (usually within a week), no further pharmacokinetic changes were evident. Paroxetine was well-tolerated in these pediatric patients [2].

1.2 Rationale

Information on the disposition of paroxetine at therapeutic doses in the pediatric population is limited. Therefore, this study descriptively assessed the steady state pharmacokinetics of paroxetine in children and adolescents receiving sequentially ascending doses of 10, 20 and 30 mg once daily for successive two-week periods. These doses were chosen because they are also the starting dose and the first two permitted dosage increments being investigated in concurrent clinical trials in pediatric patients with depression or OCD [3, 4].

2 Objectives

1. To determine the steady state pharmacokinetic profile of paroxetine following repeat oral doses of paroxetine hydrochloride to children and adolescents.

2. To assess the safety and tolerability of paroxetine following repeat oral doses of paroxetine hydrochloride to children and adolescents.

3 Methodology

3.1 Study Design

This was a multicenter, open-label, repeat dose, dose-rising study in children and adolescents with OCD and/or depression. Each patient received paroxetine hydrochloride orally according to the following schedule:

Days 1-14 (-2/+3):	10 mg once daily
Days 15-28 (-2/+3):	20 mg once daily
Days 29-42 (-2/+3):	30 mg once daily
Days 43-49 (-2/+3):	Dose-tapering (20 mg once daily)
Days 50-56 (+3):	Dose tapering (10 mg once daily)

Pharmacokinetic sampling for measurement of plasma paroxetine concentrations was conducted over an approximately 24 hour period following the final dose at each dosing level in the dose rising stage. There were follow-up visits at the end of the taper dosing period and at 14 (± three) days following the final dose of paroxetine hydrochloride. Patients completing this study were allowed to enroll in a six month, open-label extension study administrated under a separate protocol (BRL 29060/716) at the investigator's discretion. The taper dosing period was optional and the 14 day follow-up visit was not required for patients entering the open-label extension dosing study.

3.1.1 Protocol Amendments

The original protocol for the study was dated 24 February 2000 and approved by the Institutional Review Boards (IRBs) for each site as listed in Table 2, below. Subsequent to the start of the study, the original protocol was amended once on 18 December 2000 (Appendix A) as follows:

1. Revised the study visit schedule to allow flexibility (12 to 17 days) between PK visits as well as to the taper phase of the study (5 to 10 days for 20 mg taper and 14 to 17 days for taper to 10 mg);

2. Liberalized the concomitant medication exclusions.

Both of these revisions were considered necessary to ensure compliance and neither of these revisions were considered to negatively impact on the objectives of the study.

Details of the study methodology, incorporating these amendments, are described under Study Procedures (Section 3.8).

3.2 Investigators

The principal investigators of this study are listed by center in Table 1 below. (Investigator Biographies in Appendix A).

Table 1 Investigators and Site Addresses by Center Number

Center #	Investigator	Address	Subject #s
200	xx xxxxxx, MD, PhD	Cincinnati, OH	00001-00005, 00007
201	x xxxxxx, PhD, MD	Cleveland, OH	00101-00113
202	x xxxxxxx, MD	Boston, MA	00201, 00202
203	x xxxxxxx, MD	Philadelphia, PA	00301, 00303
204	x xxxxxx, MD	Gainesville, FL	00401
205	xx xxxxxx, MD	San Diego, CA	00502-00507, 00509, 00510
206	x xxxxxxxx, MD	Salt Lake City, UT	00601-00607
207	x xxxxxxxxxx, MD	Baltimore, MD	00701-00709
208	xx xxxxxx, MD	Shreveport, LA	00804-00806, 00809, 00811, 00816, 00818, 00824, 00825
209	x xxxxxxxxxxxxxxx, MD and x xxxxxx, MD	Houston, TX	No Subjects Enrolled
210	x xxxxxxxxxx, MD	Atlanta, GA	00051-00055
211	x xxxxxx, MD	Memphis, TN	No Subjects Enrolled

Source: Data on file, GlaxoSmithKline

Safety laboratory tests and urine drug screens were performed by Quest Diagnostics Clinical Trials, 7600 Tyrone Avenue, Van Nuys, CA, USA (central laboratory for protocol-specified procedures) or the local laboratory at the site(s) in the event of an urgent safety laboratory test.

Clinical data for this study are on file at the relevant sites.

3.3 Ethics

The study was conducted in accordance with Title 21 of the U.S. Code of Federal Regulations, Good Clinical Practice guidelines, and the Declaration of Helsinki (as amended in South Africa, 1996). The protocol and statement of informed consent (Sample Consent Form in Appendix A) were approved by an IRB (Table 2) prior to the start of the study. The protocol amendment (Appendix A) was also approved by each IRB as indicated.

The nature of the study was fully explained to each subject and their parent/legal guardian, and written informed consent was obtained from each subject's parent/legal guardian prior to their entry into the study. Subjects were informed that they could withdraw from the study at any time.

Table 2 IRB Names and Approval Dates by Center Number

Center Number	IRB Name	Protocol Approval Date	Amendment Approval Date
200	xxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxx	25 May 2000	15 February 2001
201	xxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxx	27 Jun 2000	06 Mar 2001
202	xxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxx	03 May 2000	18 January 2001
203	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxx	26 Jun 2000	03 Jan 2001
204	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxx	26 Jul 2000	Site Withdrew Participation
205	xxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxx	06 Apr 2000	31 January 2001
206	xxxxxxxxxxxxxxxxxxxxxxxxxxxx	09 May 2000	05 Jan 2001
207	xxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxx	18 Sep 2000	Not Submitted
208	xxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxx	26 Jun 2000	10 Jan 2001
209	xxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxx	10 Oct 2000	12 February 2001
210	xxxxxxxxxxxxxxxxxxxxxxxxxxxx	09 May 2000	05 Jan 2001
211	xxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxx	26 Jan 2001	02 Feb 2001

Source: Data on File, GlaxoSmithKline

3.4 Eligibility Criteria

Approximately 30 children (7-11 years, inclusive) and approximately 30 adolescents (12-17 years, inclusive) were enrolled in this study. Each age group was to be enrolled such that a ratio no greater than 2:1 was achieved based upon gender if possible.

3.4.1 Inclusion Criteria

1. Children of seven to 11 years of age, inclusive, and adolescents of 12 to 17 years of age, inclusive. Age determined at time of screen.

2. Current documented diagnosis of major depressive disorder and/or OCD as determined by the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV, criteria 296.2, 296.3 and/or 300.3)[5], confirmed by the Kiddie Schedule for Affective Disorders and Schizophrenia-Present and Lifetime version (K-SAD-PL) semi-structured diagnostic interview at the time of screening.

3. A total score of 45 or greater on the Children's Depression Rating Scale-Revised (CDRS-R) or a total score of 16 or greater on the Children's Yale-Brown Obsessive-Compulsive Score (CY-BOCS), depending upon the patient's primary diagnosis.

4. Patient's assent (where required) and a parent's (or legal guardian's) written informed consent prior to performance of any study-specific procedures.

5. Otherwise medically healthy as determined by physical examination, medical history, 12-lead ECG and safety laboratory tests.

3.4.2 Exclusion Criteria

1. Any clinically-relevant abnormality identified on the screening history, physical, 12-lead ECG or laboratory examination, which would, in the investigator's opinion, preclude the administration of paroxetine.

2. Patients with a primary clinically predominant Axis I disorder other than OCD and/or major depressive disorder.

3. Patients with Mental Retardation or Pervasive Developmental Disorder.

4. Any history of a psychotic disorder or episode, including schizophrenia, mania, hypomania and bipolar disorder.

5. Treatment with an investigational drug within 30 days or five half-lives (whichever was longer) preceding the first dose of study medication.

6. Pregnant or nursing females and females of childbearing potential who were unwilling or unable to use two barrier methods of contraception (i.e., diaphragm with foam/jelly or condom with foam/jelly).

7. Use of fluoxetine or depot antipsychotics and prescription or non-prescription drugs or vitamins with the potential for inducing microsomal (cytochrome P450) enzymes within three months prior to the first dose of study medication and throughout the study, including the two week follow-up visit. In addition, patients were prohibited from using any prescription drugs, non-prescription drugs, illicit drugs or herbal/naturopathic preparations within two weeks or five half-lives (whichever was longer) of the first dose of paroxetine and throughout the study, including the two week follow-up visit. As exceptions, the following medications were allowed:

    - A topical anesthetic for cannulization of the patient;
    - Acetaminophen;
    - Tetracycline;
    - Penicillin;
    - Amoxycillin;
    - Augmentin®;
    - Ibuprofen;
    - Fexofenadine (Allegra®);
    - OTC topical steroid and antifungal preparations;
    - Topical anti-acne preparations;
    - Inhaled corticosteroids.

8. Consumption of grapefruit or grapefruit juice within seven days prior to the first dose of study medication and throughout the pharmacokinetic phase of the study.

9. Donation of blood in excess of 140 mL (7 to 11 years of age) or 250 mL (12 to 17 years of age) within 56 days prior to dosing.

10. Patients with epilepsy.

11. Patients who, for any reason in the opinion of the investigator, would be non-compliant with the study schedule or procedures.

12. A known hypersensitivity to SSRIs.

13. Diagnosis with a substance abuse or dependence problem (including alcohol) within three months prior to the screening visit.

14. A current suicidal or homicidal risk in the investigator's judgment.

15. Electroconvulsive therapy (ECT) within three months of the screening visit.

16. A clear history of non-response to SSRI treatment for their depression and/or OCD, defined as non-response to at least two different SSRIs following adequate courses of treatment (i.e., received recommended dosages for four to six weeks each).

17. A positive result for illegal drug use at the screening visit.

18. Allergy to heparin.

3.5 Treatments and Administration

3.5.1 Study Medication

Study medication was supplied by the sponsor as follows:

Table 3 Study Medication Used

Study Drug	Appearance	Formulation	Dose Unit	Batch Numbers
BRL 29060 (paroxetine HCl; Paxil®	white, oval, biconvex, with no breakline	tablet, Formula FV	10 mg	U00001

Source: Appendix A, Certificate of Analysis

3.5.2 Methods of Blinding

None. This was an open-label study.

3.5.3 Dosage and Administration

The schedule of paroxetine dosing is listed in Table 4, below.

Table 4 Dosing Schedule

Study Days	Dosing Details	Regimen Description
Days 1-14 (-2/+3):	10 mg once daily	BRL29060 (paroxetine) 10 MG UID
Days 15-28 (-2/+3):	20 mg (2 x 10 mg) once daily	BRL29060 (paroxetine) 20 MG UID
Days 29-42 (-2/+3):	30 mg (3 x 10 mg) once daily	BRL29060 (paroxetine) 30 MG UID
Days 43-49 (-2/+3):	Dose-tapering [20 mg (2 x 10 mg) once daily]	BRL29060 (paroxetine) 20 MG UID-TAPER
Days 50-56 (+3):	Dose tapering (10 mg once daily)	BRL29060 (paroxetine) 10 MG UID-TAPER

Source: Appendix A

Doses were to be taken in the morning at approximately 24 hour intervals with up to 240 mL tepid water.

3.5.4 Other Protocol-Specified Therapy

There was no other protocol-specified therapy.

3.6 Compliance with Study Medication

Study medication was administered under the supervision of study personnel on study visit days. If pre-dose pharmacokinetic sampling occurred on the days prior to the 24-hour pharmacokinetic profile days, study medication was also administered after the sample under the supervision of study personnel. The oral cavity of each patient was examined following dosing to assure that study medication was taken.

Study medication was taken on an out-patient basis on non-study visit days. Compliance on out-patient dosing days was monitored by use of a dosing diary provided to the patient or parent/guardian on Day 1 of the study and by pill counts performed by study personnel on study visit days.

Every effort was made to encourage patient compliance with the dosage regimen detailed in this protocol. All patients or parent/guardian (as appropriate) were instructed to bring their study medication and dosing diary to each in-patient visit. A record of the supplies dispensed and returned was made in the CRF at each visit.

3.7 Prior and Concomitant Medication

A reasonable effort was made to document any medications the patient received within three months prior to the first dose of paroxetine. Patients were prohibited from taking any prescription, non-prescription medications, herbal/naturopathic preparations or vitamins according to the restrictions listed in the exclusion criteria (see Section 3.4.2, above). All concomitant medication taken during the study was recorded with indication, daily dose and start and stop dates of administration.

Subjects were to avoid consumption of ethanol for the duration of the study. In addition, caffeine and other xanthine-containing drinks and foods, including colas, chocolate, tea and coffee, were prohibited for 24 hours prior to and during the pharmacokinetic sampling days of the study.

3.8 Study Procedures

3.8.1 Schedule of Assessments

A flowchart of study procedures is contained in Table 10.1.

3.8.2 Prestudy Screening and Enrollment

Subjects were screened within 30 days prior to administration of study medication to confirm that they met the entrance criteria for the study. The screening visit included the following procedures:

- Complete medical history, including psychiatric history;
- Medication history for at least three months prior to screening;
- Complete physical examination;
- Standard 12-lead electrocardiogram (ECG), interpreted by a pediatric cardiologist;
- The K-SADS-PL and CY-BOCS or CDRS-R (based upon the patient's primary diagnosis) interviews;
- Subject weight and height (without shoes);
- Sitting (after 3 minutes) blood pressure and heart rate;

- Blood and urine specimens for clinical laboratory tests:
    - Hematology: hemoglobin; hematocrit; RBC count; WBC count and differential; platelet count;
    - Chemistry: BUN; creatinine; sodium; potassium; AST; ALT; alkaline phosphatase; total bilirubin;
    - Urinalysis: specific gravity; pH, glucose, protein, blood and ketones by dipstick; microscopic examination (if dipstick was positive for blood or protein)
    - Thyroid Hormones (screening only): TSH (thyroid stimulating hormone); free T3 (triiodothyronine); free T4 (tetraiodothyronine)
- Urine drug screen (amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, opiates, methoqualone, methadone, propoxyphene and phencyclidine);
- Serum human chorionic gonadotrophin (pregnancy) test for all female patients;
- A complete history of tobacco use. For patients who were using tobacco products at the time of screening, the type (e.g., pipe, cigar, chewing tobacco, or cigarette), quantity and duration of use was to be documented. Subjects who used tobacco were to be instructed that tobacco use was not permitted while they were in the Clinical Research Unit (CRU).
- The Clinical Global Impression (CGI) Severity of Illness.

3.8.3 Treatment Phases

Day 1

Patients reported to the CRU in the morning on the first day of the study session. The following assessments were performed at the CRU prior to dose administration:

- Baseline signs and symptoms recorded;
- A limited physical examination performed;
- Medical and medication histories updated;

- Blood and urine specimens obtained for clinical laboratory tests (Section 3.8.2);
- Sitting blood pressure, sitting heart rate, height and weight (without shoes) measured.
- Female patients had urine and serum samples obtained for pregnancy tests prior to study medication administration. Results of the urine test were available prior to dosing, and a negative result was required for dosing. This result was confirmed by the result of the serum pregnancy test as soon after dosing as the results were available, and a negative result was required for study continuation.

Blood pressure measurements were performed in the same arm using an appropriately-sized blood pressure cuff and, when possible, by the same person throughout the study.

Subjects were given breakfast or a snack following these procedures and prior to dosing. Study medication was administered by study personnel within 15 minutes of completing the meal. Patients or their parent/guardian (as appropriate) were provided with the dosing diary and study medication sufficient for out-patient dosing and instructed on the dosing schedule and required record-keeping procedures. Patients were then discharged from the unit.

Out-Patient Days

Patients took study medication once daily (every 24 hours) up to Day 56 (+extra days) according to the dosing schedule described in Section 3.5.3. Patients were followed on an out-patient basis through telephone contact by study personnel every three to four days. During each telephone contact, adverse experiences were assessed by asking the patient a non-leading question, such as "How have you felt since our last contact?". Concomitant medication use was also assessed, dosing instructions were re-iterated, and compliance with the dosing regimen was encouraged. As appropriate, parents and guardians were questioned regarding the patient's health and medication status during these out-patient telephone contacts. Note that optional pharmacokinetic sampling could have occurred on Days 13, 27 and 41, as described below.

Pharmacokinetic Profile Days

Patients reported to the CRU prior to dosing on Days 14, 28 and 42. These pharmacokinetic assessment visits could have occurred between -2 and +3 days

from the indicated dosing day (e.g., Day 12 to Day 17). However, a minimum of 12 days separated each pharmacokinetic assessment day. All protocol-specified assessments for Days 14, 28 and 42 occurred on the actual pharmacokinetic assessment day scheduled for the subject.

Patients could have been admitted to the unit the evening prior to the pharmacokinetic assessment day. They were instructed not to take their dose of study medication on the pharmacokinetic assessment day. In addition, patients were required to bring their study medication container(s) and dosing diary to the unit on these study days.

The following procedures were performed on Days 14, 28 and 42, unless otherwise indicated:

Assessment	Timepoint(s)
Concomitant medication usage	pre-dose
Physical examination	pre-dose
Height and weight (without shoes)	pre-dose
Sitting blood pressure and sitting heart rate	pre-dose, 24 hours post-dose
AEs	pre-dose, 12 and 24 hours post-dose
Meal	pre-dose, 4, 9-10 and 24 hours post-dose
Paroxetine hydrochloride dose	0 hour
Pharmacokinetic blood samples (minimum 1.5 mL into 2 mL EDTA tube)	pre-dose (no more than 15 minutes prior to dosing), and at 1, 2, 3, 5, 8, 12 (±1) and 24 (±2) hours post-dose.
Optional pharmacokinetic blood samples (minimum 1.5 mL into 2 mL EDTA tube)	Pre-dose on Days 13, 27, 41
Optional blood sample for CYP2D6 genotyping (2 mL into 2 mL ACD or EDTA tube)	12 hours post-dose (Day 14 only)
CGI Severity of Illness and Global Improvement assessments	Once during the 24 hour post-dose period (Day 42 only)
12-lead ECG, interpreted by a pediatric cardiologist within three days	24 hours post-dose (Day 42 only)
Urine and blood samples for laboratory tests (Section 3.8.2)	24 hours post-dose (Day 42 only)
Serum pregnancy test	24 hours post-dose (females, Day 42 only)

At the investigator's discretion, an intravenous cannula, kept patent with a dilute heparin solution (100 units/mL), was allowed for drawing of blood specimens. A topical anesthetic preparation was allowed for insertion of the cannula. The type of anesthetic was recorded in the case report form (CRF).

Subjects were given breakfast following the pre-dose procedures listed above and prior to dosing. Study medication was administered by study personnel within 15 minutes of completing breakfast. Pre-dose study procedures and dosing on Days 14, 28 and 42 were to be scheduled so that study medication was administered 24 hours after the previous day's dose.

Water was allowed ad libitum starting two hours after dosing. Soft drinks without caffeine or fruit juices (except grapefruit juice) were allowed ad libitum beginning four hours after dosing. Snacks were allowed throughout the 24 hour sampling period. Subjects abstained from ingestion of xanthine-containing drinks or

alcohol for 24 hours prior to study drug administration. Tobacco use was not permitted while the patient was in the CRU.

Blood samples (minimum of 1.5 mL into 2 mL EDTA tube) for plasma assay of paroxetine were drawn on Days 14, 28 and 42 at the times listed in the table above. The final sample at 24 hours was drawn prior to the subsequent dose.

If possible, pre-dose blood samples were collected on Days 13, 27 and 41. In the event that these samples were obtained, study medication was administered by study personnel after sampling. These samples were optional and agreement to provide these extra samples was not a condition of entry into the study.

The precise time of sampling could have been altered by the sponsor, but no more than eight blood samples were drawn for pharmacokinetic analysis on each assessment day.

Symptoms were assessed by spontaneous reporting of adverse experiences and by nursing and physician observation on study days. Patients were asked to respond to a non-leading question, such as, "How do you feel?" at the times listed in the table above.

Following the 12 hour pharmacokinetic blood draw, patients were allowed to be discharged from the CRU, but were required to return to the CRU prior to the 24 hour pharmacokinetic blood draw. Study medication containers and dosing diaries were retained by study personnel for any subjects discharged from the unit between the 12 and 24 hour pharmacokinetic timepoints.

If possible, analysis of the patient's CYP2D6 genotype was performed on Day 14 only in subjects for whom pharmacokinetic samples were obtained. However, study enrollment was not predicated on agreement by the patient and/or parent/guardian to this procedure. In order to perform genotypic analysis, a 2 mL blood sample (in a 2 mL ACD or EDTA tube) was obtained. Study and Clinical Pharmacology personnel involved in the collection and evaluation of safety data were blinded to the results of CYP2D6 genotyping until all of the safety data was collected and all safety data queries were resolved (i.e. the safety database was locked).

On Days 15, 29 and 43, study medication was administered by study personnel following the 24 hour pharmacokinetic blood sample, safety assessments and breakfast. The breakfast was provided after the 24 hour safety laboratory samples were obtained for Day 42.

Patients or their parent/guardian (as appropriate) were provided with the dosing diary and study medication sufficient for out-patient dosing and instructed on the dosing schedule and required record-keeping procedures. Patients were then discharged from the unit.

Patients eligible for enrollment in the open-label, extension study entered the extension study after the Day 42 24 hour assessments if the investigator determined that the patient should enter the extension study at a dose of 30 mg per day or higher. Alternatively, they participated in the dose tapering phase prior to enrollment into the extension study, if the investigator determined that the patient should enter the extension study at a dose of either 10 mg or 20 mg per day.

Patients not enrolling in the extension study participated in the dose tapering phase of this study and completed the Day 56 and 14 day follow-up visits described below. This tapering phase was considered necessary to decrease the possibility that patients experienced symptoms related to abrupt withdrawal of paroxetine.

If a patient was withdrawn from the study prior to completion of the Day 42 assessments, every attempt was made to obtain the following assessments if not performed within 24 hours of the withdrawal:

- Physical examination, including height and weight (without shoes), sitting blood pressure and heart rate measurements;
- 12-lead ECG, interpreted by a pediatric cardiologist within three days;
- Safety laboratory tests, including a serum pregnancy test for a female subject;
- Incidence of AEs and use of concomitant medication;
- Compliance/dosing diary collection; and
- CGI Severity of Illness and Global Improvement assessments.

3.8.4 Post-Treatment Phase

Patients returned to the unit at the end of the taper phase. For patients not enrolling in the extension study or for patients entering the extension study at 10 mg per day, this taper end visit occurred on Day 56 (or two weeks +3 days after the last 30 mg dose). For patients entering the extension study at 20 mg per day,

this taper end visit occurred on Day 49 (or one week -2/+3 days after the last 30 mg dose).

At the taper end visit the following procedures were performed:

- AEs and concomitant medication usage were assessed;
- A physical examination was performed, including measurement of sitting heart rate and sitting blood pressure;
- A 12-lead ECG was performed, and blood and urine samples obtained for clinical laboratory tests (Section 3.8.2) only if clinically relevant abnormalities were observed on a previous assessment (i.e., Day 42 or after); and
- Study medication container(s) and dosing diaries were collected.

Subjects also returned to the CRU at 14 (± three) days following the last dose of study medication for a follow-up visit. However, this follow-up visit was not required for subjects participating in the open-label, extension study. At this visit:

- AEs and concomitant medication usage were assessed;
- A physical examination was performed, including measurement of sitting heart rate and sitting blood pressure;
- A 12-lead ECG was performed, and blood and urine samples were obtained for clinical laboratory tests (Section 3.8.2) only if clinically relevant abnormalities were observed on a previous assessment (i.e., Day 56 or after); and
- A serum pregnancy test was performed for female patients only.

The patient was then discharged from the study.

If a patient was withdrawn after Day 43 but prior to either of these follow-up visits, every attempt was made to perform the follow-up assessments specified above.

3.8.5 Reasons for Withdrawal

A patient could have withdrawn from the study at any time at their own request, or they may have been withdrawn at any time at the discretion of the investigator for safety, behavioral, or administrative reasons. Patients who withdrew

prematurely from this study could have been replaced with another patient so that a minimum of 30 patients in each age group completed the Day 14 procedures and a minimum of 20 patients in each age group completed the study. Sponsor approval was required prior to replacement of an unevaluable patient.

3.8.6 Reasons for Concluding Study

Patients who elected not to enroll in the open-label extension study and participated in this study through the 14 day follow-up visit were considered to have completed this study. Patients who elected to enroll in the open-label extension study and participated in this study through either the Day 42 or the taper end visit, depending upon the investigator's decision to taper the patient and the dose to which the investigator tapered the patient, were considered to have completed this study.

Patients for whom evaluable pharmacokinetic data were available through Day 14 were considered evaluable patients for pharmacokinetic assessments. All patients who completed the Day 42 (30 mg pharmacokinetic) assessments were considered completers for the purposes of pharmacokinetic assessments. Patients were included in the pharmacokinetic analyses provided they had evaluable data from at least one dose level of paroxetine.

3.9 Safety Assessments

Safety and tolerability of Paxil® were assessed during this study by nursing and physician observation and spontaneous reporting of symptoms by subjects. These events were classified as adverse events as described in Section 3.9.1 below. In addition, routine vital sign measurements (height, weight, blood pressure, heart rate), 12-lead ECGs, and safety laboratory tests were performed. The results of these procedures were evaluated as described in Section 3.9.2 below.

3.9.1 Adverse Events

Adverse events (AEs) were elicited by study personnel asking the subject a non-leading question such as "How do you feel?". Details of any elicited AEs and their severity, including any change in study drug administration, relationship to study drug, any corrective therapy given and outcome status were documented (see Section 5.2). Relationship of AEs to study drug was judged by the investigator to be unrelated, probably unrelated, possibly related, or related. All adverse events were coded from the verbatim term according to the WHO

Adverse Reaction Terminology (ART) dictionary by body system and preferred term.

The AEs were reported as separate events for each episode in order to obtain information on AEs which occurred on days with pharmacokinetic sampling. AEs were attributed to the dosing regimen during which each episode began. AEs are summarized by subject sessions, or the number (and percent) of patients reporting that AE during each regimen. The total number of subject sessions for the study is equivalent sum of subject sessions within each regimen and, therefore, is greater than the total number of patients participating in the study.

A serious adverse event is defined as any AE which was fatal, life-threatening, permanently or temporarily disabling or incapacitating, which resulted in hospitalization or a prolonged hospital stay, was associated with a congenital abnormality, or any event which the investigator regarded as serious based upon appropriate medical judgement. In addition, the sponsor's policy dictated that events of cancer, overdose (either accidental or intentional) or pregnancy be documented and reported as for serious AEs.

3.9.2 Vital Signs, ECGs and Safety Laboratory Tests

Physical examination findings obtained during the treatment phase were compared to corresponding results prior to dosing. The criteria for determination of specific values of potential clinical concern for vital sign (blood pressure, heart rate) and safety laboratory data were outlined in the protocol and are presented in Table 5, below. Age-adjusted reference ranges were used for the vital signs and safety laboratory assessments. Any heart rate, blood pressure, or safety laboratory values exceeding these pre-defined thresholds were identified and tabulated (see Sections 5.6.1 and 5.8 below). Any such changes considered clinically significant were recorded as AEs. In addition, any changes or values for height, weight and 12-lead ECG results (see Sections 5.6.2 and 5.7 below) considered clinically significant by the investigator were recorded as AEs.

Baseline for ECG was set at screening and the baseline for vital signs (heart rate and blood pressures) was set as pre-dose on Day 1 of dosing.

Table 5 Protocol-Defined Values of Potential Clinical Concern

Vital Signs	
Heart Rate	Sitting/Supine: <35 or >130 bpm Erect: <40 or >140 bpm
Blood Pressure	Systolic >30 mmHg change or diastolic >20 mmHg change from baseline in same posture
Laboratory	
Hematology	
Hemoglobin	≤11.0 g/dL or >16.5 g/dL
Hematocrit	<35% or >49.5% (6-11 years) and <36% or >49.5% (12-17 years)
Leukocytes	>1 K/uL below or >3 K/uL above the limit of the reference range
Platelets	<80 or > 500 K/uL
Clinical Chemistry	
Total bilirubin	≥ 1.5 times upper limit of the reference range
AST	>2 times upper limit of the reference range
ALT	>2 times upper limit of the reference range
GGT	>2 times upper limit of the reference range
Alk Phosphatase	>1.5 times upper limit of the reference range
Creatinine	>1.8 mg/dL
BUN	>1.5 times upper limit of the reference range
Glucose, fasting	<60 or >126 mg/dL
Uric acid	>11 mg/dL
Sodium	>5 mEq/L above or below the limits of the reference range
Potassium	>0.5 mEq/L above or below the limits of the reference range
Calcium	<7.2 or > 12 mg/dL
Phosphate	>0.8 mg/dL below or 1.0 mg/dL above the limits of the reference range
Albumin	>0.5 g/dL above or below the limits of the reference range
Total protein	>1.0 g/dL above or below the limits of the reference range
Urinalysis	
WBC	>15/hpf
RBC	>10/hpf

Source: Protocol (Appendix D), Appendix A of the report.

3.10 Pharmacokinetic Assessments

Blood samples for the pharmacokinetic analysis of paroxetine steady state plasma concentrations were collected on the final day of dosing at each dose level, i.e., approximately two weeks after the start of dosing (at 10 mg/day) and again approximately two weeks after each successive dose increase (to 20 and 30 mg/day). In this report, these three sampling occasions are denoted nominally as Days 14, 28 and 42, respectively, but practical considerations dictated some flexibility in the schedule. In all cases, however, at least 11 days of dosing at each dose level preceded pharmacokinetic sampling.

3.10.1 Collection and Preparation of Samples

On Days 14, 28 and 42, serial blood samples (approximately 1.5 mL into EDTA-coated tubes) were collected pre-dose and at (nominally) 1, 2, 3, 5, 8, 12 and 24 hours after dosing. Additionally, in some patients, a predose sample (optional) was collected on the preceding day (nominally Days 13, 27 and 41). The exact dosing and sampling times were recorded in the CRF.

Blood samples were placed temporarily on water-ice and then centrifuged (within one hour of collection) to separate the plasma. Plasma was transferred to labelled polypropylene tubes and frozen immediately at approximately –20°C. The frozen plasma samples were transported in batches (January-September 2001) to Advion Biosciences (Ithaca, NY), where they were kept frozen while awaiting analysis.

3.10.2 Assay Methods

Plasma concentrations of paroxetine were quantitated using a validated method involving on-line solid-phase extraction followed by LC/MS/MS employing positive-ion turbo ion-spray ionization [6]. Using 0.1 mL aliquots of plasma, this method has a lower limit of quantification (LLQ) of 0.1 ng/mL. Quality and storage control (QC) plasma samples, prepared at three concentrations spanning the calibration range and stored with the experimental samples, were analyzed with each batch against separately-prepared calibration standards. The results of the analysis of these QC samples (Appendix C, Table C.62) were used to assess the day-to-day performance of the assay. Analyses were conducted between 01 March 2001 and 12 September 2001. The raw data are stored in the GLP Archive, Advion Biosciences.

3.10.3 Pharmacokinetic Analysis

Paroxetine steady state pharmacokinetic parameters at each dose level (10, 20 and 30 mg/day) were determined using the non-compartmental pharmacokinetic analysis program WinNonlin (version 2.1) [7]. Actual post-dose sampling times were used in these calculations. By scanning the plasma concentration versus time data, the highest concentration (Cmax) and the time of its first occurrence (Tmax) were obtained. The concentration measured at 24 hours post-dose, C(24), was noted. The area under the plasma concentration versus time curve during a dosing interval, AUC(0-24), was calculated using a combined linear-logarithmic trapezoidal method. To calculate some AUC(0-24) values, it was necessary to substitute a nominal concentration of 0.05 ng/mL (i.e., half the LLQ) in place of those plasma concentrations below the LLQ. In a few cases, a missing value at 0 hours was substituted by the concentration measured at 24 hours, or vice versa. These corrections, affecting only a small number of patients, are considered to provide the most objective estimates of AUC(0-24). The apparent oral clearance, CL/F, was calculated as the quotient Dose/AUC(0-24).

3.11 Data Quality Assurance

All clinical studies performed by, or on behalf of, SmithKline Beecham are conducted in accordance with the ethical considerations detailed in the Declaration of Helsinki and applicable national or regional Good Clinical Practice guidelines. Uniformity of study performance was controlled by a standard protocol and Case Report Form (Appendix A) at each study site

Adherence to the protocol requirements and verification of data generation accuracy was achieved through routine monitoring while the study was ongoing. Subsequent data handling and reporting processes were subject to in-process quality control checks and this final clinical report has, in addition, been subject to an end-stage quality control review. These procedures were performed according to SmithKline Beecham standard operating procedures.

Periodic system audits for study conduct, data handling, reporting and archiving within SmithKline Beecham indicate that the routine application of standard operating procedures and guidelines have ensured the quality and integrity of this study. No study specific audits were performed for this study.

3.12 Statistical Evaluation

3.12.1 Target Sample Size

The target sample size for completing the pharmacokinetic aspects of the study (i.e., plasma concentration versus time profiles collected on Days 14, 28 and 42) was a minimum of 20 patients in each age group, with a gender ratio no greater than 2:1 in either group. To achieve this, it was estimated that approximately 30 patients in each age group would need to reach the first sampling occasion (Day 14). The sample size was based on feasibility, but was considered sufficient to describe the pharmacokinetics of paroxetine in the pediatric population.

3.12.2 Method of Randomization

No randomization was required. All patients followed the same dosing regimen.

3.12.3 Planned Safety Analysis

Patients who received at least one dose of study medication were included in the assessments of the safety and tolerability of paroxetine. Height, weight, blood pressure, pulse rate, 12-lead ECG and clinical laboratory data were reviewed and

summarized on an ongoing basis during the study to evaluate the safety of patients. Any clinically relevant abnormalities or values of potential clinical concern (Section 3.9.2) were described. Safety data is presented in tabular and/or graphical format and summarized descriptively.

Study and Clinical Pharmacology personnel involved in the evaluation of safety data were blinded to the results of CYP2D6 analysis until all of the safety data was collected and all safety data queries were resolved. Although this was equated with safety database lock in the protocol, the draft pharmacokinetic report, containing CYP2D6 analytical results, was distributed to specific study team members on 27 November 2001 or 28 November 2001 prior to database lock. The database was locked on 28 November 2001. However, all safety data had been collected and relevant database queries had been responded to prior to the review of the pharmacokinetic report. Therefore, although the database was not officially locked prior to distribution of the CYP2D6 results, the protocol-specified blind had been practically and effectively preserved.

3.12.4 Planned Pharmacokinetic Analysis

The primary pharmacokinetic endpoints were Cmax and AUC(0-24) at each dose level. Tmax and C(24) were secondary endpoints, the latter being an approximate estimate of Cmin. CL/F was also originally designated a secondary endpoint but, upon review of the data, it was reclassified as a primary endpoint because of its utility in describing the results.

Pharmacokinetic parameters at each dose level were pooled (across all centers and both indications), summarized by descriptive statistics, and displayed graphically to show their relationship with dose. Relationships between selected parameters and demographic characteristics (age, weight and gender) were examined graphically. Although no formal statistical analysis had been planned, inspection of the resulting age and weight plots indicated that an attempt should be made to discriminate between the influence of these related factors. Hence, the following covariate analysis was performed *a posteriori*.

The parameters Cmax, AUC(0-24) and CL/F (both before and after normalizing for weight) were log-transformed (base e) and analyzed separately using a mixed effects model. The model included a random term for subject, terms for the covariates 'weight' and 'age', and a fixed term for dose. Where both the main fixed effect and the covariate term were found to be statistically significant, a term for their interaction was added to the model. Point estimates and 95% confidence intervals were constructed on the logarithmic scale for each dose level, and

exponentially back-transformed to provide point estimates and 95% confidence intervals based on the original scale. Assumptions underlying the analysis of variance were assessed by inspection of residual plots. Homogeneity of variance was assessed by plotting the studentised residuals against the predicted values from the model, whilst normality was assessed by use of normal probability plots. Visual inspection of these plots revealed no gross violations of any of the model assumptions (Appendix C, Tables C.63 to C.66). Plots of each parameter versus weight by dose level were constructed to investigate the nature of the association and its interaction with dose (Appendix C, Figures C.60 to C.62).

The pharmacokinetic analysis utilized a 3-digit patient numbering system, the leading two zeros being dropped from the 5-digit study code for brevity. All pharmacokinetic data are stored in the Archive, GlaxoSmithKline Pharmaceuticals Research & Development.

3.12.5 Planned Efficacy Analysis

The efficacy endpoints, CGI Severity of Illness Item and Global Improvement Item, were obtained at the timepoints specified in Sections 3.8.2 and 3.8.3 above for potential analysis in the open-label extension study. The results of these evaluations are listed in tabular format (Table DS30); however, no further analysis was performed for this study report.

4 Study Population

4.1 Study Dates

The first patient was screened on 15 August 2000. The first dose of study medication was administered on 12 September 2000, and the last study visit was on 27 September 2001.

4.2 Subject Disposition

Approximately 30 patients in each age group were enrolled into the study. Nineteen (19) children and twenty-two (22) adolescents completed the study. Study patient disposition is summarized in Table 6 and Table 7. Patient withdrawal details are listed in Table DS3.

Patients who completed the study had the option of enrolling into the six-month, open-label extension study, BRL 29060/716 (reported separately). The completion status of the patients, including whether or not they enrolled in the extension study and their final current study dose phase if they entered the extension study are listed in Table DS35 and summarized in Table 8.

Table 6 Summary of Study Patient Disposition

Disposition	Number of Subjects	
Total Screened	**94**	
Total Screened But Not Used:	**32**	
	Children	**Adolescents**
Total Enrolled/Dosed	**27**	**35**
Total Withdrawn After Dosing	**8**	**13**
-Deviation from Protocol	3	4
-Due to Adverse Event	2	4
-Lost to Follow-Up	2	2
-Other	1	3
Total Completed	**19**	**22**

Source: Table DS2, Table DS3, Table DS29, Table DS35 and data on file, GlaxoSmithKline.

Table 7 Patient Disposition by Study Site

	Number of Patients by Study Site											
	200	**201**	**202**	**203**	**204**	**205**	**206**	**207**	**208**	**209**	**210**	**211**
Total Screened	7	13	2	6	1	11	7	9	33	0	5	0
Total Screened But Not Used:	1	0	0	4	0	3	0	0	24	0	0	0
Total Enrolled/Dosed	6	13	2	2	1	8	7	9	9	0	5	0
Total Withdrawn After Dosing	2	4	1	1	0	4	3	2	0	0	4	0
-Due to Adverse Event	2	2	0	0	0	0	0	1	0	0	1	0
-Deviation from Protocol	0	0	0	1	0	3	1	1	0	0	1	0
-Lost to Follow-Up	0	1	1	0	0	0	1	0	0	0	1	0
-Other	0	1	0	0	0	1	1	0	0	0	1	0
Total Completed	4	9	1	1	1	4	4	7	9	0	1	0

Source: Table DS2, Table DS3 and data on file, GlaxoSmithKline.

Table 8 Summary of Patient Completion Status

Patient Group	**# Patients Who Completed Study**	**# of Patients Enrolled in Extension Study**	**# of Patients by Last Study Phase**			
			30 mg UID	**20 mg UID Taper End**	**10 mg UID Taper End**	**Follow Up**
Children	19	17	10	4	3	2
Adolescents	22	20	12	8	0	2
Total	41	37	22	12	3	4

Source: Table DS35.

4.3 Protocol Violations

Protocol violations considered significant since they had the potential to impact the pharmacokinetic objective of the study, or were deviations from inclusion/exclusion criteria or cause for withdrawal of the patient from the study are listed in Table 9, below. Other violations were considered minor deviations, and were mainly due to scheduling problems or patient noncompliance. These minor deviations are accounted for in the patient data listings for this report since data were recorded against actual timings. Compliance is also further summarized in Section 4.7.

Table 9 Protocol Violations by Subject

Protocol Violation	Patient Number (Comment)
Prohibited Prior and/or Concomitant Medication(s)	See Section 4.6
Incorrect Dose(s)	00301 (30 mg vs. 20 mg), 00504 (10 mg vs. 30 mg), 00505 (10 mg vs. 30 mg), 00602 (30 mg on PK Day vs. 20 mg), 00703 (50 mg vs. 10 mg),
Incomplete or No Taper and No Extension Study	00052, 00055, 00502, 00601, 00605, 00709
One or more Omitted Dose(s)	00109 (10 mg), 00110 (10 mg and 30 mg)
Inconsistent Diagnosis	00806 (Dysthymia per KSADSPL, MDD per Psychiatrist)

Source: Tables DS2, DS4, Tables C17, C40 and C48, Appendix C, and data on file, GlaxoSmithKline.

Patient 00301 was withdrawn from the study prior to pharmacokinetic sampling at the 20 mg UID dose level, after taking 30 mg of study medication for 2 days prior to the scheduled 20 mg UID pharmacokinetic day. This dosing error was due to a misunderstanding by the patient's parents. Patient 00504 was administered 10 mg at the 30 mg UID dose level by his mother, without consulting the investigator, since she thought that his behavior had deteriorated too much to follow the study dosing regimen. This dosing error resulted in the patient's withdrawal from the study prior to the 30 mg UID pharmacokinetic visit. Patient 00505 was withdrawn from the study since his mother did not want to increase his dose to 30 mg UID following the 20 mg UID pharmacokinetic visit. The patient was tapered at 10 mg UID instead. Patient 00602 was incorrectly administered 30 mg on the 20 mg UID pharmacokinetic day by the study site staff. As described in Section 6, this dosing error resulted in the exemption of this patient's pharmacokinetic data from the overall analysis at the 20 mg UID dose level. Patient 00703's dosing error was

an accidental overdose and was considered a serious adverse event and reason to withdraw the patient prior to pharmacokinetic sampling at the 10 mg UID dose level.

Patients 00052, 00055, 00502, 00601, 00605 and 00709 either declined the taper medication or terminated their taper phase prior to completing the one week required at 10 mg UID and did not enter the extension study. Of these patients, 00055, 00601 and 00709 are known to have been maintained on commercial Paxil® at doses greater than 10 mg UID (Table DS3).

Patient 00806 was diagnosed with MDD according to the psychiatrist at the site but was diagnosed with dysthymia by the clinical psychologist performing the K-SADS-PL (see Section 4.5). This patient was considered depressed by the psychiatrist and the discrepant K-SADS-PL score, although a deviation from the inclusion criteria (Section 3.4.1) was not considered significant to the pharmacokinetic objectives of the study. Therefore, the patient was allowed in the study.

4.4 Demographic Characteristics

Demographic data for individual patients are displayed in Tables DS1 and DS29. Summary data for enrolled patients are displayed in Table 10, below.

Table 10 Demographic Characteristics of Study Population

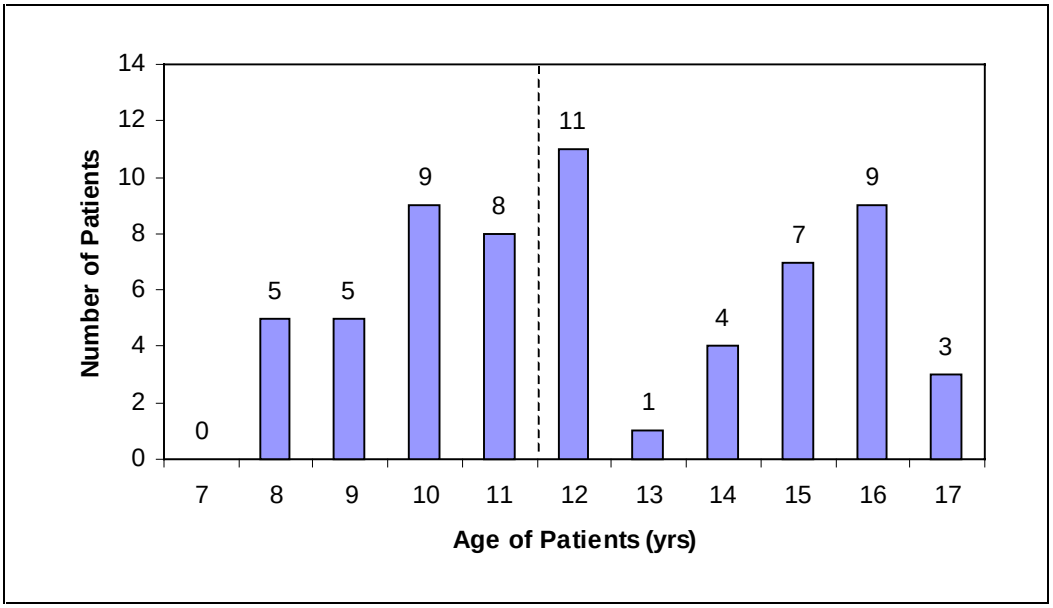
Group	Parameter	Age (years)	Height (cm)	Weight (kg)
	n	27	27	27
Children	**Mean**	10	142.9	42.1
74% Male	**SD**	1.1	9.63	13.62
26% Female	**Range**	8-11	125.5-164.0	25.9-76.5
	n	35	35	35
Adolescents	**Mean**	14	164.5	68.2
57% Male	**SD**	1.8	12.41	22.96
43% Female	**Range**	12-17	129.0-190.5	30.1-141
	n	62	62	62
Pooled	**Mean**	12	155.1	56.8
65% Male	**SD**	2.8	15.53	23.31
35% Female	**Range**	8-17	125.5-190.5	25.9-141.0

Children: 85% White; 7% Black; 7% Other
Adolescents: 83% White; 11% Black; 6% Other
Pooled: 84% White; 10% Black; 6% Other
Source: Table DS1 and Table DS29.

As expected, the mean height and mean weight for the adolescents were greater than those of the children. However, there was overlap in the height and weight of the two age groups. There was an approximate 2:1 ratio of males to female in the total population and adolescents, with a slightly greater percentage of males seen in the children.

Patients of representative age ranges were enrolled in each age group as shown in Figure 1, below.

Figure 1 Number of Patients Enrolled by Age (years)



Source: Table DS1 and Table DS29.

4.5 Presenting Conditions and Medical History

All patients were children or adolescents with a current documented diagnosis of either obsessive-compulsive disorder (OCD) and/or major depressive disorder (MDD). There were twenty-one (21) children diagnosed with MDD and six (6) children with OCD. There were thirty-one (31) adolescents diagnosed with MDD and four (4) adolescents with OCD (Table DS31). This diagnosis was confirmed by the K-SADS-PL at screen for all patients except Patient 00806 who was diagnosed with MDD according to the psychiatrist at the site but was diagnosed with dysthymia by the clinical psychologist performing the K-SADS-PL (Table DS19). Since the patient was considered depressed by the psychiatrist and the

diagnosis was not considered significant to the pharmacokinetic objectives of the study, the patient was allowed to participate.

All patients (including Patient 00806) met the inclusion criteria of a total score of 45 or greater on the CDRS-R (MDD) or a total score of 16 or greater on the CY-BOCS (OCD), depending upon their primary diagnosis (Table DS31).

Non-psychiatric and psychiatric (according to the K-SADS-PL) medical history for each patient is listed in Table DS19. Signs and symptoms present prior to the initial dose of study medication are displayed in Table DS6. None of the medical histories or baseline signs and symptoms were considered sufficient to affect the conduct of the study or to represent a potential risk to the subject during participation in the study.

4.6 Prior and Concomitant Medications

The study protocol required that subjects not receive prescription or non-prescription drugs prior to dosing or during the study as specified in the exclusion criteria (Section 3.4.2). Contrary to this restriction, however, forty-four (44) patients received one or more doses of a prohibited medication prior to or during the study (Table DS4 and Table 11, below). These medications were either considered necessary by the physician or were taken by the patients to treat concurrent symptoms. None of these medications were considered to significantly affect the interpretation of the study results or were reason to withdraw the patient from the study, with the exception of Patient 00111. This patient received treatment for an asthma exacerbation, which led to the withdrawal of this patient (see Section 5.5).

Table 11 Prohibited Prior and Concomitant Medications by Patient

Patient	Prohibited Medication
Children	
Prior Medications	
00001	Wellbutrin
00108	erythromycin*
00202	Ceftin
00301	Prozac
00504	Advil*
00709	prednisone
Continuing Medications	
00001	Advil*
00101	albuterol
00111	albuterol inhaler
00112	Vitamin C, MVI
00806	Claritin Redi Tabs, Nasonex, Biaxin
00818	Claritin, Claritin D, Aleve
Concomitant Medications	
00053	Children's Nyquil
00101	albuterol, Tylenol*#
00102	Advil*
00106	Motrin*, Zithromax, Seroquel, Adderall, Paxil^, Ativan, Celexa
00111	albuterol inhaler, dextromethorphan, Prelone
00303	Paxil^
00504	Advil*
00702	Robitussin DM, guaifenesin, Zithromax, Flonase, Childrens Motrin*
00704	Maalox (Quick Dissolve), Childrens Sudafed
00705	Suphedrine
00709	Paxil^
00806	Robitussin, Augmentin*
Adolescents	
Prior Medications	
00002	Depakote*
00003	Zoloft*
00004	Biaxin*
00007	St. John's Wort
00054	Wellbutrin
00401	Celexa*
00503	Alka Seltzer Plus Cold Tablets
00507	Tussin
00606	Sleepinal

* Medications taken not allowed in original protocol, but allowed in protocol amendment.

Acetaminophen not allowed within 48 hours of pharmacokinetic sampling under original protocol.

^ Patient maintained on commercial Paxil after last dose of study medication.

Source: Table DS4.

Table 11 (Continued) Prohibited Prior and Concomitant Medications by Patient

Patient	Prohibited Medication
Adolescents	
Prior Medications	
00607	St. John's Wort, Valerian
00706	Aleve, amoxicillin
00824	Tylenol Sinus, Zithromax, Depo-Provera
Continuing Medications	
00002	Diflucan, Loprox
00004	albuterol, Serevent, Singulair
00005	Zyrtec
00007	Multivitamin
00052	Multivitamin
00503	Pamprin
00507	Nasonex
00606	albuterol, Excedrin Migraine
00804	aspirin
00811	ibuprofen*, Pepto-Bismol
00824	benadryl, Ortho Tri-cyclen
00825	Depo-Provera, Tylenol Sinus
Concomitant Medications	
00002	ibuprofen*, Elocon
00003	Alka-Seltzer Plus
00103	Advil*
00401	Melatonin
00502	Advil*, Motrin*
00503	aspirin, codeine, Sudafed 12 Hour, amoxicillin*
00506	naproxen sodium
00510	Aleve*, Tylenol Cold and Sinus
00606	night time cold/flu medication
00607	Dramamine, Paxil^
00703	hydrocortisone cream
00805	ibuprofen*
00809	ibuprofen*
00811	Peptobismol
00816	Sudafed, Tylenol*#
00825	Tylenol Sinus

* Medications taken not allowed in original protocol, but allowed in protocol amendment.
# Acetaminophen not allowed within 48 hours of pharmacokinetic sampling under original protocol.
^ Patient maintained on commercial Paxil after last dose of study medication.
Source: Table DS4.

4.7 Treatment Administration and Compliance

Patients received single, daily oral doses of study medication, either 10 mg, 20 mg, or 30 mg, according to the dosing schedule (Section 3.5.3 and Table DS2), except as noted in Section 4.3 and Table 10.2. Subject 00703 took a single dose of 50 mg, which was considered an overdose and a serious adverse event (see Section 5.4). One child patient (00603) and two adolescent patients (00506 and 00703) were exposed to unknown doses of study medication during the study, due to omissions in the patient dosing diary. However, Patient 00603 was 100%, 79% and 81% compliant, according to pill counts, for the 10 mg, 20 mg and 30 mg dosing regimens, respectively, and Patient 00506 was 100%, 87% and 77% compliant, according to pill counts, for the 10 mg, 20 mg and 30mg dosing regimens, respectively (Table DS33). There were no other instances of dosing over 30 mg UID reported during the study.

All but one patient had compliance >75% according to pill counts during each dose-rising regimen, 10 mg UID, 20 mg UID and 30 mg UID (Table DS33). Adolescent Patient 00109 was 64% compliant for the 20 mg UID regimen. Compliance was 100% for at least 40% of the total study population at each dose. A minority of all patients (≤21.1%) returned fewer tablets than expected at each dose level. Only two patients took doses outside the range allowed during this study. The reason for these compliance discrepancies were unknown in most cases. Patient 00703 was only one known case of overdose (>30 mg). Patient 00111 took a single dose of 5 mg during the 10 mg daily regimen. The impact of compliance on the pharmacokinetic assessments in this study is addressed in Section 6.

5 Safety Results

5.1 Extent of Exposure

The extent of exposure is listed for each age group (children or adolescents) separately by site and total in Table 12, below.

Table 12 Number of Patients Who Received Each Treatment Regimen by Site

Children (8-11 Years)

	Number of Patients by Study Site												Total
Regimen Description	**200**	**201**	**202**	**203**	**204**	**205**	**206**	**207**	**208**	**209**	**210**	**211**	**Patients**
Paroxetine 10 mg UID	1	10	1	2	0	1	2	6	2	0	2	0	27
Paroxetine 20 mg UID	1	8	1	2	0	1	2	6	2	0	2	0	25
Paroxetine 30 mg UID	1	8	1	2	0	1	2	6	2	0	2	0	25
Paroxetine 20 mg UID-Taper	0	5	1	1	0	0	1	2	1	0	1	0	13
Paroxetine 10 mg UID-Taper	0	3	0	1	0	1	2	0	0	0	0	0	7

Adolescents (12-17 Years)

	Number of Patients by Study Site												Total
Regimen Description	**200**	**201**	**202**	**203**	**204**	**205**	**206**	**207**	**208**	**209**	**210**	**211**	**Patients**
Paroxetine 10 mg UID	5	3	1	0	1	7	5	3*	7	0	3	0	35*
Paroxetine 20 mg UID	5	3	1	0	1	7	5	2	7	0	2	0	33
Paroxetine 30 mg UID	4	3	0	0	1	6	5	2	7	0	2	0	30
Paroxetine 20 mg UID-Taper	0	2	0	0	0	4	2	0	6	0	2	0	16
Paroxetine 10 mg UID-Taper	1	1	0	0	0	1	1	0	1	0	0	0	5

Source: Table DS2. *Includes Patient 00703, who took an unknown dose level (no diary card entry) believed to be 10 mg, followed by a single dose of 50 mg paroxetine.

5.2 Adverse Events

Two hundred eighty-three (283) treatment-emergent adverse events (AEs) were reported in fifty-eight (58) patients during this study. When summarized across all subjects and regimens, at least one AE was reported in 52.8% (114 of 216) of all subject sessions. However, the percentage of subject sessions reporting AEs decreased with increasing dose in both children and adolescents. Furthermore, the percentage of subject sessions reporting AEs was lower during the taper phase than during the dose-rising phase of the study, regardless of age (Table 13, below).

Table 13 Number (n) and Percent (%) of Subject Sessions Reporting Treatment-Emergent Adverse Events by Dose at Onset

Age Group	Paroxetine 10 mg UID		Paroxetine 20 mg UID		Paroxetine 30 mg UID		Paroxetine 20 mg UID-Taper		Paroxetine 10 mg UID-Taper		Total	
	n (N)	(%)	n (N)	(%)	n (N)	(%)	n (N)	(%)	n (N)	(%)	n (N)	(%)
Children	18 (27)	(66.7)	12 (25)	(48.0)	11 (25)	(44.0)	5 (13)	(38.5)	2 (7)	(28.6)	48 (97)	(49.5)
Adolescents	25 (35)	(71.4)	20 (33)	(60.6)	15 (30)	(50.0)	4 (16)	(25.0)	2 (5)	(40.0)	66 (119)	(55.5)
Total	43 (62)	(69.4)	32 (58)	(55.2)	26 (55)	(47.3)	9 (29)	(31.0)	4 (12)	(33.3)	114 (216)	(52.8)

N = Total number of subject sessions (number of patients reporting that AE during each regimen).
Data Source: Table DS6.

The most frequent AE was headache, occurring in 18.5% (40 of 216) of all subject sessions (Table 14, below). Other frequent AEs were abdominal pain occurring in 7.4% (16 of 216) of all subject sessions and somnolence occurring in 6.0% (13 of 216) of all subject sessions. When partitioned by age group, headache and abdominal pain were the most frequently reported AEs in both children and adolescents, with over 7% of subject sessions reporting each type of AE. However, diarrhea, nausea, nervousness and aggressive reaction were also frequently reported by children and somnolence was frequently reported in adolescents with over 5% of subject sessions reporting each type of AE. These frequently reported AEs are highlighted in bold in Table 14, below.

All AEs were mild to moderate in intensity, except for three (3) severe AEs reported by children and four (4) severe AEs reported by adolescents. These seven (7) severe AEs represent only 2.8% of all subject sessions, with similar frequencies observed within the two age groups (3.1% for children and 2.5% for adolescents). The severe AEs in the children were the severe nervousness observed in Patient 00603 (30 mg paroxetine UID) and the severe manic reaction reported in Patient 00106 (20 mg paroxetine UID taper), both of which were considered possibly related to study medication, and the severe injury (broken leg) reported in Patient 00102 (20 mg paroxetine UID taper), which was considered unrelated to study medication. Patient 00106 was withdrawn due to the severe manic reaction, which was considered a serious AE (see Section 5.4). Patient 00603 was not withdrawn from the study due to this AE and this AE resolved without treatment. Patient 00102 was not withdrawn from the study due to this AE. This AE was treated for the pain of the broken leg (Table DS6) and the AE was ongoing at the end of the study.

The severe AEs in the adolescents were the severe upper respiratory tract infection and headache reported in Patient 00503 (30 mg paroxetine UID), the severe pain (toe pain) observed in Patient 00601 (30 mg paroxetine UID) and the severe otitis media reported in Patient 00503 (20 mg paroxetine UID taper), all of which were considered unrelated to study medication. None of these patients were withdrawn due to their AEs. Patient 00503 was treated for the headache and otitis media (Table DS6). All of these severe AEs resolved by the end of the study.

Of the AEs in children, eighty-six (86) AEs in nineteen (19) patients were related or possibly related to study medication. Of the AEs in adolescents, seventy-three (73) AEs in twenty-five (25) patients were related or possibly related to study medication. These related or possibly related AEs were manifested mostly in the

following body systems: gastrointestinal, psychiatric and central and peripheral nervous systems.

Table 14 Treatment-Emergent Adverse Events

Adverse Event	Number of Subject Sessions Reporting >=1 AE(s)												
	10 mg UID		20 mg UID		30 mg UID		20 mg UID Taper		10 mg UID Taper		Total		
(Preferred Term)	C	A	C	A	C	A	C	A	C	A	C	A	All
Total Subject Sessions (N)	**27**	**35**	**25**	**33**	**25**	**30**	**13**	**16**	**7**	**5**	**97**	**119**	**216**
Headache	8	11	4	10	2	4	0	0	0	1	**14**	**26**	**40**
Abdominal Pain	5	4	2	2	0	2	0	1	0	0	**7**	**9**	**16**
Somnolence	1	4	1	2	1	3	1	0	0	0	4	**9**	**13**
Diarrhea	4	1	1	0	0	0	1	0	1	0	**7**	1	8
Nausea	4	3	0	0	0	0	1	0	0	0	**5**	3	8
Insomnia	1	3	3	0	0	1	0	0	0	0	4	4	8
Rhinitis	1	2	0	2	2	1	0	0	0	0	4	4	8
Injury	1	1	0	2	0	1	2	0	0	1	3	5	8
Aggressive Reaction	2	0	3	1	1	0	0	0	0	0	**6**	1	7
Nervousness	2	1	1	1	2	0	0	0	0	0	**5**	2	7
Hyperkinesia	0	0	1	1	2	3	0	0	0	0	3	4	7
Dizziness	1	1	1	1	0	1	0	1	0	0	2	4	6
Coughing	2	0	1	2	0	0	0	0	0	0	3	2	5
Vomiting	1	1	0	0	1	0	1	0	0	0	3	1	4
Concentration Impaired	0	2	0	0	1	2	0	0	0	0	1	4	5
Pain	0	0	0	2	0	2	0	1	0	0	0	5	5
Agitation	1	1	1	0	1	0	0	0	0	0	3	1	4
Anorexia	1	3	0	0	0	0	0	0	0	0	1	3	4
Upper Respiratory Tract Infection	1	0	0	1	0	1	1	0	0	0	2	2	4

C = Children; A = Adolescents; Subject Session = The number of patients reporting that AE during each regimen.
Source: Table DS6.

Table 14 (Continued) Treatment-Emergent Adverse Events

Adverse Event	Number of Subject Sessions Reporting >=1 AE(s)												
	10 mg UID		20 mg UID		30 mg UID		20 mg UID Taper		10 mg UID Taper		Total		
(Preferred Term)	C	A	C	A	C	A	C	A	C	A	C	A	All
Total Subject Sessions (N)	**27**	**35**	**25**	**33**	**25**	**30**	**13**	**16**	**7**	**5**	**97**	**119**	**216**
Personality Disorder	0	0	2	0	0	2	0	0	0	0	2	2	4
Fatigue	0	2	2	0	0	0	0	0	0	0	2	2	4
Rash	0	3	1	0	0	0	0	0	0	0	1	3	4
Asthma	2	0	0	0	0	0	1	0	0	0	3	0	3
Pharyngitis	1	0	0	1	0	1	0	0	0	0	3	0	3
Manic Reaction	0	0	0	0	1	1	1	0	0	0	2	1	3
Purpura	0	1	0	0	1	0	0	0	1	0	2	1	3
Dyspepsia	2	0	0	0	0	0	0	0	0	0	2	0	2
Anxiety	1	1	0	0	0	0	0	0	0	0	1	1	2
Sweating Increased	0	0	0	1	1	0	0	0	0	0	1	1	2
Otitis Media	0	0	0	0	1	0	0	1	0	0	1	1	2
Sinusitis	0	1	0	0	0	0	1	0	0	0	1	1	2
Tremor	0	2	0	0	0	0	0	0	0	0	0	2	2
Chest Pain	0	1	0	1	0	0	0	0	0	0	0	2	2
Constipation	0	0	0	2	0	0	0	0	0	0	0	2	2
Fever	0	0	0	1	0	1	0	0	0	0	0	2	2
Vertigo	0	0	0	0	0	0	0	1	0	1	0	2	2
Myalgia	1	0	0	0	0	0	0	0	0	0	1	0	1
Back Pain	1	0	0	0	0	0	0	0	0	0	1	0	1
Skin Cold Clammy	1	0	0	0	0	0	0	0	0	0	1	0	1
Muscle Contractions Involuntary	0	0	1	0	0	0	0	0	0	0	1	0	1

C = Children; A = Adolescents; Subject Session = The number of patients reporting that AE during each regimen.
Source: Table DS6.

Table 14 (Continued) Treatment-Emergent Adverse Events

Adverse Event	Number of Subject Sessions Reporting >=1 AE(s)												
	10 mg UID		20 mg UID		30 mg UID		20 mg UID Taper		10 mg UID Taper		Total		
(Preferred Term)	C	A	C	A	C	A	C	A	C	A	C	A	All
Total Subject Sessions (N)	**27**	**35**	**25**	**33**	**25**	**30**	**13**	**16**	**7**	**5**	**97**	**119**	**216**
Neurosis	0	0	1	0	0	0	0	0	0	0	1	0	1
Tooth Ache	0	0	1	0	0	0	0	0	0	0	1	0	1
Infection Viral	0	0	0	0	1	0	0	0	0	0	1	0	1
Confusion	0	1	0	0	0	0	0	0	0	0	0	1	1
Hypertonia	0	1	0	0	0	0	0	0	0	0	0	1	1
Depersonalization	0	1	0	0	0	0	0	0	0	0	0	1	1
Emotional Lability	0	1	0	0	0	0	0	0	0	0	0	1	1
Libido Decreased	0	1	0	0	0	0	0	0	0	0	0	1	1
Ejaculation Failure	0	1	0	0	0	0	0	0	0	0	0	1	1
Tachycardia	0	1	0	0	0	0	0	0	0	0	0	1	1
Taste Perversion	0	1	0	0	0	0	0	0	0	0	0	1	1
Drug Level Increased	0	1	0	0	0	0	0	0	0	0	0	1	1
Flatulence	0	0	0	1	0	0	0	0	0	0	1	0	1
Respiratory Disorder	0	0	0	1	0	0	0	0	0	0	0	0	1
Hot Flushes	0	0	0	1	0	0	0	0	0	0	0	0	1
SGOT Increased	0	0	0	0	0	1	0	0	0	0	0	1	1
Total Number of AEs	53	72	41	41	25	29	11	6	2	3	132	151	283
Number of Patients with AEs	18	25	12	20	11	15	5	4	2	2	25	33	58

C = Children; A = Adolescents; Subject Session = The number of patients reporting that AE during each regimen.
Source: Table DS6.

5.3 Deaths

There were no deaths during this study.

5.4 Serious Non-Fatal Adverse Events (SAE)

There were two (2) serious adverse events (SAEs) reported during this study. Patient 00106 had severe mania with suicidal ideation and Patient 00703 accidentally overdosed on study medication. Patient narratives are contained in Table 10.2. Detailed descriptions of these events, supplemented with data from patient safety listings and source data on file at GlaxoSmithKline, are as follows:

Patient 00106 was a 10 year old male with a medical history which included major depressive disorder (MDD) and dysthymia. The patient had no significant prior or concomitant medication use, with only Motrin® and Zithromax® reported as taken prior to this SAE. On 25 January 2001, the patient began therapy with paroxetine. The patient appeared to tolerate well two weeks dosing at 10 mg UID followed by two weeks dosing at 20 mg UID, with a single, moderate headache reported at each dose (Table DS6). Although the only AE reported to the site following escalation to 30 mg UID for two weeks was moderate otitis media, the patient had become more violent and out of control, with aggressive and agitated behavior toward himself, according to information provided to the hospital staff by the patient's family upon admission. On 11 March 2001, after 45 days of paroxetine study medication administration and two days after beginning the 20 mg UID taper phase, the patient ran away from home to his father's house, and was returned to his mother on 12 March 2001. That afternoon, the patient's mother reported to the site that the patient was "out-of-control". She was instructed to take the patient to the hospital emergency room for treatment. The patient was initially evaluated and admitted to the hospital and then transferred on 13 March 2001, to the Preteen Inpatient Unit of a second hospital for severe mania and suicidal ideation where he was placed on suicide and escape precautions. During the intake at the Preteen Inpatient Unit, the patient was noted to have a history of attention deficit hyperactivity disorder (inattentive type) based upon discussions with the patient's mother. Since the patient had been withdrawn from the study and study medication had been discontinued on 12 March 2001, the patient was initially maintained on prescription paroxetine (Paxil®), 20 mg UID, for two days following admission to the Preteen Inpatient Unit. His symptoms were treated with amphetamine/dextroamphetamine (Adderall®), lorazepam (Ativan®), citalopram

(Celexa®), and quetiapine (Seroquel®). On 20 March 2001, 8 days after the event began, the event was considered resolved since the patient stated that he was no longer suicidal or homicidal. He denied any hallucinations or delusions, and stated that he would not hurt himself if he went home. The patient's affect was also noted to be improved, and he was discharged home in an improved condition. The investigator further clarified that the suicidal ideation was symptomatic of the severe mania and reported that the severe mania was life-threatening, disabling/incapacitating, and possibly related to treatment with study medication.

Patient 00703 was a 16 year old female with a medical history which included major depressive disorder (MDD), panic disorder, and generalized anxiety disorder. The patient had no significant prior or concomitant medication use, having reported using only hydrocortisone cream to treat a rash prior to the event (DS4). The patient was enrolled in the study and began the 10 mg UID dosing period on 08 March 2001. The patient reported skipping a couple doses of study medication because she thought the study medication contributed to the rash. Later, before the patient's pharmacokinetics study day, she stated that she felt bad that she was non-compliant and thought that she would "catch-up" by taking the remaining pills at one time. The patient's mother reported that her daughter took five pills on 19 March 2001, 11 days after beginning the study**.** The dose taken was 50 mg, which is greater than the highest dose allowed in the study. The event was therefore classified as an overdose, and coded to "drug level increased" or "therapeutic response increased", depending upon the database, although no drug concentrations or therapeutic responses were measured. The patient did not have any symptoms associated with the overdose, which is consistent with the fact that this dose was well tolerated in pediatric patients enrolled in other clinical trials with paroxetine.[3, 4] Treatment with study medication was stopped and the event was considered resolved on 19 March 2001, and the patient was withdrawn from the study on 20 March 2001. The investigator reported the overdose as not related to treatment with study medication.

5.5 Withdrawals Due to Adverse Events

Six (6) patients (two (2) children and four (4) adolescents) were withdrawn from the study due to AEs (Table 15). The Case Report Forms for these six (6) patients are presented in Appendix D. There were no apparent dose related trends in these withdrawals. Patient 00111 was withdrawn due to moderate asthma (exacerbation) following administration of 10 mg UID paroxetine, which required treatment with prohibited medications (Table DS4). This AE of unknown duration was considered unrelated to study medication. Patient 00106 was

withdrawn due to severe manic reaction, which was considered a serious AE (see Section 5.4), following administration of the 20 mg UID taper dose of paroxetine. This AE which lasted 8 days was considered possibly related to study medication. Patient 00054 was withdrawn due to a moderate rash following administration of 10 mg UID paroxetine. This AE which lasted 1 day and 20 hours duration was considered possibly related to study medication. Patient 00703 was withdrawn due to a mild drug level increase (overdose), which was considered a serious AE (see Section 5.4), following administration of 10 mg UID paroxetine. This AE was considered unrelated to study medication. Patient 00005 was withdrawn due to moderate dizziness and moderate hyperkinesia, during administration of 20 mg UID paroxetine. These AEs which lasted 10 days was considered related to study medication. This patient took a 10 mg UID tapering dose of paroxetine after withdrawal from the study. Patient 00007 was withdrawn due to moderate hyperkinesia and a moderate manic reaction, following administration of 30 mg UID paroxetine and was lost to follow up. These AEs of unknown duration were considered possibly related to study medication.

Table 15 Number of Patients Withdrawn Because of Adverse Events

Adverse Event (Preferred Term)	Number of Patients Withdrawn										
	10 mg UID		20 mg UID		30 mg UID		20 mg UID Taper		10 mg UID Taper		
	C	A	C	A	C	A	C	A	C	A	Total
Asthma	1	0	0	0	0	0	0	0	0	0	1
Manic Reaction	0	0	0	0	0	1	1	0	0	0	2
Rash	0	1	0	0	0	0	0	0	0	0	1
Drug Level Increased	0	1	0	0	0	0	0	0	0	0	1
Hyperkinesia	0	0	0	1	0	1	0	0	0	0	2
Dizziness	0	0	0	1	0	0	0	0	0	0	1
Total Number of AEs	1	2	0	2	0	2	1	0	0	0	8
Number of Subjects with AEs	1	2	0	1	0	1	1	0	0	0	6
Number of Subjects Exposed	27	35	25	33	25	30	13	16	7	5	62

C = Children; A = Adolescents.
Source: Table DS3 and Table DS6.

5.6 Vital Signs

5.6.1 Heart Rate and Blood Pressure

There were no heart rate values of potential clinical concern measured during the study. Overall, there were very few blood pressure values of potential clinical concern measured during this study and none of the transitions were considered clinically significant and reported as an AE by investigators. The single mild AE during this study related to heart rate and rhythm, tachycardia, was perceived by the patient during an outpatient time period but was not consistent with vital signs recorded during study visits. Vital signs data are presented in Table DS11 and are summarized in Table 16, below.

Table 16 Subjects Who had Post-Dose Vital Signs of Potential Clinical Concern

Subject	Treatment	Parameter	Baseline Value	Time of Assessment	Value of Concern
Children					
00112	10 mg UID	Systolic BP	100 mm Hg	10 mg PK Day	132 mm Hg
00603	10 mg UID	Systolic BP	116 mm Hg	10 mg PK Day	84 mm Hg
		Diastolic BP	74 mm Hg	10 mg PK Day + 24 H	48 mm Hg
		Systolic BP	116 mm Hg	10 mg PK Day + 24 H	80 mm Hg
00107	20 mg UID	Diastolic BP	71 mm Hg	20 mg PK Day + 24 H	48 mm Hg
00202	20 mg UID	Diastolic BP	61 mm Hg	20 mg PK Day + 24 H	40 mm Hg
00504	20 mg UID	Diastolic BP	62 mm Hg	20 mg PK Day + 24 H	41 mm Hg
00104	30 mg UID	Diastolic BP	64 mm Hg	30 mg PK Day + 24 H	32 mm Hg
00603	30 mg UID	Diastolic BP	74 mm Hg	30 mg PK Day + 24 H	52 mm Hg
		Systolic BP	116 mm Hg	30 mg PK Day + 24 H	78 mm Hg
00603	10 mg UID Taper	Systolic BP	116 mm Hg	10 mg Taper	72 mm Hg
Adolescent					
00051	10 mg UID	Diastolic BP	82 mm Hg	10 mg PK Day	60 mm Hg
00103	10 mg UID	Diastolic BP	69 mm Hg	10 mg PK Day + 24 H	48 mm Hg
00109	10 mg UID	Diastolic BP	86 mm Hg	10 mg PK Day	55 mm Hg
		Diastolic BP	86 mm Hg	10 mg PK Day + 24 H	52 mm Hg
00503	10 mg UID	Systolic BP	136 mm Hg	10 mg PK Day	104 mm Hg
00601	10 mg UID	Diastolic BP	58 mm Hg	10 mg PK Day	80 mm Hg
00706	10 mg UID	Systolic BP	117 mm Hg	10 mg PK Day	84 mm Hg
00004	20 mg UID	Systolic BP	140 mm Hg	20 mg PK Day + 24 H	106 mm Hg
00109	20 mg UID	Diastolic BP	86 mm Hg	20 mg PK Day	46 mm Hg
	20 mg UID	Systolic BP	121 mm Hg	20 mg PK Day	87 mm Hg
	20 mg UID	Diastolic BP	86 mm Hg	20 mg PK Day + 24 H	51 mm Hg
00003	30 mg UID	Systolic BP	99 mm Hg	30 mg PK Day + 24 H	135 mm Hg
00004	30 mg UID	Diastolic BP	80 mm Hg	30 mg PK Day	52 mm Hg
00506	20 mg UID Taper	Diastolic BP	58 mm Hg	20 mg Taper	80 mm Hg

BP = blood pressure, PK = pharmacokinetics, H = Hours.
Source: Table DS11.

5.6.2 Height and Weight

There were no apparent changes in mean height and weight in both the children (Table 17 and Table DS34) and in the adolescents (Table 18, Table DS34) during the course of this study. One adolescent patient, Patient 00706, had an apparent erroneous height measurement recorded on the 10 mg pharmacokinetic sampling day (85.1 cm). She was measured as 145.0 cm at Day 1 predose and 145.5 cm on the 20 mg pharmacokinetic sampling day. Elimination of this apparent erroneous height value on the 10 mg pharmacokinetic sampling day resulted in a group mean ± SD of 166.3 ± 10.2 cm (range 146 to 190 cm). This recalculated mean height was not apparently different from the mean height which included the questionable value.

Table 17 Summary of Height and Weight - Children

	Screening	**Day 1 Predose**	**10 mg PK Day**	**20 mg PK Day**	**30 mg PK Day**	**10 mg Taper**
Height (cm)						
n	27	27	25	24	24	1
Mean	142	143	143	144	144	131
SD	9.7	10.2	10.9	10.0	10.7	-
Range	125-164	122-167	122-170	129-167	123-170	-
Weight (kg)						
n	27	27	25	24	24	1
Mean	42.1	42.5	42.4	43.1	43.4	29.7
SD	13.6	13.9	14.2	14.4	14.7	-
Range	25.9-76.5	26.2-78.0	25.7-77.0	26.2-78.2	26.3-79.0	-

PK = pharmacokinetics.
Source: Table DS34.

Table 18 Summary of Height and Weight - Adolescents

	Screening	Day 1 Predose	10 mg PK Day	20 mg PK Day	30 mg PK Day	20 mg Taper	10 mg Taper
Height (cm)							
n	35	35	35	31	28	1	1
Mean	164	165	164	165	166	173	154
SD	12.3	10.7	17.0	10.4	10.0	-	-
Range	129-190	145-190	85.1-190	145-190	145-190	-	-
Weight (kg)							
n	35	35	35	31	28	1	1
Mean	68.2	68.6	68.2	68.5	68.7	86.9	42.5
SD	22.9	23.0	22.9	23.3	23.1	-	-
Range	30.1-141	30.0-143	30.2-143	30.4-144	30.4-142	-	-

PK = pharmacokinetics.
Source: Table DS34.

5.7 12-Lead Electrocardiographic Data

Similar mean values for each ECG interval were observed at screen and 30 mg UID (Tables 19 to 23, below and Table DS14). There were no apparent dose-related changes in mean interval values. Patients with ECGs measured at post-dose time points other than 30 mg had intervals within the range of those measured at screen, with the exception of one child patient (Patient 00504) at 10 mg taper whose QT was 2 msec above the upper limit of the screening range (414 msec vs. 412 msec) and one adolescent patient (Patient 00605) at 20 mg taper with a QTc interval 6 msec below the lower limit of the screening range (370 msec vs. 376 msec).

No QT or QTc values above 500 msec were observed during this study (Table DS14). However, four patients (two children – Patients 00603 and 00708 and two adolescents – Patients 00502 and 00805), representing 6.5% of the total study population, had post-dose QTc increases greater than 30 msec relative to screen. Three (3) of these patients were female (Patients 00708, 00502 and 00805) and one (1) was male (Patient 00603). The largest such increase was 42 msec in a female adolescent (Patient 00805). None of these patients had exposure (measured by AUC) near the upper range for the patients enrolled in their age group (Tables 10.7 and 10.8). In each case, the ECG was not considered to have clinically significant abnormalities by the investigator.

Table 19 Summary Statistics for 12-lead ECG Heart Rate Values (bpm) by Regimen and Age Group

	Scr	Scr-Rpt	Paroxetine 10 mg UID	Paroxetine 30 mg UID	Paroxetine 20 mg UID-Taper	Paroxetine 10 mg UID-Taper	End
Children							
n	27	-	1	23	1	1	-
Mean	76	-	85	77	74	62	-
SD	13.5	-	-	8.9	-	-	-
Min	57	-	85	60	74	62	-
Max	101	-	85	93	74	62	-
Adolescents							
n	35	1	-	26	2	2	2
Mean	68	65	-	69	64	69	72
SD	10.2	-	-	10.2	0.7	14.8	7.8
Min	52	65	-	48	63	58	66
Max	93	65	-	91	64	79	77

Rpt, Repeat; End, Follow-up visit.
Data Source: Table DS14.

Table 20 Summary Statistics for 12-lead ECG PR Interval Values (msec) by Regimen and Age Group

	Scr	Scr-Rpt	Paroxetine 10 mg UID	Paroxetine 30 mg UID	Paroxetine 20 mg UID-Taper	Paroxetine 10 mg UID-Taper	End (Follow-up)
Children							
n	27	-	1	23	1	1	-
Mean	134	-	140	133	136	126	-
SD	16.5	-	-	20.0	-	-	-
Min	92	-	140	100	136	126	-
Max	164	-	140	176	136	126	-
Adolescents							
n	35	1	-	26	2	2	2
Mean	140	152	-	141	150	138	140
SD	24.8	-	-	27.0	14.1	2.8	0.0
Min	100	152	-	108	140	136	140
Max	220	152	-	236	160	140	140

Rpt, Repeat; End, Follow-up visit.
Data Source: Table DS14.

Table 21 Summary Statistics for 12-lead ECG QRS Interval Values (msec) by Regimen and Age Group

	Scr	Scr-Rpt	Paroxetine 10 mg UID	Paroxetine 30 mg UID	Paroxetine 20 mg UID-Taper	Paroxetine 10 mg UID-Taper	End
Children							
n	27	-	1	23	1	1	-
Mean	82	-	82	80	84	84	-
SD	11.3	-	-	9.0	-	-	-
Min	58	-	82	60	84	84	-
Max	100	-	82	100	84	84	-
Adolescents							
n	35	1	-	26	2	2	2
Mean	87	96	-	85	85	85	86
SD	9.0	-	-	9.5	21.2	15.6	2.8
Min	70	96	-	60	70	74	84
Max	106	96	-	100	100	96	88

Rpt, Repeat; End, Follow-up visit.
Data Source: Table DS14

Table 22 Summary Statistics for 12-lead ECG QT Interval Values (msec) by Regimen and Age Group

	Scr	Scr-Rpt	Paroxetine 10 mg UID	Paroxetine 30 mg UID	Paroxetine 20 mg UID-Taper	Paroxetine 10 mg UID-Taper	End
Children							
n	27	-	1	23	1	1	-
Mean	369	-	336	367	384	414	-
SD	27.9	-	-	19.6	-	-	-
Min	320	-	336	344	384	414	-
Max	412	-	336	412	384	414	-
Adolescents							
n	35	1	-	26	2	2	2
Mean	387	372	-	385	381	371	370
SD	28.9	-	-	30.9	29.7	29.7	19.8
Min	334	372	-	342	360	350	356
Max	452	372	-	476	402	392	384

Rpt, Repeat; End, Follow-up visit.
Data Source: Table DS14.

Table 23 Summary Statistics for 12-lead ECG QTc Interval Values (msec) by Regimen and Age Group

	Scr	Scr-Rpt	Paroxetine 10 mg UID	Paroxetine 30 mg UID	Paroxetine 20 mg UID-Taper	Paroxetine 10 mg UID-Taper	End
Children							
n	27	-	1	23	1	1	-
Mean	414	-	399	414	422	420	-
SD	20.8	-	-	15.2	-	-	-
Min	380	-	399	390	422	420	-
Max	480	-	399	453	422	420	-
Adolescents							
n	35	1	-	26	2	2	2
Mean	406	384	-	407	392	393	400
SD	16.9	-	-	16.7	31.1	11.3	3.5
Min	376	384	-	372	370	385	397
Max	448	384	-	436	414	401	402

Rpt, Repeat; End, Follow-up visit.
Data Source: Table DS14.

5.8 Laboratory Tests

There were sixteen (16) patients (eight (8) children and eight (8) adolescents) with a post-dose laboratory value of potential clinical concern (Table 24, below and Appendix B, Table DS17). There were no apparent dose-related trends in these values of potential clinical concern. With the exception of low hematocrit, each post-dose value of potential clinical concern was reported in a single patient per regimen for each age group. None of the low post-dose hematocrit values were considered adverse events by the investigators. The increased serum potassium concentration observed for Patient 00102 was asymptomatic and consistent with specimen hemolysis. The increased serum potassium concentration observed for Patient 00303 was asymptomatic, although no hemolysis was noted. The increased serum potassium concentration reported for Patient 00706 was obtained on a hemolyzed specimen (data on file).

A male adolescent patient (Patient 00601) receiving 30 mg UID paroxetine had an increased AST of 97 IU/L (reference range 0-42 IU/L). This increased AST was considered clinically significant and classified as an AE during this study (Table DS6 and Appendix B, Table DS17). This AST value was considered probably unrelated to study medication and resolved in approximately two weeks to 33 IU/L. No symptoms related to this transiently increased liver function test value were observed (Table DS6).

Elevated post-dose AST (281 IU/L, reference range 0-42 IU/L) and ALT (266 IU/L, reference range 0-48 IU/L) values of potential clinical concern were also reported for a female adolescent patient (Patient 00503) at 20 mg UID-taper paroxetine. These values were within the reference range (17 IU/L and 11 IU/L, respectively) when re-tested 27 days later (Appendix B, Table DS17). These two (2) abnormal values were not considered to be clinically significant by the investigator, since the patient was on antibiotics and pain medication for otitis media at that time (Tables DS4 and DS6).

Table 24 Subjects Who had Post-Dose Clinical Laboratory Values of Potential Clinical Concern

Subject	Treatment Paroxetine	Parameter	Reference Range	Baseline Value	Time of Assessment	Value of Concern
Children						
00055	20 mg UID Taper	Hematocrit	35.0-45.0%	31.8%*	20 mg Taper	34.8%
00102	30 mg UID	Potassium	3.5-5.5 mEq/L	5.2 mEq/L	30 mg PK Day	8.3 mEq/L
00104	30 mg UID	Hematocrit	35.0-45.0%	36.0%	30 mg PK Day	34.0%
00108	30 mg UID	Hematocrit	35.0-45.0%	35.0%	30 mg PK Day	32.7%
00202	30 mg UID	Hematocrit	35.0-45.0%	38.3%	30 mg PK Day	34.0%
00303	20 mg UID Taper	Potassium	3.5-5.5 mEq/L	4.7 mEq/L	20 mg Taper	7.7 mEq/L
00702	30 mg UID	WBC	4.5-13.5 x 10^3/uL	10.2 x 10^3/uL	30 mg PK Day	3.3 x 10^3/uL
00708	30 mg UID	Hematocrit	35.0-45.0%	34.0%*	30 mg PK +24H Repeat	32.0%
Adolescent						
00003	30 mg UID	Hematocrit	36.0-49.0%	34.7%*	30 mg PK Day	34.3%
00051	30 mg UID	Platelets	130,000-400,000 /mm^3	359,000 /mm^3	30 mg PK Day	535,000 /mm^3
		Hematocrit	36.0-49.0%	38.5%		34.5%
00502	30 mg UID	Hemoglobin	12.0-16.0 g/dL	9.7 g/dL*	30 mg PK Day	9.8 g/dL
		Hematocrit	36.0-49.0%	30.6%*		32.7%
00503	20 mg UID Taper	Hematocrit	36.0-49.0%	37.5%	20 mg Taper	34.5%
		ALT	0-48 IU/L	12 IU/L		266 IU/L
		AST	0-42 IU/L	17 IU/L		281 IU/L
00601	30 mg UID	AST	0-42 IU/L	20 IU/L	30 mg PK Day	97 IU/L
00701	30 mg UID	Hematocrit	36.0-49.0%	36.6%	30 mg PK Day	35.4%
00703	10 mg UID	Hematocrit	36.0-49.0%	35.6%*	10 mg PK Day	34.4%
00706	30 mg UID	Potassium	3.5-5.5 mEq/L	4.3 mEq/L	30 mg PK Day	6.4 mEq/L

PK = Pharmacokinetic, WBC = White Blood Cell, AST = aspartate aminotransferase, ALT = alanine aminotransferase.
* Baseline (Day 1 Pre-dose) value is value of potential clinical concern.
Source: Appendix B, Table DS17.

6 Pharmacokinetic Evaluation

Of the 62 pediatric patients (27 children and 35 adolescents) entered into the study, a total of 59 (25 children and 34 adolescents) completed the first period of dosing (10 mg/day) and provided plasma samples for pharmacokinetic analysis. Most of these patients (23 children and 28 adolescents) went on to complete the dose-rising phase and provided samples at all three dose levels (10, 20 and 30 mg/day).

The paroxetine plasma concentration data are presented in full in Appendix C. Tables C.1-25 (children) and C.26-59 (adolescents) list the concentrations measured over a 24 hour period at steady state at each of the three dose levels (nominally Days 14, 28 and 42). These data are shown graphically in Figures C.1-25 and C.26-59, respectively. Tables C.60 (children) and C.61 (adolescents) list the pre-dose concentrations measured on the preceding days (nominally Days 13, 27 and 41). Only one-third of the patients consented to provide these optional samples, and no further analysis was performed on the resulting limited data. In general, however, these pre-dose concentrations (where available) were similar to the corresponding concentrations measured approximately 24 and 48 hours later.

Inspection of the steady state plasma concentration versus time curves, in conjunction with other study records, led to the following conclusions regarding the validity of certain data for inclusion in the overall pharmacokinetic analysis:

Patient 101 (Child; Table C.4): Whereas low (but measurable) concentrations were recorded at 10 mg, concentrations at 20 mg remained below the LLQ throughout the 24 hour dosing interval. Concentrations at 30 mg were readily measurable, but the pre-dose value was more than three-fold lower than the corresponding value measured 24 hours later. Although compliance in this child was reportedly good, these irregularities were considered to render the entire data-set unreliable.

Patient 110 (Child; Table C.10): At 10 mg, the pre-dose concentration was four-fold lower than the corresponding value measured 24 hours later, probably because no dose was taken on the previous day. In addition, at 30 mg, several doses were missed during the previous week. Since the plasma concentration versus time curves at these dose levels could not be considered to represent a true steady state, both were deemed inevaluable.

Patient 109 (Adolescent; Table C.36): At all three dose levels, concentrations were below the LLQ pre-dose (and for up to 2 hours post-dose). However, at 24 hours post-dose, concentrations were readily measurable and, by inference, at least 5- to 50-fold higher than the pre-dose values. Since compliance in this adolescent patient was found to be unreliable, the entire data-set was discounted.

Patient 602 (Adolescent; Table C.47): The first 30 mg dose was inadvertently administered on the day scheduled for pharmacokinetic sampling at 20 mg. Therefore, the concentrations measured on this day are uninterpretable.

Although these data were excluded from all subsequent analyses, pharmacokinetic parameters were nevertheless calculated from the measured plasma concentrations (where possible) and are listed in the summary tables, for completeness. Exclusion of data from these four patients is not considered to have materially affected the study conclusions.

Mean steady state paroxetine plasma concentrations, by dose and age-group, are compared in Figures 11.1 to 11.4. Although the between-subject variability was considerable, mean concentrations at all three dose levels tended to be higher in the younger group. A disproportionate increase in plasma concentrations with increasing dose was evident in both groups.

The paroxetine steady state pharmacokinetic parameters Cmax, Tmax, AUC(0-24) and C(24), subdivided by age-group, are presented in Tables 10.3 to 10.10. Values of CL/F, before and after normalization for weight, are presented in Tables 10.11 to 10.14. Each of these Tables includes the gender of each patient, and their age and weight at the start of the study. The pharmacokinetic parameters are summarized collectively by dose and age-group in Table 25, below.

Table 25 Summary of paroxetine steady-state pharmacokinetic parameters

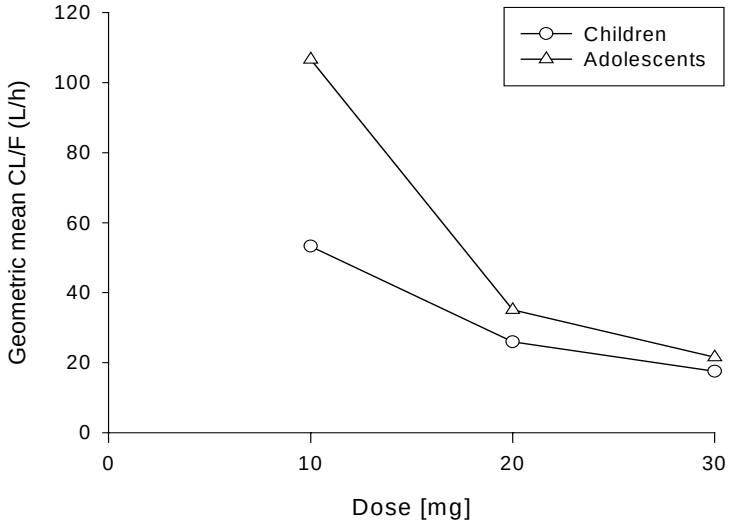
Parameter [units]		**Children**			**Adolescents**		
		10 mg [n=23]	**20 mg** [n=23]	**30 mg** [n=21]	**10 mg** [n=33]	**20 mg** [n=29]	**30 mg** [n=27]
Cmax	Mean	19.5	58.6	129.0	12.0	42.7	94.0
[ng/mL]	SD	18.2	34.5	106.9	13.0	30.0	51.4
	Minimum	1.3	19.4	28.3	0.3	10.7	28.5
	Maximum	90.9	142.4	552.6	62.8	129.9	262.9
	Geom. mean	**14.0**	**50.0**	**105.5**	**6.6**	**35.0**	**82.4**
	CVb	**109%**	**63%**	**68%**	**191%**	**70%**	**56%**
Tmax	Median	4.9	5.0	3.1	5.0	5.0	3.3
[hours]	Minimum	1.9	2.0	1.8	2.0	2.0	2.0
	Maximum	12.1	8.0	14.1	12.3	24.0	12.1
AUC(0-24)	Mean	285	899	2081	189	733	1631
[ng.h/mL]	SD	291	552	1737	227	581	1040
	Minimum	14	295	529	4	150	501
	Maximum	1424	2633	9018	1134	2628	5485
	Geom. mean	**188**	**772**	**1711**	**94**	**570**	**1395**
	CVb	**131%**	**60%**	**66%**	**227%**	**82%**	**60%**
C24	Mean	7.7	27.1	67.9	6.2	25.6	56.5
[ng/mL]	SD	7.5	18.4	64.4	9.6	25.7	50.1
	Minimum	NQ	7.9	19.0	NQ	2.8	8.7
	Maximum	30.9	92.0	328.9	49.4	129.9	253.5
	Geom. mean	4.2	22.7	54.1	2.2	17.3	42.5
	CVb	255%	66%	70%	366%	116%	88%
CL/F	Mean	93.3	29.8	20.6	273.3	44.4	24.8
[L/h]	SD	144.1	15.9	12.4	495.8	32.3	13.2
	Minimum	7.0	7.6	3.3	8.8	7.6	5.5
	Maximum	708.7	67.9	56.7	2597.4	133.8	59.8
	Geom. mean	**53.2**	**25.9**	**17.5**	**106.6**	**35.1**	**21.5**
	CVb	**131%**	**60%**	**66%**	**227%**	**82%**	**60%**
CL/F	Mean	2.22	0.73	0.50	3.63	0.65	0.36
(weight-	SD	3.66	0.37	0.33	5.79	0.38	0.16
normalized)	Minimum	0.26	0.20	0.12	0.16	0.09	0.12
[(L/h)/kg]	Maximum	18.36	1.76	1.47	29.58	1.52	0.78
	Geom. mean	**1.31**	**0.64**	**0.42**	**1.64**	**0.54**	**0.33**
	CVb	**117%**	**58%**	**66%**	**202%**	**76%**	**53%**

Source: Tables 10.3 to 10.14.

The Cmax and AUC(0-24) data confirm that, at each dose level, paroxetine steady state systemic exposure was higher in children (7-11 years) than in adolescents (12-17 years). However, for both parameters, the differences diminished with increasing dose; geometric mean values in children were approximately 100% higher at 10 mg but less than 30% higher at 30 mg. Mean Cmax and AUC(0-24) values increased disproportionately with dose in both groups, but this was accompanied by a marked reduction in variability (CVb), most notably between the 10 and 20 mg dose levels. Expressed in terms of clearance, geometric mean CL/F (un-normalized) at 10 mg in children was approximately 50% lower than in

adolescents, but only 25% lower at 20 mg and 20% lower at 30 mg. Within each group, geometric mean CL/F fell more than two-fold between 10 and 20 mg, but by less than 40% between 20 and 30 mg. These relationships with dose are illustrated graphically in Figures 11.5 to 11.10, and summarized (geometric mean data) in Figure 2, below.

Figure 2 Relationship between paroxetine oral clearance and daily dose in pediatric patients



Source: Table 10.11 and Table 10.12.

At corresponding doses, median Tmax values in the two populations were similar, suggesting comparable rates of absorption.

The influence of gender on paroxetine steady state Cmax, AUC(0-24) and CL/F is examined graphically in Figures 11.11 to 11.19. No marked differences were evident in either age-group at any of the three dose levels.

The influence of age on paroxetine steady state Cmax, AUC(0-24) and CL/F is examined graphically in Figures 11.20 to 11.28. As suggested by the groupwise (mean) data, Cmax and AUC(0-24) tended to fall with increasing age, while CL/F tended to rise. Variability was, however, considerable.

The influence of weight on paroxetine steady state Cmax, AUC(0-24) and CL/F is examined graphically in Figures 11.29 to 11.37. Mirroring the effect of age, Cmax and AUC(0-24) also tended to fall with increasing weight, while CL/F again tended to rise.

Since age and weight are not independent factors, the influence of each cannot be determined in isolation. However, weight-normalized CL/F values at each dose level appeared to remain relatively constant across the age range studied (Figures 11.38 to 11.40). In fact, weight-normalized CL/F may even be slightly higher in younger patients; although geometric mean values in children were approximately 20% lower than in adolescents at 10 mg, these values were 20% and 30% higher at 20 mg and 30 mg, respectively.

Because the combined effects of age, weight and dose on the pharmacokinetics of paroxetine in the pediatric population are evidently rather complex, a covariate analysis was performed (see Section 3.12.4). Strong associations were observed between weight and Cmax ($P<0.001$), AUC(0-24) ($P=0.001$) and un-normalized CL/F ($P=0.001$), but no statistically significant association was observed with weight-normalized CL/F ($P=0.852$). After adjusting for weight, no significant effect was found for any of the four parameters, Cmax, AUC(0-24), CL/F and weight normalized CL/F ($P=0.236$, 0.365, 0.362 and 0.528, respectively) when age was added to the model (data on file). However, significant interactions between weight and dose were observed for Cmax ($P=0.038$), AUC(0-24) ($P=0.044$) and CL/F ($P=0.044$). Inspection of Figures C.60 to C.62 (Appendix C) reveals that these interactions are the result of small differences between the 10 mg dose level and the two higher doses in the degree of change with increasing weight.

CYP2D6 genotype analysis was performed for 53 of the 59 patients providing pharmacokinetic data, enabling their baseline phenotypes to be predicted (Tables 10.15 and 10.16). As expected, the EM phenotype (either homozygous or heterozygous) predominated. No PMs were identified among the younger group, but three of the adolescents (patients 00051, 00103 and 00510) were predicted to possess this phenotype. Although patient 00510 had the highest Cmax and AUC(0-24) and the lowest clearance in this age-group, parameter values in the other two putative PM patients were less readily distinguishable from the EM patients.

7 Discussion

This study has described, in both children and adolescents, the steady state pharmacokinetics of paroxetine at the proposed clinical starting dose (10 mg/day) and at two higher doses (20 and 30 mg/day) which might be reached during dose optimization in these populations. In summary, paroxetine systemic exposure (Cmax and AUC(0-24)) tended to be higher and oral clearance (CL/F) lower in the younger group, but Tmax values suggested no difference in absorption rate.

In the evaluable study population (over 50 pediatric patients spanning a 10-year age range), systemic exposure appeared to be inversely related to both age and weight. Although oral clearance increased with both, normalization of CL/F for weight abolished the effect of age. This suggests that, as is the case for many drugs [8], weight may be the more important determinant of paroxetine pharmacokinetics in the pediatric population. This conclusion is consistent with that reported for another SSRI, sertraline: in a study of similar design [9], age-related changes in sertraline steady state Cmax and AUC(0-24) disappeared after these parameters were normalized for weight. Also, as with sertraline, gender had no discernible effect on the steady state pharmacokinetics of paroxetine in either age group.

The relationships between paroxetine daily dose and steady state pharmacokinetic parameters in the pediatric population were complex, but in all important respects mirrored those seen in adults at doses between 20 to 50 mg/day. In both children and adolescents, as in adults, steady state Cmax and AUC(0-24) increased disproportionately with dose, but this was accompanied by a marked reduction in between-subject variability. These observations are best explained in terms of clearance, which decreased with dose (Figures 11.9 and 11.10). Firstly, the largest falls were seen in those patients with the greatest clearance at the initial dose level (10 mg/day); those patients with low clearance exhibited much more modest falls. Secondly, the reduction in clearance was generally greater during the first dose escalation stage (10 to 20 mg/day) than during the second (20 to 30 mg/day). As noted previously (see Section 1.1), these pharmacokinetic characteristics in adults (non-linearity and variability which both diminish with increasing dose) are consistent with involvement of CYP2D6 in paroxetine's metabolism. As the daily dose is increased, this variably-expressed but saturable enzyme becomes a progressively less influential factor governing the steady state pharmacokinetics of paroxetine, while non-saturable (linear) clearance processes begin to predominate [1, 10].

Although this behavior was evident both in children and adolescents, it tended to be less pronounced in the younger group. That is, although the geometric mean AUC(0-24) at 10 mg/day in this group was double that in the older group, it increased less disproportionately with dose, such that at 30 mg/day it was only 23% higher. Between-subject variability, initially greater in adolescents, also became more similar with increasing dose. This implies that the age-related pharmacokinetic changes seen in this study (in addition to being related to weight) also partly reflect, in younger patients, reduced CYP2D6 activity and/or enhanced activity of those enzymes mediating the linear clearance process. Although, generally, hepatic enzyme activity is higher in pre-pubescent children than in adolescents (and in adults), definitive data following changes in the activity of individual cytochrome P450 enzymes with age are lacking [11]. Since, after normalization for weight, mean clearance in children was 20% lower than in adolescents at 10 mg/day but 30% higher at 30 mg/day, it is possible that both reduced CYP2D6 activity and enhanced activity of other enzymes contribute to the overall effect of age on paroxetine pharmacokinetics in this study. Alternatively, considering the high pharmacokinetic variability which persists even after normalizing for weight, these small mean differences may be due to chance alone.

The three putative PM (i.e., CYP2D6-deficient based upon genotyping) patients in this study would have been expected to exhibit not only the highest paroxetine plasma concentrations but also a linear relationship with increasing dose, as in adults [1]. However, this was not the case with these three adolescent PM patients. Although predictions of CYP2D6 phenotype from DNA (genotype) analysis are not infallible [12], it seems unlikely that all three patients were mis-classified. Therefore, the explanation for these findings is unknown. Nevertheless, as in adults [1], there is no reason to believe that CYP2D6 status will affect clinical outcomes during chronic treatment in the pediatric population.

The results of this pharmacokinetic study in pediatric patients are consistent with the data previously reported by Findling *et al* [2], in particular, the disproportional increases in paroxetine steady state plasma concentrations with increasing dose (see section 1.1). Interestingly, the two PM patients in that study did exhibit the highest plasma concentrations (as expected), while clearance was significantly correlated with CYP2D6 activity in the EM patients. Due to the continuous dosing, dose-rising scheme required to obtain steady-state pharmacokinetic data at multiple doses, it was not possible to determine the half-life of paroxetine in the present study, therefore, the value reported by Findling *et al* (mean 11.1 hours, range 2.6-21.1 hours after a single 10 mg dose) cannot be corroborated. However,

their conclusion that the half-life in pediatric patients is shorter than in adults may be unsound. Firstly, although their analytical method was unreliable below 1 ng/mL, some of the half-life values must (by inference) have been derived either using plasma concentrations below this limit or, if only higher concentrations were used, over too short an interval to ensure adequate delineation of the terminal elimination phase. It is noteworthy that the shortest half-lives are associated with the lowest Cmax values in their study. Secondly, they found no correlation between half-life and age in their study population (6-17 years), suggesting that there is no systematic increase in half-life during maturation.

Since the pharmacokinetic characteristics of paroxetine most relevant to its clinical use in the pediatric population are those relating to steady state conditions, the reduction in clearance which occurs during the approach to steady state (due to CYP2D6 saturation) renders single dose data uninformative. Therefore, it is more appropriate to compare steady state pharmacokinetic data from the present study with corresponding data in the adult population.

For this comparison, a data-set was compiled from six studies in which paroxetine was administered to a total of approximately 140 healthy adults (18-64 years) for two weeks at 20 mg/day (insufficient data are available at 10 mg/day) [13, 14, 15, 16, 17, 18]. Geometric mean values of Cmax (33.7 ng/mL), AUC(0-24) (537 ng.h/mL), CL/F (37.3 L/h) and weight-normalized CL/F (0.50 L/h/kg) in this adult population were very similar to the corresponding values in the adolescent patient group in the present study (35.0, 570, 35.1 and 0.54, respectively). The range of values (maximum and minimum) observed for each parameter were also comparable in the adolescent and adult populations (data on file, GlaxoSmithKline). It is noteworthy that steady state Cmax and AUC(0-24) values at 10 mg/day, the pediatric starting dose used in this study and in two concurrent clinical studies [3, 4] are, even in the younger pediatric patient group, less than half of the adult values at 20 mg/day (Table 25, Section 6 of this report).

In conclusion, the steady state pharmacokinetic characteristics of paroxetine in pediatric patients (children and adolescents) mirror the behavior of the drug in adults. The association of paroxetine plasma concentrations with dose and weight (age) in this study may at first appear to support a weight-based dosing recommendation in pediatric patients; however, normalization of clearance for weight did not significantly reduce the very broad between-subject pharmacokinetic variability at any dose level. Moreover, noting the similarities between the adolescent and adult exposure data and the absence of a clear relationship of exposure to effectiveness in adult patients treated with paroxetine

[19], the results of this study do not warrant a weight-based dosing regimen in the pediatric patient population.

The four patients withdrawn from this study due to AEs, and who also provided pharmacokinetic data (00005, 00007, 00106, and 00054), were not the lightest within their respective age groups and had unremarkable pharmacokinetic data with Cmax, AUC and CL/F values well within the ranges for their respective age groups. In contrast, the two patients with the most extreme values (highest Cmax and AUC and lowest CL/F) for their age groups, 00705 for children and 00510 for adolescents, tolerated paroxetine during the study and enrolled in the extension study directly after completing 30 mg UID, the highest dose level during this study. These two patients did not have the lowest weights in their age groups, but 00510 was considered a poor metabolizer based upon his CYP2D6 genotype. The two patients with the lowest weights for their respective age groups, 00704 for children and 00401 for adolescents, also tolerated paroxetine during the study and enrolled in the extension study directly after completing 30 mg UID. Although an informal and limited comparison, these results appear to support the statements above that a weight-based dosing regimen would not be warranted for this patient population.

Paroxetine was generally safe and well-tolerated by the pediatric patients ages 8 to 17 years participating in the current study. The safety and tolerability were evidenced by the low number of SAEs reported during the study (2 out of 62 patients; 3.2%) and the completion of the dose-rising phase of the study by the majority of patients (51 of 62; 82.3%). Although AEs were reported during approximately one-half of all subject sessions, most were considered mild to moderate in intensity, and overall AE frequency was highest at the beginning of the study and appeared to decrease with increasing dose and duration of exposure. In particular, the number and percentage of patients reporting AEs did not increase during the taper phase of the study. Also, less than 10% of the patient population (6 of 62 patients) were withdrawn due to AEs. There were no deaths during the study.

Although the study did not include a placebo control arm for comparison due to its primary pharmacokinetic objective, the trends in the safety data from the current study appear consistent with previous observations in pediatric and/or adult patients. The most common AEs in at least one age group were headache, abdominal pain, somnolence, diarrhea, aggressive reaction, nausea and nervousness. The frequency of these AEs, except the aggressive reaction, were not unexpected from adult data since they have been observed with some frequency in adult MDD, OCD, or panic disorder patient trials [10]. The

aggressive reaction was more frequently reported by younger male patients during the study. The more common occurrence of this particular AE in the younger age group (8-11 years) is consistent with previous acute pediatric safety studies [20, 21], in which hostility (including aggressiveness) was observed more frequently in the younger patients (<15 or <12 years of age, depending upon the study). In addition, the psychiatric and central/peripheral nervous system AEs leading to withdrawal from this study (hyperkinesia, manic reaction and dizziness) have been observed in previous pediatric patient studies with paroxetine [20, 21]. Of these, only dizziness was among the more commonly reported AEs in either the current study or the previous pediatric studies.

There were no clinically significant changes in vital sign (heart rate or blood pressure) or 12-lead ECG parameters following exposure to paroxetine during the study. In addition, the number of laboratory potential clinical concern values following exposure to paroxetine was low, and all, except one, were considered clinically insignificant by investigators. A single transient and asymptomatic increase in AST activity was considered an AE by the investigator. There were no obvious dose-related trends in either vital sign, 12-lead ECG or laboratory value changes during the study.

8 Conclusions

In both pediatric age-groups, paroxetine steady state systemic exposure (Cmax and AUC(0-24)) increased disproportionately with dose, but also became less variable, mirroring the behavior of paroxetine in the adult population. Cmax and AUC(0-24) were higher and clearance lower in children than in adolescents. The association of paroxetine plasma concentrations with dose and weight (age) in this study may at first appear to support a weight-based dosing recommendation in pediatric patients. However, normalization of clearance for weight did not significantly reduce the very broad between-subject pharmacokinetic variability at any dose level. Moreover, noting the similarities between the adolescent and adult exposure data, and the absence of a clear relationship of exposure to effectiveness in adult patients treated with paroxetine, the results do not warrant a weight-based dosing regimen in the pediatric patient population. Paroxetine was generally safe and well-tolerated by pediatric patients ages 8 to 17 years.

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10 Data Source Tables

Table 10.1 Flowchart of Study Procedures

Screening: medical, medicine and tobacco histories, K-SADS-PL and CDRS-R or CY-BOCS (depending upon primary diagnosis), CGI Severity of Illness, physical examination, including height, weight and sitting blood pressure and heart rate measurements, 12-lead ECG, safety laboratory tests, urine drug screen, serum pregnancy test (females only).

Days	**1**		**2-13, 16-27, 30-41, 44-55, 57-70**	**14, 28 and 42**											**56**
Time After Dose (Hours)	**Predose**	**0**	**0**	**Predose**	**0**	**1**	**2**	**3**	**4**	**5**	**8**	**10**	**12**	**24**	**NA**
Admission to CRU	X			X										X	X
Physical Examination	X			X											X
Medical/Medication Hx Updates	X														
Con Meds/Compliance Check			X**	X											X
CGI Severity of Illness and Global Improvement						→	→	→	→	→	→	→	→	$	
Meal Served	X			X					X			X		X	
Paroxetine Administration		X	X*		X									X^	X*
Clinical lab tests	X													X$	X#
Pregnancy test (females only)	X													X$	
12-lead ECG														X$	X#
Height & Weight	X			X											
Sitting Heart Rate/Blood Pressure	X			X										X	X
Baseline Signs/Symptoms	X														
Adverse Experiences			X**	X									X	X	X
CYP2D6 genotyping (if possible)													X@		
PK Blood Samples			X^^	X		X	X	X		X	X		X	X	
Discharge from CRU		X											X	X	X
Telephone Contact			X**												

*once daily out-patient dosing through Day 56; **Every 3-4 days; ^After 24 hour safety assessments, PK blood sampling and meal; ^^Prior to dosing on Days 13, 27 and 41, if possible; @ = Day 14 only; $ = Day 42 only; # = Only if clinically relevant abnormal result on previous test; NA = Not applicable

14 (± 3) Day Follow-up Visit: physical examination, including sitting blood pressure and heart rate measurements, AEs, concomitant medications, 12-lead ECG#, safety laboratory tests#, serum pregnancy test (females only).

= Only if clinically relevant abnormal result on previous test

Table DS29

DEMOGRAPHY DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub no		Sex	Age (Yrs)	Height (cm)	Weight (kg)	Race
00001		Male	9	139.7	33.6	Bi-racial
00053		Female	10	154.9	65.5	White
00055	*g	Male	10	142.2	38.6	Black
00101		Female	9	138.4	40.7	White
00102		Male	8	134.6	29.5	White
00104		Female	11	158.8	64.1	White
00106	*a	Male	10	149.9	49.5	White
00107		Male	10	148.6	61.4	White
00108		Female	11	152.4	48.2	White
00110		Male	9	128.9	29.8	White
00111	*a	Male	10	135.3	35.9	White
00112		Male	11	134.6	36.1	White
00113	*c	Male	10	146.0	48.0	White
00202		Male	10	147.5	51.0	White
00301	*d	Male	8	125.5	26.9	White
00303		Male	11	146.4	35.7	White
00504	*d	Male	8	130.3	29.2	Hispanic
00603	*c	Male	11	142.2	34.0	White
00604		Male	11	164.0	76.5	White
00702		Female	11	146.9	34.2	White
00704		Male	9	131.5	25.9	White
00705		Male	9	133.0	27.4	White
00707		Male	8	142.3	34.2	White
00708		Female	8	145.8	38.2	Black
00709	*d	Male	10	135.7	34.0	White
00806		Female	10	153.0	60.8	White
00818		Male	11	151.0	46.8	White
Mean			10	142.9	42.1	
SDev			1.1	9.63	13.62	
n			27	27	27	
Min			8	125.5	25.9	
Max			11	164.0	76.5	

Male 74%, Female 26%
White 85%, Other 7%, Black 7%

* = Withdrawn after dosing
a = Adverse experience
b = OTHER - WITHDREW CONSENT.
c = Lost to follow-up
d = Protocol deviation (including non-compliance)
e = OTHER - ADMINISTRATIVE UNABLE TO DO DAY 42PK VISIT DUE TO HOLIDAY SCHEDULE
f = OTHER - MAINTAINED ON COMMERCIAL PAXIL AT 30MG
g = OTHER - MAINTAINED ON 20MG OF COMMERCIAL PAXIL AND DID NOT PARTICIPATE IN TAPER PHASE OF STUDY.
. = No data available

[DEMOG093:LIS] [11DEC2001:13:15]

Table DS29

DEMOGRAPHY DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub no	Sex	Age (Yrs)	Height (cm)	Weight (kg)	Race
00002	Male	14	157.3	49.8	White
00003	Female	16	162.8	67.7	White
00004	Male	15	175.8	85.3	White
00005 *a	Male	12	151.7	41.3	White
00007 *a	Male	14	172.9	69.7	White
00051 *c	Male	12	162.6	90.5	Black
00052 *d	Male	15	190.5	71.4	Black
00054 *a	Male	16	180.3	96.8	White
00103	Male	15	171.5	57.3	White
00105 *b	Female	12	152.4	65.9	White
00109	Female	17	171.5	49.3	White
00201 *c	Male	12	177.0	65.0	White
00401	Female	12	147.3	30.1	White
00502 *d	Female	16	161.6	98.3	Hispanic
00503 *e	Female	15	174.0	87.8	White
00505 *d	Male	12	146.0	31.0	White
00506	Male	12	156.0	59.4	Black
00507	Male	12	164.3	67.4	White
00509	Male	15	177.3	61.3	White
00510	Male	12	156.5	45.5	White
00601 *f	Male	17	172.7	58.6	White
00602	Male	15	172.7	67.6	White
00605 *d	Female	13	160.0	53.1	White
00606	Male	14	164.0	86.8	White

00607		Female	17	129.0	68.0	White
00701		Female	15	164.0	55.3	White
00703	*a	Female	16	176.2	63.2	White
00706		Male	12	145.0	44.0	White
00804		Male	16	167.0	58.6	White
00805		Female	16	161.5	43.0	White
00809		Male	16	181.6	141.0	White
00811		Female	12	155.0	71.5	White
00816		Female	14	159.0	105.4	Mixed Race
00824		Female	16	174.0	99.1	White
00825		Female	16	165.0	80.7	Black
Mean			14	164.5	68.2	
SDev			1.8	12.41	22.96	
n			35	35	35	
Min			12	129.0	30.1	
Max			17	190.5	141.0	

Male 57%, Female 43%
White 83%, Black 11%, Other 6%

* = Withdrawn after dosing
a = Adverse experience
b = OTHER - WITHDREW CONSENT.
c = Lost to follow-up
d = Protocol deviation (including non-compliance)
e = OTHER - ADMINISTRATIVE UNABLE TO DO DAY 42PK VISIT DUE TO HOLIDAY SCHEDULE
f = OTHER - MAINTAINED ON COMMERCIAL PAXIL AT 30MG
g = OTHER - MAINTAINED ON 20MG OF COMMERCIAL PAXIL AND DID NOT PARTICIPATE IN TAPER PHASE OF STUDY.
. = No data available

Table DS1

DEMOGRAPHY DETAILS OF STUDY SB29060/715

Sub no		Sex	Age (Yrs)	Height (cm)	Weight (kg)	Race
00001		Male	9	139.7	33.6	Bi-racial
00002		Male	14	157.3	49.8	White
00003		Female	16	162.8	67.7	White
00004		Male	15	175.8	85.3	White
00005	*a	Male	12	151.7	41.3	White
00007	*a	Male	14	172.9	69.7	White
00051	*c	Male	12	162.6	90.5	Black
00052	*d	Male	15	190.5	71.4	Black
00053		Female	10	154.9	65.5	White
00054	*a	Male	16	180.3	96.8	White
00055	*g	Male	10	142.2	38.6	Black
00101		Female	9	138.4	40.7	White
00102		Male	8	134.6	29.5	White
00103		Male	15	171.5	57.3	White
00104		Female	11	158.8	64.1	White
00105	*b	Female	12	152.4	65.9	White
00106	*a	Male	10	149.9	49.5	White
00107		Male	10	148.6	61.4	White
00108		Female	11	152.4	48.2	White
00109		Female	17	171.5	49.3	White
00110		Male	9	128.9	29.8	White
00111	*a	Male	10	135.3	35.9	White
00112		Male	11	134.6	36.1	White
00113	*c	Male	10	146.0	48.0	White
00201	*c	Male	12	177.0	65.0	White
00202		Male	10	147.5	51.0	White
00301	*d	Male	8	125.5	26.9	White
00303		Male	11	146.4	35.7	White
00401		Female	12	147.3	30.1	White
00502	*d	Female	16	161.6	98.3	Hispanic
00503	*e	Female	15	174.0	87.8	White
00504	*d	Male	8	130.3	29.2	Hispanic
00505	*d	Male	12	146.0	31.0	White
00506		Male	12	156.0	59.4	Black
00507		Male	12	164.3	67.4	White
00509		Male	15	177.3	61.3	White
00510		Male	12	156.5	45.5	White
00601	*f	Male	17	172.7	58.6	White
00602		Male	15	172.7	67.6	White
00603	*c	Male	11	142.2	34.0	White
00604		Male	11	164.0	76.5	White
00605	*d	Female	13	160.0	53.1	White
00606		Male	14	164.0	86.8	White
00607		Female	17	129.0	68.0	White
00701		Female	15	164.0	55.3	White
00702		Female	11	146.9	34.2	White
00703	*a	Female	16	176.2	63.2	White
00704		Male	9	131.5	25.9	White
00705		Male	9	133.0	27.4	White

00706	Male	12	145.0	44.0	White
00707	Male	8	142.3	34.2	White
00708	Female	8	145.8	38.2	Black
00709 *d	Male	10	135.7	34.0	White
00804	Male	16	167.0	58.6	White

Male 65%, Female 35%
White 84%, Black 10%, Other 6%

* = Withdrawn after dosing
a = Adverse experience
b = OTHER - WITHDREW CONSENT.
c = Lost to follow-up
d = Protocol deviation (including non-compliance)
e = OTHER - ADMINISTRATIVE UNABLE TO DO DAY 42PK VISIT DUE TO HOLIDAY SCHEDULE
f = OTHER - MAINTAINED ON COMMERCIAL PAXIL AT 30MG
g = OTHER - MAINTAINED ON 20MG OF COMMERCIAL PAXIL AND DID NOT PARTICIPATE IN TAPER PHASE OF STUDY.
. = No data available

Table DS1

DEMOGRAPHY DETAILS OF STUDY SB29060/715

Sub no	Sex	Age (Yrs)	Height (cm)	Weight (kg)	Race
00805	Female	16	161.5	43.0	White
00806	Female	10	153.0	60.8	White
00809	Male	16	181.6	141.0	White
00811	Female	12	155.0	71.5	White
00816	Female	14	159.0	105.4	Mixed Race
00818	Male	11	151.0	46.8	White
00824	Female	16	174.0	99.1	White
00825	Female	16	165.0	80.7	Black
Mean		12	155.1	56.8	
SDev		2.8	15.53	23.31	
n		62	62	62	
Min		8	125.5	25.9	
Max		17	190.5	141.0	

Male 65%, Female 35%
White 84%, Black 10%, Other 6%

```
    *  = Withdrawn after dosing
     a = Adverse experience
     b = OTHER - WITHDREW CONSENT.
     c = Lost to follow-up
     d = Protocol deviation (including non-compliance)
     e = OTHER - ADMINISTRATIVE UNABLE TO DO DAY 42PK
         VISIT DUE TO HOLIDAY SCHEDULE
     f = OTHER - MAINTAINED ON COMMERCIAL PAXIL AT 30MG
     g = OTHER - MAINTAINED ON 20MG OF COMMERCIAL PAXIL
         AND DID NOT PARTICIPATE IN TAPER PHASE OF STUDY.
. = No data available
```

Table DS3

WITHDRAWAL DATA OF STUDY SB29060/715

Subject Group - CHILDREN

Sub no	Date and time of withdrawal	Date and time of last study medication	Sess no	Regimen	Coded withdrawal reason [Verbatim]
00055	07JUN01 12:00	07JUN01 06:30	4	BRL29060 20MG UID-TAPER	Other [MAINTAINED ON 20MG OF COMMERCIAL PAXIL AND DID NOT PARTICIPATE IN TAPER PHASE OF STUDY.]
00106	12MAR01 15:50	12MAR01 10:30	4	BRL29060 20MG UID-TAPER	Adverse experience
00111	05APR01 11:10	04APR01 08:20	1	BRL29060 10MG UID	Adverse experience
00113	11JUN01 08:30	29MAY01 10:20	1	BRL29060 10MG UID	Lost to follow-up
00301	08JUN01 10:00	05JUN01 08:15	3	BRL29060 30MG UID	Protocol deviation (including non-compliance) [PARENTS MISUNDERSTOOD DOSING INSTRUCTIONS, PT TOOK 30MG 2 DAYS PRIOR TO 20MG PK STUDY]
00504	10FEB01 19:30	22FEB01 19:30	5	BRL29060 10MG UID-TAPER	Protocol deviation (including non-compliance)
00603	21FEB01 15:35	20FEB01 07:00	5	BRL29060 10MG UID-TAPER	Lost to follow-up
00709	10AUG01 10:00	10AUG01	4	BRL29060 20MG UID-TAPER	Protocol deviation (including non-compliance) [THE PATIENT TAPERED DOWN TO PAXIL 20MG QD, THE OPTIMAL DOSE FOR THIS PATIENT, AND MAINTAINED ON

COMMERICAL PAXIL 20MG QD OUT OF
THE STUDY.]

. = No data available

[WTHDR026:LIS]
[11DEC2001:12:55]

Table DS3

WITHDRAWAL DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub no	Date and time of withdrawal	Date and time of last study medication	Sess no	Regimen	Coded withdrawal reason [Verbatim]
00005	27MAR01 13:00	03APR01 09:30	5	BRL29060 10MG UID-TAPER	Adverse experience
00007	18MAY01 08:26	16MAY01 08:26	3	BRL29060 30MG UID	Adverse experience [PATIENT LOST TO FOLLOW-UP AFTER REPORTINGS OF HYPERACTIVITY AND MANIA]
00051	30APR01	22MAR01 10:00	4	BRL29060 20MG UID-TAPER	Lost to follow-up
00052	20APR01 09:30	20APR01 09:30	4	BRL29060 20MG UID-TAPER	Protocol deviation (including non-compliance)
00054	12APR01 08:45	11APR01 07:45	1	BRL29060 10MG UID	Adverse experience
00105	05MAR01 10:00	05MAR01 08:05	5	BRL29060 10MG UID-TAPER	Other [WITHDREW CONSENT.]
00201	24MAR01 08:45	24MAR01 08:45	2	BRL29060 20MG UID	Lost to follow-up [PT. WITHDREW CONSENT VOLUNTARILY.]
00502	08DEC00 17:15	07DEC00 19:54	4	BRL29060 20MG UID-TAPER	Protocol deviation (including non-compliance) [SUBJECT DID NOT COMPLETE TAPER]
00503	28DEC00 17:20	03JAN01 17:30	4	BRL29060 20MG UID-TAPER	Other [ADMINISTRATIVE UNABLE TO DO DAY 42PK VISIT DUE TO HOLIDAY SCHEDULE]

00505	24FEB01	17:30	02MAR01	17:30	5	BRL29060 10MG UID-TAPER	Protocol deviation (including non-compliance) [DID NOT WANT TO DOSE INCREASE TO 30MG]
00601	07NOV00	18:00	23OCT00	06:45	3	BRL29060 30MG UID	Other [MAINTAINED ON COMMERCIAL PAXIL AT 30MG]
00605	19APR01	09:20	12APR01	08:00	4	BRL29060 20MG UID-TAPER	Protocol deviation (including non-compliance)

. = No data available

[WTHDR026:LIS]
[11DEC2001:12:55]

Table DS3

WITHDRAWAL DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub no	Date and time of withdrawal	Date and time of last study medication	Sess no	Regimen	Coded withdrawal reason [Verbatim]
00703	20MAR01 10:00	19MAR01 11:30	1	BRL29060 10MG UID	Adverse experience [TOOK TOO MANY PILLS TO CATCH UP. THE PATIENT TOOK 5 PILLS]

. = No data available

[WTHDR026:LIS]
[11DEC2001:12:55]

Table DS35

Study Completion Details OF STUDY SB29060/715

Subject Group - CHILDREN

Subject No.	Completed Study	Enrolled in Extension Study	Last Study Phase
00001	YES	YES	30MG UID
00053	YES	YES	30MG UID
00055	NO	NA	NA
00101	YES	YES	30MG UID
00102	YES	YES	10mg UID taper end
00104	YES	YES	20MG UID taper end
00106	NO	NA	NA
00107	YES	YES	10mg UID taper end
00108	YES	YES	30MG UID
00110	YES	YES	30MG UID
00111	NO	NA	NA
00112	YES	YES	10mg UID taper end
00113	NO	NA	NA
00202	YES	YES	20MG UID taper end
00301	NO	NA	NA
00303	YES	NO	Follow-Up
00504	NO	NA	NA
00603	NO	NA	NA
00604	YES	NO	Follow-Up
00702	YES	YES	20MG UID taper end
00704	YES	YES	30MG UID
00705	YES	YES	30MG UID
00707	YES	YES	30MG UID
00708	YES	YES	30MG UID
00709	NO	NA	NA
00806	YES	YES	20MG UID taper end
00818	YES	YES	30MG UID

NA = Not Applicable
. = No data available

[S0244036:LIS]
[11DEC2001:11:21]

Table DS35

Study Completion Details OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Subject No.	Completed Study	Enrolled in Extension Study	Last Study Phase
00002	YES	YES	30MG UID
00003	YES	YES	30MG UID
00004	YES	YES	30MG UID
00005	NO	NA	NA
00007	NO	NA	NA
00051	NO	NA	NA
00052	NO	NA	NA
00054	NO	NA	NA
00103	YES	YES	30MG UID
00105	NO	NA	NA
00109	YES	YES	20MG UID taper end
00201	NO	NA	NA
00401	YES	YES	30MG UID
00502	NO	NA	NA
00503	NO	NA	NA
00505	NO	NA	NA
00506	YES	YES	20MG UID taper end
00507	YES	YES	20MG UID taper end
00509	YES	YES	30MG UID
00510	YES	YES	30MG UID
00601	NO	NA	NA
00602	YES	YES	30MG UID
00605	NO	NA	NA
00606	YES	YES	30MG UID
00607	YES	NO	Follow-Up
00701	YES	YES	30MG UID
00703	NO	NA	NA
00706	YES	YES	30MG UID
00804	YES	YES	20MG UID taper end
00805	YES	NO	Follow-Up
00809	YES	YES	20MG UID taper end
00811	YES	YES	20MG UID taper end

00816	YES	YES	30MG UID
00824	YES	YES	20MG UID taper end

NA = Not Applicable
. = No data available

[S0244036:LIS]
[11DEC2001:11:21]

Table DS35

Study Completion Details OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Subject No.	Completed Study	Enrolled in Extension Study	Last Study Phase
00825	YES	YES	20MG UID taper end

NA = Not Applicable
. = No data available

[S0244036:LIS]
[11DEC2001:11:21]

Table DS19

MEDICAL HISTORY AND PHYSICAL EXAMINATION DATA OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Date of first diagnosis	Diagnosis	Status
00001	1992	ALLERGIES (DUST & POLLEN)	Current/Active
	1992	HEADACHES	Current/Active
	JUN1993	ENURESIS	Current/Active
	JUN1995	ATTENTION DEFICIT DISORDER	Previously/Currently
	OCT1998	ATTENTION DEFICIT HYPERACTIVITY DISORDER	Current/Active
	OCT1998	SEPARATION ANXIETY DISORDER	Previously/Currently
	FEB1999	MAJOR DEPRESSIVE DISORDER	Current/Active
00053	1998	POLLEN ALLERGY	Current/Active
	1998	SEASONAL ALLERGY	Current/Active
	1998	INTERMITTENT HEADACHES	Current/Active
	1998	INTERMITTENT SINUSITIS	Current/Active
	1998	MOLD ALLERGY	Current/Active
	2000	INTERMITTENT DRY SKIN ON BOTH HANDS	Current/Active
	SEP2000	OBSESSIVE-COMPULSIVE DISORDER	Current/Active

	2001	INTERMITTENT SHORTNESS OF BREATH	
Current/Active			
	2001	KIDNEY INFECTION	
Previously			
	2001	INTERMITTENT DIARRHEA	
Current/Active			
00055	1997	INTERMITTENT HEADACHES	
Current/Active			
	1998	INTERMITTENT ABDOMINAL CRAMPING	
Current/Active			
	SEP1999	MAJOR DEPRESSIVE DISORDER	
Previously/Currently			
00101	1994	SEASONAL ALLERGIES	
Current/Active			
	1998	ASTHMA	
Current/Active			
	MAY1999	MAJOR DEPRESSIVE DISORDER	
Current/Active			
00102	NOV1999	MAJOR DEPRESSIVE DISORDER	
Current/Active			
	2000	RINGWORM LESION ON CHIN	
Current/Active			
00104	1989	ERBS PALSY	
Previously			
	AUG1995	MAJOR DEPRESSIVE DISORDER	
Current/Active			
00106	AUG1993	DYSTHYMIA	
Current/Active			

. = No data available

[HISEX022:LIS]
[11DEC2001:11:20]

Table DS19

MEDICAL HISTORY AND PHYSICAL EXAMINATION DATA OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Date of first diagnosis	Diagnosis	Status
00106	1994	CHRONIC OTITIS MEDIA	Previously
	DEC1999	MAJOR DEPRESSIVE DISORDER	Current/Active
00107	JAN1999	MAJOR DEPRESSIVE DISORDER	Current/Active
00108	APR1996	OBSESSIVE-COMPULSIVE DISORDER	Current/Active
	2001	CERUMEN OCCLUDING EAR CANAL	Current/Active
	2001	ACNE	Current/Active
00110	1991	RECURRENT OTITIS MEDIA	Previously
	1993	CROUP	Previously
	DEC1993	MAJOR DEPRESSIVE DISORDER	Current/Active
	2000	BROKEN RIGHT ARM	Previously
00111	.	SPORTS INDUCED ASTHMA	Current/Active
	JAN1994	OBSESSIVE-COMPULSIVE DISORDER	Current/Active
	MAR1996	MAJOR DEPRESSIVE DISORDER	Current/Active

	2001	FRACTURE OF RIGHT METACARPALS	
Current/Active			
00112	FEB2000	MAJOR DEPRESSIVE DISORDER	
Current/Active			
	2001	FOOT INFECTION	
Previously			
00113	NOV2000	MAJOR DEPRESSIVE DISORDER	
Current/Active			
	2001	EOSINOPHILIA	
Current/Active			
00202	1992	TONSILLECTOMY	
Previously			
	1992	EAR TUBE PLACEMENT	
Previously			
	1992	ADENOIDECTOMY	
Previously			
	1996	OPPOSITIONAL DEFIANT DISORDER	
Previously/Currently			
	1997	OBSESSIVE-COMPULSIVE DISORDER	
Previously/Currently			
	APR1997	TOURETTE'S {DISORDER}	
Previously/Currently			
	APR1999	MAJOR DEPRESSIVE DISORDER	
Previously/Currently			
	2001	SINUSITIS	
Current/Active			

. = No data available

[HISEX022:LIS]
[11DEC2001:11:20]

Table DS19

MEDICAL HISTORY AND PHYSICAL EXAMINATION DATA OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Date of first diagnosis	Diagnosis	Status
00301	APR1995	TOURETTE'S {DISORDER}	Previously/Currently
	APR1996	OBSESSIVE-COMPULSIVE DISORDER	Previously/Currently
	APR1996	PANIC DISORDER	Previously/Currently
00303	.	ENURESIS	Previously
	.	GENERALIZED ANXIETY DISORDER	Previously/Currently
	1999	RASH BOTH ANTECUBITALS	Current/Active
	JAN2001	OBSESSIVE-COMPULSIVE DISORDER	Previously/Currently
00504	2000	HEADACHES	Current/Active
	JUL2000	MAJOR DEPRESSIVE DISORDER	Current/Active
00603	1996	ALLERGY (RABBITS AND CATS)	Current/Active
	AUG2000	MAJOR DEPRESSIVE DISORDER	Previously/Currently
00604	.	POST-TRAUMATIC STRESS DISORDER	Previously
	1990	DOUBLE HERNIA SURGERY	Previously

	1990	DOUBLE HERNIA	
Previously			
	1991	SEASONAL ALLERGIES	
Current/Active			
	1991	ANIMAL ALLERGIES	
Current/Active			
	1991	ATOPIC DERMATITIS	
Current/Active			
	1994	SINUS CONGESTION (FREQUENT)	
Current/Active			
	1995	ASTHMA (EXERCISE INDUCED)	
Current/Active			
	1995	ALLERGY TO CHOCOLATE	
Current/Active			
	1997	FREQUENT HEADACHES	
Current/Active			
	1998	IMPAIRED EYESIGHT	
Current/Active			
	NOV1999	MAJOR DEPRESSIVE DISORDER	
Current/Active			
00702	1992	KIDNEY REPAIRED {NOS}	
Previously			
	1992	KIDNEY REFLUX {NOS}	
Previously			
	2000	HEARTBURN	
Previously			
	2000	HEADACHE	
Previously			
	2000	CONGESTION {LUNG}	
Previously			
	JUN2000	CHRONIC MOTOR DISORDER	
Current/Active			

. = No data available

[HISEX022:LIS]
[11DEC2001:11:20]

Table DS19

MEDICAL HISTORY AND PHYSICAL EXAMINATION DATA OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Date of first diagnosis	Diagnosis	Status
00702	JUN2000	GENERALIZED ANXIETY DISORDER	Current/Active
	JUN2000	MAJOR DEPRESSIVE DISORDER	Current/Active
00704	JAN1997	TOURETTE'S {DISORDER}	Previously/Currently
	JAN1997	OBSESSIVE-COMPULSIVE DISORDER	Previously/Currently
	JAN1997	MAJOR DEPRESSIVE DISORDER	Previously/Currently
00705	APR1999	CHRONIC MOTOR DISORDER	Previously/Currently
	APR1999	VOCAL TIC DISORDER	Previously/Currently
	MAR2001	OBSESSIVE-COMPULSIVE DISORDER	Current/Active
	MAR2001	MAJOR DEPRESSIVE DISORDER	Current/Active
00707	.	MOOD SWINGS	Previously
	1999	OPPOSITIONAL DEFIANT DISORDER	Previously/Currently
	JAN2000	DEPRESSIVE DISORDER NOS	Previously/Currently
	JAN2000	MAJOR DEPRESSIVE DISORDER	Previously/Currently

```
              2001    HEADACHE
Previously

00708         2001    CONJUNCTIVITIS
Previously
            MAR2001   MAJOR DEPRESSIVE DISORDER
Current/Active

00709         2001    RASH
Previously
            JUN2001   MAJOR DEPRESSIVE DISORDER
Previously/Currently

00806            .    HEADACHE
Previously
                 .    SEROUS OTITIS MEDIA
Current/Active
              1990    EAR INFECTIONS
Current/Active
              1996    REACTIVE AIRWAY DISEASE
Current/Active
              1997    PRESSURE EQUALIZING TUBES BILATERAL {EARS}
Previously
              1997    ADENOIDECTOMY
Previously
              2000    NASAL CONGESTION
Current/Active
            NOV2000   DYSTHYMIA
Current/Active
            NOV2000   MAJOR DEPRESSIVE DISORDER
Current/Active


. = No data available
```

Table DS19

MEDICAL HISTORY AND PHYSICAL EXAMINATION DATA OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Date of first diagnosis	Diagnosis	Status
00818	.	NASAL CONGESTION	Current/Active
	1999	STOMACH ACHES	Current/Active
	DEC1999	DYSTHYMIA	Current/Active
	2000	HEAD ACHES	Current/Active
	NOV2000	MAJOR DEPRESSIVE DISORDER	Current/Active

. = No data available

[HISEX022:LIS]
[11DEC2001:11:20]

Table DS19

MEDICAL HISTORY AND PHYSICAL EXAMINATION DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Date of first diagnosis	Diagnosis	Status
00002	.	OBSESSIVE- COMPULSIVE DISORDER	Previously
	1989	DIFFICULTY HEARING	Previously
	SEP1992	ATTENTION DEFICIT DISORDER	Previously/Currently
	SEP1992	MAJOR DEPRESSIVE DISORDER	Previously/Currently
	JUN1993	SIMPLE PHOBIA	Previously/Currently
	JAN1997	OPPOSITIONAL DEFIANT DISORDER	Previously/Currently
	2000	RINGWORM	Current/Active
00003	.	ADJUSTMENT DISORDER	Previously
	.	DEPRESSIVE DISORDER NOS	Previously
	.	MAJOR DEPRESSIVE DISORDER	Previously
	.	DEPRESSED MOOD	Previously
	.	DYSTHYMIA	Previously
	JUN1986	OBSESSIVE-COMPULSIVE DISORDER	Previously/Currently
	JUN1996	POST-TRAUMATIC STRESS DISORDER	Previously/Currently

	1998	LEFT ARM CYST
Previously		
00004	NOV1998	OPPOSITIONAL DEFIANT DISORDER
Previously/Currently		
	1999	ASTHMA
Current/Active		
	2000	BRONCHITIS
Previously		
	MAY2000	MAJOR DEPRESSIVE DISORDER
Previously/Currently		
00005	1990	ALLERGIES (MOLD AND MILDEW)
Current/Active		
	FEB1993	ATTENTION DEFICIT DISORDER
Previously/Currently		
	JUN1996	GENERALIZED ANXIETY DISORDER
Previously/Currently		
	APR1998	MAJOR DEPRESSIVE DISORDER
Previously/Currently		
	APR1998	DYSTHYMIA
Previously/Currently		
	2000	HEADACHES
Current/Active		
00007	SEP1989	ATTENTION DEFICIT DISORDER
Previously/Currently		
	JUN1995	POST-TRAUMATIC STRESS DISORDER
Previously/Currently		
	JUN1995	MAJOR DEPRESSIVE DISORDER
Previously/Currently		
00051	1990	INTERMITTENT NOSE BLEEDS
Current/Active		

. = No data available

[HISEX022:LIS]
[11DEC2001:11:20]

Table DS19

MEDICAL HISTORY AND PHYSICAL EXAMINATION DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Date of first diagnosis	Diagnosis	Status
00051	1997	INTERMITTENT HEADACHES	Current/Active
	1999	INTERMITTENT INSOMNIA	Current/Active
	JAN2000	MAJOR DEPRESSIVE DISORDER	Previously/Currently
00052	1985	MILK ALLERGY	Current/Active
	1998	INTERMITTENT AGITATION	Previously/Currently
	NOV2000	MAJOR DEPRESSIVE DISORDER	Current/Active
00054	1984	UMBILICAL HERNIA	Previously
	1984	HERNIA REPAIR	Previously
	1990	STREP THROAT	Previously
	1994	LEFT LEG BROKEN	Previously
	1994	LEFT SMALLEST DIGIT BROKEN	Previously
	1995	SULFA DRUG ALLERGY	Current/Active
	1995	LEFT FOOT BROKEN	Previously
	1995	SEAFOOD ALLERGY	Current/Active

	1995	MONONSODIUM GLUTAMATE ALLERGY	
Current/Active			
	1998	INTERMITTENT HEADACHES	
Current/Active			
	JAN2001	MAJOR DEPRESSIVE DISORDER	
Current/Active			
00103	AUG1997	MAJOR DEPRESSIVE DISORDER	
Current/Active			
	1998	HEADACHES	
Current/Active			
00105	.	HEADACHE	
Current/Active			
	1991	ADENOIDECTOMY	
Previously			
	1991	ENLARGED ADENOIDS	
Previously			
	1991	ENLARGED TONSILS	
Previously			
	1991	TONSILLECTOMY	
Previously			
	NOV1998	MAJOR DEPRESSIVE DISORDER	
Current/Active			
00109	AUG1996	MAJOR DEPRESSIVE DISORDER	
Current/Active			
00201	.	MYRINGOTOMY X3	
Previously			
	.	ENURESIS	
Previously			

. = No data available

[HISEX022:LIS]
[11DEC2001:11:20]

Table DS19

MEDICAL HISTORY AND PHYSICAL EXAMINATION DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Date of first diagnosis	Diagnosis	Status
00201	1989	RECURRENT OTITIS	Previously
	1990	SCARLET FEVER	Previously
	1991	CHICKEN POX	Previously
	2000	FRACTURED RADIUS	Previously
	AUG2000	OPPOSITIONAL DEFIANT DISORDER	Previously/Currently
	AUG2000	DYSTHYMIA	Previously/Currently
	AUG2000	MAJOR DEPRESSIVE DISORDER	Previously/Currently
00401	1988	LACTOSE INTOLERANCE	Current/Active
	SEP1993	OBSESSIVE-COMPULSIVE DISORDER	Previously/Currently
	1995	ALLERGY TO DUST MITES	Current/Active
	1995	ASTHMA (CHILDHOOD)	Current/Active
00502	OCT1998	MAJOR DEPRESSIVE DISORDER	Current/Active
	2000	HEADACHE	Previously

00503 1885 PULMONARY IMMATURITY AT BIRTH
Previously
JUL1994 GENERALIZED ANXIETY DISORDER
Previously/Currently
JUL1994 OVERANXIOUS DISORDER
Previously/Currently
JUL1994 SOCIAL PHOBIA
Previously/Currently
1999 MENSTRUAL CRAMPS
Current/Active
JUL1999 MAJOR DEPRESSIVE DISORDER
Previously/Currently
2000 FLU
Previously

00505 JAN1998 MAJOR DEPRESSIVE DISORDER
Previously/Currently

00506 FEB1996 SOCIAL PHOBIA
Previously/Currently
FEB1996 AVOIDANT DISORDER OF CHILDHOOD
Previously/Currently
AUG1999 MAJOR DEPRESSIVE DISORDER
Previously/Currently
AUG1999 GENERALIZED ANXIETY DISORDER
Current/Active

00507 2000 UPPER RESPIRATORY INFECTION
Previously
2000 NASAL ALLERGY, SEASONAL
Current/Active
MAY2000 SOCIAL PHOBIA
Current/Active

. = No data available

[HISEX022:LIS]
[11DEC2001:11:20]

Table DS19

MEDICAL HISTORY AND PHYSICAL EXAMINATION DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Date of first diagnosis	Diagnosis	Status
00507	MAY2000	MAJOR DEPRESSIVE DISORDER	Current/Active
	MAY2000	OVERANXIOUS DISORDER	Current/Active
	MAY2000	AVOIDANT DISORDER OF CHILDHOOD	Current/Active
	MAY2000	GENERALIZED ANXIETY DISORDER	Current/Active
	MAY2000	SEPARATION ANXIETY DISORDER	Current/Active
	2001	1ST DEGREE ATRIAL VENTRICULAR BLOCK	Current/Active
	2001	SINUS BRADYCARDIA	Current/Active
00509	.	OPPOSITIONAL DEFIANT DISORDER	Previously
	FEB1994	DYSTHYMIA	Current/Active
	FEB2000	MAJOR DEPRESSIVE DISORDER	Current/Active
00510	1990	CHRONIC INTERMITTENT EPISTAXIS	Current/Active
	1998	APPENDECTOMY	Previously
	FEB2000	MAJOR DEPRESSIVE DISORDER	Current/Active

00601 1988 BROKEN COLLAR BONE
Previously
SEP1999 MAJOR DEPRESSIVE DISORDER
Previously/Currently
SEP1999 OBSESSIVE-COMPULSIVE DISORDER
Previously/Currently

00602 1996 CORRECTIVE LENSES
Current/Active
1998 MAJOR DEPRESSIVE DISORDER
Previously/Currently
2000 LEFT ELBOW FRACTURE
Previously

00605 1988 PENICILLIN (ALLERGY)
Current/Active
1991 ALLERGY TO CATS
Current/Active
1995 ALLERGY TO STRAWBERRIES
Current/Active
2000 ECZEMA
Current/Active
FEB2000 MAJOR DEPRESSIVE DISORDER
Current/Active

00606 1986 PNEUMONIA
Previously
1986 TUBES IN EARS
Current/Active
1986 EAR INFECTION
Current/Active
1989 TONSILS REMOVED
Previously

. = No data available

[HISEX022:LIS]
[11DEC2001:11:20]

Table DS19

MEDICAL HISTORY AND PHYSICAL EXAMINATION DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Date of first diagnosis	Diagnosis	Status
00606	1994	ASTHMA	Current/Active
	1994	HAYFEVER (STUFFY OR RUNNY NOSE)	Current/Active
	1996	BODY ACHES (WHOLE BODY)	Current/Active
	1996	BODY ACHES (JOINT AREAS)	Current/Active
	1998	ACNE	Current/Active
	1999	MIGRAINE HEADACHES	Current/Active
	2000	MAJOR DEPRESSIVE DISORDER	Previously/Currently
	2000	INSOMNIA	Current/Active
	2001	BONE FRACTURE (LEFT WRIST)	Previously
00607	1993	CONTACT LENSES (NEARSIGHTED)	Current/Active
	FEB2000	MAJOR DEPRESSIVE DISORDER	Previously/Currently
00701	.	CRAMPS (PREMENSTRUAL SYNDROME)	Current/Active
	1989	SEASONAL ALLERGIES	Current/Active
	DEC1992	CONDUCT DISORDER	Previously/Currently

	AUG2000	MAJOR DEPRESSIVE DISORDER	
Current/Active			
00703	FEB2001	GENERALIZED ANXIETY DISORDER	
Previously/Currently			
	FEB2001	PANIC DISORDER	
Previously/Currently			
	FEB2001	MAJOR DEPRESSIVE DISORDER	
Previously/Currently			
00706	1989	TUBES PLACED IN EARS	
Previously			
	1989	FLUID IN EARS	
Previously			
	1989	ADENOIDS REMOVED	
Previously			
	1995	BROKEN RIGHT ELBOW	
Previously			
	JAN1999	MAJOR DEPRESSIVE DISORDER	
Previously/Currently			
	2001	FLU	
Previously			
00804	2000	HEADACHE	
Current/Active			
	2000	MILD ACNE	
Current/Active			
	OCT2000	MAJOR DEPRESSIVE DISORDER	
Current/Active			
00805	1984	STRABISMUS	
Current/Active			

. = No data available

[HISEX022:LIS]
[11DEC2001:11:20]

Table DS19

MEDICAL HISTORY AND PHYSICAL EXAMINATION DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Date of first diagnosis	Diagnosis	Status
00805	1988	SURGERY FOR STRABISMUS	Previously
	JAN1997	OBSESSIVE-COMPULSIVE DISORDER	Current/Active
	JAN1999	SOCIAL PHOBIA	Current/Active
	JAN1999	AVOIDANT DISORDER OF CHILDHOOD	Current/Active
00809	.	DEPRESSIVE DISORDER NOS	Previously
	.	OBESITY	Current/Active
	1991	TONSILLECTOMY	Previously
	1997	HEADACHES	Current/Active
	1997	SOCIAL PHOBIA	Current/Active
	1997	SINUS CONGESTION	Current/Active
	1997	AVOIDANT DISORDER OF CHILDHOOD	Current/Active
	MAY2000	MAJOR DEPRESSIVE DISORDER	Current/Active
00811	.	HEADACHE	Current/Active
	.	STOMACH ACHE	Current/Active

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           JUL1997    OBSESSIVE-COMPULSIVE DISORDER
Previously/Currently

00816            .    HEADACHES
Current/Active
                 .    CRAMPS
Current/Active
                 .    BILATERAL INGROWN TOENAILS
Current/Active
                 .    OBESITY
Current/Active
                 .    ACNE
Current/Active
              1988    ALLERGIC CROUP
Previously
              1988    DEAF IN LEFT EAR
Current/Active
              1989    SLEEP APNEA
Previously
              1991    INGUINAL HERNIA REPAIR
Previously
              1991    ADENOIDISM
Previously
              1991    TONSILLECTOMY
Previously
           JAN1992    ENURESIS
Current/Active
           JAN1998    AVOIDANT DISORDER OF CHILDHOOD
Current/Active
           JUN1999    MAJOR DEPRESSIVE DISORDER
Current/Active
           FEB2000    BULIMIA
Current/Active


. = No data available
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Table DS19

MEDICAL HISTORY AND PHYSICAL EXAMINATION DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Date of first diagnosis	Diagnosis	Status
00824	.	SINUS CONGESTION/ALLERGIES	Current/Active
	1984	ROTOVIRUS	Previously
	FEB1997	DYSTHYMIA	Current/Active
	2000	OVERWEIGHT	Current/Active
	2000	MENORRHAGIA	Current/Active
	2000	DYSMENORRHEA	Current/Active
	DEC2000	MAJOR DEPRESSIVE DISORDER	Current/Active
	2001	CHLAMYDIA	Current/Active
00825	1986	ORAL SURGERY	Previously
	MAY1998	DYSTHYMIA	Current/Active
	1999	SINUS PROBLEMS	Current/Active
	NOV2000	MAJOR DEPRESSIVE DISORDER	Current/Active

. = No data available

[HISEX022:LIS]
[11DEC2001:11:20]

Table DS31

Diagnostic Data OF STUDY SB29060/715

Subject Group - CHILDREN
SCR

Subject No.	Primary Diagnosis	CDRS-R Total Score	CY-BOCS Total Score
00001	Major Depressive Disorder (MDD)	59	NA
00053	Obsessive-Compulsive Disorder (OCD)	NA	24
00055	Major Depressive Disorder (MDD)	53	NA
00101	Major Depressive Disorder (MDD)	61	NA
00102	Major Depressive Disorder (MDD)	46	NA
00104	Major Depressive Disorder (MDD)	60	NA
00106	Major Depressive Disorder (MDD)	73	NA
00107	Major Depressive Disorder (MDD)	61	NA
00108	Obsessive-Compulsive Disorder (OCD)	NA	19
00110	Major Depressive Disorder (MDD)	56	NA
00111	Obsessive-Compulsive Disorder (OCD)	NA	23
00112	Major Depressive Disorder (MDD)	50	NA
00113	Major Depressive Disorder (MDD)	55	NA
00202	Obsessive-Compulsive Disorder (OCD)	NA	23
00301	Obsessive-Compulsive Disorder (OCD)	NA	29
00303	Obsessive-Compulsive Disorder (OCD)	NA	25
00504	Major Depressive Disorder (MDD)	60	NA
00603	Major Depressive Disorder (MDD)	66	NA
00604	Major Depressive Disorder (MDD)	78	NA
00702	Major Depressive Disorder (MDD)	65	NA
00704	Major Depressive Disorder (MDD)	59	NA
00705	Major Depressive Disorder (MDD)	51	NA
00707	Major Depressive Disorder (MDD)	60	NA
00708	Major Depressive Disorder (MDD)	51	NA
00709	Major Depressive Disorder (MDD)	67	NA
00806	Major Depressive Disorder (MDD)	47	NA
00818	Major Depressive Disorder (MDD)	55	NA

CDRS-R = Children’s Depression Rating Scale-Revised
CY-BOCS = Children’s Yale-Brown Obsessive-Compulsive Score
NA   = Not Applicable
. = No data available

[S0243030:LIS]
[11DEC2001:11:20]

Table DS31

Diagnostic Data OF STUDY SB29060/715

Subject Group - ADOLESCENTS
SCR

Subject No.	Primary Diagnosis	CDRS-R Total Score	CY-BOCS Total Score
00002	Major Depressive Disorder (MDD)	63	NA
00003	Obsessive-Compulsive Disorder (OCD)	NA	19
00004	Major Depressive Disorder (MDD)	61	NA
00005	Major Depressive Disorder (MDD)	61	NA
00007	Major Depressive Disorder (MDD)	45	NA
00051	Major Depressive Disorder (MDD)	54	NA
00052	Major Depressive Disorder (MDD)	57	NA
00054	Major Depressive Disorder (MDD)	60	NA
00103	Major Depressive Disorder (MDD)	64	NA
00105	Major Depressive Disorder (MDD)	50	NA
00109	Major Depressive Disorder (MDD)	64	NA
00201	Major Depressive Disorder (MDD)	50	NA
00401	Obsessive-Compulsive Disorder (OCD)	NA	32
00502	Major Depressive Disorder (MDD)	61	NA
00503	Major Depressive Disorder (MDD)	59	NA
00505	Major Depressive Disorder (MDD)	62	NA
00506	Major Depressive Disorder (MDD)	71	NA
00507	Major Depressive Disorder (MDD)	76	NA
00509	Major Depressive Disorder (MDD)	57	NA
00510	Major Depressive Disorder (MDD)	62	NA
00601	Major Depressive Disorder (MDD)	72	NA
00602	Major Depressive Disorder (MDD)	72	NA
00605	Major Depressive Disorder (MDD)	63	NA
00606	Major Depressive Disorder (MDD)	69	NA
00607	Major Depressive Disorder (MDD)	68	NA
00701	Major Depressive Disorder (MDD)	79	NA
00703	Major Depressive Disorder (MDD)	69	NA
00706	Major Depressive Disorder (MDD)	58	NA
00804	Major Depressive Disorder (MDD)	59	NA
00805	Obsessive-Compulsive Disorder (OCD)	NA	30

00809	Major Depressive Disorder (MDD)	62		NA

CDRS-R = Children’s Depression Rating Scale-Revised
CY-BOCS = Children’s Yale-Brown Obsessive-Compulsive Score
NA = Not Applicable
. = No data available

[S0243030:LIS]
[11DEC2001:11:20]

Table DS31

Diagnostic Data OF STUDY SB29060/715

Subject Group - ADOLESCENTS
SCR

Subject No.	Primary Diagnosis	CDRS-R Total Score	CY-BOCS Total Score
00811	Obsessive-Compulsive Disorder (OCD)	NA	24
00816	Major Depressive Disorder (MDD)	62	NA
00824	Major Depressive Disorder (MDD)	59	NA
00825	Major Depressive Disorder (MDD)	51	NA

CDRS-R = Children's Depression Rating Scale-Revised
CY-BOCS = Children's Yale-Brown Obsessive-Compulsive Score
NA = Not Applicable
. = No data available

[S0243030:LIS]
[11DEC2001:11:20]

Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Prior Medications

Subject Group - CHILDREN

Sub No	Drug Name	Dose	Frequency	Route	Duration	Indication	Date and Time of First Dose	Stopped	of Study Drug
00001	WELLBUTRIN	100MG	BID	PO	11 mths	DEPRESSION	11OCT2000	23OCT2000	08:20
00053	MULTIVITAMIN	1CAP	OD	PO	1 yr	DIETARY SUPPLEMENT	01JAN2001	13MAR2001	10:00
	CHILDRENS TYLENOL	3TSP	PRN	PO	3 yrs	INTERMITTENT HEADACHES	01JAN2001	13MAR2001	10:00
00106	MOTRIN	1TAB	SD	PO	1 day	HEADACHE	DEC2000	25JAN2001	09:20
00107	COUGH SYRUP	15CC	OD	PO	X3 days	COLD	JAN2001	01MAR2001	09:17
	TYLENOL	325MG	SD	PO	1 day	HEADACHE	JAN2001	01MAR2001	09:17
00108	ERYTHROMYCIN	250MG	OD	PO	1 mth	ACNE	15FEB2001	28FEB2001	15:45
00110	TYLENOL	265MG	BID	PO	1 wk	BROKEN ARM	NOV2000	13MAR2001	09:50
00111	TYLENOL WITH CODEINE	UNK	Q4HR-X3DOSES	PO	1 day	BROKEN METACARPALS	28FEB2001	22MAR2001	09:36
	CHILDRENS MOTRIN	100MG	OD	PO	2 days	UPPER RESPIRATORY INFECTION	FEB2001	22MAR2001	09:36

00112 CIPROFLOXACIN		250MG	BID	PO	7 days	FOOT INFECTION
01MAR2001	26APR2001:09:35					
00113 RITALIN		15MG	QAM	PO	2 yrs	BEHAVIOUR
01MAR2001	29MAY2001:10:20					
RITALIN		5MG	QPM	PO	2 yrs	BEHAVIOUR
01MAR2001	29MAY2001:10:20					
00202 CEFTIN		250MG	BID	PO	10 days	SINUSITIS
24FEB2001	27FEB2001:11:35					
00301 PROZAC		40MG	DAILY	PO	5 yrs	OCD
FEB2001	07MAY2001:12:00					
HALDOL		0.05MG	DAILY	PO	3-4 wks	TOURETTES
23APR2001	07MAY2001:12:00					
00504 ADVIL		200MG	NOCTE	PO	1 mth	HEADACHE
11JAN2001	10JAN2001:19:10					

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

[OMED023:LIS]
[02JAN2002:13:37]

Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Prior Medications

Subject Group - CHILDREN

Sub No	Drug Name	Dose	Frequency	Route	Duration	Indication	Date and Time of First Dose	Stopped	Date and Time of Study Drug
00603	VENLAFAXINE	UNK	UNK	PO	UNK	DEPRESSION	28SEP2000	21DEC2000:10:00	
00604	ALLEGRA	60MG	BID PRN	PO	5 mths	SEASONAL ALLERGIES	SEP2000	13FEB2001:09:50	
00702	FLONASE	ONE	BID	IH	2 days	CONGESTION	17OCT2000	29JAN2001:09:07	
	TYLENOL (CHILDRENS)	240MG	OD	PO	1 day	HEADACHE	17OCT2000	29JAN2001:09:07	
	TUMS	1TAB	OD	PO	1 day	(HEARTBURN) GI AGENT	27DEC2000	29JAN2001:09:07	
00704	CHILDREN'S LIQUID TYLENOL	2TSPS	SD	PO	1 day	HEADACHE	05MAR2001	08MAR2001:08:00	
00707	NEURONTIN	100MG	TID	PO	10 mths	MOOD SWINGS	22MAR2001	05APR2001:08:00	
00708	ANTIBIOTIC UNKNOWN	2DROPS	TID	OU	7 days	CONJUNCTIVITIS	15MAR2001	06APR2001:09:55	
00709	HYDROCORTISONE CREAM	1TBS	SD	TO	1 day	RASH	15MAR2001	22JUN2001:08:59	
	PREDNISONE	UNK	TID	PO	7 days	RASH	22MAR2001	22JUN2001:08:59	

PREDNISONE		UNK	TID	PO	7 days	RASH
24APR2001	22JUN2001:08:59					
00806 TYLENOL		500MG	SD	PO	3 mths	HEADACHE
JUL2000	17NOV2000:09:10					
PANCOF HC		UNK	BID	PO	1 mth	CONGESTION
25OCT2000	17NOV2000:09:10					

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

[OMED023:LIS]
[02JAN2002:13:37]

Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Prior Medications

Subject Group - ADOLESCENTS

Sub No	Drug Name	Dose	Frequency	Route	Duration	Indication	Date and Time of First Dose	Stopped	Date and Time of Study Drug
00002	RITALIN	10MG	OD	PO	1 mth	ATTENTION DEFICIT DISORDER	16NOV2000:08:30	MAR2000	
	DEPAKOTE	250MG	TID	PO	5 mths	OBSESSIVE COMPULSIVE,ATTENTION DEFICIT,OPPOSITIONAL DEFIANCE DISORDERS	16NOV2000:08:30	01NOV2000	
00003	ZOLOFT	50MG	OD	PO	9 mths	DEPRESSION	29NOV2000:08:45	06NOV2000	
00004	BIAXIN	500MG	OD	PO	2 wks	BRONCHITIS	15DEC2000:09:30	30OCT2000	
00005	DEXEDRINE	10MG	OD	PO	3 yrs	ATTENTION DEFICIT DIORDER	28FEB2001:09:50	14FEB2001	
00007	ST. JOHN'S WORT	2TABS	TID	PO	2 mths	DEPRESSION	20APR2001:08:50	02APR2001	
00054	WELLBUTRIN	100MG	OD	PO	2 days	DEPRESSION	29MAR2001:08:35	20MAR2001	
	WELLBUTRIN	150MG	OD	PO	1 day	DEPRESSION	29MAR2001:08:35	21MAR2001	
00103	ADVIL	400MG	PRN	PO	2.5 yrs	HEADACHE	01DEC2000:09:33	01OCT2000	

00105	TYLENOL	500MG	SD	PO	1 day	HEADACHE
OCT2000	10JAN2001:11:48					
00401	BUSPAR	10MG	BID	PO	10.5 mths	OBSESSIVE COMPULSIVE
10OCT2000	25OCT2000:12:30					
						DISORDER
	CELEXA	15MG	QD	PO	11.5 mths	OBSESSIVE COMPULSIVE
10OCT2000	25OCT2000:12:30					
						DISORDER
	EMLA CREAM	1CC	SD	TD	1 hr	PAIN PREVENTION FOR BLOOD
20OCT2000	25OCT2000:12:30					
						DRAW
	EMLA CREAM	1CC	SD	TD	1 hr	PAIN PREVENTION FOR BLOOD
25OCT2000	25OCT2000:12:30					
						DRAW

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

[OMED023:LIS]
[02JAN2002:13:37]

Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Prior Medications

Subject Group - ADOLESCENTS

Sub No	Drug Name	Dose	Frequency	Route	Duration	Indication	Date and Time of First Dose / Stopped / of Study Drug
00502	EXCEDRIN EXTRA STRENGTH	2TABS	PRN	PO	1 day	HEADACHE	06OCT2000 / 23OCT2000:10:30
00503	ALKA SELTZER PLUS COLD TABLETS	2TABS	OD	PO	4 days	FLU	06NOV2000 / 17NOV2000:22:30
00507	TUSSIN	2TSP	BID	PO	5 days	UPPER RESPIRATORY INFECTIONS	01DEC2000 / 08FEB2001:18:03
	CLARITIN	10MG	OD	PO	3 mths	NASAL ALLERGY (SEASONAL)	22MAR2001 / 08FEB2001:18:03
	NASONEX	1PUFF IN EACH NOSTRIL	OD	NA	3 mths	NASAL ALLERGY (SEASONAL)	22MAR2001 / 08FEB2001:18:03
	TUSSIN	2TSP	BID	PO	Unknown	UPPER RESPIRATORY INFECTION	Continuing / 08FEB2001:18:03
00601	PROTEIN SHAKE	1SERVING	OD	PO	14 days	DIETARY SUPPLEMENT	14AUG2001 / 12SEP2000:09:50
00606	SLEEPINAL	50MG	PRN	PO	1 mth	INSOMNIA	07FEB2001 / 20FEB2001:09:00

00607	ST. JOHN'S WORT	300MG	OD	PO	13 mths	DEPRESSION
15FEB2001	21FEB2001:09:25					
	VALERIAN	400MG	OD	PO	Unknown	MENSTRUAL CRAMPS
Continuing	21FEB2001:09:25					
00701	MIDOL	2TABS	SD	PO	1 day	CRAMPS
AUG2000	30NOV2000:08:15					
	TYLENOL	250MG	SD	PO	1 day	CRAMPS
OCT2000	30NOV2000:08:15					
00706	ALEVE	1TAB	OD	PO	2 days	FLU
02APR2001	05APR2001:07:05					
	AMOXICILLIN	250MG	OD	PO	2 days	FLU
02APR2001	05APR2001:07:05					
00804	VITAMIN C	1TAB	SD	PO	1 day	DIETARY SUPPLEMENT
SEP2000	31OCT2000:08:12					

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

[OMED023:LIS]
[02JAN2002:13:37]

Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Prior Medications

Subject Group - ADOLESCENTS

Sub No	Drug Name	Dose	Frequency	Route	Duration	Indication	Date and Time of First Dose	Stopped	Date and Time of Study Drug
00809	TYLENOL	500MG	SD	PO	ONE days	HEADACHE	OCT2000	08DEC2000:08:51	
	CLARITIN	10UG	PRN	PO	3 yrs	SINUS	OCT2000	08DEC2000:08:51	
00824	DEPO PROVERA	150MG	SD	IM	ONCE	BIRTH CONTROL	21DEC2000	21MAR2001:15:54	
	TYLENOL SINUS	1TAB	UID	PO	2 wks	SINUS CONGESTION	14MAR2001	21MAR2001:15:54	
	ZITHROMAX	1GRAM	SD	IM	ONCE	CHLAMYDIA	15MAR2001	21MAR2001:15:54	

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

[OMED023:LIS]
[02JAN2002:13:37]

Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Continuing Medications

Subject Group - CHILDREN

Sub No	Drug Name	Dose	Frequency	Route	Duration	Indication	Date and Time of First Dose of Study Drug
00001	ADVIL	200MG	PRN	PO	9 yrs	HEADACHE/ALLERGIES	23OCT2000:08:20
	TYLENOL	325MG	PRN	PO	9 yrs	HEADACHE/ALLERGIES	23OCT2000:08:20
00101	ALBUTEROL	2PUFFS	PRN	IH	2 yrs	ASTHMA	02NOV2000:09:55
00111	ALBUTEROL INHALER	2PUFFS	PRN	IH	UNK	SPORTS INDUCED ASTHMA	22MAR2001:09:36
00112	VITAMIN C	250MG	OD	PO	1 yr	CAN'T EAT CITRUS	26APR2001:09:35
	MVI	UNK	OD	PO	1 yr	SUPPLEMENT	26APR2001:09:35
00806	CLARITIN REDI TABS	10MG	OD	PO	2 mths	EAR INFECTION	17NOV2000:09:10
	NASONEX	50UGMS	OD	IH	2 mths	EAR INFECTION	17NOV2000:09:10
	BIAXIN	250MG	TID	PO	1 mth	REACTIVE AIRWAY DISEASE	17NOV2000:09:10
00818	CLARITIN	UNK	PRN	PO	1 mth	CONGESTION	08FEB2001:08:21
	CLARITIN D	10MG	PRN	PO	1 mth	CONGESTION	08FEB2001:08:21

ALEVE	250MG	PRN	PO	3 mths	HEADACHES

08FEB2001:08:21

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

[OMED023:LIS]
[02JAN2002:13:37]

Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Continuing Medications

Subject Group - ADOLESCENTS

Sub No	Drug Name	Dose	Frequency	Route	Duration	Indication	Date and Time of First Dose of Study Drug
00002	DIFLUCAN	100MG	2XWK	PO	1 mth	RINGWORM	16NOV2000:08:30
	LOPROX	1APP	TID	TO	1 mth	RINGWORM	16NOV2000:08:30
00004	ALBUTEROL	1-2PUFFS	PRN	IH	1 yr	ASTHMA	15DEC2000:09:30
	SEREVENT	10MG	BID	IH	9 mths	ASTHMA	15DEC2000:09:30
	SINGULAIR	10MG	OD	PO	1 yr	ASTHMA	15DEC2000:09:30
00005	ZYRTEC	10MG	PRN	PO	3 yrs	ALLERGIES	28FEB2001:09:50
	ADVIL	500MG	PRN	PO	6 mths	HEADACHES	28FEB2001:09:50
00007	MULTIVITAMIN	1TAB	OD	PO	5 mths	GENERAL WELLBEING	20APR2001:08:50
00052	MULTIVITAMIN	1TAB	PRN	PO	3 yrs	DIETARY SUPPLEMENT	09MAR2001:09:45
00503	PAMPRIN	2TABS	PRN	PO	1 yr	MENSTRUAL CRAMPS	17NOV2000:22:30

00606	ALBUTEROL	2PUFFS	PRN	IH	7 yrs	ASTHMA
20FEB2001:09:00						
	IBUPROFEN	800MG	PRN	PO	5 yrs	BODY ACHES
20FEB2001:09:00						
	EXCEDRIN MIGRAINE	500MG	PRN	PO	3 yrs	MIGRAINE
20FEB2001:09:00						
00804	ASPIRIN	UNK	PRN/	PO	4 wks	HEADACHE
31OCT2000:08:12						
			OD			
00811	IBUPROFEN	400MG	PRN	PO	UNK	HEADACHE
09JAN2001:09:18						
	TYLENOL	500MG	PRN	PO	UNK	HEADACHE
09JAN2001:09:18						
	PEPTO-BISMOL	1TSP	PRN	PO	UNK	STOMACH ACHE
09JAN2001:09:18						
00816	TYLENOL	500MG	PRN	PO	4 yrs	CRAMPS
06FEB2001:09:10						
	TYLENOL	500MG	PRN	PO	3 yrs	HEADACHE
06FEB2001:09:10						

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

[OMED023:LIS]
[02JAN2002:13:37]

Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Continuing Medications

Subject Group - ADOLESCENTS

Sub No	Drug Name	Dose	Frequency	Route	Duration	Indication	Date and Time of First Dose of Study Drug
00824	BENADRYL	25MG	PRN	PO	UNK	ALLERGIES	21MAR2001:15:54
	MOTRIN	600MG	PRN	PO	UNK	MENSTRAL CRAMPS	21MAR2001:15:54
	ORTHO TRI-CYCLEN	1TAB	OD	PO	2 wks	MENSTRATION REGULATION	21MAR2001:15:54
00825	DEPO-PROVERA	100MG	EVERY 3 MONTHS	IM	8 mths	BIRTH CONTROL	21MAR2001:15:25
	TYLENOL SINUS	1000MG	PRN	PO	2 yrs	SINUS TROUBLE	21MAR2001:15:25

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

[OMED023:LIS]
[02JAN2002:13:37]

Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Concomitant Medications

Subject Group - CHILDREN

Drug Name	Dose	Frequency	Route	Start Date and Time	End Date and Time	Indication	Sess No	Regimen	Date and Time of First Dose of Regimen
Subject : 00053									
CHILDRENS 30MG UID	3TSP	QID	PO	17APR2001:09:00	19APR2001:21:00	FLU	3	BRL29060	10APR2001:09:05
TYLENOL CHILDREN'S NYQUIL 30MG UID	2TSP	PRN	PO	18APR2001:23:00	18APR2001:23:01	FLU	3	BRL29060	10APR2001:09:05
Subject : 00101									
TYLENOL 10MG UID	200MG	PRN	PO	14NOV2000	14NOV2000	HEADACHE	1	BRL29060	02NOV2000:09:55
ALBUTEROL 10MG UID	2PUFFS	SD	IH	15NOV2000	15NOV2000	ASTHMA	1	BRL29060	02NOV2000:09:55
Subject : 00102									
EMLA CREAM 10MG UID	1APP	PRN	TO	24NOV2000:08:45	24NOV2000:09:45	TOPICAL ANESTHETIC	1	BRL29060	11NOV2000:08:30
EMLA CREAM 20MG UID	1APP	PRN	TO	09DEC2000:08:00	09DEC2000:08:55	TOPICAL ANESTHETIC	2	BRL29060	25NOV2000:10:15
EMLA CREAM 30MG UID	1APP	PRN	TO	22DEC2000:09:00	22DEC2000:09:55	TOPICAL ANESTHETIC	3	BRL29060	10DEC2000:07:15

ADVIL 20MG	200MG	PRN	PO	02JAN2001:06:00	06JAN2001:21:00	PAIN FROM BROKEN LEG	4	BRL29060 UID-TAPER
	23DEC2000:10:05							

Subject : 00106

MOTRIN 20MG UID	200MG	SD	PO	19FEB2001:18:15	19FEB2001:18:15	HEADACHE	2	BRL29060
	09FEB2001:11:00							
ZITHROMAX 30MG UID	250MG	BID	PO	27FEB2001:13:00	27FEB2001:13:00	EAR INFECTION	3	BRL29060
	24FEB2001:10:00							
ZITHROMAX 30MG UID	250MG	UID	PO	28FEB2001:08:20	03MAR2001:09:00	EAR INFECTION	3	BRL29060
	24FEB2001:10:00							
SEROQUEL 20MG	50MG	SD	PO	13MAR2001	13MAR2001	AGITATED OUTBURSTS	4	BRL29060 UID-TAPER
	10MAR2001:10:30							

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

[OMED023:LIS]
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Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Concomitant Medications

Subject Group - CHILDREN

Drug Name	Dose	Frequency	Route	Start Date and Time	End Date and Time	Indication	Sess No	Regimen	Date and Time of First Dose of Regimen
Subject : 00106									
ADDERALL 20MG	5MG	BID	PO	13MAR2001	15MAR2001	MANIA	4	BRL29060 UID-TAPER	10MAR2001:10:30
PAXIL 20MG	20MG	OD	PO	13MAR2001:09:00	15MAR2001	DEPRESSION	4	BRL29060 UID-TAPER	10MAR2001:10:30
ATIVAN 20MG	1MG	3X	PO	13MAR2001:18:30	13MAR2001:22:40	AGITATED	4	BRL29060 UID-TAPER	10MAR2001:10:30
SEROQUEL 20MG	50MG	QID	PO	15MAR2001:11:00	15MAR2001:11:00	OUTBURSTS PROPHYLAXIS OF AGITATED OUTBURSTS	4	BRL29060 UID-TAPER	10MAR2001:10:30
TYLENOL 20MG	325MG	PRN	PO	15MAR2001:13:30	18MAR2001:11:30	PAIN FROM BRUISING FROM RESTRAINTS	4	BRL29060 UID-TAPER	10MAR2001:10:30
ATIVAN 20MG	1MG	OD	PO	16MAR2001:10:00	17MAR2001:10:00	PROPHYLAXIS FOR AGITATED OUTBURSTS	4	BRL29060 UID-TAPER	10MAR2001:10:30
SEROQUEL 20MG	100MG	QID	PO	16MAR2001:13:00	20MAR2001:18:00	PROPHYLAXIS FOR AGITATED OUTBURSTS	4	BRL29060 UID-TAPER	10MAR2001:10:30

CELEXA 20MG	10MGS	OD	PO	18MAR2001 10MAR2001:10:30	18MAR2001	SUICIDAL IDEATION	4	BRL29060 UID-TAPER
CELEXA 20MG	20MG	OD	PO	19MAR2001:13:00 10MAR2001:10:30	Continuing	SUICIDAL IDEATION	4	BRL29060 UID-TAPER
SEROQUEL 20MG	200MG	BID	PO	20MAR2001 10MAR2001:10:30	Continuing	PROPHYLAXIS FOR AGITATED OUTBURSTS	4	BRL29060 UID-TAPER

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

[OMED023:LIS]
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Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Concomitant Medications

Subject Group - CHILDREN

Drug Name	Dose	Frequency	Route	Start Date and Time	End Date and Time	Indication	Sess No	Regimen Date and Time of First Dose of Regimen
Subject : 00107								
ACETAMINOPHEN 10MG UID	500MG	SD	PO	05MAR2001:18:00	05MAR2001:18:00	HEADACHE	1	BRL29060 01MAR2001:09:17
TYLENOL 30MG UID	530MG	SD	PO	08APR2001	08APR2001	HEADACHE	3	BRL29060 30MAR2001:11:35
Subject : 00111								
ALBUTEROL INHALER 10MG UID	2PUFFS	PRN	IH	01APR2001	Continuing	ASTHMA EXACERBATION	1	BRL29060 22MAR2001:09:36
TYLENOL 10MG UID	265MG	OD	PO	01APR2001	03APR2001	HEADACHES	1	BRL29060 22MAR2001:09:36
DEXTROMETHORPHAN 10MG UID	0.5TSP	SD	PO	02APR2001	02APR2001	SORE THROAT COUGH	1	BRL29060 22MAR2001:09:36
PRELONE 10MG UID	10MG	BID	PO	05APR2001	Continuing	ASTHMA EXACERBATION	1	BRL29060 22MAR2001:09:36
Subject : 00202								
TYLENOL 10MG UID	UNK	SD	PO	27FEB2001:19:20	27FEB2001:19:20	HEADACHE	1	BRL29060 27FEB2001:11:35
TYLENOL 10MG UID	UNK	SD	PO	05MAR2001:21:30	05MAR2001:21:30	HEADACHE	1	BRL29060 27FEB2001:11:35

IBUPROFEN 20MG UID	UNK 11MAR2001:08:50	SD	PO	18MAR2001	18MAR2001	HEADACHE	2	BRL29060

Subject : 00301

MOTRIN 10MG UID	200MG 07MAY2001:12:00	SD	PO	07MAY2001:19:10	07MAY2001:19:10	HEAD/NECK PAIN	1	BRL29060

Subject : 00303

PAXIL 10MG	10MG 05SEP2001:10:30	DAILY	PO	12SEP2001	Continuing	OCD	5	BRL29060 UID-TAPER

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

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Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Concomitant Medications

Subject Group - CHILDREN

Drug Name	Dose	Frequency	Route	Start Date and Time	End Date and Time	Indication	Sess No	Regimen Date and Time of First Dose of Regimen
Subject : 00504								
ADVIL 20MG UID	200MG 25JAN2001:19:30	SD	PO	31JAN2001:08:30	31JAN2001	HEADACHE	2	BRL29060
ADVIL 20MG UID	200MG 25JAN2001:19:30	SD	PO	06FEB2001:19:15	07FEB2001	TEETH ACHING	2	BRL29060
Subject : 00604								
ALLEGRA 10MG UID	60MG 13FEB2001:09:50	OD	PO	14FEB2001:21:00	03MAR2001:21:00	SEASONAL ALLERGIES	1	BRL29060
Subject : 00702								
ROBITUSSIN DM 20MG UID	2TSP 13FEB2001:08:45	PRN	PO	25FEB2001:20:10	25FEB2001:20:11	COUGH	2	BRL29060
GUAIFENESIN 20MG UID	150MG 13FEB2001:08:45	PRN	PO	26FEB2001:15:10	11MAR2001:23:00	COUGH	2	BRL29060
ROBITUSSIN DM 20MG UID	2TSP 13FEB2001:08:45	PRN	PO	26FEB2001:17:00	26FEB2001:22:00	COUGH	2	BRL29060
ZITHROMAX 20MG	100MG 13MAR2001:10:00	OD	PO	14MAR2001	19MAR2001	COUGH, COLD, ENLARGED TONSILS	4	BRL29060 UID-TAPER
FLONASE 20MG	1PUFF 13MAR2001:10:00	OD	IH	16MAR2001	16MAR2001	ASTHMA	4	BRL29060 UID-TAPER

CHILDRENS 150MG TID PO 16MAR2001 16MAR2001 HEADACHE 4 BRL29060
20MG 13MAR2001:10:00
MOTRIN UID-TAPER

Subject : 00704

MAALOX 1000MG SD PO 08MAR2001:08:45 08MAR2001:08:45 DIARRHEA 1 BRL29060
10MG UID 08MAR2001:08:00
(QUICK 1 TAB
DISSOLVE)
CHILDRENS 2TSPS SD PO 12MAR2001:07:40 12MAR2001:07:40 COLD 1 BRL29060
10MG UID 08MAR2001:08:00
SUDAFED

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

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Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Concomitant Medications

Subject Group - CHILDREN

Drug Name	Dose	Frequency	Route	Start Date and Time	End Date and Time	Indication	Sess No	Regimen	Date and Time of First Dose of Regimen
Subject : 00705									
SUPHEDRINE	30MG	SD	PO	09MAY2001:09:15	09MAY2001	NASAL CONGESTION	3	BRL29060 30MG UID	02MAY2001:08:50
Subject : 00707									
TYLENOL (CHILDRENS)	80MG	OD	PO	15APR2001:14:00	15APR2001:14:00	ARM PAIN AFTER FALL	1	BRL29060 10MG UID	05APR2001:08:00
Subject : 00709									
PAXIL	20MG	OD	PO	11AUG2001	Continuing	DEPRESSION	4	BRL29060 UID-TAPER 20MG	03AUG2001:10:00
Subject : 00806									
ROBITUSSIN	UNK	TID	PO	05DEC2000:14:00	15DEC2000:07:00	COUGH AND CONGESTION	2	BRL29060 20MG UID	01DEC2000:07:25
AUGMENTIN	500MG	TID	PO	05DEC2000:14:00	15DEC2000:07:00	EAR INFECTION	2	BRL29060 20MG UID	01DEC2000:07:25

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

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Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Concomitant Medications

Subject Group - ADOLESCENTS

Drug Name	Dose	Frequency	Route	Start Date and Time	End Date and Time	Indication	Sess No	Regimen Date and Time of First Dose of Regimen
Subject : 00002								
IBUPROFEN 10MG UID	200MG	BID	PO	20NOV2000:17:00	21NOV2000:17:00	KNEE STRAIN	1	BRL29060 16NOV2000:08:30
ELOCON 10MG UID	1APP	OD	TO	27NOV2000:22:00	28NOV2000:18:00	BACK RASH	1	BRL29060 16NOV2000:08:30
Subject : 00003								
ALKA-SELTZER PLUS 30MG UID	2TABS	QPM	PO	08JAN2001	09JAN2001	RUNNY NOSE + CONGESTION	3	BRL29060 27DEC2000:09:32
Subject : 00103								
ADVIL 30MG UID	400MG	SD	PO	09JAN2001:08:30	09JAN2001:08:30	HEADACHE	3	BRL29060 30DEC2000:10:27
TYLENOL 30MG UID	1000MG	SD	PO	09JAN2001:13:00	09JAN2001:13:00	HEADACHE	3	BRL29060 30DEC2000:10:27
Subject : 00401								
MELATONIN 10MG UID	3MG	OD	PO	26OCT2000:21:00	29OCT2000:20:00	INSOMNIA	1	BRL29060 25OCT2000:12:30
Subject : 00502								

ADVIL 10MG UID	400MG 23OCT2000:10:30	PRN	PO	07NOV2000:07:00	07NOV2000	HEADACHE	1	BRL29060
MOTRIN 20MG UID	600MG 07NOV2000:18:30	OD	PO	20NOV2000:17:30	20NOV2000:17:30	HEADACHE	2	BRL29060

Subject : 00503

ASPIRIN 30MG UID	650MG 16DEC2000:18:20	PRN	PO	28DEC2000:17:00	28DEC2000:23:31	HEADACHE	3	BRL29060
CODEINE 20MG	2TABS 28DEC2000:17:30	QID	PO	01JAN2001:13:30	04JAN2001	EAR INFECTION	4	BRL29060
		PRN						UID-TAPER

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

[OMED023:LIS]
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Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Concomitant Medications

Subject Group - ADOLESCENTS

Drug Name	Dose	Frequency	Route	Start Date and Time	End Date and Time	Indication	Sess No	Regimen Date and Time of First Dose of Regimen
Subject : 00503								
SUDAFED 12 HOUR	120MG	BID	PO	01JAN2001:13:30	10JAN2001	EAR INFECTION	4	BRL29060 UID-TAPER 20MG 28DEC2000:17:30
AMOXICILLIN 20MG	500MG	TID	PO	01JAN2001:13:30	11JAN2001	EAR INFECTION	4	BRL29060 UID-TAPER 20MG 28DEC2000:17:30
Subject : 00506								
NAPROXEN SODIUM	220MG	OD	PO	07MAR2001:15:55	08MAR2001	HEADACHE	2	BRL29060 20MG UID 25FEB2001:07:05
Subject : 00507								
TUSSIN	2TSP	BID	PO	07FEB2001:20:00	10FEB2001:22:30	UPPER RESPIRATORY INFECTION		No dose given Pre-trial
Subject : 00510								
ALEVE	220MG	X1	PO	26MAR2001:02:00	26MAR2001:02:00	HEADACHE	2	BRL29060 20MG UID 17MAR2001:18:14
TYLENOL COLD	1TAB	X1	PO	31MAR2001:16:45	31MAR2001:16:45	UPPER	2	BRL29060 20MG UID 17MAR2001:18:14

AND SINUS RESPIRATORY INFECTION

Subject : 00605

IBUPROFEN 20MG UID	200MG 28FEB2001:07:00	PRN	PO	11MAR2001:18:00	11MAR2001:18:00	HEADACHE	2	BRL29060
ADVIL 20MG	400MG 28MAR2001:09:15	PRN	PO	03APR2001:16:00	03APR2001:20:30	PAIN	4	BRL29060 UID-TAPER

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

[OMED023:LIS]
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Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Concomitant Medications

Subject Group - ADOLESCENTS

Drug Name	Dose	Frequency	Route	Start Date and Time	End Date and Time	Indication	Sess No	Regimen Date and Time of First Dose of Regimen
Subject : 00606								
NIGHT TIME 20MG UID COLD/FLU MEDICATION {UNKNOWN INGREDIENTS}	120MG	PRN	PO	15MAR2001:21:00	16MAR2001:23:35	COUGH	2	BRL29060 07MAR2001:06:45
Subject : 00607								
VALERIAN given	400MG	OD	PO	21FEB2001:06:30	02MAR2001:07:12	MENSTRUAL CRAMPS		No dose Pre-trial
WOMEN'S 30MG UID TYLENOL	2CAPS	OD	PO	28MAR2001:15:08	28MAR2001:15:08	CRAMPS	3	BRL29060 22MAR2001:06:55
DRAMAMINE 20MG	100MG	OD	PO	06APR2001:10:00	06APR2001:10:00	MOTION SICKNESS	4	BRL29060 UID-TAPER 05APR2001:07:00
DRAMAMINE 10MG	100MG	OD	PO	12APR2001:14:30	12APR2001:14:30	MOTION SICKNESS	5	BRL29060 UID-TAPER 12APR2001:06:00
PAXIL 10MG	10MG	OD	PO	25APR2001:00:00	28APR2001:23:59	DEPRESSION	5	BRL29060 UID-TAPER 12APR2001:06:00
PAXIL 10MG	20MG	OD	PO	29APR2001:00:00	Continuing	DEPRESSION	5	BRL29060 UID-TAPER 12APR2001:06:00

Subject : 00703

HYDROCORTISO- 0.05% OD TO 13MAR2001:22:00 Continuing RASH 1 BRL29060
10MG UID 08MAR2001:11:30
NE CREAM

Subject : 00805

ACETAMINOPHEN 500MG SD PO 02DEC2000:01:19 02DEC2000:01:19 LEG ACHE 2 BRL29060
20MG UID 01DEC2000:07:45

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

[OMED023:LIS]
[02JAN2002:13:37]

Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Concomitant Medications

Subject Group - ADOLESCENTS

Drug Name	Dose	Frequency	Route	Start Date and Time	End Date and Time	Indication	Sess No	Regimen Date and Time of First Dose of Regimen
Subject : 00805								
IBUPROFEN 20MG UID	400MG	SD	PO	09DEC2000:23:05	09DEC2000:23:05	LEG ACHE	2	BRL29060 01DEC2000:07:45
ACETAMINOPHEN 20MG UID	500MG	SD	PO	10DEC2000:16:30	10DEC2000:16:30	LEG ACHE	2	BRL29060 01DEC2000:07:45
EXTRA STRENGTH TYLENOL 30MG UID	500MG	SD	PO	15DEC2000:17:45	15DEC2000:17:45	LEG ACHE	3	BRL29060 15DEC2000:07:43
EXTRA STRENGTH TYLENOL 30MG UID	500MG	SD	PO	17DEC2000:22:08	17DEC2000:22:08	LEG ACHE	3	BRL29060 15DEC2000:07:43
EXTRA STRENGTH TYLENOL 30MG UID	1000MG	SD	PO	23DEC2000:22:08	23DEC2000:22:08	HEADACHE	3	BRL29060 15DEC2000:07:43
Subject : 00809								
IBUPROFEN 10MG UID	1000MG	SD	PO	11DEC2000:00:30	11DEC2000:00:30	HEADACHE	1	BRL29060 08DEC2000:08:51
Subject : 00811								
IBUPROFEN 10MG UID	200MG	SD	PO	14JAN2001:11:15	14JAN2001:11:15	HEADACHE	1	BRL29060 09JAN2001:09:18

PEPTOBISMOL 10MG UID	1TBS 09JAN2001:09:18	SD	PO	20JAN2001:10:12	20JAN2001:10:12	STOMACH ACHE	1	BRL29060
EMLA 10MG UID	2.5GMS 09JAN2001:09:18	SD	TO	23JAN2001	23JAN2001	IV INSERTION	1	BRL29060
PEPTOBISMOL 20MG UID	262MG 24JAN2001:07:32	SD	PO	27JAN2001:17:15	27JAN2001:17:15	STOMACH ACHE	2	BRL29060
PEPTOBISMOL 20MG UID	1TBS 24JAN2001:07:32	SD	PO	30JAN2001:08:45	30JAN2001:08:45	STOMACH ACHE	2	BRL29060
IBUPROFEN 20MG UID	200MG 24JAN2001:07:32	SD	PO	02FEB2001:06:34	02FEB2001:06:34	HEADACHE	2	BRL29060
PEPTOBISMOL 20MG	15ML 21FEB2001:08:00	SD	PO	26FEB2001:13:07	26FEB2001:13:07	STOMACH ACHE	4	BRL29060 UID-TAPER
PEPTOBISMOL 20MG	1TBS 21FEB2001:08:00	SD	PO	01MAR2001:07:02	01MAR2001:07:02	STOMACH ACHE	4	BRL29060 UID-TAPER

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

[OMED023:LIS]
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Table DS4

OTHER MEDICATION DATA OF STUDY SB29060/715 - Concomitant Medications

Subject Group - ADOLESCENTS

Drug Name	Dose	Frequency	Route	Start Date and Time	End Date and Time	Indication	Sess No	Regimen Date and Time of First Dose of Regimen
Subject : 00816								
TYLENOL 10MG UID	1000MG	SD	PO	18FEB2001:22:00	18FEB2001:22:00	CHEST PAIN AND HEADACHE	1	BRL29060 06FEB2001:09:10
TYLENOL 20MG UID	1000MG	SD	PO	01MAR2001	01MAR2001	CRAMPS AND HEADACHE	2	BRL29060 21FEB2001:10:20
TYLENOL 20MG UID	1000MG	SD	PO	05MAR2001	05MAR2001	CRAMPS AND HEADACHE	2	BRL29060 21FEB2001:10:20
SUDAFED 20MG UID	UNK	PRN	PO	07MAR2001:01:00	12MAR2001:07:00	RESPIRATORY INFECTION	2	BRL29060 21FEB2001:10:20
Subject : 00824								
TYLENOL 20MG UID	1000MG	SD	PO	11APR2001:21:30	11APR2001:21:30	HEADACHE	2	BRL29060 07APR2001:08:40
Subject : 00825								
TYLENOL SINUS 10MG UID	500MG	PRN	PO	26MAR2001:11:45	01APR2001	SINUS TROUBLE	1	BRL29060 21MAR2001:15:25

Route : IH = Inhalation, IM = Intramuscular, NA = Nasal, OU = Both Eyes, PO = Oral, TD = Transdermal, TO = Topical
Frequency : 3X = Three times daily, BID = Twice a day, NOCTE = At bed time, OD = Every day, PRN = When required,
QAM = Every morning, QD = Every day, QID = Four times a day, QPM = Every night, SD = Single dose,
TID = Three times a day, UID = Once a day, X1 = Single dose
. = No data available

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Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00001	23OCT00	08:20	BRL29060 10mg
	24OCT00	06:30	BRL29060 10mg
	25OCT00	06:30	BRL29060 10mg
	26OCT00	06:30	BRL29060 10mg
	27OCT00	06:30	BRL29060 10mg
	28OCT00	06:30	BRL29060 10mg
	29OCT00	06:30	BRL29060 10mg
	30OCT00	06:30	BRL29060 10mg
	31OCT00	06:30	BRL29060 10mg
	01NOV00	06:30	BRL29060 10mg
	02NOV00	06:30	BRL29060 10mg
	03NOV00	07:00	BRL29060 10mg
	04NOV00	07:00	BRL29060 10mg
	05NOV00	07:00	BRL29060 10mg
	06NOV00	08:50	BRL29060 10mg
	07NOV00	08:00	BRL29060 20mg
	08NOV00	06:45	BRL29060 20mg
	09NOV00	06:30	BRL29060 20mg
	10NOV00	06:35	BRL29060 20mg
	11NOV00	07:45	BRL29060 20mg
	12NOV00	08:15	BRL29060 20mg
	13NOV00	06:30	BRL29060 20mg
	15NOV00	06:30	BRL29060 10mg
	16NOV00	06:55	BRL29060 10mg
	16NOV00	10:20	BRL29060 10mg
	17NOV00	06:55	BRL29060 20mg
	18NOV00	06:00	BRL29060 20mg
	19NOV00	08:15	BRL29060 20mg
	20NOV00	08:26	BRL29060 20mg
	21NOV00	08:58	BRL29060 30mg
	22NOV00	06:45	BRL29060 30mg
	23NOV00	08:00	BRL29060 30mg
	24NOV00	06:30	BRL29060 30mg
	25NOV00	08:15	BRL29060 30mg
	26NOV00	07:30	BRL29060 30mg
	27NOV00	06:30	BRL29060 30mg
	28NOV00	06:45	BRL29060 30mg
	29NOV00	06:50	BRL29060 30mg
	30NOV00	06:30	BRL29060 30mg
	01DEC00	06:50	BRL29060 30mg
	02DEC00	08:10	BRL29060 30mg
	03DEC00	09:00	BRL29060 30mg
	04DEC00	08:29	BRL29060 30mg
	05DEC00	07:57	BRL29060 30mg
00053	13MAR01	10:00	BRL29060 10mg
	14MAR01	08:30	BRL29060 10mg

15MAR01	08:30	BRL29060 10mg
16MAR01	08:30	BRL29060 10mg
17MAR01	08:30	BRL29060 10mg
18MAR01	08:30	BRL29060 10mg
19MAR01	08:30	BRL29060 10mg
20MAR01	08:30	BRL29060 10mg
21MAR01	08:30	BRL29060 10mg
22MAR01	08:30	BRL29060 10mg
23MAR01	08:30	BRL29060 10mg
24MAR01	08:30	BRL29060 10mg
25MAR01	08:30	BRL29060 10mg
26MAR01	07:50	BRL29060 10mg
27MAR01	09:30	BRL29060 20mg
28MAR01	08:00	BRL29060 20mg
29MAR01	08:00	BRL29060 20mg
30MAR01	08:00	BRL29060 20mg
31MAR01	08:00	BRL29060 20mg
01APR01	08:00	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00053	02APR01	08:00	BRL29060 20mg
	03APR01	08:00	BRL29060 20mg
	04APR01	08:00	BRL29060 20mg
	05APR01	08:00	BRL29060 20mg
	06APR01	08:00	BRL29060 20mg
	07APR01	08:00	BRL29060 20mg
	08APR01	08:00	BRL29060 20mg
	09APR01	08:45	BRL29060 20mg
	10APR01	09:05	BRL29060 30mg
	11APR01	08:00	BRL29060 30mg
	12APR01	08:00	BRL29060 30mg
	13APR01	08:00	BRL29060 30mg
	14APR01	08:00	BRL29060 30mg
	15APR01	08:00	BRL29060 30mg
	16APR01	08:00	BRL29060 30mg
	17APR01	08:00	BRL29060 30mg
	18APR01	08:00	BRL29060 30mg
	19APR01	08:00	BRL29060 30mg
	20APR01	08:00	BRL29060 30mg
	21APR01	08:00	BRL29060 30mg
	22APR01	08:00	BRL29060 30mg
	23APR01	09:10	BRL29060 30mg
00055	20APR01	07:00	BRL29060 10mg
	21APR01	07:15	BRL29060 10mg
	22APR01	08:30	BRL29060 10mg
	23APR01	07:15	BRL29060 10mg
	24APR01	07:10	BRL29060 10mg
	25APR01	06:30	BRL29060 10mg
	26APR01	06:30	BRL29060 10mg
	27APR01	06:45	BRL29060 10mg
	28APR01	08:30	BRL29060 10mg
	29APR01	08:30	BRL29060 10mg
	30APR01	06:30	BRL29060 10mg
	01MAY01	06:30	BRL29060 10mg
	02MAY01	06:30	BRL29060 10mg
	03MAY01	08:45	BRL29060 10mg
	04MAY01	06:00	BRL29060 20mg
	05MAY01	07:30	BRL29060 20mg
	06MAY01	07:50	BRL29060 20mg
	07MAY01	06:05	BRL29060 20mg
	08MAY01	06:04	BRL29060 20mg
	09MAY01	06:09	BRL29060 20mg
	10MAY01	06:00	BRL29060 20mg
	11MAY01	06:07	BRL29060 20mg
	12MAY01	10:00	BRL29060 20mg
	13MAY01	11:00	BRL29060 20mg

14MAY01	06:05	BRL29060 20mg
15MAY01	06:09	BRL29060 20mg
16MAY01	06:00	BRL29060 20mg
17MAY01	07:55	BRL29060 20mg
18MAY01	09:30	BRL29060 30mg
19MAY01	10:30	BRL29060 30mg
20MAY01	08:45	BRL29060 30mg
21MAY01	06:05	BRL29060 30mg
22MAY01	06:05	BRL29060 30mg
23MAY01	06:05	BRL29060 30mg
24MAY01	06:10	BRL29060 30mg
25MAY01	07:20	BRL29060 30mg
26MAY01	08:20	BRL29060 30mg
27MAY01	13:30	BRL29060 30mg
28MAY01	06:05	BRL29060 30mg
29MAY01	06:20	BRL29060 30mg
30MAY01	06:20	BRL29060 30mg
31MAY01	08:45	BRL29060 30mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00055	01JUN01	09:15	BRL29060 20mg
	02JUN01	10:00	BRL29060 20mg
	03JUN01	11:00	BRL29060 20mg
	04JUN01	10:00	BRL29060 20mg
	05JUN01	10:00	BRL29060 20mg
	06JUN01	10:00	BRL29060 20mg
	07JUN01	06:30	BRL29060 20mg
00101	02NOV00	09:55	BRL29060 10mg
	03NOV00	08:00	BRL29060 10mg
	04NOV00	08:30	BRL29060 10mg
	05NOV00	08:40	BRL29060 10mg
	06NOV00	08:31	BRL29060 10mg
	07NOV00	08:30	BRL29060 10mg
	08NOV00	08:30	BRL29060 10mg
	09NOV00	08:30	BRL29060 10mg
	10NOV00	08:30	BRL29060 10mg
	11NOV00	12:30	BRL29060 10mg
	12NOV00	08:30	BRL29060 10mg
	13NOV00	08:30	BRL29060 10mg
	14NOV00	08:30	BRL29060 10mg
	15NOV00	08:30	BRL29060 10mg
	16NOV00	10:40	BRL29060 10mg
	17NOV00	12:00	BRL29060 20mg
	18NOV00	08:30	BRL29060 20mg
	19NOV00	08:30	BRL29060 20mg
	20NOV00	08:20	BRL29060 20mg
	21NOV00	08:30	BRL29060 20mg
	22NOV00	08:45	BRL29060 20mg
	23NOV00	09:40	BRL29060 20mg
	24NOV00	09:20	BRL29060 20mg
	25NOV00	08:30	BRL29060 20mg
	26NOV00	08:30	BRL29060 20mg
	27NOV00	08:20	BRL29060 20mg
	28NOV00	08:30	BRL29060 20mg
	29NOV00	08:20	BRL29060 20mg
	30NOV00	09:56	BRL29060 20mg
	01DEC00	10:30	BRL29060 30mg
	02DEC00	08:30	BRL29060 30mg
	03DEC00	14:30	BRL29060 30mg
	04DEC00	08:20	BRL29060 30mg
	05DEC00	08:30	BRL29060 30mg
	06DEC00	08:35	BRL29060 30mg
	07DEC00	08:30	BRL29060 30mg
	08DEC00	08:35	BRL29060 30mg
	09DEC00	09:05	BRL29060 30mg
	10DEC00	08:30	BRL29060 30mg

	11DEC00	08:25	BRL29060 30mg
	12DEC00	08:10	BRL29060 30mg
	13DEC00	08:45	BRL29060 30mg
	14DEC00	09:45	BRL29060 30mg
	15DEC00	11:30	BRL29060 30mg
	16DEC00	08:30	BRL29060 30mg
	17DEC00	08:30	BRL29060 30mg
	18DEC00	08:30	BRL29060 30mg
00102	11NOV00	08:30	BRL29060 10mg
	12NOV00	11:23	BRL29060 10mg
	13NOV00	07:00	BRL29060 10mg
	14NOV00	07:00	BRL29060 10mg
	15NOV00	07:00	BRL29060 10mg
	16NOV00	07:30	BRL29060 10mg
	17NOV00	07:00	BRL29060 10mg
	18NOV00	08:30	BRL29060 10mg
	19NOV00	08:30	BRL29060 10mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00102	20NOV00	07:00	BRL29060 10mg
	21NOV00	07:00	BRL29060 10mg
	22NOV00	07:00	BRL29060 10mg
	23NOV00	09:00	BRL29060 10mg
	24NOV00	10:18	BRL29060 10mg
	25NOV00	10:15	BRL29060 20mg
	26NOV00	08:00	BRL29060 20mg
	27NOV00	07:30	BRL29060 20mg
	28NOV00	07:30	BRL29060 20mg
	29NOV00	07:30	BRL29060 20mg
	30NOV00	07:30	BRL29060 20mg
	01DEC00	07:30	BRL29060 20mg
	02DEC00	09:00	BRL29060 20mg
	03DEC00	09:00	BRL29060 20mg
	04DEC00	07:30	BRL29060 20mg
	05DEC00	07:30	BRL29060 20mg
	06DEC00	07:30	BRL29060 20mg
	07DEC00	07:30	BRL29060 20mg
	08DEC00	07:30	BRL29060 20mg
	09DEC00	09:03	BRL29060 20mg
	10DEC00	07:15	BRL29060 30mg
	11DEC00	07:24	BRL29060 30mg
	12DEC00	07:31	BRL29060 30mg
	13DEC00	07:04	BRL29060 30mg
	14DEC00	07:40	BRL29060 30mg
	15DEC00	08:00	BRL29060 30mg
	16DEC00	08:00	BRL29060 30mg
	17DEC00	08:10	BRL29060 30mg
	18DEC00	07:15	BRL29060 30mg
	19DEC00	07:14	BRL29060 30mg
	20DEC00	07:30	BRL29060 30mg
	21DEC00	07:30	BRL29060 30mg
	22DEC00	10:00	BRL29060 30mg
	23DEC00	10:05	BRL29060 20mg
	24DEC00	10:05	BRL29060 20mg
	25DEC00	10:05	BRL29060 20mg
	26DEC00	10:05	BRL29060 20mg
	27DEC00	10:05	BRL29060 20mg
	28DEC00	10:05	BRL29060 20mg
	29DEC00	10:05	BRL29060 20mg
	30DEC00	10:05	BRL29060 20mg
	31DEC00	10:05	BRL29060 20mg
	01JAN01	10:05	BRL29060 20mg
	02JAN01	07:30	BRL29060 10mg
	03JAN01	07:30	BRL29060 10mg
	04JAN01	07:30	BRL29060 10mg
	05JAN01	07:30	BRL29060 10mg

	06JAN01	07:30	BRL29060 10mg
	07JAN01	07:30	BRL29060 10mg
	08JAN01	07:30	BRL29060 10mg
00104	15DEC00	14:10	BRL29060 10mg
	16DEC00	09:04	BRL29060 10mg
	17DEC00	09:14	BRL29060 10mg
	18DEC00	08:34	BRL29060 10mg
	19DEC00	09:54	BRL29060 10mg
	20DEC00	09:24	BRL29060 10mg
	21DEC00	09:02	BRL29060 10mg
	22DEC00	09:06	BRL29060 10mg
	23DEC00	08:51	BRL29060 10mg
	24DEC00	08:31	BRL29060 10mg
	25DEC00	08:00	BRL29060 10mg
	26DEC00	10:06	BRL29060 10mg
	27DEC00	10:36	BRL29060 10mg
	28DEC00	09:45	BRL29060 10mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00104	29DEC00	09:50	BRL29060 20mg
	30DEC00	10:23	BRL29060 20mg
	31DEC00	09:34	BRL29060 20mg
	01JAN01	10:10	BRL29060 20mg
	02JAN01	06:35	BRL29060 20mg
	03JAN01	06:37	BRL29060 20mg
	04JAN01	06:34	BRL29060 20mg
	05JAN01	06:48	BRL29060 20mg
	07JAN01	10:11	BRL29060 20mg
	08JAN01	06:37	BRL29060 20mg
	09JAN01	06:41	BRL29060 20mg
	10JAN01	06:32	BRL29060 20mg
	11JAN01	08:30	BRL29060 20mg
	12JAN01	08:33	BRL29060 30mg
	13JAN01	08:23	BRL29060 30mg
	14JAN01	09:05	BRL29060 30mg
	15JAN01	08:47	BRL29060 30mg
	16JAN01	06:44	BRL29060 30mg
	17JAN01	10:06	BRL29060 30mg
	18JAN01	08:55	BRL29060 30mg
	19JAN01	10:04	BRL29060 30mg
	20JAN01	06:44	BRL29060 30mg
	21JAN01	06:46	BRL29060 30mg
	22JAN01	06:36	BRL29060 30mg
	23JAN01	06:21	BRL29060 30mg
	24JAN01	06:39	BRL29060 30mg
	25JAN01	08:40	BRL29060 30mg
	26JAN01	08:45	BRL29060 20mg
	27JAN01	08:53	BRL29060 20mg
	28JAN01	08:24	BRL29060 20mg
	29JAN01	06:51	BRL29060 20mg
	30JAN01	06:49	BRL29060 20mg
	31JAN01	06:38	BRL29060 20mg
	01FEB01	06:48	BRL29060 20mg
00106	25JAN01	09:20	BRL29060 10mg
	26JAN01	08:40	BRL29060 10mg
	27JAN01	09:00	BRL29060 10mg
	28JAN01	09:00	BRL29060 10mg
	29JAN01	08:30	BRL29060 10mg
	30JAN01	08:30	BRL29060 10mg
	31JAN01	08:30	BRL29060 10mg
	01FEB01	08:30	BRL29060 10mg
	02FEB01	08:30	BRL29060 10mg
	03FEB01	09:00	BRL29060 10mg
	04FEB01	09:30	BRL29060 10mg
	05FEB01	08:30	BRL29060 10mg

06FEB01	08:30	BRL29060 10mg
07FEB01	08:30	BRL29060 10mg
08FEB01	10:40	BRL29060 10mg
09FEB01	11:00	BRL29060 20mg
10FEB01	09:00	BRL29060 20mg
11FEB01	09:30	BRL29060 20mg
12FEB01	08:15	BRL29060 20mg
13FEB01	08:20	BRL29060 20mg
14FEB01	08:20	BRL29060 20mg
15FEB01	08:15	BRL29060 20mg
16FEB01	08:20	BRL29060 20mg
17FEB01	09:00	BRL29060 20mg
18FEB01	09:00	BRL29060 20mg
19FEB01	09:00	BRL29060 20mg
20FEB01	08:20	BRL29060 20mg
21FEB01	08:20	BRL29060 20mg
22FEB01	08:20	BRL29060 20mg
23FEB01	09:30	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00106	24FEB01	10:00	BRL29060 30mg
	25FEB01	09:00	BRL29060 30mg
	26FEB01	08:30	BRL29060 30mg
	27FEB01	08:30	BRL29060 30mg
	28FEB01	08:20	BRL29060 30mg
	01MAR01	08:30	BRL29060 30mg
	02MAR01	08:30	BRL29060 30mg
	03MAR01	09:00	BRL29060 30mg
	04MAR01	08:30	BRL29060 30mg
	05MAR01	08:30	BRL29060 30mg
	06MAR01	09:00	BRL29060 30mg
	07MAR01	08:30	BRL29060 30mg
	08MAR01	08:30	BRL29060 30mg
	09MAR01	10:15	BRL29060 30mg
	10MAR01	10:30	BRL29060 20mg
	11MAR01	10:30	BRL29060 20mg
	12MAR01	10:30	BRL29060 20mg
00107	01MAR01	09:17	BRL29060 10mg
	02MAR01	06:27	BRL29060 10mg
	04MAR01	07:30	BRL29060 10mg
	05MAR01	07:30	BRL29060 10mg
	06MAR01	07:00	BRL29060 10mg
	07MAR01	07:05	BRL29060 10mg
	08MAR01	06:50	BRL29060 10mg
	09MAR01	07:00	BRL29060 10mg
	10MAR01	09:40	BRL29060 10mg
	11MAR01	09:20	BRL29060 10mg
	12MAR01	07:00	BRL29060 10mg
	13MAR01	07:10	BRL29060 10mg
	14MAR01	07:30	BRL29060 10mg
	15MAR01	07:00	BRL29060 10mg
	16MAR01	11:10	BRL29060 10mg
	17MAR01	11:31	BRL29060 20mg
	18MAR01	09:06	BRL29060 20mg
	19MAR01	07:00	BRL29060 20mg
	20MAR01	06:50	BRL29060 20mg
	21MAR01	07:20	BRL29060 20mg
	22MAR01	07:10	BRL29060 20mg
	23MAR01	06:50	BRL29060 20mg
	24MAR01	09:15	BRL29060 20mg
	25MAR01	07:00	BRL29060 20mg
	26MAR01	07:20	BRL29060 20mg
	27MAR01	07:10	BRL29060 20mg
	28MAR01	07:00	BRL29060 20mg
	29MAR01	11:10	BRL29060 20mg
	30MAR01	11:35	BRL29060 30mg

31MAR01	11:35	BRL29060 30mg
01APR01	11:35	BRL29060 30mg
02APR01	11:35	BRL29060 30mg
03APR01	11:35	BRL29060 30mg
04APR01	11:35	BRL29060 30mg
05APR01	11:35	BRL29060 30mg
06APR01	11:35	BRL29060 30mg
07APR01	11:35	BRL29060 30mg
08APR01	11:35	BRL29060 30mg
09APR01	11:35	BRL29060 30mg
10APR01	11:35	BRL29060 30mg
11APR01	11:35	BRL29060 30mg
12APR01	11:35	BRL29060 30mg
13APR01	10:59	BRL29060 30mg
14APR01	11:20	BRL29060 20mg
15APR01	11:35	BRL29060 20mg
16APR01	11:35	BRL29060 20mg
17APR01	11:35	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00107	18APR01	11:35	BRL29060 20mg
	19APR01	11:35	BRL29060 20mg
	20APR01	11:35	BRL29060 20mg
	21APR01	07:00	BRL29060 10mg
	22APR01	07:10	BRL29060 10mg
	23APR01	07:15	BRL29060 10mg
	24APR01	07:00	BRL29060 10mg
	25APR01	07:00	BRL29060 10mg
	26APR01	07:34	BRL29060 10mg
	27APR01	07:40	BRL29060 10mg
00108	28FEB01	15:45	BRL29060 10mg
	01MAR01	16:00	BRL29060 10mg
	02MAR01	16:10	BRL29060 10mg
	03MAR01	16:45	BRL29060 10mg
	04MAR01	16:45	BRL29060 10mg
	05MAR01	16:45	BRL29060 10mg
	06MAR01	17:00	BRL29060 10mg
	07MAR01	17:30	BRL29060 10mg
	08MAR01	16:20	BRL29060 10mg
	09MAR01	16:20	BRL29060 10mg
	10MAR01	16:30	BRL29060 10mg
	11MAR01	16:30	BRL29060 10mg
	12MAR01	16:20	BRL29060 10mg
	13MAR01	17:30	BRL29060 10mg
	14MAR01	18:24	BRL29060 10mg
	15MAR01	18:00	BRL29060 20mg
	16MAR01	16:15	BRL29060 20mg
	17MAR01	17:20	BRL29060 20mg
	18MAR01	17:00	BRL29060 20mg
	19MAR01	17:30	BRL29060 20mg
	20MAR01	17:00	BRL29060 20mg
	21MAR01	17:30	BRL29060 20mg
	22MAR01	16:30	BRL29060 20mg
	23MAR01	16:30	BRL29060 20mg
	24MAR01	17:45	BRL29060 20mg
	25MAR01	16:45	BRL29060 20mg
	26MAR01	16:30	BRL29060 20mg
	27MAR01	17:00	BRL29060 20mg
	28MAR01	18:10	BRL29060 20mg
	29MAR01	18:30	BRL29060 30mg
	30MAR01	18:00	BRL29060 30mg
	31MAR01	17:00	BRL29060 30mg
	01APR01	17:00	BRL29060 30mg
	02APR01	16:00	BRL29060 30mg
	03APR01	16:30	BRL29060 30mg
	04APR01	18:00	BRL29060 30mg

	05APR01	17:00	BRL29060 30mg
	06APR01	16:30	BRL29060 30mg
	07APR01	16:00	BRL29060 30mg
	08APR01	16:30	BRL29060 30mg
	09APR01	16:15	BRL29060 30mg
	10APR01	18:00	BRL29060 30mg
	11APR01	17:52	BRL29060 30mg
00110	13MAR01	09:50	BRL29060 10mg
	14MAR01	08:43	BRL29060 10mg
	15MAR01	08:52	BRL29060 10mg
	16MAR01	08:43	BRL29060 10mg
	17MAR01	09:30	BRL29060 10mg
	18MAR01	10:05	BRL29060 10mg
	19MAR01	08:52	BRL29060 10mg
	20MAR01	08:47	BRL29060 10mg
	21MAR01	08:42	BRL29060 10mg
	22MAR01	08:48	BRL29060 10mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00110	23MAR01	08:50	BRL29060 10mg
	24MAR01	10:02	BRL29060 10mg
	25MAR01	10:35	BRL29060 10mg
	27MAR01	10:19	BRL29060 10mg
	28MAR01	10:51	BRL29060 20mg
	29MAR01	08:50	BRL29060 20mg
	30MAR01	08:53	BRL29060 20mg
	31MAR01	10:01	BRL29060 20mg
	01APR01	10:15	BRL29060 20mg
	02APR01	08:48	BRL29060 20mg
	03APR01	08:47	BRL29060 20mg
	04APR01	08:47	BRL29060 20mg
	05APR01	08:46	BRL29060 20mg
	06APR01	08:43	BRL29060 20mg
	07APR01	10:01	BRL29060 20mg
	08APR01	09:35	BRL29060 20mg
	09APR01	08:42	BRL29060 20mg
	10APR01	11:11	BRL29060 20mg
	11APR01	11:57	BRL29060 30mg
	12APR01	02:00	BRL29060 30mg
	13APR01	11:00	BRL29060 30mg
	15APR01	11:25	BRL29060 30mg
	16APR01	10:40	BRL29060 30mg
	17APR01	10:48	BRL29060 30mg
	18APR01	09:57	BRL29060 30mg
	21APR01	09:45	BRL29060 30mg
	22APR01	09:30	BRL29060 30mg
	23APR01	08:30	BRL29060 30mg
	24APR01	10:20	BRL29060 30mg
00111	22MAR01	09:36	BRL29060 10mg
	23MAR01	08:15	BRL29060 10mg
	24MAR01	08:15	BRL29060 10mg
	25MAR01	12:45	BRL29060 10mg
	26MAR01	09:00	BRL29060 10mg
	27MAR01	08:15	BRL29060 10mg
	28MAR01	08:20	BRL29060 10mg
	29MAR01	08:20	BRL29060 10mg
	30MAR01	08:20	BRL29060 10mg
	31MAR01	12:45	BRL29060 10mg
	01APR01	12:45	BRL29060 10mg
	02APR01	08:20	BRL29060 5mg
	03APR01	08:20	BRL29060 10mg
	04APR01	08:20	BRL29060 10mg
00112	26APR01	09:35	BRL29060 10mg
	27APR01	08:31	BRL29060 10mg

28APR01	09:41	BRL29060 10mg
29APR01	09:32	BRL29060 10mg
30APR01	08:30	BRL29060 10mg
02MAY01	08:39	BRL29060 10mg
03MAY01	08:42	BRL29060 10mg
04MAY01	08:40	BRL29060 10mg
05MAY01	10:01	BRL29060 10mg
06MAY01	09:45	BRL29060 10mg
07MAY01	08:32	BRL29060 10mg
08MAY01	08:32	BRL29060 10mg
09MAY01	10:15	BRL29060 10mg
10MAY01	10:42	BRL29060 20mg
11MAY01	08:41	BRL29060 20mg
12MAY01	10:41	BRL29060 20mg
13MAY01	10:00	BRL29060 20mg
14MAY01	08:41	BRL29060 20mg
15MAY01	08:50	BRL29060 20mg
16MAY01	08:30	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00112	17MAY01	07:18	BRL29060 20mg
	18MAY01	03:38	BRL29060 20mg
	19MAY01	09:30	BRL29060 20mg
	20MAY01	09:20	BRL29060 20mg
	21MAY01	21:30	BRL29060 20mg
	22MAY01	15:30	BRL29060 20mg
	23MAY01	10:00	BRL29060 20mg
	24MAY01	10:35	BRL29060 30mg
	25MAY01	20:10	BRL29060 30mg
	26MAY01	20:00	BRL29060 30mg
	27MAY01	20:30	BRL29060 30mg
	29MAY01	08:00	BRL29060 30mg
	30MAY01	08:30	BRL29060 30mg
	31MAY01	08:28	BRL29060 30mg
	01JUN01	08:30	BRL29060 30mg
	02JUN01	10:00	BRL29060 30mg
	03JUN01	10:05	BRL29060 30mg
	04JUN01	08:31	BRL29060 30mg
	05JUN01	08:30	BRL29060 30mg
	06JUN01	10:46	BRL29060 30mg
	07JUN01	11:30	BRL29060 20mg
	08JUN01	09:10	BRL29060 20mg
	09JUN01	09:53	BRL29060 20mg
	10JUN01	08:55	BRL29060 20mg
	11JUN01	10:01	BRL29060 20mg
	12JUN01	10:00	BRL29060 20mg
	13JUN01	10:31	BRL29060 20mg
	14JUN01	09:00	BRL29060 10mg
	15JUN01	08:30	BRL29060 10mg
	16JUN01	08:50	BRL29060 10mg
	17JUN01	09:45	BRL29060 10mg
	18JUN01	08:30	BRL29060 10mg
00113	29MAY01	10:20	BRL29060 10mg
00202	27FEB01	11:35	BRL29060 10mg
	28FEB01	08:20	BRL29060 10mg
	01MAR01	09:20	BRL29060 10mg
	02MAR01	10:30	BRL29060 10mg
	03MAR01	11:40	BRL29060 10mg
	04MAR01	10:41	BRL29060 10mg
	05MAR01	08:20	BRL29060 10mg
	06MAR01	10:50	BRL29060 10mg
	07MAR01	09:20	BRL29060 10mg
	08MAR01	08:00	BRL29060 10mg
	09MAR01	08:15	BRL29060 10mg
	10MAR01	09:40	BRL29060 10mg

11MAR01	08:50	BRL29060 20mg
12MAR01	08:10	BRL29060 20mg
13MAR01	08:35	BRL29060 20mg
14MAR01	08:10	BRL29060 20mg
15MAR01	08:00	BRL29060 20mg
16MAR01	08:30	BRL29060 20mg
17MAR01	08:20	BRL29060 20mg
18MAR01	08:40	BRL29060 20mg
19MAR01	08:30	BRL29060 20mg
20MAR01	07:20	BRL29060 20mg
21MAR01	07:10	BRL29060 20mg
22MAR01	07:40	BRL29060 20mg
23MAR01	07:45	BRL29060 20mg
24MAR01	09:45	BRL29060 20mg
25MAR01	09:20	BRL29060 30mg
26MAR01	08:00	BRL29060 30mg
27MAR01	07:50	BRL29060 30mg
28MAR01	07:52	BRL29060 30mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00202	29MAR01	07:50	BRL29060 30mg
	30MAR01	07:50	BRL29060 30mg
	31MAR01	09:10	BRL29060 30mg
	01APR01	10:00	BRL29060 30mg
	02APR01	08:10	BRL29060 30mg
	03APR01	08:21	BRL29060 30mg
	04APR01	08:16	BRL29060 30mg
	05APR01	08:10	BRL29060 30mg
	06APR01	08:20	BRL29060 30mg
	07APR01	10:05	BRL29060 30mg
	08APR01	10:25	BRL29060 20mg
	09APR01	10:25	BRL29060 20mg
	10APR01	10:25	BRL29060 20mg
	11APR01	10:25	BRL29060 20mg
	12APR01	10:25	BRL29060 20mg
	13APR01	10:25	BRL29060 20mg
	14APR01	10:25	BRL29060 20mg
	15APR01	10:25	BRL29060 20mg
	16APR01	10:25	BRL29060 20mg
	17APR01	10:25	BRL29060 20mg
	18APR01	10:25	BRL29060 20mg
	19APR01	10:25	BRL29060 20mg
	20APR01	10:25	BRL29060 20mg
	21APR01	10:25	BRL29060 20mg
	22APR01	10:25	BRL29060 20mg
	23APR01	10:25	BRL29060 20mg
	24APR01	10:25	BRL29060 20mg
	25APR01	10:25	BRL29060 20mg
00301	07MAY01	12:00	BRL29060 10mg
	08MAY01	08:10	BRL29060 10mg
	09MAY01	07:30	BRL29060 10mg
	10MAY01	07:10	BRL29060 10mg
	11MAY01	07:45	BRL29060 10mg
	12MAY01	10:00	BRL29060 10mg
	13MAY01	08:00	BRL29060 10mg
	14MAY01	07:30	BRL29060 10mg
	15MAY01	07:30	BRL29060 10mg
	16MAY01	07:10	BRL29060 10mg
	17MAY01	07:45	BRL29060 10mg
	18MAY01	07:30	BRL29060 10mg
	19MAY01	08:10	BRL29060 10mg
	20MAY01	08:15	BRL29060 10mg
	21MAY01	07:55	BRL29060 10mg
	22MAY01	08:15	BRL29060 20mg
	23MAY01	08:15	BRL29060 20mg
	24MAY01	08:15	BRL29060 20mg

	25MAY01	08:15	BRL29060 20mg
	26MAY01	08:15	BRL29060 20mg
	27MAY01	08:15	BRL29060 20mg
	28MAY01	08:15	BRL29060 20mg
	29MAY01	08:15	BRL29060 20mg
	30MAY01	08:15	BRL29060 20mg
	31MAY01	08:15	BRL29060 20mg
	01JUN01	08:15	BRL29060 20mg
	02JUN01	08:15	BRL29060 20mg
	03JUN01	08:15	BRL29060 20mg
	04JUN01	08:15	BRL29060 30mg
	05JUN01	08:15	BRL29060 30mg
00303	09JUL01	11:45	BRL29060 10mg
	10JUL01	09:30	BRL29060 10mg
	11JUL01	09:30	BRL29060 10mg
	12JUL01	09:30	BRL29060 10mg
	13JUL01	09:30	BRL29060 10mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00303	14JUL01	09:40	BRL29060 10mg
	15JUL01	09:30	BRL29060 10mg
	16JUL01	09:22	BRL29060 10mg
	17JUL01	09:30	BRL29060 10mg
	18JUL01	09:30	BRL29060 10mg
	19JUL01	09:30	BRL29060 10mg
	20JUL01	11:30	BRL29060 10mg
	21JUL01	09:30	BRL29060 10mg
	22JUL01	09:30	BRL29060 10mg
	23JUL01	09:30	BRL29060 10mg
	24JUL01	09:30	BRL29060 10mg
	25JUL01	09:30	BRL29060 10mg
	26JUL01	11:00	BRL29060 10mg
	27JUL01	11:00	BRL29060 20mg
	28JUL01	11:00	BRL29060 20mg
	29JUL01	11:30	BRL29060 20mg
	30JUL01	12:00	BRL29060 20mg
	31JUL01	12:00	BRL29060 20mg
	01AUG01	12:00	BRL29060 20mg
	02AUG01	12:00	BRL29060 20mg
	03AUG01	12:30	BRL29060 20mg
	04AUG01	10:30	BRL29060 20mg
	05AUG01	11:00	BRL29060 20mg
	06AUG01	10:00	BRL29060 20mg
	07AUG01	10:00	BRL29060 20mg
	08AUG01	12:35	BRL29060 20mg
	09AUG01	12:45	BRL29060 30mg
	10AUG01	11:00	BRL29060 30mg
	11AUG01	10:45	BRL29060 30mg
	12AUG01	11:00	BRL29060 30mg
	13AUG01	11:30	BRL29060 30mg
	14AUG01	11:45	BRL29060 30mg
	15AUG01	10:35	BRL29060 30mg
	16AUG01	09:30	BRL29060 30mg
	17AUG01	10:00	BRL29060 30mg
	18AUG01	10:00	BRL29060 30mg
	19AUG01	09:30	BRL29060 30mg
	20AUG01	09:45	BRL29060 30mg
	21AUG01	12:45	BRL29060 30mg
	22AUG01	12:30	BRL29060 20mg
	23AUG01	09:30	BRL29060 20mg
	24AUG01	09:30	BRL29060 20mg
	25AUG01	09:30	BRL29060 20mg
	26AUG01	10:30	BRL29060 20mg
	27AUG01	10:30	BRL29060 20mg
	28AUG01	10:30	BRL29060 20mg
	29AUG01	10:30	BRL29060 20mg

	30AUG01	10:30	BRL29060 20mg
	31AUG01	10:30	BRL29060 20mg
	01SEP01	10:30	BRL29060 20mg
	02SEP01	10:30	BRL29060 20mg
	03SEP01	10:30	BRL29060 20mg
	04SEP01	10:30	BRL29060 20mg
	05SEP01	10:30	BRL29060 10mg
	06SEP01	10:30	BRL29060 10mg
	07SEP01	10:30	BRL29060 10mg
	08SEP01	10:30	BRL29060 10mg
	09SEP01	10:30	BRL29060 10mg
	10SEP01	10:30	BRL29060 10mg
	11SEP01	10:30	BRL29060 10mg
00504	10JAN01	19:10	BRL29060 10mg
	11JAN01	17:56	BRL29060 10mg
	12JAN01	17:28	BRL29060 10mg
	13JAN01	19:40	BRL29060 10mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00504	14JAN01	18:00	BRL29060 10mg
	15JAN01	18:05	BRL29060 10mg
	16JAN01	17:58	BRL29060 10mg
	17JAN01	18:35	BRL29060 10mg
	18JAN01	18:05	BRL29060 10mg
	19JAN01	18:10	BRL29060 10mg
	20JAN01	18:00	BRL29060 10mg
	21JAN01	18:30	BRL29060 10mg
	22JAN01	17:45	BRL29060 10mg
	23JAN01	19:40	BRL29060 10mg
	24JAN01	19:30	BRL29060 10mg
	25JAN01	19:30	BRL29060 20mg
	26JAN01	20:13	BRL29060 20mg
	27JAN01	20:30	BRL29060 20mg
	28JAN01	18:00	BRL29060 20mg
	29JAN01	17:45	BRL29060 20mg
	30JAN01	18:13	BRL29060 20mg
	31JAN01	18:00	BRL29060 20mg
	01FEB01	17:47	BRL29060 20mg
	02FEB01	18:00	BRL29060 20mg
	03FEB01	18:00	BRL29060 20mg
	04FEB01	18:03	BRL29060 20mg
	05FEB01	18:15	BRL29060 20mg
	06FEB01	18:30	BRL29060 20mg
	07FEB01	19:45	BRL29060 20mg
	08FEB01	20:25	BRL29060 30mg
	09FEB01	20:00	BRL29060 30mg
	10FEB01	19:30	BRL29060 10mg
	11FEB01	19:30	BRL29060 10mg
	12FEB01	19:30	BRL29060 10mg
	13FEB01	19:30	BRL29060 10mg
	14FEB01	19:30	BRL29060 10mg
	15FEB01	19:30	BRL29060 10mg
	16FEB01	19:30	BRL29060 10mg
	17FEB01	19:30	BRL29060 10mg
	18FEB01	19:30	BRL29060 10mg
	19FEB01	19:30	BRL29060 10mg
	20FEB01	19:30	BRL29060 10mg
	21FEB01	19:30	BRL29060 10mg
	22FEB01	19:30	BRL29060 10mg
00603	21DEC00	10:00	BRL29060 10mg
	22DEC00	07:00	BRL29060 10mg
	23DEC00	10:00	BRL29060 10mg
	24DEC00	07:00	BRL29060 10mg
	25DEC00	07:00	BRL29060 10mg
	26DEC00	07:00	BRL29060 10mg

27DEC00	07:00	BRL29060 10mg
28DEC00	07:30	BRL29060 10mg
29DEC00	07:00	BRL29060 10mg
30DEC00	07:00	BRL29060 10mg
31DEC00	07:00	BRL29060 10mg
01JAN01	07:00	BRL29060 10mg
02JAN01	07:00	BRL29060 10mg
03JAN01	07:00	BRL29060 10mg
04JAN01	06:55	BRL29060 10mg
05JAN01	06:55	BRL29060 20mg
06JAN01	06:50	BRL29060 20mg
07JAN01	07:30	BRL29060 20mg
08JAN01	07:45	BRL29060 20mg
09JAN01	07:49	BRL29060 20mg
10JAN01	07:00	BRL29060 20mg
11JAN01	07:20	BRL29060 20mg
12JAN01	07:20	BRL29060 20mg
13JAN01	07:20	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00603	14JAN01	07:20	BRL29060 20mg
	15JAN01	07:20	BRL29060 20mg
	16JAN01	07:20	BRL29060 20mg
	17JAN01	07:20	BRL29060 20mg
	18JAN01	06:55	BRL29060 20mg
	19JAN01	07:00	BRL29060 30mg
	20JAN01	07:00	BRL29060 30mg
	21JAN01	07:00	BRL29060 30mg
	22JAN01	07:00	BRL29060 30mg
	23JAN01	07:00	BRL29060 30mg
	24JAN01	07:00	BRL29060 30mg
	25JAN01	07:30	BRL29060 30mg
	26JAN01	07:30	BRL29060 30mg
	27JAN01	07:30	BRL29060 30mg
	28JAN01	07:00	BRL29060 30mg
	29JAN01	08:00	BRL29060 30mg
	30JAN01	07:30	BRL29060 30mg
	31JAN01	07:00	BRL29060 30mg
	01FEB01	06:55	BRL29060 30mg
	02FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	03FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	04FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	05FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	06FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	07FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	08FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	09FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	10FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	11FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	12FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	13FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	14FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	15FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	16FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	17FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	18FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	19FEB01	06:55	BRL29060 UNKmg UNKNOWN AMOUNT
	20FEB01	07:00	BRL29060 10mg
00604	13FEB01	09:50	BRL29060 10mg
	14FEB01	07:00	BRL29060 10mg
	15FEB01	06:55	BRL29060 10mg
	17FEB01	06:50	BRL29060 10mg
	18FEB01	06:50	BRL29060 10mg
	19FEB01	09:00	BRL29060 10mg
	20FEB01	06:55	BRL29060 10mg
	21FEB01	06:50	BRL29060 10mg

22FEB01	07:00	BRL29060 10mg
23FEB01	06:50	BRL29060 10mg
24FEB01	07:10	BRL29060 10mg
25FEB01	06:50	BRL29060 10mg
26FEB01	06:36	BRL29060 10mg
27FEB01	07:15	BRL29060 10mg
28FEB01	07:17	BRL29060 20mg
01MAR01	06:45	BRL29060 20mg
02MAR01	06:50	BRL29060 20mg
03MAR01	06:50	BRL29060 20mg
04MAR01	08:55	BRL29060 20mg
05MAR01	06:30	BRL29060 20mg
06MAR01	07:05	BRL29060 20mg
07MAR01	07:10	BRL29060 20mg
08MAR01	06:50	BRL29060 20mg
09MAR01	06:50	BRL29060 20mg
10MAR01	07:40	BRL29060 20mg
11MAR01	07:00	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00604	12MAR01	06:55	BRL29060 20mg
	13MAR01	06:50	BRL29060 20mg
	14MAR01	06:50	BRL29060 20mg
	15MAR01	07:01	BRL29060 30mg
	16MAR01	08:00	BRL29060 30mg
	17MAR01	08:00	BRL29060 30mg
	18MAR01	06:45	BRL29060 30mg
	19MAR01	07:00	BRL29060 30mg
	20MAR01	06:50	BRL29060 30mg
	21MAR01	06:55	BRL29060 30mg
	22MAR01	07:20	BRL29060 30mg
	23MAR01	08:00	BRL29060 30mg
	24MAR01	07:45	BRL29060 30mg
	25MAR01	07:30	BRL29060 30mg
	26MAR01	07:50	BRL29060 30mg
	27MAR01	06:45	BRL29060 30mg
	28MAR01	08:10	BRL29060 30mg
	29MAR01	08:50	BRL29060 20mg
	30MAR01	07:00	BRL29060 20mg
	31MAR01	06:55	BRL29060 20mg
	01APR01	07:10	BRL29060 20mg
	02APR01	06:50	BRL29060 20mg
	03APR01	07:15	BRL29060 20mg
	04APR01	07:00	BRL29060 20mg
	05APR01	06:45	BRL29060 10mg
	06APR01	06:50	BRL29060 10mg
	07APR01	07:10	BRL29060 10mg
	08APR01	07:15	BRL29060 10mg
	09APR01	07:30	BRL29060 10mg
	10APR01	07:20	BRL29060 10mg
	11APR01	08:00	BRL29060 10mg
00702	29JAN01	09:07	BRL29060 10mg
	30JAN01	06:43	BRL29060 10mg
	31JAN01	06:51	BRL29060 10mg
	01FEB01	06:51	BRL29060 10mg
	02FEB01	06:45	BRL29060 10mg
	03FEB01	06:50	BRL29060 10mg
	04FEB01	06:47	BRL29060 10mg
	05FEB01	06:45	BRL29060 10mg
	06FEB01	06:48	BRL29060 10mg
	07FEB01	06:53	BRL29060 10mg
	08FEB01	06:52	BRL29060 10mg
	09FEB01	06:50	BRL29060 10mg
	10FEB01	06:55	BRL29060 10mg
	11FEB01	08:30	BRL29060 10mg
	12FEB01	08:50	BRL29060 10mg

13FEB01	08:45	BRL29060 20mg
14FEB01	06:42	BRL29060 20mg
15FEB01	07:00	BRL29060 20mg
16FEB01	06:47	BRL29060 20mg
17FEB01	10:03	BRL29060 20mg
18FEB01	10:21	BRL29060 20mg
19FEB01	11:37	BRL29060 20mg
20FEB01	06:46	BRL29060 20mg
21FEB01	06:44	BRL29060 20mg
22FEB01	06:52	BRL29060 20mg
23FEB01	06:31	BRL29060 20mg
24FEB01	11:06	BRL29060 20mg
25FEB01	08:30	BRL29060 20mg
26FEB01	08:55	BRL29060 20mg
27FEB01	08:55	BRL29060 30mg
28FEB01	06:55	BRL29060 30mg
01MAR01	06:50	BRL29060 30mg
02MAR01	06:52	BRL29060 30mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00702	03MAR01	10:30	BRL29060 30mg
	04MAR01	13:30	BRL29060 30mg
	05MAR01	06:50	BRL29060 30mg
	06MAR01	06:50	BRL29060 30mg
	07MAR01	06:53	BRL29060 30mg
	08MAR01	06:52	BRL29060 30mg
	09MAR01	06:55	BRL29060 30mg
	10MAR01	10:30	BRL29060 30mg
	11MAR01	08:30	BRL29060 30mg
	12MAR01	09:21	BRL29060 30mg
	13MAR01	10:00	BRL29060 20mg
	14MAR01	10:00	BRL29060 20mg
	15MAR01	10:00	BRL29060 20mg
	16MAR01	10:00	BRL29060 20mg
	17MAR01	10:00	BRL29060 20mg
	18MAR01	10:00	BRL29060 20mg
	19MAR01	10:00	BRL29060 20mg
	20MAR01	10:00	BRL29060 20mg
	21MAR01	10:00	BRL29060 20mg
00704	08MAR01	08:00	BRL29060 10mg
	09MAR01	08:00	BRL29060 10mg
	10MAR01	08:00	BRL29060 10mg
	11MAR01	08:30	BRL29060 10mg
	12MAR01	08:00	BRL29060 10mg
	13MAR01	08:00	BRL29060 10mg
	14MAR01	08:00	BRL29060 10mg
	15MAR01	08:00	BRL29060 10mg
	16MAR01	08:00	BRL29060 10mg
	17MAR01	08:15	BRL29060 10mg
	18MAR01	08:00	BRL29060 10mg
	19MAR01	08:30	BRL29060 10mg
	20MAR01	09:05	BRL29060 10mg
	21MAR01	08:40	BRL29060 20mg
	22MAR01	08:10	BRL29060 20mg
	23MAR01	08:00	BRL29060 20mg
	24MAR01	08:15	BRL29060 20mg
	25MAR01	08:00	BRL29060 20mg
	26MAR01	08:00	BRL29060 20mg
	27MAR01	08:00	BRL29060 20mg
	28MAR01	08:00	BRL29060 20mg
	29MAR01	08:00	BRL29060 20mg
	30MAR01	08:00	BRL29060 20mg
	31MAR01	08:00	BRL29060 20mg
	01APR01	08:00	BRL29060 20mg
	02APR01	08:30	BRL29060 20mg
	03APR01	09:10	BRL29060 20mg

	04APR01	08:30	BRL29060 30mg
	05APR01	08:00	BRL29060 30mg
	07APR01	08:15	BRL29060 30mg
	08APR01	08:00	BRL29060 30mg
	09APR01	08:00	BRL29060 30mg
	10APR01	08:00	BRL29060 30mg
	11APR01	10:30	BRL29060 30mg
	12APR01	08:00	BRL29060 30mg
	13APR01	08:00	BRL29060 30mg
	14APR01	08:00	BRL29060 30mg
	15APR01	08:00	BRL29060 30mg
	16APR01	08:30	BRL29060 30mg
	17APR01	08:50	BRL29060 30mg
00705	04APR01	08:25	BRL29060 10mg
	05APR01	08:10	BRL29060 10mg
	06APR01	08:05	BRL29060 10mg
	07APR01	08:56	BRL29060 10mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00705	08APR01	08:06	BRL29060 10mg
	09APR01	08:22	BRL29060 10mg
	10APR01	08:06	BRL29060 10mg
	11APR01	09:03	BRL29060 10mg
	12APR01	08:10	BRL29060 10mg
	13APR01	08:15	BRL29060 10mg
	14APR01	08:25	BRL29060 10mg
	15APR01	08:18	BRL29060 10mg
	16APR01	07:58	BRL29060 10mg
	17APR01	08:49	BRL29060 10mg
	18APR01	08:45	BRL29060 20mg
	19APR01	08:09	BRL29060 20mg
	20APR01	08:40	BRL29060 20mg
	21APR01	08:16	BRL29060 20mg
	22APR01	07:16	BRL29060 20mg
	23APR01	08:18	BRL29060 20mg
	24APR01	09:35	BRL29060 20mg
	25APR01	08:47	BRL29060 20mg
	26APR01	09:00	BRL29060 20mg
	27APR01	08:53	BRL29060 20mg
	28APR01	09:20	BRL29060 20mg
	29APR01	07:35	BRL29060 20mg
	30APR01	07:39	BRL29060 20mg
	01MAY01	09:30	BRL29060 20mg
	02MAY01	08:50	BRL29060 30mg
	03MAY01	07:56	BRL29060 30mg
	04MAY01	08:26	BRL29060 30mg
	05MAY01	09:25	BRL29060 30mg
	06MAY01	08:45	BRL29060 30mg
	07MAY01	09:04	BRL29060 30mg
	08MAY01	09:20	BRL29060 30mg
	09MAY01	09:07	BRL29060 30mg
	10MAY01	07:45	BRL29060 30mg
	11MAY01	08:38	BRL29060 30mg
	12MAY01	09:34	BRL29060 30mg
	13MAY01	08:18	BRL29060 30mg
	14MAY01	08:44	BRL29060 30mg
	15MAY01	09:15	BRL29060 30mg
00707	05APR01	08:00	BRL29060 10mg
	06APR01	08:00	BRL29060 10mg
	07APR01	09:30	BRL29060 10mg
	08APR01	09:30	BRL29060 10mg
	09APR01	08:00	BRL29060 10mg
	10APR01	08:00	BRL29060 10mg
	11APR01	08:00	BRL29060 10mg
	12APR01	08:00	BRL29060 10mg

13APR01	09:30	BRL29060 10mg
14APR01	09:30	BRL29060 10mg
15APR01	09:30	BRL29060 10mg
16APR01	08:00	BRL29060 10mg
17APR01	08:00	BRL29060 10mg
18APR01	09:35	BRL29060 10mg
19APR01	09:10	BRL29060 20mg
20APR01	08:00	BRL29060 20mg
21APR01	08:30	BRL29060 20mg
22APR01	08:30	BRL29060 20mg
23APR01	08:00	BRL29060 20mg
24APR01	08:00	BRL29060 20mg
25APR01	08:00	BRL29060 20mg
26APR01	08:00	BRL29060 20mg
27APR01	08:00	BRL29060 20mg
28APR01	08:30	BRL29060 20mg
29APR01	08:30	BRL29060 20mg
30APR01	08:00	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00707	01MAY01	08:00	BRL29060 20mg
	02MAY01	09:10	BRL29060 20mg
	03MAY01	09:45	BRL29060 30mg
	04MAY01	08:00	BRL29060 30mg
	05MAY01	08:30	BRL29060 30mg
	06MAY01	08:30	BRL29060 30mg
	07MAY01	08:00	BRL29060 30mg
	08MAY01	08:00	BRL29060 30mg
	09MAY01	08:00	BRL29060 30mg
	10MAY01	08:00	BRL29060 30mg
	11MAY01	08:00	BRL29060 30mg
	12MAY01	08:30	BRL29060 30mg
	13MAY01	08:30	BRL29060 30mg
	14MAY01	08:00	BRL29060 30mg
	15MAY01	08:00	BRL29060 30mg
	16MAY01	09:00	BRL29060 30mg
00708	06APR01	09:55	BRL29060 10mg
	07APR01	08:10	BRL29060 10mg
	08APR01	07:10	BRL29060 10mg
	09APR01	06:10	BRL29060 10mg
	10APR01	06:10	BRL29060 10mg
	11APR01	06:10	BRL29060 10mg
	12APR01	07:10	BRL29060 10mg
	13APR01	07:10	BRL29060 10mg
	14APR01	08:00	BRL29060 10mg
	15APR01	07:30	BRL29060 10mg
	16APR01	07:30	BRL29060 10mg
	17APR01	07:30	BRL29060 10mg
	18APR01	08:10	BRL29060 10mg
	19APR01	09:30	BRL29060 10mg
	20APR01	09:00	BRL29060 20mg
	21APR01	07:00	BRL29060 20mg
	22APR01	07:30	BRL29060 20mg
	23APR01	06:30	BRL29060 20mg
	24APR01	06:30	BRL29060 20mg
	25APR01	06:30	BRL29060 20mg
	26APR01	06:30	BRL29060 20mg
	27APR01	06:30	BRL29060 20mg
	28APR01	07:30	BRL29060 20mg
	29APR01	07:30	BRL29060 20mg
	30APR01	06:30	BRL29060 20mg
	01MAY01	06:30	BRL29060 20mg
	02MAY01	06:30	BRL29060 20mg
	03MAY01	09:25	BRL29060 20mg
	04MAY01	08:50	BRL29060 30mg
	05MAY01	07:30	BRL29060 30mg

	06MAY01	07:30	BRL29060 30mg
	07MAY01	06:30	BRL29060 30mg
	08MAY01	06:30	BRL29060 30mg
	09MAY01	06:30	BRL29060 30mg
	10MAY01	06:30	BRL29060 30mg
	11MAY01	06:30	BRL29060 30mg
	13MAY01	07:30	BRL29060 30mg
	14MAY01	06:30	BRL29060 30mg
	15MAY01	06:30	BRL29060 30mg
	16MAY01	08:00	BRL29060 30mg
	17MAY01	09:35	BRL29060 30mg
00709	22JUN01	08:59	BRL29060 10mg
	23JUN01	07:01	BRL29060 10mg
	24JUN01	09:57	BRL29060 10mg
	25JUN01	08:57	BRL29060 10mg
	26JUN01	09:53	BRL29060 10mg
	27JUN01	09:57	BRL29060 10mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00709	28JUN01	11:01	BRL29060 10mg
	29JUN01	09:38	BRL29060 10mg
	30JUN01	08:52	BRL29060 10mg
	01JUL01	11:17	BRL29060 10mg
	02JUL01	08:54	BRL29060 10mg
	03JUL01	10:11	BRL29060 10mg
	04JUL01	08:30	BRL29060 10mg
	05JUL01	08:45	BRL29060 10mg
	06JUL01	08:45	BRL29060 20mg
	07JUL01	07:40	BRL29060 20mg
	08JUL01	09:59	BRL29060 20mg
	09JUL01	09:15	BRL29060 20mg
	10JUL01	09:45	BRL29060 20mg
	11JUL01	09:58	BRL29060 20mg
	12JUL01	11:35	BRL29060 20mg
	13JUL01	09:02	BRL29060 20mg
	14JUL01	10:20	BRL29060 20mg
	15JUL01	08:59	BRL29060 20mg
	16JUL01	08:58	BRL29060 20mg
	17JUL01	08:45	BRL29060 20mg
	18JUL01	08:30	BRL29060 20mg
	19JUL01	09:05	BRL29060 20mg
	20JUL01	09:15	BRL29060 30mg
	21JUL01	10:13	BRL29060 30mg
	22JUL01	10:27	BRL29060 30mg
	23JUL01	06:28	BRL29060 30mg
	24JUL01	06:34	BRL29060 30mg
	25JUL01	07:03	BRL29060 30mg
	26JUL01	12:19	BRL29060 30mg
	27JUL01	10:10	BRL29060 30mg
	28JUL01	10:30	BRL29060 30mg
	30JUL01	07:10	BRL29060 30mg
	31JUL01	06:45	BRL29060 30mg
	01AUG01	08:15	BRL29060 30mg
	02AUG01	11:20	BRL29060 30mg
	03AUG01	10:00	BRL29060 20mg
	04AUG01	10:30	BRL29060 20mg
	05AUG01	08:28	BRL29060 20mg
	06AUG01	10:30	BRL29060 20mg
	07AUG01	09:11	BRL29060 20mg
	08AUG01	07:21	BRL29060 20mg
	09AUG01	08:07	BRL29060 20mg
	10AUG01	08:07	BRL29060 20mg
00806	17NOV00	09:10	BRL29060 10mg
	18NOV00	07:20	BRL29060 10mg
	19NOV00	07:50	BRL29060 10mg

20NOV00	08:20	BRL29060 10mg
21NOV00	07:25	BRL29060 10mg
22NOV00	09:20	BRL29060 10mg
23NOV00	07:50	BRL29060 10mg
24NOV00	09:20	BRL29060 10mg
25NOV00	07:40	BRL29060 10mg
26NOV00	09:15	BRL29060 10mg
27NOV00	07:00	BRL29060 10mg
28NOV00	07:00	BRL29060 10mg
29NOV00	08:16	BRL29060 10mg
30NOV00	06:25	BRL29060 10mg
01DEC00	07:25	BRL29060 20mg
02DEC00	08:05	BRL29060 20mg
03DEC00	09:00	BRL29060 20mg
04DEC00	06:45	BRL29060 20mg
05DEC00	06:40	BRL29060 20mg
06DEC00	06:21	BRL29060 20mg
07DEC00	06:40	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00806	08DEC00	06:20	BRL29060 20mg
	09DEC00	08:20	BRL29060 20mg
	10DEC00	08:00	BRL29060 20mg
	11DEC00	07:00	BRL29060 20mg
	12DEC00	06:55	BRL29060 20mg
	13DEC00	07:40	BRL29060 20mg
	14DEC00	08:05	BRL29060 20mg
	15DEC00	07:26	BRL29060 30mg
	16DEC00	07:40	BRL29060 30mg
	17DEC00	07:24	BRL29060 30mg
	18DEC00	06:50	BRL29060 30mg
	19DEC00	07:15	BRL29060 30mg
	20DEC00	06:45	BRL29060 30mg
	21DEC00	07:05	BRL29060 30mg
	22DEC00	09:05	BRL29060 30mg
	23DEC00	09:30	BRL29060 30mg
	24DEC00	10:10	BRL29060 30mg
	25DEC00	07:40	BRL29060 30mg
	26DEC00	08:10	BRL29060 30mg
	27DEC00	07:29	BRL29060 30mg
	28DEC00	07:00	BRL29060 30mg
	29DEC00	07:30	BRL29060 20mg
	30DEC00	10:30	BRL29060 20mg
	31DEC00	11:30	BRL29060 20mg
	01JAN01	10:10	BRL29060 20mg
	02JAN01	08:00	BRL29060 20mg
	03JAN01	08:05	BRL29060 20mg
00818	08FEB01	08:21	BRL29060 10mg
	09FEB01	06:20	BRL29060 10mg
	10FEB01	08:12	BRL29060 10mg
	11FEB01	07:20	BRL29060 10mg
	12FEB01	06:45	BRL29060 10mg
	13FEB01	06:35	BRL29060 10mg
	14FEB01	06:30	BRL29060 10mg
	15FEB01	06:34	BRL29060 10mg
	16FEB01	06:29	BRL29060 10mg
	17FEB01	10:00	BRL29060 10mg
	18FEB01	08:00	BRL29060 10mg
	19FEB01	07:40	BRL29060 10mg
	20FEB01	07:30	BRL29060 10mg
	21FEB01	07:10	BRL29060 20mg
	23FEB01	06:36	BRL29060 20mg
	24FEB01	08:30	BRL29060 20mg
	25FEB01	08:36	BRL29060 20mg
	26FEB01	06:31	BRL29060 20mg
	27FEB01	06:30	BRL29060 20mg

28FEB01	06:30	BRL29060 20mg
01MAR01	06:21	BRL29060 20mg
02MAR01	06:34	BRL29060 20mg
03MAR01	08:31	BRL29060 20mg
04MAR01	08:30	BRL29060 20mg
05MAR01	07:46	BRL29060 20mg
06MAR01	07:30	BRL29060 20mg
07MAR01	07:37	BRL29060 30mg
08MAR01	06:25	BRL29060 30mg
09MAR01	06:30	BRL29060 30mg
10MAR01	08:31	BRL29060 30mg
11MAR01	08:04	BRL29060 30mg
12MAR01	06:34	BRL29060 30mg
13MAR01	06:31	BRL29060 30mg
14MAR01	06:30	BRL29060 30mg
15MAR01	06:35	BRL29060 30mg
16MAR01	06:32	BRL29060 30mg
17MAR01	08:30	BRL29060 30mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - CHILDREN

Sub No	Dosing Date	Time	Actual dose
00818	18MAR01	08:15	BRL29060 30mg
	19MAR01	07:35	BRL29060 30mg
	20MAR01	07:36	BRL29060 30mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00002	16NOV00	08:30	BRL29060 10mg
	17NOV00	06:30	BRL29060 10mg
	18NOV00	09:30	BRL29060 10mg
	19NOV00	09:30	BRL29060 10mg
	20NOV00	06:30	BRL29060 10mg
	21NOV00	06:30	BRL29060 10mg
	22NOV00	09:00	BRL29060 10mg
	23NOV00	09:00	BRL29060 10mg
	24NOV00	09:00	BRL29060 10mg
	25NOV00	09:30	BRL29060 10mg
	26NOV00	09:00	BRL29060 10mg
	27NOV00	06:30	BRL29060 10mg
	28NOV00	06:30	BRL29060 10mg
	29NOV00	09:30	BRL29060 10mg
	30NOV00	09:15	BRL29060 20mg
	01DEC00	06:30	BRL29060 20mg
	02DEC00	09:30	BRL29060 20mg
	03DEC00	09:30	BRL29060 20mg
	04DEC00	06:30	BRL29060 20mg
	05DEC00	06:30	BRL29060 20mg
	06DEC00	06:30	BRL29060 20mg
	07DEC00	06:30	BRL29060 20mg
	08DEC00	06:30	BRL29060 20mg
	09DEC00	09:30	BRL29060 20mg
	10DEC00	09:30	BRL29060 20mg
	11DEC00	06:30	BRL29060 20mg
	12DEC00	06:30	BRL29060 20mg
	13DEC00	08:15	BRL29060 20mg
	14DEC00	08:30	BRL29060 30mg
	15DEC00	06:30	BRL29060 30mg
	16DEC00	09:30	BRL29060 30mg
	17DEC00	09:30	BRL29060 30mg
	18DEC00	06:30	BRL29060 30mg
	19DEC00	06:30	BRL29060 30mg
	20DEC00	06:30	BRL29060 30mg
	21DEC00	09:30	BRL29060 30mg
	22DEC00	09:30	BRL29060 30mg
	23DEC00	09:30	BRL29060 30mg
	24DEC00	09:30	BRL29060 30mg
	25DEC00	09:30	BRL29060 30mg
	26DEC00	10:00	BRL29060 30mg
	27DEC00	09:00	BRL29060 30mg
	28DEC00	10:30	BRL29060 30mg
00003	29NOV00	08:45	BRL29060 10mg
	30NOV00	06:45	BRL29060 10mg
	01DEC00	06:47	BRL29060 10mg

02DEC00	06:30	BRL29060 10mg
03DEC00	09:17	BRL29060 10mg
04DEC00	06:47	BRL29060 10mg
05DEC00	06:50	BRL29060 10mg
06DEC00	06:45	BRL29060 10mg
07DEC00	06:47	BRL29060 10mg
08DEC00	06:30	BRL29060 10mg
09DEC00	11:10	BRL29060 10mg
10DEC00	08:30	BRL29060 10mg
11DEC00	06:47	BRL29060 10mg
12DEC00	08:44	BRL29060 10mg
13DEC00	09:15	BRL29060 20mg
14DEC00	06:50	BRL29060 20mg
15DEC00	06:45	BRL29060 20mg
16DEC00	06:40	BRL29060 20mg
17DEC00	10:00	BRL29060 20mg
18DEC00	06:47	BRL29060 20mg
19DEC00	06:49	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00003	20DEC00	06:48	BRL29060 20mg
	21DEC00	06:40	BRL29060 20mg
	22DEC00	08:00	BRL29060 20mg
	23DEC00	11:00	BRL29060 20mg
	24DEC00	08:00	BRL29060 20mg
	25DEC00	06:50	BRL29060 20mg
	26DEC00	10:20	BRL29060 20mg
	27DEC00	09:32	BRL29060 30mg
	28DEC00	08:00	BRL29060 30mg
	29DEC00	10:30	BRL29060 30mg
	30DEC00	10:00	BRL29060 30mg
	31DEC00	12:00	BRL29060 30mg
	01JAN01	15:00	BRL29060 30mg
	02JAN01	12:00	BRL29060 30mg
	03JAN01	11:00	BRL29060 30mg
	04JAN01	06:50	BRL29060 30mg
	05JAN01	06:47	BRL29060 30mg
	06JAN01	06:42	BRL29060 30mg
	07JAN01	11:00	BRL29060 30mg
	08JAN01	08:30	BRL29060 30mg
	09JAN01	08:30	BRL29060 30mg
	10JAN01	08:50	BRL29060 30mg
	11JAN01	09:10	BRL29060 30mg
00004	15DEC00	09:30	BRL29060 10mg
	16DEC00	08:00	BRL29060 10mg
	17DEC00	08:00	BRL29060 10mg
	18DEC00	08:00	BRL29060 10mg
	19DEC00	08:00	BRL29060 10mg
	20DEC00	08:00	BRL29060 10mg
	21DEC00	08:00	BRL29060 10mg
	22DEC00	08:00	BRL29060 10mg
	23DEC00	09:00	BRL29060 10mg
	24DEC00	09:15	BRL29060 10mg
	25DEC00	08:00	BRL29060 10mg
	26DEC00	09:03	BRL29060 10mg
	27DEC00	08:34	BRL29060 20mg
	28DEC00	07:00	BRL29060 20mg
	29DEC00	09:00	BRL29060 20mg
	30DEC00	09:00	BRL29060 20mg
	31DEC00	08:00	BRL29060 20mg
	01JAN01	07:00	BRL29060 20mg
	02JAN01	07:00	BRL29060 20mg
	03JAN01	07:00	BRL29060 20mg
	04JAN01	07:00	BRL29060 20mg
	05JAN01	08:00	BRL29060 20mg
	06JAN01	09:00	BRL29060 20mg

07JAN01	09:00	BRL29060 20mg
08JAN01	08:00	BRL29060 20mg
09JAN01	08:45	BRL29060 20mg
10JAN01	08:21	BRL29060 30mg
11JAN01	07:00	BRL29060 30mg
12JAN01	07:00	BRL29060 30mg
13JAN01	09:00	BRL29060 30mg
14JAN01	09:00	BRL29060 30mg
15JAN01	07:00	BRL29060 30mg
16JAN01	07:00	BRL29060 30mg
17JAN01	07:00	BRL29060 30mg
18JAN01	07:00	BRL29060 30mg
19JAN01	07:00	BRL29060 30mg
20JAN01	09:00	BRL29060 30mg
21JAN01	09:00	BRL29060 30mg
22JAN01	07:00	BRL29060 30mg
23JAN01	08:35	BRL29060 30mg
24JAN01	08:50	BRL29060 30mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00005	28FEB01	09:50	BRL29060 10mg
	01MAR01	07:30	BRL29060 10mg
	02MAR01	07:30	BRL29060 10mg
	03MAR01	09:30	BRL29060 10mg
	04MAR01	09:30	BRL29060 10mg
	05MAR01	07:30	BRL29060 10mg
	06MAR01	07:30	BRL29060 10mg
	07MAR01	07:30	BRL29060 10mg
	08MAR01	07:30	BRL29060 10mg
	09MAR01	07:30	BRL29060 10mg
	10MAR01	09:30	BRL29060 10mg
	11MAR01	09:30	BRL29060 10mg
	12MAR01	07:30	BRL29060 10mg
	13MAR01	07:30	BRL29060 10mg
	14MAR01	09:30	BRL29060 10mg
	15MAR01	09:37	BRL29060 20mg
	16MAR01	07:30	BRL29060 20mg
	17MAR01	09:30	BRL29060 20mg
	18MAR01	09:30	BRL29060 20mg
	19MAR01	07:30	BRL29060 20mg
	20MAR01	07:30	BRL29060 20mg
	21MAR01	07:30	BRL29060 20mg
	22MAR01	07:30	BRL29060 20mg
	23MAR01	07:30	BRL29060 20mg
	24MAR01	09:30	BRL29060 20mg
	25MAR01	09:30	BRL29060 20mg
	26MAR01	09:30	BRL29060 20mg
	27MAR01	09:30	BRL29060 20mg
	28MAR01	09:30	BRL29060 10mg
	29MAR01	09:30	BRL29060 10mg
	30MAR01	09:30	BRL29060 10mg
	31MAR01	09:30	BRL29060 10mg
	01APR01	09:30	BRL29060 10mg
	02APR01	09:30	BRL29060 10mg
	03APR01	09:30	BRL29060 10mg
00007	20APR01	08:50	BRL29060 10mg
	21APR01	10:53	BRL29060 10mg
	22APR01	09:13	BRL29060 10mg
	23APR01	07:03	BRL29060 10mg
	24APR01	07:01	BRL29060 10mg
	25APR01	07:07	BRL29060 10mg
	26APR01	07:01	BRL29060 10mg
	27APR01	07:05	BRL29060 10mg
	28APR01	09:45	BRL29060 10mg
	29APR01	11:45	BRL29060 10mg
	30APR01	07:06	BRL29060 10mg

	01MAY01	06:53	BRL29060 10mg
	02MAY01	08:34	BRL29060 10mg
	03MAY01	08:04	BRL29060 20mg
	04MAY01	06:53	BRL29060 20mg
	05MAY01	10:15	BRL29060 20mg
	06MAY01	11:12	BRL29060 20mg
	07MAY01	06:57	BRL29060 20mg
	08MAY01	06:59	BRL29060 20mg
	09MAY01	07:07	BRL29060 20mg
	10MAY01	07:01	BRL29060 20mg
	11MAY01	07:05	BRL29060 20mg
	12MAY01	11:15	BRL29060 20mg
	13MAY01	08:23	BRL29060 20mg
	14MAY01	06:50	BRL29060 20mg
	15MAY01	08:58	BRL29060 20mg
	16MAY01	08:26	BRL29060 30mg
00051	08FEB01	09:00	BRL29060 10mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00051	09FEB01	07:30	BRL29060 10mg
	10FEB01	08:30	BRL29060 10mg
	11FEB01	08:19	BRL29060 10mg
	12FEB01	07:55	BRL29060 10mg
	13FEB01	07:30	BRL29060 10mg
	14FEB01	07:30	BRL29060 10mg
	15FEB01	07:25	BRL29060 10mg
	16FEB01	07:26	BRL29060 10mg
	17FEB01	08:02	BRL29060 10mg
	19FEB01	07:35	BRL29060 10mg
	20FEB01	09:00	BRL29060 10mg
	21FEB01	09:10	BRL29060 10mg
	22FEB01	09:45	BRL29060 20mg
	23FEB01	07:33	BRL29060 20mg
	24FEB01	07:30	BRL29060 20mg
	25FEB01	08:03	BRL29060 20mg
	26FEB01	07:25	BRL29060 20mg
	27FEB01	07:28	BRL29060 20mg
	28FEB01	07:30	BRL29060 20mg
	01MAR01	07:26	BRL29060 20mg
	02MAR01	07:30	BRL29060 20mg
	03MAR01	07:33	BRL29060 20mg
	04MAR01	07:30	BRL29060 20mg
	05MAR01	07:40	BRL29060 20mg
	06MAR01	07:28	BRL29060 20mg
	07MAR01	08:45	BRL29060 20mg
	08MAR01	09:00	BRL29060 30mg
	09MAR01	07:28	BRL29060 30mg
	10MAR01	07:40	BRL29060 30mg
	11MAR01	07:35	BRL29060 30mg
	12MAR01	07:30	BRL29060 30mg
	13MAR01	07:30	BRL29060 30mg
	14MAR01	07:30	BRL29060 30mg
	15MAR01	08:05	BRL29060 30mg
	16MAR01	07:30	BRL29060 30mg
	17MAR01	09:00	BRL29060 30mg
	18MAR01	08:02	BRL29060 30mg
	19MAR01	07:28	BRL29060 30mg
	20MAR01	07:30	BRL29060 30mg
	21MAR01	08:10	BRL29060 30mg
	22MAR01	10:00	BRL29060 20mg
00052	09MAR01	09:45	BRL29060 10mg
	10MAR01	09:30	BRL29060 10mg
	11MAR01	09:45	BRL29060 10mg
	12MAR01	09:15	BRL29060 10mg
	13MAR01	07:25	BRL29060 10mg

14MAR01	07:20	BRL29060 10mg
15MAR01	07:25	BRL29060 10mg
16MAR01	07:45	BRL29060 10mg
17MAR01	07:50	BRL29060 10mg
18MAR01	07:20	BRL29060 10mg
19MAR01	09:10	BRL29060 10mg
20MAR01	07:30	BRL29060 10mg
21MAR01	07:30	BRL29060 10mg
22MAR01	07:45	BRL29060 10mg
23MAR01	07:35	BRL29060 20mg
24MAR01	12:05	BRL29060 20mg
25MAR01	09:30	BRL29060 20mg
26MAR01	07:30	BRL29060 20mg
27MAR01	07:31	BRL29060 20mg
28MAR01	07:40	BRL29060 20mg
29MAR01	07:35	BRL29060 20mg
30MAR01	07:45	BRL29060 20mg
31MAR01	07:15	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00052	01APR01	07:35	BRL29060 20mg
	02APR01	15:30	BRL29060 20mg
	03APR01	14:25	BRL29060 20mg
	04APR01	13:30	BRL29060 20mg
	05APR01	08:25	BRL29060 20mg
	06APR01	09:30	BRL29060 30mg
	07APR01	21:00	BRL29060 30mg
	08APR01	14:30	BRL29060 30mg
	09APR01	08:00	BRL29060 30mg
	10APR01	07:45	BRL29060 30mg
	11APR01	07:45	BRL29060 30mg
	12APR01	08:00	BRL29060 30mg
	13APR01	14:45	BRL29060 30mg
	14APR01	12:30	BRL29060 30mg
	15APR01	10:00	BRL29060 30mg
	16APR01	08:00	BRL29060 30mg
	17APR01	07:30	BRL29060 30mg
	18APR01	07:50	BRL29060 30mg
	19APR01	08:45	BRL29060 30mg
	20APR01	09:30	BRL29060 20mg
00054	29MAR01	08:35	BRL29060 10mg
	30MAR01	06:57	BRL29060 10mg
	31MAR01	07:01	BRL29060 10mg
	01APR01	11:32	BRL29060 10mg
	02APR01	07:15	BRL29060 10mg
	03APR01	07:10	BRL29060 10mg
	04APR01	06:51	BRL29060 10mg
	05APR01	06:55	BRL29060 10mg
	06APR01	07:00	BRL29060 10mg
	07APR01	07:05	BRL29060 10mg
	08APR01	12:57	BRL29060 10mg
	09APR01	07:32	BRL29060 10mg
	10APR01	07:13	BRL29060 10mg
	11APR01	07:45	BRL29060 10mg
00103	01DEC00	09:33	BRL29060 10mg
	02DEC00	08:52	BRL29060 10mg
	03DEC00	09:30	BRL29060 10mg
	04DEC00	07:05	BRL29060 10mg
	05DEC00	07:12	BRL29060 10mg
	06DEC00	07:10	BRL29060 10mg
	07DEC00	07:15	BRL29060 10mg
	08DEC00	07:22	BRL29060 10mg
	09DEC00	10:10	BRL29060 10mg
	10DEC00	10:00	BRL29060 10mg
	11DEC00	07:10	BRL29060 10mg

12DEC00	07:10	BRL29060 10mg
13DEC00	07:15	BRL29060 10mg
14DEC00	07:20	BRL29060 10mg
15DEC00	10:10	BRL29060 10mg
16DEC00	10:30	BRL29060 20mg
17DEC00	09:30	BRL29060 20mg
18DEC00	12:20	BRL29060 20mg
19DEC00	11:20	BRL29060 20mg
20DEC00	07:15	BRL29060 20mg
21DEC00	07:15	BRL29060 20mg
22DEC00	07:00	BRL29060 20mg
23DEC00	05:45	BRL29060 20mg
24DEC00	09:30	BRL29060 20mg
25DEC00	10:00	BRL29060 20mg
26DEC00	12:30	BRL29060 20mg
27DEC00	11:55	BRL29060 20mg
28DEC00	10:30	BRL29060 20mg
29DEC00	10:15	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00103	30DEC00	10:27	BRL29060 30mg
	01JAN01	11:05	BRL29060 30mg
	02JAN01	10:30	BRL29060 30mg
	03JAN01	10:16	BRL29060 30mg
	04JAN01	16:12	BRL29060 30mg
	05JAN01	06:45	BRL29060 30mg
	06JAN01	06:30	BRL29060 30mg
	07JAN01	10:30	BRL29060 30mg
	08JAN01	07:20	BRL29060 30mg
	09JAN01	11:30	BRL29060 30mg
	10JAN01	10:15	BRL29060 30mg
	11JAN01	06:57	BRL29060 30mg
	12JAN01	10:35	BRL29060 30mg
00105	10JAN01	11:48	BRL29060 10mg
	11JAN01	07:37	BRL29060 10mg
	12JAN01	07:55	BRL29060 10mg
	13JAN01	12:30	BRL29060 10mg
	14JAN01	10:29	BRL29060 10mg
	15JAN01	13:30	BRL29060 10mg
	16JAN01	07:45	BRL29060 10mg
	17JAN01	07:40	BRL29060 10mg
	18JAN01	07:37	BRL29060 10mg
	19JAN01	07:45	BRL29060 10mg
	20JAN01	08:31	BRL29060 10mg
	21JAN01	09:10	BRL29060 10mg
	22JAN01	10:20	BRL29060 10mg
	23JAN01	10:30	BRL29060 20mg
	24JAN01	07:50	BRL29060 20mg
	25JAN01	07:50	BRL29060 20mg
	26JAN01	07:35	BRL29060 20mg
	27JAN01	08:29	BRL29060 20mg
	29JAN01	07:35	BRL29060 20mg
	30JAN01	08:55	BRL29060 20mg
	31JAN01	08:55	BRL29060 20mg
	01FEB01	06:50	BRL29060 20mg
	02FEB01	08:15	BRL29060 20mg
	03FEB01	10:33	BRL29060 20mg
	04FEB01	09:08	BRL29060 20mg
	05FEB01	10:15	BRL29060 20mg
	06FEB01	10:25	BRL29060 30mg
	07FEB01	07:59	BRL29060 30mg
	08FEB01	07:55	BRL29060 30mg
	09FEB01	07:45	BRL29060 30mg
	11FEB01	02:00	BRL29060 30mg
	12FEB01	07:40	BRL29060 30mg
	13FEB01	07:47	BRL29060 30mg

14FEB01	07:45	BRL29060 30mg
15FEB01	07:55	BRL29060 30mg
16FEB01	07:20	BRL29060 30mg
17FEB01	09:55	BRL29060 30mg
18FEB01	09:30	BRL29060 30mg
19FEB01	11:08	BRL29060 30mg
20FEB01	11:35	BRL29060 20mg
21FEB01	08:10	BRL29060 20mg
22FEB01	07:30	BRL29060 20mg
23FEB01	07:25	BRL29060 20mg
25FEB01	08:55	BRL29060 20mg
26FEB01	08:50	BRL29060 20mg
27FEB01	08:05	BRL29060 10mg
28FEB01	08:05	BRL29060 10mg
01MAR01	07:57	BRL29060 10mg
02MAR01	08:05	BRL29060 10mg
03MAR01	12:31	BRL29060 10mg
04MAR01	12:04	BRL29060 10mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00105	05MAR01	08:05	BRL29060 10mg
00109	07MAR01	17:20	BRL29060 10mg
	08MAR01	19:19	BRL29060 10mg
	09MAR01	19:00	BRL29060 10mg
	10MAR01	19:10	BRL29060 10mg
	11MAR01	20:05	BRL29060 10mg
	12MAR01	21:08	BRL29060 10mg
	13MAR01	16:00	BRL29060 10mg
	14MAR01	16:15	BRL29060 10mg
	16MAR01	07:10	BRL29060 10mg
	17MAR01	07:11	BRL29060 10mg
	18MAR01	07:04	BRL29060 10mg
	19MAR01	07:15	BRL29060 10mg
	20MAR01	07:15	BRL29060 10mg
	21MAR01	10:05	BRL29060 10mg
	22MAR01	10:10	BRL29060 20mg
	23MAR01	10:00	BRL29060 20mg
	24MAR01	10:00	BRL29060 20mg
	25MAR01	10:00	BRL29060 20mg
	26MAR01	10:00	BRL29060 20mg
	27MAR01	10:00	BRL29060 20mg
	28MAR01	10:00	BRL29060 20mg
	29MAR01	10:00	BRL29060 20mg
	30MAR01	10:00	BRL29060 20mg
	31MAR01	10:00	BRL29060 20mg
	01APR01	10:00	BRL29060 20mg
	02APR01	10:00	BRL29060 20mg
	03APR01	10:00	BRL29060 20mg
	04APR01	10:47	BRL29060 20mg
	05APR01	11:30	BRL29060 30mg
	06APR01	10:00	BRL29060 30mg
	07APR01	10:00	BRL29060 30mg
	08APR01	10:00	BRL29060 30mg
	09APR01	10:00	BRL29060 30mg
	10APR01	10:00	BRL29060 30mg
	11APR01	10:00	BRL29060 30mg
	12APR01	10:00	BRL29060 30mg
	13APR01	10:00	BRL29060 30mg
	14APR01	10:00	BRL29060 30mg
	15APR01	10:00	BRL29060 30mg
	16APR01	10:00	BRL29060 30mg
	17APR01	10:00	BRL29060 30mg
	18APR01	10:40	BRL29060 30mg
	19APR01	11:12	BRL29060 20mg
	20APR01	10:00	BRL29060 20mg
	21APR01	10:00	BRL29060 20mg

	22APR01	10:00	BRL29060 20mg
	23APR01	10:00	BRL29060 20mg
	24APR01	10:00	BRL29060 20mg
	25APR01	10:00	BRL29060 20mg
	26APR01	10:00	BRL29060 20mg
00201	26FEB01	07:34	BRL29060 10mg
	27FEB01	07:34	BRL29060 10mg
	28FEB01	07:30	BRL29060 10mg
	01MAR01	07:35	BRL29060 10mg
	02MAR01	07:25	BRL29060 10mg
	03MAR01	09:30	BRL29060 10mg
	04MAR01	10:10	BRL29060 10mg
	05MAR01	09:00	BRL29060 10mg
	06MAR01	09:15	BRL29060 10mg
	08MAR01	07:40	BRL29060 10mg
	09MAR01	07:30	BRL29060 10mg
	10MAR01	09:40	BRL29060 10mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00201	11MAR01	09:00	BRL29060 20mg
	12MAR01	09:00	BRL29060 20mg
	13MAR01	09:00	BRL29060 20mg
	14MAR01	09:00	BRL29060 20mg
	15MAR01	09:00	BRL29060 20mg
	16MAR01	09:00	BRL29060 20mg
	17MAR01	09:00	BRL29060 20mg
	18MAR01	09:00	BRL29060 20mg
	19MAR01	09:00	BRL29060 20mg
	20MAR01	09:00	BRL29060 20mg
	21MAR01	09:00	BRL29060 20mg
	22MAR01	09:00	BRL29060 20mg
	23MAR01	09:00	BRL29060 20mg
	24MAR01	08:45	BRL29060 20mg
00401	25OCT00	12:30	BRL29060 10mg
	26OCT00	08:30	BRL29060 10mg
	27OCT00	08:45	BRL29060 10mg
	28OCT00	10:40	BRL29060 10mg
	29OCT00	10:30	BRL29060 10mg
	30OCT00	08:15	BRL29060 10mg
	31OCT00	08:00	BRL29060 10mg
	01NOV00	12:00	BRL29060 10mg
	02NOV00	18:45	BRL29060 10mg
	03NOV00	19:00	BRL29060 10mg
	04NOV00	15:00	BRL29060 10mg
	05NOV00	09:30	BRL29060 10mg
	06NOV00	08:40	BRL29060 10mg
	07NOV00	09:30	BRL29060 20mg
	08NOV00	07:45	BRL29060 20mg
	09NOV00	08:00	BRL29060 20mg
	10NOV00	08:00	BRL29060 20mg
	11NOV00	07:30	BRL29060 20mg
	12NOV00	08:30	BRL29060 20mg
	13NOV00	08:15	BRL29060 20mg
	14NOV00	07:45	BRL29060 20mg
	15NOV00	08:00	BRL29060 20mg
	16NOV00	08:00	BRL29060 20mg
	17NOV00	08:00	BRL29060 20mg
	18NOV00	08:00	BRL29060 20mg
	19NOV00	08:00	BRL29060 20mg
	20NOV00	08:15	BRL29060 20mg
	21NOV00	09:00	BRL29060 30mg
	22NOV00	08:15	BRL29060 30mg
	23NOV00	08:00	BRL29060 30mg
	24NOV00	09:00	BRL29060 30mg
	25NOV00	09:30	BRL29060 30mg

	26NOV00	09:15	BRL29060 30mg
	27NOV00	08:00	BRL29060 30mg
	28NOV00	09:00	BRL29060 30mg
	29NOV00	10:15	BRL29060 30mg
	30NOV00	09:00	BRL29060 30mg
	01DEC00	09:00	BRL29060 30mg
	02DEC00	09:00	BRL29060 30mg
	03DEC00	09:00	BRL29060 30mg
	04DEC00	09:00	BRL29060 30mg
00502	23OCT00	10:30	BRL29060 10mg
	24OCT00	17:30	BRL29060 10mg
	25OCT00	17:30	BRL29060 10mg
	26OCT00	17:30	BRL29060 10mg
	27OCT00	19:00	BRL29060 10mg
	28OCT00	19:30	BRL29060 10mg
	29OCT00	17:30	BRL29060 10mg
	30OCT00	18:00	BRL29060 10mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00502	31OCT00	17:30	BRL29060 10mg
	01NOV00	18:00	BRL29060 10mg
	02NOV00	17:30	BRL29060 10mg
	03NOV00	18:00	BRL29060 10mg
	04NOV00	18:30	BRL29060 10mg
	05NOV00	19:00	BRL29060 10mg
	06NOV00	19:10	BRL29060 10mg
	07NOV00	18:30	BRL29060 20mg
	08NOV00	18:00	BRL29060 20mg
	09NOV00	19:00	BRL29060 20mg
	10NOV00	18:50	BRL29060 20mg
	11NOV00	18:12	BRL29060 20mg
	12NOV00	19:20	BRL29060 20mg
	13NOV00	18:55	BRL29060 20mg
	14NOV00	19:00	BRL29060 20mg
	15NOV00	18:10	BRL29060 20mg
	16NOV00	18:45	BRL29060 20mg
	17NOV00	19:15	BRL29060 20mg
	18NOV00	18:13	BRL29060 20mg
	19NOV00	18:00	BRL29060 20mg
	20NOV00	18:00	BRL29060 20mg
	21NOV00	18:05	BRL29060 30mg
	22NOV00	18:05	BRL29060 30mg
	23NOV00	18:05	BRL29060 30mg
	24NOV00	18:05	BRL29060 30mg
	25NOV00	18:05	BRL29060 30mg
	26NOV00	18:05	BRL29060 30mg
	27NOV00	18:05	BRL29060 30mg
	28NOV00	18:05	BRL29060 30mg
	29NOV00	18:05	BRL29060 30mg
	30NOV00	18:05	BRL29060 30mg
	01DEC00	18:15	BRL29060 30mg
	02DEC00	18:30	BRL29060 20mg
	03DEC00	19:00	BRL29060 20mg
	04DEC00	17:30	BRL29060 20mg
	05DEC00	18:45	BRL29060 20mg
	06DEC00	18:30	BRL29060 20mg
	07DEC00	19:54	BRL29060 20mg
00503	17NOV00	22:30	BRL29060 10mg
	18NOV00	17:30	BRL29060 10mg
	19NOV00	21:30	BRL29060 10mg
	20NOV00	17:30	BRL29060 10mg
	21NOV00	17:30	BRL29060 10mg
	22NOV00	17:30	BRL29060 10mg
	23NOV00	17:30	BRL29060 10mg
	24NOV00	17:30	BRL29060 10mg

25NOV00	17:30	BRL29060 10mg
26NOV00	17:30	BRL29060 10mg
27NOV00	17:30	BRL29060 10mg
28NOV00	17:30	BRL29060 10mg
30NOV00	17:30	BRL29060 10mg
01DEC00	19:30	BRL29060 10mg
02DEC00	19:30	BRL29060 20mg
03DEC00	17:30	BRL29060 20mg
04DEC00	17:30	BRL29060 20mg
05DEC00	17:30	BRL29060 20mg
06DEC00	17:30	BRL29060 20mg
07DEC00	17:30	BRL29060 20mg
08DEC00	17:30	BRL29060 20mg
09DEC00	17:30	BRL29060 20mg
10DEC00	17:30	BRL29060 20mg
11DEC00	17:30	BRL29060 20mg
12DEC00	17:30	BRL29060 20mg
13DEC00	17:30	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00503	14DEC00	18:30	BRL29060 20mg
	15DEC00	18:00	BRL29060 20mg
	16DEC00	18:20	BRL29060 30mg
	17DEC00	17:30	BRL29060 30mg
	18DEC00	17:30	BRL29060 30mg
	19DEC00	17:30	BRL29060 30mg
	20DEC00	17:30	BRL29060 30mg
	21DEC00	17:30	BRL29060 30mg
	22DEC00	17:30	BRL29060 30mg
	23DEC00	17:30	BRL29060 30mg
	24DEC00	17:30	BRL29060 30mg
	25DEC00	17:30	BRL29060 30mg
	26DEC00	17:30	BRL29060 30mg
	27DEC00	17:30	BRL29060 30mg
	28DEC00	17:30	BRL29060 20mg
	29DEC00	17:30	BRL29060 20mg
	30DEC00	17:30	BRL29060 20mg
	31DEC00	17:30	BRL29060 20mg
	01JAN01	17:30	BRL29060 20mg
	02JAN01	17:30	BRL29060 20mg
	03JAN01	17:30	BRL29060 20mg
00505	26JAN01	17:05	BRL29060 10mg
	27JAN01	18:15	BRL29060 10mg
	28JAN01	19:17	BRL29060 10mg
	29JAN01	19:32	BRL29060 10mg
	30JAN01	19:30	BRL29060 10mg
	31JAN01	19:40	BRL29060 10mg
	01FEB01	16:14	BRL29060 30mg
	02FEB01	17:59	BRL29060 10mg
	03FEB01	18:25	BRL29060 10mg
	04FEB01	18:45	BRL29060 10mg
	05FEB01	18:42	BRL29060 10mg
	06FEB01	19:02	BRL29060 10mg
	07FEB01	19:31	BRL29060 10mg
	08FEB01	17:34	BRL29060 10mg
	09FEB01	17:40	BRL29060 10mg
	10FEB01	16:55	BRL29060 20mg
	11FEB01	19:09	BRL29060 20mg
	12FEB01	19:14	BRL29060 20mg
	13FEB01	18:48	BRL29060 20mg
	14FEB01	18:46	BRL29060 20mg
	15FEB01	19:32	BRL29060 20mg
	16FEB01	17:44	BRL29060 20mg
	17FEB01	19:07	BRL29060 20mg
	18FEB01	19:04	BRL29060 20mg
	19FEB01	18:35	BRL29060 20mg

	20FEB01	18:30	BRL29060 20mg
	21FEB01	18:18	BRL29060 20mg
	22FEB01	19:02	BRL29060 20mg
	23FEB01	18:00	BRL29060 20mg
	24FEB01	19:20	BRL29060 10mg
	25FEB01	18:53	BRL29060 10mg
	26FEB01	19:05	BRL29060 10mg
	27FEB01	19:00	BRL29060 10mg
	28FEB01	19:50	BRL29060 10mg
	01MAR01	18:15	BRL29060 10mg
	02MAR01	17:30	BRL29060 10mg
00506	12FEB01	17:35	BRL29060 10mg
	13FEB01	17:30	BRL29060 10mg
	14FEB01	17:33	BRL29060 10mg
	15FEB01	17:46	BRL29060 10mg
	16FEB01	17:36	BRL29060 10mg
	17FEB01	17:30	BRL29060 10mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00506	18FEB01	17:35	BRL29060 10mg
	19FEB01	17:29	BRL29060 10mg
	20FEB01	17:43	BRL29060 10mg
	21FEB01	17:44	BRL29060 10mg
	22FEB01	17:58	BRL29060 10mg
	23FEB01	19:00	BRL29060 10mg
	25FEB01	07:05	BRL29060 20mg
	26FEB01	06:28	BRL29060 20mg
	27FEB01	06:31	BRL29060 20mg
	28FEB01	06:36	BRL29060 20mg
	01MAR01	06:32	BRL29060 20mg
	02MAR01	05:49	BRL29060 20mg
	03MAR01	10:16	BRL29060 20mg
	04MAR01	11:27	BRL29060 20mg
	05MAR01	05:58	BRL29060 20mg
	06MAR01	07:03	BRL29060 20mg
	07MAR01	06:26	BRL29060 20mg
	08MAR01	06:12	BRL29060 20mg
	09MAR01	05:45	BRL29060 20mg
	10MAR01	09:10	BRL29060 20mg
	11MAR01	09:10	BRL29060 UNKmg UNKNOWN AMOUNT
	12MAR01	06:27	BRL29060 30mg
	13MAR01	18:47	BRL29060 30mg
	14MAR01	17:42	BRL29060 30mg
	15MAR01	18:21	BRL29060 30mg
	16MAR01	17:31	BRL29060 30mg
	17MAR01	17:39	BRL29060 30mg
	18MAR01	19:00	BRL29060 30mg
	19MAR01	18:03	BRL29060 30mg
	20MAR01	17:45	BRL29060 30mg
	21MAR01	18:26	BRL29060 30mg
	22MAR01	18:11	BRL29060 30mg
	23MAR01	19:15	BRL29060 30mg
	24MAR01	19:25	BRL29060 20mg
	25MAR01	18:20	BRL29060 20mg
	26MAR01	17:35	BRL29060 20mg
	27MAR01	18:24	BRL29060 20mg
	28MAR01	17:31	BRL29060 20mg
	29MAR01	18:42	BRL29060 20mg
00507	08FEB01	18:03	BRL29060 10mg
	09FEB01	20:45	BRL29060 10mg
	10FEB01	20:30	BRL29060 10mg
	11FEB01	20:00	BRL29060 10mg
	12FEB01	20:00	BRL29060 10mg
	13FEB01	20:06	BRL29060 10mg
	14FEB01	20:00	BRL29060 10mg

15FEB01	20:10	BRL29060 10mg
16FEB01	20:10	BRL29060 10mg
17FEB01	20:00	BRL29060 10mg
18FEB01	20:00	BRL29060 10mg
19FEB01	20:00	BRL29060 10mg
20FEB01	19:45	BRL29060 10mg
21FEB01	18:15	BRL29060 10mg
22FEB01	18:30	BRL29060 10mg
23FEB01	19:30	BRL29060 20mg
24FEB01	19:00	BRL29060 20mg
25FEB01	18:15	BRL29060 20mg
26FEB01	18:45	BRL29060 20mg
27FEB01	19:30	BRL29060 20mg
28FEB01	19:00	BRL29060 20mg
01MAR01	18:15	BRL29060 20mg
02MAR01	20:00	BRL29060 20mg
03MAR01	18:30	BRL29060 20mg
04MAR01	19:40	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00507	05MAR01	18:20	BRL29060 20mg
	06MAR01	18:00	BRL29060 20mg
	07MAR01	18:15	BRL29060 20mg
	08MAR01	19:00	BRL29060 20mg
	09MAR01	19:15	BRL29060 30mg
	10MAR01	20:00	BRL29060 30mg
	11MAR01	18:30	BRL29060 30mg
	12MAR01	18:30	BRL29060 30mg
	13MAR01	19:00	BRL29060 30mg
	14MAR01	18:50	BRL29060 30mg
	15MAR01	18:30	BRL29060 30mg
	16MAR01	19:00	BRL29060 30mg
	17MAR01	18:40	BRL29060 30mg
	18MAR01	18:20	BRL29060 30mg
	19MAR01	19:15	BRL29060 30mg
	20MAR01	18:45	BRL29060 30mg
	21MAR01	18:10	BRL29060 30mg
	22MAR01	19:00	BRL29060 30mg
	23MAR01	19:00	BRL29060 20mg
	24MAR01	18:50	BRL29060 20mg
	25MAR01	18:40	BRL29060 20mg
	26MAR01	17:45	BRL29060 20mg
	27MAR01	18:30	BRL29060 20mg
	28MAR01	18:40	BRL29060 20mg
00509	22FEB01	17:25	BRL29060 10mg
	23FEB01	16:15	BRL29060 10mg
	24FEB01	16:18	BRL29060 10mg
	25FEB01	16:30	BRL29060 10mg
	26FEB01	16:00	BRL29060 10mg
	27FEB01	16:30	BRL29060 10mg
	28FEB01	16:12	BRL29060 10mg
	01MAR01	16:30	BRL29060 10mg
	02MAR01	16:15	BRL29060 10mg
	03MAR01	16:00	BRL29060 10mg
	04MAR01	16:28	BRL29060 10mg
	05MAR01	16:15	BRL29060 10mg
	06MAR01	16:19	BRL29060 10mg
	07MAR01	17:35	BRL29060 10mg
	08MAR01	18:15	BRL29060 10mg
	09MAR01	18:10	BRL29060 20mg
	10MAR01	16:18	BRL29060 20mg
	11MAR01	16:15	BRL29060 20mg
	12MAR01	16:00	BRL29060 20mg
	13MAR01	16:11	BRL29060 20mg
	14MAR01	16:00	BRL29060 20mg
	15MAR01	15:55	BRL29060 20mg

16MAR01	16:30	BRL29060 20mg
17MAR01	16:21	BRL29060 20mg
18MAR01	16:00	BRL29060 20mg
19MAR01	16:04	BRL29060 20mg
20MAR01	16:00	BRL29060 20mg
21MAR01	17:02	BRL29060 20mg
22MAR01	17:45	BRL29060 20mg
23MAR01	17:45	BRL29060 30mg
24MAR01	16:30	BRL29060 30mg
25MAR01	17:00	BRL29060 30mg
26MAR01	17:15	BRL29060 30mg
27MAR01	16:00	BRL29060 30mg
28MAR01	16:30	BRL29060 30mg
29MAR01	16:30	BRL29060 30mg
30MAR01	16:00	BRL29060 30mg
31MAR01	16:12	BRL29060 30mg
01APR01	16:00	BRL29060 30mg
02APR01	16:18	BRL29060 30mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00509	03APR01	18:00	BRL29060 30mg
	04APR01	17:09	BRL29060 30mg
	05APR01	18:20	BRL29060 30mg
00510	02MAR01	17:35	BRL29060 10mg
	03MAR01	18:00	BRL29060 10mg
	04MAR01	18:00	BRL29060 10mg
	05MAR01	18:00	BRL29060 10mg
	06MAR01	18:00	BRL29060 10mg
	07MAR01	18:00	BRL29060 10mg
	08MAR01	18:00	BRL29060 10mg
	09MAR01	18:00	BRL29060 10mg
	10MAR01	18:00	BRL29060 10mg
	11MAR01	18:00	BRL29060 10mg
	12MAR01	19:15	BRL29060 10mg
	13MAR01	19:15	BRL29060 10mg
	14MAR01	18:00	BRL29060 10mg
	15MAR01	18:00	BRL29060 10mg
	16MAR01	18:35	BRL29060 10mg
	17MAR01	18:14	BRL29060 20mg
	18MAR01	18:00	BRL29060 20mg
	19MAR01	18:00	BRL29060 20mg
	20MAR01	18:17	BRL29060 20mg
	21MAR01	18:00	BRL29060 20mg
	22MAR01	18:12	BRL29060 20mg
	23MAR01	18:15	BRL29060 20mg
	24MAR01	18:37	BRL29060 20mg
	25MAR01	18:00	BRL29060 20mg
	26MAR01	19:15	BRL29060 20mg
	27MAR01	18:30	BRL29060 20mg
	28MAR01	18:00	BRL29060 20mg
	29MAR01	18:00	BRL29060 20mg
	30MAR01	18:30	BRL29060 20mg
	31MAR01	18:15	BRL29060 30mg
	01APR01	09:00	BRL29060 30mg
	02APR01	09:00	BRL29060 30mg
	03APR01	09:00	BRL29060 30mg
	04APR01	09:00	BRL29060 30mg
	05APR01	09:00	BRL29060 30mg
	06APR01	09:00	BRL29060 30mg
	07APR01	09:00	BRL29060 30mg
	08APR01	09:00	BRL29060 30mg
	09APR01	09:00	BRL29060 30mg
	10APR01	09:30	BRL29060 30mg
	11APR01	10:15	BRL29060 30mg
	12APR01	10:15	BRL29060 30mg
	13APR01	10:05	BRL29060 30mg

00601	12SEP00	09:50	BRL29060 10mg
	13SEP00	06:40	BRL29060 10mg
	14SEP00	06:40	BRL29060 10mg
	15SEP00	06:39	BRL29060 10mg
	16SEP00	06:40	BRL29060 10mg
	17SEP00	06:40	BRL29060 10mg
	18SEP00	06:40	BRL29060 10mg
	19SEP00	06:40	BRL29060 10mg
	20SEP00	06:40	BRL29060 10mg
	21SEP00	06:40	BRL29060 10mg
	22SEP00	06:40	BRL29060 10mg
	23SEP00	17:15	BRL29060 10mg
	24SEP00	10:00	BRL29060 10mg
	25SEP00	06:40	BRL29060 10mg
	26SEP00	06:50	BRL29060 20mg
	27SEP00	06:40	BRL29060 20mg
	28SEP00	06:40	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00601	29SEP00	06:40	BRL29060 20mg
	30SEP00	06:55	BRL29060 20mg
	01OCT00	06:45	BRL29060 20mg
	02OCT00	06:40	BRL29060 20mg
	03OCT00	06:40	BRL29060 20mg
	04OCT00	06:39	BRL29060 20mg
	05OCT00	06:40	BRL29060 20mg
	06OCT00	06:40	BRL29060 20mg
	07OCT00	07:15	BRL29060 20mg
	08OCT00	06:59	BRL29060 20mg
	09OCT00	06:40	BRL29060 20mg
	10OCT00	06:50	BRL29060 30mg
	11OCT00	06:46	BRL29060 30mg
	12OCT00	06:40	BRL29060 30mg
	13OCT00	06:40	BRL29060 30mg
	14OCT00	06:47	BRL29060 30mg
	15OCT00	06:40	BRL29060 30mg
	16OCT00	06:40	BRL29060 30mg
	17OCT00	06:40	BRL29060 30mg
	18OCT00	06:40	BRL29060 30mg
	19OCT00	06:40	BRL29060 30mg
	20OCT00	06:37	BRL29060 30mg
	21OCT00	07:27	BRL29060 30mg
	22OCT00	06:40	BRL29060 30mg
	23OCT00	06:45	BRL29060 30mg
00602	14NOV00	09:05	BRL29060 10mg
	15NOV00	07:05	BRL29060 10mg
	16NOV00	07:02	BRL29060 10mg
	17NOV00	07:01	BRL29060 10mg
	18NOV00	07:02	BRL29060 10mg
	19NOV00	07:00	BRL29060 10mg
	20NOV00	07:00	BRL29060 10mg
	21NOV00	07:00	BRL29060 10mg
	22NOV00	07:10	BRL29060 10mg
	23NOV00	07:00	BRL29060 10mg
	24NOV00	07:40	BRL29060 10mg
	25NOV00	07:02	BRL29060 10mg
	26NOV00	07:16	BRL29060 10mg
	27NOV00	06:55	BRL29060 10mg
	28NOV00	06:45	BRL29060 10mg
	29NOV00	06:55	BRL29060 20mg
	30NOV00	07:59	BRL29060 20mg
	01DEC00	07:02	BRL29060 20mg
	02DEC00	07:00	BRL29060 20mg
	03DEC00	07:00	BRL29060 20mg
	04DEC00	07:01	BRL29060 20mg

05DEC00	07:02	BRL29060 20mg
06DEC00	07:01	BRL29060 20mg
07DEC00	07:05	BRL29060 20mg
08DEC00	07:06	BRL29060 20mg
09DEC00	07:07	BRL29060 20mg
10DEC00	07:00	BRL29060 20mg
11DEC00	06:46	BRL29060 20mg
12DEC00	06:55	BRL29060 30mg
13DEC00	06:55	BRL29060 30mg
14DEC00	06:45	BRL29060 30mg
15DEC00	07:00	BRL29060 30mg
16DEC00	07:03	BRL29060 30mg
17DEC00	07:01	BRL29060 30mg
18DEC00	07:05	BRL29060 30mg
19DEC00	07:10	BRL29060 30mg
20DEC00	07:03	BRL29060 30mg
21DEC00	07:04	BRL29060 30mg
22DEC00	07:02	BRL29060 30mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00602	23DEC00	07:03	BRL29060 30mg
	24DEC00	07:00	BRL29060 30mg
	25DEC00	07:06	BRL29060 30mg
	26DEC00	06:55	BRL29060 30mg
	27DEC00	07:00	BRL29060 30mg
00605	13FEB01	09:15	BRL29060 10mg
	14FEB01	06:45	BRL29060 10mg
	15FEB01	07:00	BRL29060 10mg
	16FEB01	07:15	BRL29060 10mg
	17FEB01	07:00	BRL29060 10mg
	18FEB01	07:00	BRL29060 10mg
	19FEB01	07:00	BRL29060 10mg
	20FEB01	07:20	BRL29060 10mg
	21FEB01	07:00	BRL29060 10mg
	22FEB01	07:00	BRL29060 10mg
	23FEB01	07:10	BRL29060 10mg
	25FEB01	08:00	BRL29060 10mg
	26FEB01	06:00	BRL29060 10mg
	27FEB01	07:00	BRL29060 10mg
	28FEB01	07:00	BRL29060 20mg
	01MAR01	07:00	BRL29060 20mg
	02MAR01	07:00	BRL29060 20mg
	03MAR01	07:00	BRL29060 20mg
	04MAR01	07:00	BRL29060 20mg
	05MAR01	07:00	BRL29060 20mg
	06MAR01	07:00	BRL29060 20mg
	07MAR01	07:00	BRL29060 20mg
	08MAR01	07:00	BRL29060 20mg
	09MAR01	11:00	BRL29060 20mg
	10MAR01	09:30	BRL29060 20mg
	11MAR01	07:00	BRL29060 20mg
	12MAR01	07:00	BRL29060 20mg
	13MAR01	07:08	BRL29060 20mg
	14MAR01	07:00	BRL29060 30mg
	15MAR01	06:45	BRL29060 30mg
	16MAR01	06:45	BRL29060 30mg
	17MAR01	06:45	BRL29060 30mg
	18MAR01	06:45	BRL29060 30mg
	19MAR01	07:00	BRL29060 30mg
	20MAR01	08:00	BRL29060 30mg
	21MAR01	07:13	BRL29060 30mg
	22MAR01	07:00	BRL29060 30mg
	23MAR01	07:00	BRL29060 30mg
	24MAR01	07:00	BRL29060 30mg
	25MAR01	07:00	BRL29060 30mg
	26MAR01	06:30	BRL29060 30mg

27MAR01	07:05	BRL29060 30mg
28MAR01	09:15	BRL29060 20mg
29MAR01	07:00	BRL29060 20mg
30MAR01	07:00	BRL29060 20mg
31MAR01	07:00	BRL29060 20mg
01APR01	07:00	BRL29060 20mg
02APR01	07:00	BRL29060 20mg
03APR01	07:00	BRL29060 20mg
04APR01	07:00	BRL29060 20mg
05APR01	07:00	BRL29060 20mg
06APR01	07:00	BRL29060 20mg
07APR01	09:15	BRL29060 20mg
08APR01	07:00	BRL29060 20mg
09APR01	07:00	BRL29060 20mg
10APR01	07:00	BRL29060 20mg
11APR01	08:00	BRL29060 20mg
12APR01	08:00	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00606	20FEB01	09:00	BRL29060 10mg
	21FEB01	07:12	BRL29060 10mg
	22FEB01	07:25	BRL29060 10mg
	23FEB01	07:18	BRL29060 10mg
	24FEB01	07:15	BRL29060 10mg
	25FEB01	09:20	BRL29060 10mg
	26FEB01	07:17	BRL29060 10mg
	27FEB01	07:13	BRL29060 10mg
	28FEB01	07:20	BRL29060 10mg
	01MAR01	07:25	BRL29060 10mg
	02MAR01	09:20	BRL29060 10mg
	03MAR01	07:05	BRL29060 10mg
	04MAR01	07:05	BRL29060 10mg
	05MAR01	07:00	BRL29060 10mg
	06MAR01	06:55	BRL29060 10mg
	07MAR01	06:45	BRL29060 20mg
	08MAR01	07:15	BRL29060 20mg
	09MAR01	07:32	BRL29060 20mg
	10MAR01	07:00	BRL29060 20mg
	11MAR01	09:40	BRL29060 20mg
	12MAR01	07:30	BRL29060 20mg
	13MAR01	07:20	BRL29060 20mg
	16MAR01	07:35	BRL29060 20mg
	17MAR01	09:35	BRL29060 20mg
	18MAR01	10:50	BRL29060 20mg
	19MAR01	06:55	BRL29060 20mg
	20MAR01	07:00	BRL29060 20mg
	21MAR01	06:55	BRL29060 30mg
	22MAR01	07:40	BRL29060 30mg
	23MAR01	07:30	BRL29060 30mg
	24MAR01	11:15	BRL29060 30mg
	25MAR01	10:15	BRL29060 30mg
	26MAR01	07:35	BRL29060 30mg
	27MAR01	07:50	BRL29060 30mg
	28MAR01	07:40	BRL29060 30mg
	29MAR01	07:35	BRL29060 30mg
	30MAR01	12:10	BRL29060 30mg
	31MAR01	11:20	BRL29060 30mg
	01APR01	01:10	BRL29060 30mg
	02APR01	07:05	BRL29060 30mg
	03APR01	06:50	BRL29060 30mg
00607	21FEB01	09:25	BRL29060 10mg
	22FEB01	06:25	BRL29060 10mg
	23FEB01	06:46	BRL29060 10mg
	24FEB01	05:42	BRL29060 10mg
	25FEB01	06:40	BRL29060 10mg

26FEB01	06:19	BRL29060 10mg
27FEB01	06:42	BRL29060 10mg
28FEB01	06:31	BRL29060 10mg
01MAR01	07:05	BRL29060 10mg
02MAR01	06:46	BRL29060 10mg
03MAR01	06:32	BRL29060 10mg
04MAR01	06:30	BRL29060 10mg
05MAR01	07:10	BRL29060 10mg
06MAR01	06:55	BRL29060 20mg
07MAR01	06:41	BRL29060 20mg
08MAR01	06:47	BRL29060 20mg
09MAR01	07:16	BRL29060 20mg
10MAR01	07:05	BRL29060 20mg
11MAR01	05:30	BRL29060 20mg
12MAR01	05:30	BRL29060 20mg
13MAR01	05:30	BRL29060 20mg
14MAR01	06:50	BRL29060 20mg
15MAR01	06:40	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00607	16MAR01	06:07	BRL29060 20mg
	17MAR01	05:30	BRL29060 20mg
	18MAR01	06:20	BRL29060 20mg
	19MAR01	07:02	BRL29060 20mg
	20MAR01	06:15	BRL29060 20mg
	21MAR01	06:50	BRL29060 20mg
	22MAR01	06:55	BRL29060 30mg
	23MAR01	05:47	BRL29060 30mg
	24MAR01	06:18	BRL29060 30mg
	25MAR01	06:15	BRL29060 30mg
	26MAR01	06:22	BRL29060 30mg
	27MAR01	06:23	BRL29060 30mg
	28MAR01	06:05	BRL29060 30mg
	29MAR01	06:45	BRL29060 30mg
	30MAR01	06:23	BRL29060 30mg
	31MAR01	07:00	BRL29060 30mg
	01APR01	06:15	BRL29060 30mg
	02APR01	06:15	BRL29060 30mg
	03APR01	06:50	BRL29060 30mg
	04APR01	06:55	BRL29060 30mg
	05APR01	07:00	BRL29060 20mg
	06APR01	06:50	BRL29060 20mg
	07APR01	05:30	BRL29060 20mg
	08APR01	06:00	BRL29060 20mg
	09APR01	05:30	BRL29060 20mg
	10APR01	06:00	BRL29060 20mg
	11APR01	06:40	BRL29060 20mg
	12APR01	06:00	BRL29060 10mg
	13APR01	05:30	BRL29060 10mg
	14APR01	04:00	BRL29060 10mg
	15APR01	03:40	BRL29060 10mg
	16APR01	06:40	BRL29060 10mg
	17APR01	05:30	BRL29060 10mg
	18APR01	06:15	BRL29060 10mg
00701	30NOV00	08:15	BRL29060 10mg
	01DEC00	06:48	BRL29060 10mg
	02DEC00	12:38	BRL29060 10mg
	03DEC00	13:18	BRL29060 10mg
	04DEC00	06:55	BRL29060 10mg
	05DEC00	07:11	BRL29060 10mg
	06DEC00	07:00	BRL29060 10mg
	07DEC00	06:50	BRL29060 10mg
	08DEC00	06:55	BRL29060 10mg
	09DEC00	11:00	BRL29060 10mg
	10DEC00	10:30	BRL29060 10mg
	11DEC00	06:55	BRL29060 10mg

12DEC00	08:35	BRL29060 10mg
13DEC00	08:35	BRL29060 10mg
14DEC00	08:40	BRL29060 20mg
15DEC00	06:30	BRL29060 20mg
16DEC00	11:28	BRL29060 20mg
17DEC00	10:32	BRL29060 20mg
18DEC00	06:56	BRL29060 20mg
19DEC00	06:58	BRL29060 20mg
20DEC00	06:53	BRL29060 20mg
21DEC00	06:50	BRL29060 20mg
22DEC00	08:38	BRL29060 20mg
23DEC00	02:03	BRL29060 20mg
24DEC00	11:11	BRL29060 20mg
25DEC00	12:05	BRL29060 20mg
26DEC00	08:33	BRL29060 20mg
27DEC00	08:30	BRL29060 20mg
28DEC00	08:35	BRL29060 30mg
29DEC00	14:30	BRL29060 30mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00701	30DEC00	11:52	BRL29060 30mg
	31DEC00	12:30	BRL29060 30mg
	01JAN01	12:30	BRL29060 30mg
	02JAN01	09:57	BRL29060 30mg
	03JAN01	06:51	BRL29060 30mg
	04JAN01	07:00	BRL29060 30mg
	05JAN01	07:00	BRL29060 30mg
	06JAN01	10:38	BRL29060 30mg
	07JAN01	09:57	BRL29060 30mg
	08JAN01	07:00	BRL29060 30mg
	09JAN01	07:34	BRL29060 30mg
	10JAN01	07:41	BRL29060 30mg
	11JAN01	08:19	BRL29060 30mg
00703	08MAR01	11:30	BRL29060 UNKmg UNKNOWN AMOUNT
	09MAR01	11:30	BRL29060 UNKmg UNKNOWN AMOUNT
	10MAR01	11:30	BRL29060 UNKmg UNKNOWN AMOUNT
	11MAR01	11:30	BRL29060 UNKmg UNKNOWN AMOUNT
	12MAR01	11:30	BRL29060 UNKmg UNKNOWN AMOUNT
	13MAR01	11:30	BRL29060 UNKmg UNKNOWN AMOUNT
	14MAR01	11:30	BRL29060 UNKmg UNKNOWN AMOUNT
	15MAR01	11:30	BRL29060 UNKmg UNKNOWN AMOUNT
	16MAR01	11:30	BRL29060 UNKmg UNKNOWN AMOUNT
	17MAR01	11:30	BRL29060 UNKmg UNKNOWN AMOUNT
	18MAR01	11:30	BRL29060 UNKmg UNKNOWN AMOUNT
	19MAR01	11:30	BRL29060 50mg
00706	05APR01	07:05	BRL29060 10mg
	06APR01	06:44	BRL29060 10mg
	07APR01	07:00	BRL29060 10mg
	08APR01	09:30	BRL29060 10mg
	09APR01	06:45	BRL29060 10mg
	10APR01	06:59	BRL29060 10mg
	11APR01	08:32	BRL29060 10mg
	12APR01	08:43	BRL29060 10mg
	13APR01	07:48	BRL29060 10mg
	14APR01	07:20	BRL29060 10mg
	15APR01	08:45	BRL29060 10mg
	16APR01	09:21	BRL29060 10mg
	17APR01	08:30	BRL29060 10mg
	18APR01	09:00	BRL29060 10mg
	19APR01	09:15	BRL29060 20mg
	20APR01	06:54	BRL29060 20mg
	21APR01	07:45	BRL29060 20mg
	22APR01	07:57	BRL29060 20mg
	23APR01	06:52	BRL29060 20mg
	24APR01	06:59	BRL29060 20mg

25APR01	07:12	BRL29060 20mg
26APR01	06:54	BRL29060 20mg
27APR01	06:59	BRL29060 20mg
29APR01	07:40	BRL29060 20mg
30APR01	06:43	BRL29060 20mg
01MAY01	08:30	BRL29060 20mg
02MAY01	09:10	BRL29060 20mg
03MAY01	09:45	BRL29060 30mg
04MAY01	06:58	BRL29060 30mg
05MAY01	08:35	BRL29060 30mg
06MAY01	09:02	BRL29060 30mg
07MAY01	06:51	BRL29060 30mg
08MAY01	07:01	BRL29060 30mg
09MAY01	06:57	BRL29060 30mg
10MAY01	06:51	BRL29060 30mg
11MAY01	06:45	BRL29060 30mg
12MAY01	07:59	BRL29060 30mg
13MAY01	09:30	BRL29060 30mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00706	14MAY01	07:03	BRL29060 30mg
	15MAY01	08:30	BRL29060 30mg
	16MAY01	09:07	BRL29060 30mg
00804	31OCT00	08:12	BRL29060 10mg
	01NOV00	07:02	BRL29060 10mg
	02NOV00	07:00	BRL29060 10mg
	03NOV00	07:00	BRL29060 10mg
	04NOV00	07:00	BRL29060 10mg
	05NOV00	07:01	BRL29060 10mg
	06NOV00	07:00	BRL29060 10mg
	07NOV00	06:55	BRL29060 10mg
	08NOV00	07:00	BRL29060 10mg
	09NOV00	07:00	BRL29060 10mg
	10NOV00	07:01	BRL29060 10mg
	11NOV00	07:10	BRL29060 10mg
	12NOV00	07:00	BRL29060 10mg
	13NOV00	07:35	BRL29060 10mg
	14NOV00	06:50	BRL29060 10mg
	15NOV00	07:27	BRL29060 20mg
	16NOV00	07:15	BRL29060 20mg
	17NOV00	07:00	BRL29060 20mg
	18NOV00	07:00	BRL29060 20mg
	19NOV00	07:10	BRL29060 20mg
	20NOV00	07:00	BRL29060 20mg
	21NOV00	06:50	BRL29060 20mg
	22NOV00	07:00	BRL29060 20mg
	23NOV00	07:00	BRL29060 20mg
	24NOV00	07:00	BRL29060 20mg
	25NOV00	10:07	BRL29060 20mg
	26NOV00	07:00	BRL29060 20mg
	27NOV00	07:49	BRL29060 20mg
	28NOV00	06:40	BRL29060 20mg
	29NOV00	07:35	BRL29060 30mg
	30NOV00	07:00	BRL29060 30mg
	01DEC00	07:00	BRL29060 30mg
	02DEC00	07:25	BRL29060 30mg
	03DEC00	07:00	BRL29060 30mg
	04DEC00	07:00	BRL29060 30mg
	05DEC00	07:10	BRL29060 30mg
	06DEC00	07:00	BRL29060 30mg
	07DEC00	07:00	BRL29060 30mg
	08DEC00	07:00	BRL29060 30mg
	09DEC00	06:45	BRL29060 30mg
	10DEC00	07:00	BRL29060 30mg
	11DEC00	07:40	BRL29060 30mg
	12DEC00	06:54	BRL29060 30mg

	13DEC00	07:00	BRL29060 20mg
	14DEC00	07:00	BRL29060 20mg
	15DEC00	06:45	BRL29060 20mg
	16DEC00	07:15	BRL29060 20mg
	17DEC00	07:00	BRL29060 20mg
	18DEC00	07:05	BRL29060 20mg
	19DEC00	07:00	BRL29060 20mg
	20DEC00	07:00	BRL29060 20mg
00805	17NOV00	10:32	BRL29060 10mg
	18NOV00	09:14	BRL29060 10mg
	19NOV00	09:03	BRL29060 10mg
	20NOV00	09:18	BRL29060 10mg
	21NOV00	09:09	BRL29060 10mg
	22NOV00	09:12	BRL29060 10mg
	23NOV00	09:05	BRL29060 10mg
	24NOV00	09:16	BRL29060 10mg
	25NOV00	09:17	BRL29060 10mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00805	26NOV00	09:04	BRL29060 10mg
	27NOV00	09:09	BRL29060 10mg
	28NOV00	09:06	BRL29060 10mg
	29NOV00	09:40	BRL29060 10mg
	30NOV00	06:20	BRL29060 10mg
	01DEC00	07:45	BRL29060 20mg
	02DEC00	09:02	BRL29060 20mg
	03DEC00	09:12	BRL29060 20mg
	04DEC00	09:09	BRL29060 20mg
	05DEC00	09:06	BRL29060 20mg
	06DEC00	09:13	BRL29060 20mg
	07DEC00	09:06	BRL29060 20mg
	08DEC00	09:09	BRL29060 20mg
	09DEC00	09:10	BRL29060 20mg
	10DEC00	09:14	BRL29060 20mg
	11DEC00	09:09	BRL29060 20mg
	12DEC00	09:07	BRL29060 20mg
	13DEC00	08:04	BRL29060 20mg
	14DEC00	08:10	BRL29060 20mg
	15DEC00	07:43	BRL29060 30mg
	16DEC00	09:14	BRL29060 30mg
	17DEC00	09:58	BRL29060 30mg
	18DEC00	09:32	BRL29060 30mg
	19DEC00	09:48	BRL29060 30mg
	20DEC00	09:33	BRL29060 30mg
	21DEC00	10:12	BRL29060 30mg
	22DEC00	10:43	BRL29060 30mg
	23DEC00	10:12	BRL29060 30mg
	24DEC00	10:47	BRL29060 30mg
	25DEC00	10:02	BRL29060 30mg
	26DEC00	09:52	BRL29060 30mg
	27DEC00	07:57	BRL29060 30mg
	28DEC00	07:05	BRL29060 30mg
	29DEC00	08:10	BRL29060 20mg
	30DEC00	08:04	BRL29060 20mg
	31DEC00	09:10	BRL29060 20mg
	01JAN01	10:16	BRL29060 20mg
	02JAN01	10:19	BRL29060 20mg
	03JAN01	09:14	BRL29060 20mg
	04JAN01	09:37	BRL29060 20mg
	05JAN01	08:56	BRL29060 10mg
	06JAN01	09:48	BRL29060 10mg
	07JAN01	09:11	BRL29060 10mg
	08JAN01	10:05	BRL29060 10mg
	09JAN01	10:14	BRL29060 10mg
	10JAN01	09:04	BRL29060 10mg

00809	08DEC00	08:51	BRL29060 10mg
	09DEC00	08:13	BRL29060 10mg
	10DEC00	07:07	BRL29060 10mg
	11DEC00	07:15	BRL29060 10mg
	12DEC00	07:20	BRL29060 10mg
	13DEC00	07:17	BRL29060 10mg
	14DEC00	07:15	BRL29060 10mg
	15DEC00	07:14	BRL29060 10mg
	16DEC00	11:11	BRL29060 10mg
	17DEC00	11:35	BRL29060 10mg
	18DEC00	11:50	BRL29060 10mg
	19DEC00	12:09	BRL29060 10mg
	20DEC00	08:02	BRL29060 10mg
	21DEC00	06:35	BRL29060 10mg
	22DEC00	07:41	BRL29060 20mg
	23DEC00	12:00	BRL29060 20mg
	24DEC00	12:00	BRL29060 20mg
	25DEC00	12:30	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00809	26DEC00	12:00	BRL29060 20mg
	27DEC00	12:00	BRL29060 20mg
	28DEC00	12:00	BRL29060 20mg
	29DEC00	12:30	BRL29060 20mg
	30DEC00	12:30	BRL29060 20mg
	31DEC00	12:31	BRL29060 20mg
	01JAN01	12:32	BRL29060 20mg
	02JAN01	07:21	BRL29060 20mg
	03JAN01	08:36	BRL29060 20mg
	04JAN01	06:35	BRL29060 20mg
	05JAN01	09:14	BRL29060 30mg
	06JAN01	09:14	BRL29060 30mg
	07JAN01	07:30	BRL29060 30mg
	08JAN01	07:25	BRL29060 30mg
	09JAN01	07:25	BRL29060 30mg
	10JAN01	07:25	BRL29060 30mg
	11JAN01	07:20	BRL29060 30mg
	12JAN01	07:25	BRL29060 30mg
	13JAN01	07:20	BRL29060 30mg
	14JAN01	07:15	BRL29060 30mg
	15JAN01	07:20	BRL29060 30mg
	16JAN01	07:15	BRL29060 30mg
	17JAN01	07:00	BRL29060 30mg
	18JAN01	06:35	BRL29060 30mg
	19JAN01	10:00	BRL29060 20mg
	20JAN01	07:00	BRL29060 20mg
	21JAN01	07:00	BRL29060 20mg
	22JAN01	07:05	BRL29060 20mg
	23JAN01	11:05	BRL29060 20mg
	24JAN01	07:09	BRL29060 20mg
00811	09JAN01	09:18	BRL29060 10mg
	10JAN01	07:11	BRL29060 10mg
	11JAN01	06:53	BRL29060 10mg
	12JAN01	07:45	BRL29060 10mg
	13JAN01	09:38	BRL29060 10mg
	14JAN01	10:09	BRL29060 10mg
	15JAN01	09:30	BRL29060 10mg
	16JAN01	06:49	BRL29060 10mg
	17JAN01	07:07	BRL29060 10mg
	18JAN01	06:40	BRL29060 10mg
	19JAN01	06:38	BRL29060 10mg
	20JAN01	10:00	BRL29060 10mg
	21JAN01	09:45	BRL29060 10mg
	22JAN01	08:10	BRL29060 10mg
	23JAN01	07:36	BRL29060 10mg
	24JAN01	07:32	BRL29060 20mg

25JAN01	06:32	BRL29060 20mg
26JAN01	07:25	BRL29060 20mg
27JAN01	10:20	BRL29060 20mg
28JAN01	09:36	BRL29060 20mg
29JAN01	07:00	BRL29060 20mg
30JAN01	07:17	BRL29060 20mg
31JAN01	07:25	BRL29060 20mg
01FEB01	10:30	BRL29060 20mg
02FEB01	07:20	BRL29060 20mg
03FEB01	10:30	BRL29060 20mg
04FEB01	09:31	BRL29060 20mg
05FEB01	07:50	BRL29060 20mg
06FEB01	08:00	BRL29060 20mg
07FEB01	08:25	BRL29060 30mg
08FEB01	07:04	BRL29060 30mg
09FEB01	07:08	BRL29060 30mg
10FEB01	08:32	BRL29060 30mg
11FEB01	12:19	BRL29060 30mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00811	12FEB01	06:36	BRL29060 30mg
	13FEB01	06:47	BRL29060 30mg
	14FEB01	06:42	BRL29060 30mg
	15FEB01	06:35	BRL29060 30mg
	16FEB01	07:47	BRL29060 30mg
	17FEB01	08:40	BRL29060 30mg
	18FEB01	08:14	BRL29060 30mg
	19FEB01	08:00	BRL29060 30mg
	20FEB01	08:40	BRL29060 30mg
	21FEB01	08:00	BRL29060 20mg
	22FEB01	07:03	BRL29060 20mg
	23FEB01	06:45	BRL29060 20mg
	24FEB01	08:56	BRL29060 20mg
	25FEB01	11:15	BRL29060 20mg
	26FEB01	06:56	BRL29060 20mg
	27FEB01	07:05	BRL29060 20mg
	28FEB01	07:04	BRL29060 20mg
	01MAR01	06:50	BRL29060 20mg
00816	06FEB01	09:10	BRL29060 10mg
	07FEB01	08:53	BRL29060 10mg
	08FEB01	07:03	BRL29060 10mg
	09FEB01	01:44	BRL29060 10mg
	10FEB01	11:07	BRL29060 10mg
	11FEB01	12:07	BRL29060 10mg
	12FEB01	07:15	BRL29060 10mg
	13FEB01	07:05	BRL29060 10mg
	15FEB01	07:05	BRL29060 10mg
	16FEB01	07:15	BRL29060 10mg
	17FEB01	11:25	BRL29060 10mg
	18FEB01	10:17	BRL29060 10mg
	19FEB01	11:00	BRL29060 10mg
	20FEB01	08:25	BRL29060 10mg
	21FEB01	10:20	BRL29060 20mg
	22FEB01	07:43	BRL29060 20mg
	23FEB01	08:31	BRL29060 20mg
	24FEB01	08:05	BRL29060 20mg
	25FEB01	08:10	BRL29060 20mg
	26FEB01	07:25	BRL29060 20mg
	27FEB01	07:14	BRL29060 20mg
	28FEB01	07:15	BRL29060 20mg
	01MAR01	07:30	BRL29060 20mg
	02MAR01	08:00	BRL29060 20mg
	03MAR01	08:05	BRL29060 20mg
	04MAR01	07:30	BRL29060 20mg
	05MAR01	09:00	BRL29060 20mg
	06MAR01	08:30	BRL29060 20mg

	07MAR01	08:57	BRL29060 30mg
	08MAR01	07:05	BRL29060 30mg
	09MAR01	07:15	BRL29060 30mg
	10MAR01	07:00	BRL29060 30mg
	11MAR01	07:05	BRL29060 30mg
	12MAR01	07:05	BRL29060 30mg
	13MAR01	07:10	BRL29060 30mg
	14MAR01	07:30	BRL29060 30mg
	16MAR01	07:05	BRL29060 30mg
	17MAR01	07:15	BRL29060 30mg
	18MAR01	07:05	BRL29060 30mg
	19MAR01	09:30	BRL29060 30mg
	20MAR01	08:08	BRL29060 30mg
00824	21MAR01	15:54	BRL29060 10mg
	22MAR01	07:00	BRL29060 10mg
	23MAR01	07:00	BRL29060 10mg
	24MAR01	12:00	BRL29060 10mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00824	25MAR01	12:00	BRL29060 10mg
	26MAR01	12:00	BRL29060 10mg
	27MAR01	11:30	BRL29060 10mg
	28MAR01	11:30	BRL29060 10mg
	29MAR01	12:00	BRL29060 10mg
	30MAR01	12:30	BRL29060 10mg
	31MAR01	14:30	BRL29060 10mg
	01APR01	13:30	BRL29060 10mg
	02APR01	11:30	BRL29060 10mg
	03APR01	12:00	BRL29060 10mg
	04APR01	11:30	BRL29060 10mg
	05APR01	10:00	BRL29060 10mg
	06APR01	07:20	BRL29060 10mg
	07APR01	08:40	BRL29060 20mg
	08APR01	10:00	BRL29060 20mg
	09APR01	07:00	BRL29060 20mg
	10APR01	07:00	BRL29060 20mg
	11APR01	07:00	BRL29060 20mg
	12APR01	07:00	BRL29060 20mg
	14APR01	12:00	BRL29060 20mg
	15APR01	12:00	BRL29060 20mg
	16APR01	07:00	BRL29060 20mg
	17APR01	07:00	BRL29060 20mg
	18APR01	08:30	BRL29060 20mg
	19APR01	07:19	BRL29060 20mg
	20APR01	08:28	BRL29060 30mg
	21APR01	09:30	BRL29060 30mg
	22APR01	09:30	BRL29060 30mg
	23APR01	07:00	BRL29060 30mg
	24APR01	07:00	BRL29060 30mg
	25APR01	07:00	BRL29060 30mg
	26APR01	07:00	BRL29060 30mg
	27APR01	07:00	BRL29060 30mg
	28APR01	10:30	BRL29060 30mg
	29APR01	10:30	BRL29060 30mg
	30APR01	07:00	BRL29060 30mg
	01MAY01	07:00	BRL29060 30mg
	02MAY01	07:26	BRL29060 30mg
	03MAY01	07:16	BRL29060 30mg
	04MAY01	07:33	BRL29060 20mg
	05MAY01	10:30	BRL29060 20mg
	06MAY01	10:30	BRL29060 20mg
	07MAY01	07:00	BRL29060 20mg
	08MAY01	07:00	BRL29060 20mg
	09MAY01	07:00	BRL29060 20mg
00825	21MAR01	15:25	BRL29060 10mg

22MAR01	08:00	BRL29060 10mg
23MAR01	08:00	BRL29060 10mg
24MAR01	08:00	BRL29060 10mg
25MAR01	08:00	BRL29060 10mg
26MAR01	08:00	BRL29060 10mg
27MAR01	08:00	BRL29060 10mg
28MAR01	08:00	BRL29060 10mg
29MAR01	08:00	BRL29060 10mg
30MAR01	08:00	BRL29060 10mg
31MAR01	08:00	BRL29060 10mg
01APR01	08:00	BRL29060 10mg
02APR01	08:00	BRL29060 10mg
03APR01	08:00	BRL29060 10mg
04APR01	08:00	BRL29060 10mg
05APR01	08:00	BRL29060 10mg
06APR01	07:25	BRL29060 10mg
07APR01	08:52	BRL29060 20mg
08APR01	08:00	BRL29060 20mg

. = No data available

Table DS2

DOSING DETAILS OF STUDY SB29060/715

Subject Group - ADOLESCENTS

Sub No	Dosing Date	Time	Actual dose
00825	09APR01	08:00	BRL29060 20mg
	10APR01	08:00	BRL29060 20mg
	11APR01	08:00	BRL29060 20mg
	12APR01	08:00	BRL29060 20mg
	13APR01	08:00	BRL29060 20mg
	14APR01	08:00	BRL29060 20mg
	15APR01	08:00	BRL29060 20mg
	16APR01	08:00	BRL29060 20mg
	17APR01	08:00	BRL29060 20mg
	18APR01	07:33	BRL29060 20mg
	19APR01	07:11	BRL29060 20mg
	20APR01	07:44	BRL29060 30mg
	21APR01	08:30	BRL29060 30mg
	22APR01	08:30	BRL29060 30mg
	23APR01	08:30	BRL29060 30mg
	24APR01	08:30	BRL29060 30mg
	25APR01	08:30	BRL29060 30mg
	26APR01	08:30	BRL29060 30mg
	27APR01	08:30	BRL29060 30mg
	28APR01	08:30	BRL29060 30mg
	29APR01	08:30	BRL29060 30mg
	30APR01	08:30	BRL29060 30mg
	01MAY01	08:30	BRL29060 30mg
	02MAY01	07:17	BRL29060 30mg
	03MAY01	07:18	BRL29060 30mg
	04MAY01	08:40	BRL29060 20mg
	05MAY01	09:00	BRL29060 20mg
	06MAY01	09:00	BRL29060 20mg
	07MAY01	09:00	BRL29060 20mg
	08MAY01	09:00	BRL29060 20mg
	09MAY01	09:00	BRL29060 20mg

. = No data available

Table DS33

Compliance Data OF STUDY

SB29060/715

Subject Group - CHILDREN

Subject No.		Relative Time	Tablets Dispensed	Tablets Returned	Compliance %
00001	10mg Compliance	Day 15	17	2	100
	20mg Compliance	Day 29	34	9	89
	30mg Compliance	Day 43	51	0	121
00053	10mg Compliance	Day 14	17	2	107
	20mg Compliance	Day 28	34	4	107
	30mg Compliance	Day 42	51	9	100
00055	10mg Compliance	Day 14	17	2	107
	20mg Compliance	Day 28	34	6	100
	30mg Compliance	Day 42	51	9	100
00101	10mg Compliance	Day 15	17	2	100
	20mg Compliance	Day 29	34	8	93
	30mg Compliance	Day 43	51	6	107
00102	10mg Compliance	Day 14	17	3	100
	20mg Compliance	Day 29	34	4	100
	30mg Compliance	Day 41	51	12	108
00104	10mg Compliance	Day 14	17	3	100
	20mg Compliance	Day 28	34	8	93
	30mg Compliance	Day 42	51	11	95
00106	10mg Compliance	Day 15	17	2	100

			20mg Compliance	Day 30	34
4	100				
			30mg Compliance	Day 44	51
9	100				
		00107	10mg Compliance	Day 16	17
3	88				
			20mg Compliance	Day 29	34
10	92				
			30mg Compliance	Day 44	51
15	80				
		00108	10mg Compliance	Day 15	17
2	100				
			20mg Compliance	Day 29	34
6	100				
			30mg Compliance	Day 43	51
9	100				

. = No data available

[S0245058:LIS]
[11DEC2001:11:21]

Table DS33

Compliance Data OF STUDY

SB29060/715

Subject Group - CHILDREN

Subject No.		Relative Time		Tablets Dispensed	Tablets Returned	Compliance %
00110	10mg Compliance	Day 15		17	2	100
	20mg Compliance	Day 29		34	6	100
	30mg Compliance	Day 43		51	15	86
00111	10mg Compliance	Day	.	17	3.5	.
	20mg Compliance	Day	.		.	
	30mg Compliance	Day	.		.	
00112	10mg Compliance	Day 14		17	4	93
	20mg Compliance	Day 28		34	4	107
	30mg Compliance	Day 42		51	11	95

		00113	10mg Compliance	Day	.	17
0	.					
			20mg Compliance	Day	.	
.						
			30mg Compliance	Day	.	
.						
		00202	10mg Compliance	Day	12	17
5	100					
			20mg Compliance	Day	26	34
6	100					
			30mg Compliance	Day	40	51
9	100					
		00301	10mg Compliance	Day	15	17
3	93					
			20mg Compliance	Day	.	34
0	.					
			30mg Compliance	Day	.	
.						
		00303	10mg Compliance	Day	18	17
0	94					
			20mg Compliance	Day	31	34
9	96					
			30mg Compliance	Day	44	51
15	92					
		00504	10mg Compliance	Day	15	17
2	100					
			20mg Compliance	Day	29	34
6	100					
			30mg Compliance	Day	.	51
32	.					
		00603	10mg Compliance	Day	15	17
2	100					
			20mg Compliance	Day	29	34
12	79					
			30mg Compliance	Day	43	51
17	81					

. = No data available

[S0245058:LIS]
[11DEC2001:11:21]

Table DS33

Compliance Data OF STUDY

SB29060/715

Subject Group - CHILDREN

Subject	Relative Time	Tablets	Tablets	Compliance

	No.			Dispensed	Returned	%
	00604	10mg Compliance	Day 15	17	3	93
		20mg Compliance	Day 30	34	6	93
		30mg Compliance	Day 44	51	12	93
	00702	10mg Compliance	Day 15	17	1	107
		20mg Compliance	Day 29	34	7	96
		30mg Compliance	Day 43	51	12	93
	00704	10mg Compliance	Day 13	17	4	100
		20mg Compliance	Day 27	34	6	100
		30mg Compliance	Day 41	51	12	93
	00705	10mg Compliance	Day 14	17	3	100
		20mg Compliance	Day 28	34	6	100
		30mg Compliance	Day 42	51	9	100
	00707	10mg Compliance	Day 14	17	3	100
		20mg Compliance	Day 28	34	6	100
		30mg Compliance	Day 42	51	9	100
	00708	10mg Compliance	Day 14	17	3	100
		20mg Compliance	Day 28	34	6	100
		30mg Compliance	Day 42	51	12	93
	00709	10mg Compliance	Day 14	17	3	100
		20mg Compliance	Day 28	34	5	104
		30mg Compliance	Day 42	51	13	90
	00806	10mg Compliance	Day 14	17	3	100
		20mg Compliance	Day 28	34	9	89

			30mg Compliance	Day 42	51
9	100				
		00818	10mg Compliance	Day 13	17
4	100				
			20mg Compliance	Day 27	34
10	86				
			30mg Compliance	Day 41	51
12	93				

. = No data available

[S0245058:LIS]
[11DEC2001:11:21]

Table DS33

Compliance Data OF STUDY

SB29060/715

Subject Group - ADOLESCENTS

Subject No.		Relative Time	Tablets Dispensed	Tablets Returned	Compliance %
00002	10mg Compliance	Day 14	17	3	100
	20mg Compliance	Day 28	34	10	86
	30mg Compliance	Day 42	51	9	100
00003	10mg Compliance	Day 14	17	3	100
	20mg Compliance	Day 28	34	6	100
	30mg Compliance	Day 43	51	3	107
00004	10mg Compliance	Day 12	17	5	100
	20mg Compliance	Day 26	34	8	93
	30mg Compliance	Day 40	51	9	100
00005	10mg Compliance	Day 15	17	2	100
	20mg Compliance	Day .	34	11	.
	30mg Compliance	Day .		.	

		00007	10mg Compliance	Day 13	17	
4	100					
			20mg Compliance	Day 26	34	
10	92					
			30mg Compliance	Day .	51	
0	.					
		00051	10mg Compliance	Day 14	17	
1	114					
			20mg Compliance	Day 28	33	
0	118					
			30mg Compliance	Day 42	51	
8	102					
		00052	10mg Compliance	Day 14	17	
2	107					
			20mg Compliance	Day 28	34	
6	100					
			30mg Compliance	Day 42	51	
1	119					
		00054	10mg Compliance	Day 14	17	
3	100					
			20mg Compliance	Day .		
.						
			30mg Compliance	Day .		
.						
		00103	10mg Compliance	Day 15	17	
2	100					
			20mg Compliance	Day 29	34	
8	93					
			30mg Compliance	Day 43	51	
12	93					

. = No data available

[S0245058:LIS]
[11DEC2001:11:21]

Table DS33

Compliance Data OF STUDY

SB29060/715

Subject Group - ADOLESCENTS

Subject No.		Relative Time		Tablets Dispensed	Tablets Returned	Compliance %
00105	10mg Compliance	Day 13		17	4	100
	20mg Compliance	Day 27		34	7	96

			30mg Compliance	Day	41	51
12	93					
		00109	10mg Compliance	Day	15	17
3	93					
			20mg Compliance	Day	29	34
16	64					
			30mg Compliance	Day	43	51
15	86					
		00201	10mg Compliance	Day	13	17
5	92					
			20mg Compliance	Day	.	34
6	.					
			30mg Compliance	Day	.	51
0	.					
		00401	10mg Compliance	Day	13	17
4	100					
			20mg Compliance	Day	27	34
6	100					
			30mg Compliance	Day	41	51
9	100					
		00502	10mg Compliance	Day	15	17
5	80					
			20mg Compliance	Day	29	34
6	100					
			30mg Compliance	Day	40	51
13	115					
		00503	10mg Compliance	Day	15	17
3	93					
			20mg Compliance	Day	29	34
8	93					
			30mg Compliance	Day	42	51
1	128					
		00505	10mg Compliance	Day	15	17
0	113					
			20mg Compliance	Day	29	34
6	100					
			30mg Compliance	Day	.	17
10	.					
		00506	10mg Compliance	Day	12	17
5	100					
			20mg Compliance	Day	27	34
8	87					
			30mg Compliance	Day	40	51
21	77					
		00507	10mg Compliance	Day	15	17
0	113					
			20mg Compliance	Day	29	34
8	93					

			30mg Compliance	Day 43	51	
9	100					

. = No data available

[S0245058:LIS]
[11DEC2001:11:21]

Table DS33

Compliance Data OF STUDY

SB29060/715

Subject Group - ADOLESCENTS

Subject No.		Relative Time	Tablets Dispensed	Tablets Returned	Compliance %
00509	10mg Compliance	Day 15	17	2	100
	20mg Compliance	Day 29	34	6	100
	30mg Compliance	Day 43	51	0	121
00510	10mg Compliance	Day 15	17	3	93
	20mg Compliance	Day 29	34	6	100
	30mg Compliance	Day 43	51	9	100
00601	10mg Compliance	Day 14	17	3	100
	20mg Compliance	Day 28	34	6	100
	30mg Compliance	Day 42	51	9	100
00602	10mg Compliance	Day 15	17	2	100
	20mg Compliance	Day 29	34	6	100
	30mg Compliance	Day 44	51	9	93
00605	10mg Compliance	Day 15	17	4	87
	20mg Compliance	Day 29	34	8	93
	30mg Compliance	Day 43	51	6	107

		00606	10mg Compliance	Day 15	17	2
100						
			20mg Compliance	Day 29	34	8
93						
			30mg Compliance	Day 43	51	9
100						
		00607	10mg Compliance	Day 13	17	4
100						
			20mg Compliance	Day 29	34	2
100						
			30mg Compliance	Day 43	51	9
100						
		00701	10mg Compliance	Day 14	17	3
100						
			20mg Compliance	Day 28	34	8
93						
			30mg Compliance	Day 42	51	7
105						
		00703	10mg Compliance	Day .	17	0
.						
			20mg Compliance	Day .		.
			30mg Compliance	Day .		.

. = No data available

[S0245058:LIS]
[11DEC2001:11:21]

Table DS33

Compliance Data OF STUDY

SB29060/715

Subject Group - ADOLESCENTS

Subject No.		Relative Time	Tablets Dispensed	Tablets Returned	Compliance %
00706	10mg Compliance	Day 14	17	2	107
	20mg Compliance	Day 28	34	8	93
	30mg Compliance	Day 42	51	12	93
00804	10mg Compliance	Day 15	17	2	100
	20mg Compliance	Day 29	34	5	104

			30mg Compliance	Day 43	51
9	100				
		00805	10mg Compliance	Day 14	17
3	100				
			20mg Compliance	Day 28	34
5	104				
			30mg Compliance	Day 42	51
9	100				
		00809	10mg Compliance	Day 14	17
4	93				
			20mg Compliance	Day 28	34
8	93				
			30mg Compliance	Day 42	51
12	93				
		00811	10mg Compliance	Day 15	17
2	100				
			20mg Compliance	Day 29	34
10	86				
			30mg Compliance	Day 43	51
9	100				
		00816	10mg Compliance	Day 15	17
1	107				
			20mg Compliance	Day 29	34
4	107				
			30mg Compliance	Day 43	51
15	86				
		00824	10mg Compliance	Day 17	17
0	100				
			20mg Compliance	Day 30	34
10	92				
			30mg Compliance	Day 44	51
9	100				
		00825	10mg Compliance	Day 17	17
0	100				
			20mg Compliance	Day 30	34
8	100				
			30mg Compliance	Day 44	51
9	100				

. = No data available

[S0245058:LIS]
[11DEC2001:11:21]

Table DS5
SIGNS AND SYMPTOMS / ADVERSE EVENTS KEY OF STUDY SB29060/715

Field	Column Heading	Decode
Action	Action	DIR=Dose interrupted/restarted DOI=Dose increased DOR=Dose reduced DST=Drug stopped NON=None
Course	Course	CNT=Constant INT=Intermittent UNK=Unknown nnn=nnn episodes
Outcome	Outcome	1=Fatal 2=Life threatening 3=Disabling/incapacitating 4=Results in hospitalisation 5=Prolongs a hospital stay 6=Associated with an abnormality 7=Associated with cancer 8=Associated with overdose 9=Other D=Died O=Ongoing R=Resolved T=Corrective Therapy given UNK=Unknown W=Withdrawn
Relation	Rel	PRU=Probably unrelated PSR=Possibly related REL=Related UNR=Unrelated
Severity	Sev	MIL=Mild MOD=Moderate SEV=Severe

Table DS6

SIGNS AND SYMPTOMS OF STUDY SB29060/715 - PRE-STUDY

Subject Group - CHILDREN

Sub no	Preferred Term [Verbatim]	Duration	Time from Onset to	Sev	Course	Outcome	Start date and time	Dose
00806	COUGHING [COUGH]	9 Days	10 Days	MOD	CNT	R	07NOV2000:09:00	
	RHINITIS [CONGESTION]	9 Days	10 Days	MOD	CNT	R	07NOV2000:09:00	

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

SIGNS AND SYMPTOMS OF STUDY SB29060/715 - PRE-STUDY

Subject Group - ADOLESCENTS

Sub no	Preferred Term [Verbatim]	Duration	Time from Onset to	Sev	Course	Outcome	Start date and time	Dose
00701	MYALGIA [CRAMP]	1h 00m	5d 14h	MIL	CNT	R	24NOV2000:18:30	
	NAUSEA [NAUSEA]	10 min	5d 13h	MIL	CNT	R	24NOV2000:19:30	

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

SIGNS AND SYMPTOMS OF STUDY SB29060/715 - BASELINE

Subject Group - CHILDREN

Sub no	Preferred Term [Verbatim]	Duration	Time from Onset to Dose	Sev	Course	Outcome	Start date and time
00104	COUGHING [COUGH]	7 Days	17h 10m	MIL	CNT	R	14DEC2000:21:00
00111	BACK PAIN [BACK PAIN]	Unknown	5d 16h	MOD	CNT	O	16MAR2001:18:00
00702	LARYNGITIS ["LARYNGITIS" (LOSS OF VOICE)]	17 Days	2d 21h	MOD	CNT	R	26JAN2001:12:00
	PHARYNGITIS [TONSILS ENLARGED]	17 Days	2d 21h	MIL	CNT	R	26JAN2001:12:00
	HEADACHE [HEADACHE]	14 Days	2h 07m	MIL	CNT	R	29JAN2001:07:00
00704	INSOMNIA [INSOMNIA]	45 Days	4d 08h	MIL	CNT	R	04MAR2001:00:00
00818	BLEPHARITIS [BLEPHARITIS OF LOWER LIDS OF BOTH EYES]	Unknown	7 Days	MIL	CNT	O,T	01FEB2001:00:00

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

SIGNS AND SYMPTOMS OF STUDY SB29060/715 - BASELINE

Subject Group - ADOLESCENTS

Sub no	Preferred Term [Verbatim]	Start date and time	Duration	Time from Onset to	Sev	Course	Outcome	Dose
00109	ABDOMINAL PAIN [STOMACH ACHE]	07MAR2001:00:00	1d 12h	17h 20m	MOD	CNT	R	
00507	UPPER RESP TRACT INFECTION [UPPER RESPIRATORY INFECTIONS]	04FEB2001:00:00	16 Days	4d 18h	MIL	CNT	R,T	

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - CHILDREN

Sub no	Sess no	Preferred Term [Verbatim]						Start date and time	Duration Last Dose	Time from ion	Rel to Onset
Regimen - BRL29060 10MG UID											
00001	1	DIARRHEA [DIARRHOEA]	PSR	MOD	CNT	NON	R	24OCT2000:00:00	23h 59m	15h 40m	
	1	ABDOMINAL PAIN [STOMACH ACHE]	PSR	MIL	CNT	NON	R	24OCT2000:00:00	14 Days	15h 40m	
	1	DIARRHEA [DIARRHOEA]	PSR	MOD	CNT	NON	R	30OCT2000:00:00	23h 59m	17h 30m	
00101	1	ABDOMINAL PAIN [STOMACHACHE]	PSR	MIL	CNT	NON	R	13NOV2000:00:00	23h 59m	15h 30m	
	1	HEADACHE [HEADACHE]	PSR	MIL	CNT	NON	R,T	14NOV2000:00:00	11h 59m	15h 30m	
	1	ABDOMINAL PAIN [STOMACHACHE]	PSR	MIL	CNT	NON	R	14NOV2000:00:00	23h 59m	15h 30m	
	1	HEADACHE [HEADACHE]	PSR	MIL	CNT	NON	R	14NOV2000:12:00	11h 59m	3h 30m	
	1	ABDOMINAL PAIN [STOMACHACHE]	PSR	MIL	CNT	NON	R	15NOV2000:00:00	23h 59m	15h 30m	
	1	ASTHMA	UNR	MIL	CNT	NON	R,T	15NOV2000:00:00	23h 59m	15h 30m	

[ASTHMA FLARE-UP]

1 ABDOMINAL PAIN 16NOV2000:00:00 23h 59m 15h 30m PSR MIL CNT NON R
[STOMACHACHE]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - CHILDREN

Sub no	Sess no	Preferred Term [Verbatim]	Start date and time	Duration	Time from Last Dose	Rel	Sev	Course	Action	Outcome

Regimen - BRL29060 10MG UID

00102	1	NAUSEA [NAUSEA]	13NOV2000:00:00	23h 59m	12h 37m	PSR	MIL	CNT	NON	R
	1	NERVOUSNESS [FIDGETINESS]	16NOV2000:00:00	23h 59m	17h 00m	PSR	MIL	CNT	NON	R
00104	1	RHINITIS [NASAL CONGESTION]	18DEC2000:00:00	30 Days	14h 46m	UNR	MIL	CNT	NON	R
00106	1	HEADACHE [HEADACHE]	28JAN2001:00:00	23h 59m	15h 00m	PSR	MOD	CNT	NON	R
00107	1	HEADACHE [HEADACHE]	05MAR2001:17:50	2h 00m	10h 20m	UNR	MOD	CNT	NON	R,T
00110	1	HEADACHE [INTERMITTENT HEADACHES]	14MAR2001:00:00	9 Days	14h 10m	PSR	MIL	CNT	NON	R

1 ABDOMINAL PAIN 14MAR2001:00:00 3d
00h 14h 10m PSR MIL CNT NON R
[INTERMITTENT STOMACH ACHES]

00111 1 ANOREXIA 29MAR2001:17:00 10
Days 8h 40m PSR MIL CNT NON R
[LOSS OF APPETITE]

1 ANXIETY 29MAR2001:17:00
Unknown 8h 40m PSR MIL INT NON O
[ANXIOUSNESS]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - CHILDREN

Sub no | Sess no | Preferred Term [Verbatim] | Start date and time | Duration Last Dose | Time from Rel Sev Course Action Outcome

Regimen - BRL29060 10MG UID

00111 1 NAUSEA 29MAR2001:17:00 10
Days 8h 40m PSR MIL CNT NON R
[NAUSEA]

1 HEADACHE 01APR2001:00:00 3d
00h 11h 15m PSR MIL CNT NON R,T
[INTERMITTENT HEADACHE]

1 COUGHING 01APR2001:00:00
Unknown 11h 15m UNR MOD CNT NON O,T
[INTERMITTENT COUGH]

1 PHARYNGITIS 01APR2001:00:00
Unknown 11h 15m UNR MIL CNT NON O,T
[SORE THROAT]

1 DYSPEPSIA 01APR2001:19:00 3h
00m 6h 15m UNR MIL INT NON R
[UPSET STOMACH]

1 AGGRESSIVE REACTION 02APR2001:14:00 3h 00m 5h 40m PSR MIL CNT NON R
[DEFIANCE]

1 NERVOUSNESS 02APR2001:14:00 3h 00m 5h 40m PSR MIL CNT NON R
[FIGITYNESS]

1 ASTHMA 04APR2001:00:00
Unknown 15h 40m UNR MOD CNT DST O,W,T
[ASTHMA EXACERBATION]

00112 1 ABDOMINAL PAIN 27APR2001:00:00 23h 59m 14h 25m PSR MIL CNT NON R
[STOMACH ACHE]

00202 1 HEADACHE 27FEB2001:19:20 1h 00m 7h 45m PSR MIL CNT NON R,T
[HEADACHE]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - CHILDREN

Sub no | Sess no | Preferred Term [Verbatim] | Start date and time | Duration Last Dose | Time from ion | Rel | Sev | Course | Act- | Outcome | to Onset

Regimen - BRL29060 10MG UID

00202 1 DIARRHEA 27FEB2001:19:30 15 min 7h 55m PRU MIL CNT NON R
[LOOSE STOOLS]

1 AGITATION 02MAR2001:18:00 5m 00s 7h 30m PSR MOD CNT NON R
[AGITATION]

1 AGGRESSIVE REACTION 03MAR2001:00:00 23h 59m 13h 30m PSR MOD CNT NON R
[OUTBURST]

	1	AGITATION						03MAR2001:00:00	23h 59m	13h 30m	PSR MIL 2 NON R [AGITATION]
	1	INSOMNIA						04MAR2001:00:00	23h 59m	12h 20m	PSR MOD CNT NON R [INSOMNIA]
	1	MYALGIA						04MAR2001:22:15	10 min	11h 34m	PSR MIL CNT NON R [SHOULDER/CHEST PAIN]
	1	NAUSEA						05MAR2001:00:00	23h 59m	13h 19m	PSR MIL CNT NON R [NAUSEA]
	1	HEADACHE						05MAR2001:21:30	1h 00m	13h 10m	PSR MIL CNT NON R,T [HEADACHE]
00301	1	HEADACHE						07MAY2001:19:00	1h 00m	7h 00m	PRU MIL CNT NON R,T [HEAD PAIN]
	1	BACK PAIN						07MAY2001:19:00	1h 00m	7h 00m	PRU MIL CNT NON R,T [NECK PAIN]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - CHILDREN

Sub no	Sess no	Preferred Term [Verbatim]					Start date and time	Duration Last Dose	Time from to Onset	Rel	Sev	Course	Act-ion	Outcome
Regimen - BRL29060 10MG UID														
00303	1	DIARRHEA					10JUL2001:00:00	23h 59m	12h 15m	PRU	MIL	CNT	NON	R [LOOSE STOOLS]

00604 1 VOMITING 24FEB2001:23:00 4h
00m 15h 50m PRU MOD CNT NON R
[VOMITING]

1 NAUSEA 24FEB2001:23:00 4h
00m 15h 50m PRU MOD CNT NON R
[NAUSEA]

00704 1 DIARRHEA 08MAR2001:08:45 11
Days 45 min UNR MIL CNT NON R,T
[DIARRHEA]

1 DIZZINESS 11MAR2001:15:00 2m
00s 6h 30m PRU MIL CNT NON R
[DIZZY]

1 UPPER RESP TRACT INFECTION 12MAR2001:07:40 7
Days 23h 10m UNR MIL CNT NON R,T
[COLD]

1 DIZZINESS 13MAR2001:15:00 1m
00s 7h 00m PRU MIL CNT NON R
[DIZZY]

1 HEADACHE 14MAR2001:18:00 2h
30m 10h 00m PRU MIL CNT NON R
[HEADACHE]

1 DYSPEPSIA 21MAR2001:08:20 15
min 23h 15m UNR MIL CNT NON R
[UPSET STOMACH]

1 SKIN COLD CLAMMY 21MAR2001:08:20 15
min 23h 15m UNR MIL CNT NON R
[CLAMMY]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - CHILDREN

Sub no | Sess no | Preferred Term [Verbatim] | Start date and time | Duration | Time from Last Dose | Rel | Sev | Course | Action | Outcome | to Onset

Regimen - BRL29060 10MG UID

00707 1 INJURY 15APR2001:14:00 0.0
sec 4h 30m UNR MIL CNT NON R,T
[ARM PAIN SECONDARY TO FALL]

00708 1 ABDOMINAL PAIN 07APR2001:08:40 2h
50m 30 min PSR MIL CNT NON R
[STOMACH ACHE]

00806 1 COUGHING 17NOV2000:09:11 28
Days 1m 00s UNR MIL CNT NON R,T
[COUGH]

00818 1 SOMNOLENCE 15FEB2001:12:00 3d
02h 5h 26m PRU MIL 3 NON R
[SLEEPINESS]

Regimen - BRL29060 20MG UID

00055 2 FATIGUE 07MAY2001:00:00 29
Days 16h 10m PSR MIL CNT NON R
[FATIGUE]

00101 2 ABDOMINAL PAIN 24NOV2000:00:00 23h
59m 14h 20m PSR MIL CNT NON R
[STOMACHACHE]

2 HEADACHE 25NOV2000:00:00 23h
59m 14h 40m PSR MIL CNT NON R
[HEADACHE]

2 ABDOMINAL PAIN 25NOV2000:00:00 23h
59m 14h 40m PSR MIL CNT NON R
[STOMACHACHE]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - CHILDREN

Sub no	Sess no	Preferred Term [Verbatim]						Start date and time	Duration Last Dose to Onset
Regimen - BRL29060 20MG UID									
00101	2	HEADACHE	PSR	MIL	CNT	NON	R	26NOV2000:00:00	23h 59m
		[HEADACHE]							15h 30m
	2	HEADACHE	PSR	MIL	CNT	NON	R	27NOV2000:00:00	23h 59m
		[HEADACHE]							15h 30m
	2	ABDOMINAL PAIN	PSR	MIL	CNT	NON	R	27NOV2000:00:00	23h 59m
		[STOMACHACHE]							15h 30m
	2	ABDOMINAL PAIN	PSR	MIL	CNT	NON	R	28NOV2000:00:00	23h 59m
		[STOMACHACHE]							15h 40m
	2	HEADACHE	PSR	MIL	CNT	NON	R	29NOV2000:00:00	23h 59m
		[HEADACHE]							15h 30m
00102	2	MUSCLE CONTRACTIONS INVOLUNTARY	PSR	MIL	CNT	NON	R	03DEC2000:15:30	32 Days
		[NECK TWITCHES]							6h 30m
	2	HEADACHE	UNR	MIL	CNT	NON	R	03DEC2000:20:00	3h 59m
		[HEADACHE]							11h 00m
	2	NERVOUSNESS	PSR	MOD	CNT	NON	R	06DEC2000:00:00	23h 59m
		[JITTERINESS]							16h 30m
	2	PERSONALITY DISORDER	PSR	MOD	CNT	NON	R	06DEC2000:00:00	23h 59m
		[WORSENED TEMPERMENT]							16h 30m
	2	INSOMNIA	PSR	MIL	CNT	NON	R	07DEC2000:00:00	23h 59m
		[DIFFICULTY SLEEPING]							16h 30m

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - CHILDREN

Sub no	Sess no	Preferred Term [Verbatim]	Start date and time	Duration Last Dose	Time from ion	Rel	Sev	Course	Act-ion	Outcome
Regimen - BRL29060 20MG UID										
00106	2	HEADACHE [HEADACHE]	19FEB2001:08:30	15h 29m	23h 30m	PSR	MOD	CNT	NON	R,T
00112	2	NEUROSIS [DISINHIBITION]	17MAY2001:00:00	30 Days	15h 30m	PSR	MIL	CNT	NON	R
00202	2	HEADACHE [HEADACHE]	11MAR2001:10:30	1h 00m	1h 40m	PSR	MOD	CNT	NON	R
	2	AGGRESSIVE REACTION [OUTBURST]	17MAR2001:00:00	23h 59m	15h 30m	PSR	MIL	CNT	NON	R
	2	HEADACHE [HEADACHE]	18MAR2001:14:00	1h 00m	5h 20m	PSR	MIL	CNT	NON	R,T
	2	AGGRESSIVE REACTION [OUTBURST]	18MAR2001:15:00	10 min	6h 20m	PSR	MIL	CNT	NON	R
	2	INSOMNIA [INSOMNIA]	20MAR2001:02:00	1h 00m	17h 30m	PSR	MIL	CNT	NON	R
	2	ABDOMINAL PAIN [STOMACH ACHE]	20MAR2001:02:00	1h 00m	17h 30m	PSR	MOD	CNT	NON	R
00504	2	AGITATION [AGITATED]	30JAN2001:00:00	7 Days	6h 15m	PSR	MIL	CNT	NON	R

2 DIZZINESS 30JAN2001:06:30 1h 00m 12h 45m PSR MIL CNT NON R
[DIZZINESS]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - CHILDREN

Sub no	Sess no	Preferred Term [Verbatim]	Start date and time	Duration	Time from Last Dose	Rel	Sev	Course	Act-ion	Outcome to Onset
Regimen - BRL29060 20MG UID										
00504	2	DIARRHEA	31JAN2001:00:00	23h 59m	5h 47m	PSR	MIL	CNT	NON	R
		[DIARRHOEA]								
	2	HYPERKINESIA	02FEB2001:00:00	27 Days	6h 13m	PSR	MIL	CNT	DOR	R
		[INCREASE IN HYPERACTIVITY]								
	2	PERSONALITY DISORDER	02FEB2001:00:00	Unknown	6h 13m	PSR	MIL	CNT	DOR	O
		[PERSONALITY CHANGE]								
	2	TOOTH ACHE	06FEB2001:00:00	3d 00h	5h 45m	PSR	MOD	CNT	NON	R,T
		[TEETH ACHING]								
	2	AGITATION	06FEB2001:12:00	22 Days	17h 45m	PSR	MOD	CNT	DOR	R
		[AGITATED]								
	2	AGGRESSIVE REACTION	07FEB2001:00:00	22 Days	5h 30m	PSR	MIL	CNT	DOR	R
		[INCREASE IN DEFIANT BEHAVIOUR]								
00604	2	AGGRESSIVE REACTION	04MAR2001:16:00	2h 00m	7h 05m	PSR	MOD	CNT	NON	R
		[ANGER OUTBURST]								
	2	AGGRESSIVE REACTION	08MAR2001:16:00	2h 00m	9h 10m	PSR	MOD	CNT	NON	R

[ANGER OUTBURST]

2 AGGRESSIVE REACTION 12MAR2001:16:00 2h 00m 9h 05m PSR MOD CNT NON R
[ANGER OUTBURST]

00702 2 FATIGUE 15FEB2001:17:00 25 Days 10h 00m PSR MIL CNT NON R
[FATIGUE]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - CHILDREN

Sub no	Sess no	Preferred Term [Verbatim]	Start date and time	Duration Last Dose	Time from Onset	Rel	Sev	Course	Act-ion	Outcome

Regimen - BRL29060 20MG UID

00702 2 COUGHING 24FEB2001:17:00 23 Days 5h 54m PRU MIL CNT NON R,T
[COUGH]

2 PHARYNGITIS 26FEB2001:00:00 14 Days 15h 30m UNR MIL CNT NON R
[ENLARGED TONSILS]

00705 2 INSOMNIA 23APR2001:00:00 Unknown 16h 44m PRU MIL CNT NON O
[EARLY ONSET INSOMNIA]

2 INSOMNIA 23APR2001:00:00 Unknown 16h 44m REL MOD CNT NON O
[LATE ONSET INSOMNIA]

00709 2 RASH 09JUL2001:12:00 1d 00h 2h 45m UNR MIL CNT NON R
[RASH STOMACH]

2 RASH 09JUL2001:12:00 1d
00h 2h 45m UNR MIL CNT NON R
[RASH ELBOW]

2 RASH 10JUL2001:08:00 4h
00m 22h 45m UNR MIL CNT NON R
[RASH BACK]

00818 2 SOMNOLENCE 22FEB2001:16:00 11
Days 1d 09h PRU MIL 12 NON R
[SLEEPINESS]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - CHILDREN

Sub no | Sess no | Preferred Term [Verbatim] | Start date and time | Duration Last Dose | Time from ion | Rel | Sev | Course | Act- | Outcome to Onset

Regimen - BRL29060 30MG UID

00053 3 INFECTION VIRAL 16APR2001:13:45 3d
06h 5h 45m UNR MOD CNT NON R,T
[FLU]

00102 3 PURPURA 22DEC2000:00:00 12
Days 16h 30m UNR MIL CNT NON R
[BRUISING]

00106 3 OTITIS MEDIA 27FEB2001:00:00 11
Days 15h 30m UNR MOD CNT NON R,T
[EAR INFECTION]

00107 3 HEADACHE 02APR2001:00:00 23h 59m 12h 25m PSR MOD CNT NON R
[HEADACHE]

3 RHINITIS 04APR2001:00:00 16 Days 12h 25m UNR MIL CNT NON R
[NASAL CONGESTION]

3 HEADACHE 08APR2001:00:00 23h 59m 12h 25m PSR MOD CNT NON R,T
[HEADACHE]

3 HEADACHE 10APR2001:00:00 23h 59m 12h 25m PSR MOD CNT NON R
[HEADACHE]

00202 3 AGITATION 25MAR2001:12:00 11h 59m 2h 40m PSR MIL CNT NON R
[AGITATION]

3 AGGRESSIVE REACTION 26MAR2001:15:45 30 min 7h 45m PSR MOD CNT NON R
[OUTBURST]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - CHILDREN

Sub no | Sess no | Preferred Term [Verbatim] | Start date and time | Duration Last Dose | Time from ion | Rel | Sev | Course | Act- | Outcome | to Onset

Regimen - BRL29060 30MG UID

00202 3 AGGRESSIVE REACTION 27MAR2001:12:00 10 min 4h 10m PSR MIL CNT NON R
[OUTBURST]

3 AGGRESSIVE REACTION 30MAR2001:00:00 23h 59m 16h 10m PSR MIL CNT NON R
[OUTBURST]

	3	AGGRESSIVE REACTION						31MAR2001:11:00		1h 00m	1h 50m
		PSR	MIL	CNT		NON	R				
		[OUTBURST]									
00303	3	HYPERKINESIA						13AUG2001:00:00		18 Days	13h 00m
		REL	MIL	CNT		DOR	R				
		[AKATHISIA]									
	3	MANIC REACTION						13AUG2001:00:00		18 Days	13h 00m
		REL	MIL	CNT		DOR	R				
		[MILD HYPOMANIA]									
00603	3	NERVOUSNESS						22JAN2001:00:00		23 Days	17h 00m
		PSR	SEV	CNT		NON	R				
		[IRRITABILITY]									
	3	CONCENTRATION IMPAIRED						22JAN2001:00:00		23 Days	17h 00m
		PSR	MOD	CNT		NON	R				
		[LOSS OF CONCENTRATION]									
00702	3	HEADACHE						11MAR2001:19:30		8 Days	11h 00m
		UNR	MIL	CNT		NON	R,T				
		[HEADACHE]									
	3	SWEATING INCREASED						12MAR2001:00:00		Unknown	15h 30m
		PSR	MIL	CNT		NON	O				
		[HOT AND SWEATY]									

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - CHILDREN

Sub no	Sess no	Preferred Term [Verbatim]	Start date and time	Duration Last Dose	Time from Onset	Rel	Sev	Course	Act-ion	Outcome

Regimen - BRL29060 30MG UID

00704 3 NERVOUSNESS 14APR2001:12:00 2h 00m
4h 00m PRU MIL CNT NON R
[IRRITABLE]

3 NERVOUSNESS 16APR2001:17:00 1h 00m
8h 30m PRU MIL CNT NON R
[IRRITABLE]

00705 3 RHINITIS 09MAY2001:09:15 14h 44m
8m 00s UNR MIL CNT NON R,T
[NASAL CONGESTION]

00708 3 HEADACHE 04MAY2001:13:00 1h 30m
4h 10m PRU MOD CNT NON R
[HEADACHE]

3 SOMNOLENCE 04MAY2001:13:00 1h 30m
4h 10m PRU MOD CNT NON R
[SLEEPY]

3 VOMITING 07MAY2001:10:00 15 min
3h 30m PSR MIL CNT NON R
[EMESIS]

3 HYPERKINESIA 15MAY2001:17:00 Unknown
10h 30m PSR MOD CNT NON O
[HYPERACTIVE]

3 VOMITING 17MAY2001:18:30 5m 00s
8h 55m PRU MIL CNT NON R
[EMESIS]

Regimen - BRL29060 20MG UID-TAPER

00102 4 INJURY 27DEC2000:00:00 Unknown
13h 55m UNR SEV CNT NON O,T
[BROKEN LEG]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - CHILDREN

Sub Sess Preferred Term Start date Duration Time from Rel Sev Course Act- Outcome

no no [Verbatim] and time
Last Dose ion

to Onset

Regimen - BRL29060 20MG UID-TAPER

00104 4 COUGHING 27JAN2001:00:00 3d
00h 15h 15m UNR MIL CNT NON R
[INTERMITTENT COUGH]

4 SINUSITIS 27JAN2001:00:00 4d
00h 15h 15m UNR MIL CNT NON R
[SINUS CONGESTION]

00106 4 MANIC REACTION 12MAR2001:15:50 8
Days 5h 20m PSR SEV CNT DST R,W,T,-
[SEVERE MANIA AND SUICIDAL IDEATION]
2,3

4 INJURY 15MAR2001:13:30 2d
22h 3d 03h UNR MOD CNT NON R,T
[PAIN FROM BRUISING FROM RESTRAINTS]

00702 4 PHARYNGITIS 14MAR2001:00:00 9
Days 14h 00m UNR MIL CNT NON R,T
[ENLARGED TONSILS]

4 UPPER RESP TRACT INFECTION 14MAR2001:00:00 9
Days 14h 00m UNR MIL CNT NON R,T
[COLD]

4 ASTHMA 16MAR2001:00:01 23h
58m 14h 01m UNR MIL CNT NON R,T
[ASTHMA]

4 SOMNOLENCE 21MAR2001:00:00
Unknown 14h 00m PSR MIL CNT NON O
[SLEEPY]

4 SOMNOLENCE 21MAR2001:00:00
Unknown 14h 00m PSR MIL CNT NON O
[HARD TO WAKE UP IN MORNING]

00709 4 VOMITING 14AUG2001:09:00 15
min 4d 01h PSR MIL CNT NON R
[EMESIS]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - CHILDREN

Sub no	Sess no	Preferred Term [Verbatim]	Start date and time	Duration	Time from Last Dose	Rel	Sev	Course	Act-ion	Outcome	Time to Onset
Regimen - BRL29060 20MG UID-TAPER											
00709	4	NAUSEA [NAUSEA]	14AUG2001:09:00	15 min	4d 01h	PSR	MIL	CNT	NON	R	
	4	DIARRHEA [DIARRHEA]	14AUG2001:10:00	15 min	4d 02h	PSR	MIL	CNT	NON	R	
Regimen - BRL29060 10MG UID-TAPER											
00107	5	PURPURA [BRUISED ANKLE]	30APR2001:00:00	Unknown	2d 16h	UNR	MIL	CNT	NON	O	
00604	5	DIARRHEA [DIARRHEA]	07APR2001:07:00	2d 13h	1d 00h	PSR	MOD	CNT	NON	R	

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no	Sess no	Preferred Term [Verbatim]					Start date and time	Duration Last Dose	Time from ion	Rel	Sev	Course	Act-	Outcome	to Onset
Regimen - BRL29060 10MG UID															
00002	1	CONCENTRATION IMPAIRED					18NOV2000:10:00	4h 00m	30 min	PSR	MIL	CNT	NON	R	
		[PROBLEMS CONCENTRATING]													
	1	INJURY					20NOV2000:17:00	1d 00h	10h 30m	UNR	MIL	CNT	NON	R,T	
		[KNEE STRAIN]													
	1	RASH					26NOV2000:20:00	1d 22h	11h 00m	PSR	MIL	CNT	NON	R,T	
		[BACK RASH]													
00003	1	HEADACHE					10DEC2000:16:10	2h 00m	7h 40m	PSR	MIL	CNT	NON	R	
		[HEADACHE]													
	1	HEADACHE					12DEC2000:15:30	8h 15m	6h 46m	PSR	MOD	CNT	NON	R	
		[HEADACHE]													
00007	1	HEADACHE					22APR2001:16:00	7h 00m	6h 47m	PRU	MOD	CNT	NON	R	
		[HEADACHE]													
00051	1	NAUSEA					09FEB2001:10:00	4h 00m	2h 30m	PRU	MOD	CNT	NON	R	
		[NAUSEA]													
	1	NAUSEA					10FEB2001:10:00	4h 00m	1h 30m	PRU	MOD	CNT	NON	R	
		[NAUSEA]													
	1	NAUSEA					11FEB2001:10:00	4h 00m	1h 41m	PRU	MOD	CNT	NON	R	

[NAUSEA]

1 NAUSEA 12FEB2001:10:00 12h 00m 2h 05m PRU MOD CNT NON R
[NAUSEA]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no	Sess no	Preferred Term [Verbatim]	Start date and time	Duration Last Dose	Time from ion	Rel	Sev	Course	Act-	Outcome to Onset
Regimen - BRL29060 10MG UID										
00051	1	SOMNOLENCE	17FEB2001:13:00	15 Days	4h 58m	PRU	MIL	CNT	NON	R
		[SEDATION]								
00054	1	RASH	11APR2001:12:00	1d 20h	4h 15m	PSR	MOD	CNT	DST	R,W
		[RASH]								
00103	1	ANOREXIA	01DEC2000:09:34	14h 25m	1m 00s	PSR	MIL	CNT	NON	R
		[LOSS OF APPETITE]								
	1	SOMNOLENCE	01DEC2000:09:34	14h 25m	1m 00s	PSR	MOD	CNT	NON	R
		[DROWSY]								
	1	NAUSEA	01DEC2000:09:34	14h 25m	1m 00s	PSR	MIL	CNT	NON	R
		[NAUSEA]								
	1	FATIGUE	01DEC2000:09:34	14h 25m	1m 00s	PSR	MOD	CNT	NON	R
		[FATIGUE]								
	1	TREMOR	02DEC2000:00:00	23h 59m	14h 27m	PSR	MIL	CNT	NON	R
		[SHAKINESS]								

1 TASTE PERVERSION 02DEC2000:00:00 23h 59m 14h 27m PSR MIL INT NON R
[SAND TASTE IN MOUTH]

1 FATIGUE 02DEC2000:00:00 23h 59m 14h 27m PSR MOD CNT NON R
[TIRED]

1 FATIGUE 02DEC2000:00:00 23h 59m 14h 27m PSR MIL CNT NON R
[FATIGUE]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no	Sess no	Preferred Term [Verbatim]	Start date and time	Duration Last Dose	Time from ion	Rel	Sev	Course	Act-	Outcome
					to Onset					
Regimen - BRL29060 10MG UID										
00103	1	CONCENTRATION IMPAIRED [DAYDREAMING]	02DEC2000:00:00	23h 59m	14h 27m	PSR	MOD	CNT	NON	R
	1	TREMOR [TREMBLING]	12DEC2000:00:00	31 Days	16h 50m	PSR	MIL	INT	NON	R
	1	HYPERTONIA [TENSE SHOULDERS]	13DEC2000:00:00	28 Days	16h 50m	PSR	MOD	CNT	NON	R
00105	1	ABDOMINAL PAIN [STOMACH ACHE]	17JAN2001:00:00	23h 59m	16h 15m	PSR	MIL	CNT	NON	R
00109	1	HEADACHE [INTERMITTENT HEADACHES]	08MAR2001:00:00	8 Days	6h 40m	PSR	MOD	CNT	NON	R

1 INSOMNIA 08MAR2001:00:00 10 Days
6h 40m PSR MIL CNT DIR R
[INSOMNIA]

1 TACHYCARDIA 08MAR2001:00:00 3d 00h
6h 40m PSR MIL CNT NON R
[HEART RACING]

1 ABDOMINAL PAIN 08MAR2001:12:01 17 Days
18h 41m PSR MIL CNT NON R
[INTERMITTENT STOMACH ACHES]

1 RHINITIS 10MAR2001:00:00 30 Days
5h 00m UNR MIL CNT NON R
[NASAL CONGESTION]

00201 1 HEADACHE 01MAR2001:10:30 30 min
2h 55m PSR MIL CNT NON R
[HEADACHE]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no | Sess no | Preferred Term [Verbatim] | Start date and time | Duration | Time from Last Dose | Rel | Sev | Course | Action | Outcome

Regimen - BRL29060 10MG UID

00201 1 NERVOUSNESS 11MAR2001:00:00 Unknown
14h 20m PSR MIL CNT NON O
[JITTERY]

00401 1 INSOMNIA 26OCT2000:21:00 3d 10h
12h 30m PSR MOD CNT NON R,T
[INSOMNIA]

1 SOMNOLENCE 31OCT2000:12:00 2d 06h
4h 00m REL MOD CNT NON R
[DAYTIME SLEEPINESS]

00502 1 HEADACHE 07NOV2000:07:00 16h
59m 11h 50m PRU MOD CNT NON R,T
[HEADACHE]

00506 1 HEADACHE 20FEB2001:18:51 15
min 1h 08m PSR MIL CNT NON R
[HEADACHE]

1 SOMNOLENCE 21FEB2001:09:44 47
min 16h 01m PSR MIL CNT NON R
[DROWSINESS]

00507 1 ABDOMINAL PAIN 19FEB2001:20:45 1h
15m 45 min PSR MIL CNT NON R
[STOMACH ACHE]

00510 1 TREMOR 03MAR2001:08:30 1h
20m 14h 55m PSR MIL CNT NON R
[FACIAL TREMORS]

1 DEPERSONALIZATION 03MAR2001:09:00 14h
00m 15h 25m UNR MIL CNT NON R
[FUNNY FEELING IN NECK]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no | Sess no | Preferred Term [Verbatim] | Start date and time | Duration Last Dose | Time from to Onset | Rel | Sev | Course | Act-ion | Outcome

Regimen - BRL29060 10MG UID

00510 1 INSOMNIA 06MAR2001:00:00
Unknown 6h 00m PSR MOD CNT NON O
[SLEEP DISTURBANCE]

1 AGITATION 17MAR2001:00:00
Unknown 5h 25m PSR MOD CNT NON O

[AGITATED]

1 ANXIETY 17MAR2001:00:00
Unknown 5h 25m PSR MOD CNT NON O
[ANXIOUS]

00601 1 CONFUSION 13SEP2000:10:00 12h
00m 3h 20m PSR MOD CNT NON R
[DISORIENTATION]

1 LIBIDO DECREASED 19SEP2000:02:00
Unknown 19h 20m REL MOD CNT NON O
[DECREASED LIBIDO]

1 EJACULATION FAILURE 19SEP2000:02:00
Unknown 19h 20m REL MOD CNT NON O
[DELAYED EJACULATION]

1 EMOTIONAL LABILITY 23SEP2000:17:00 1d
19h 1d 10h UNR MOD CNT NON R
[INCREASED CRYING]

00606 1 ANOREXIA 24FEB2001:20:00 6d
19h 12h 45m PSR MOD CNT NON R
[LOSS OF APPETITE]

00701 1 HEADACHE 07DEC2000:07:00 1d
00h 10 min PSR MIL CNT NON R
[HEADACHE]

1 ABDOMINAL PAIN 07DEC2000:07:00 1d
01h 10 min PSR MIL CNT NON R
[STOMACH ACHE]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no | Sess no | Preferred Term [Verbatim] | Start date and time | Duration | Time from Last Dose | Rel to Onset | Sev | Course | Act-ion | Outcome

Regimen - BRL29060 10MG UID

00701 1 RHINITIS 07DEC2000:07:00 4d
13h 10 min PRU MIL CNT NON R
[NASAL CONGESTION]

00703 1 RASH 13MAR2001:00:00
Unknown 12h 30m UNR MIL CNT NON O,T
[RASH ON LIPS]

1 RASH 13MAR2001:00:00
Unknown 12h 30m UNR MIL CNT NON O,T
[RASH BEHIND RIGHT EAR]

1 RASH 13MAR2001:07:00
Unknown 19h 30m UNR MIL CNT NON O,T
[RASH (NECK)]

1 DRUG LEVEL INCREASED 19MAR2001:11:30 0.0
sec 0.0 sec UNR MIL CNT DST R,W,8
[OVERDOSE]

1 PURPURA 24MAR2001:19:00
Unknown 5d 08h PSR MIL CNT NON O
[BRUISING LEFT THIGH]

00706 1 DIARRHEA 18APR2001:07:00 1h
30m 22h 30m UNR MIL CNT NON R
[DIARRHEA]

00805 1 ANOREXIA 01DEC2000:00:00 31
Days 17h 40m PSR MIL CNT DOR R
[LOSS OF APPETITE]

1 FATIGUE 01DEC2000:00:00 31
Days 17h 40m PSR MIL CNT DOR R
[TIRED]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no	Sess no	Preferred Term [Verbatim]					Start date and time	Duration Last Dose	Time from to Onset
Regimen - BRL29060 10MG UID									
00809	1	HEADACHE [HEADACHE]	UNR	MIL	CNT	NON	11DEC2000:00:30	6h 00m	17h 23m
00811	1	HEADACHE [HEADACHE]	UNR	MIL	CNT	NON	11JAN2001:13:56	30 min	7h 03m
	1	HEADACHE [HEADACHE]	UNR	MIL	CNT	NON	14JAN2001:11:15	18 Days	1h 06m
	1	ABDOMINAL PAIN [STOMACH ACHE]	UNR	MIL	CNT	NON	20JAN2001:10:12	7 Days	12 min
00816	1	VOMITING [VOMITING]	UNR	MIL	2	NON	14FEB2001:07:00	4h 00m	23h 55m
	1	NAUSEA [NAUSEA]	UNR	MIL	CNT	NON	14FEB2001:07:00	4h 00m	23h 55m
	1	CHEST PAIN [CHEST PAIN]	UNR	MIL	CNT	NON	18FEB2001:22:00	1h 59m	11h 43m
00824	1	DIZZINESS [DIZZINESS]	PRU	MIL	CNT	NON	22MAR2001:07:01	15 Days	1m 00s
	1	HEADACHE [HEADACHE]	PRU	MIL	CNT	NON	22MAR2001:07:01	15 Days	1m 00s

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no	Sess no	Preferred Term [Verbatim]	Start date and time	Duration Last Dose	Time from ion	Rel	Sev	Course	Act-	Outcome	to Onset
Regimen - BRL29060 10MG UID											
00825	1	SINUSITIS [SINUS PROBLEMS]	26MAR2001:11:45	5d 12h	3h 45m	UNR	MOD	CNT	NON	R,T	
	1	SINUSITIS [SINUS PROBLEMS]	01APR2001:00:00	6d 00h	16h 00m	UNR	MOD	CNT	NON	R,T	
	1	HEADACHE [HEADACHE]	03APR2001:11:00	2h 00m	3h 00m	UNR	MOD	CNT	NON	R	
	1	HEADACHE [HEADACHE]	04APR2001:09:00	1h 00m	1h 00m	UNR	MOD	CNT	NON	R	
	1	HEADACHE [HEADACHE]	05APR2001:12:00	3h 00m	4h 00m	UNR	MOD	CNT	NON	R	
Regimen - BRL29060 20MG UID											
00005	2	DIZZINESS [GIDDINESS]	23MAR2001:00:00	10 Days	16h 30m	REL	MOD	CNT	DST	R,W	
	2	HYPERKINESIA [HYPERACTIVITY]	23MAR2001:00:00	10 Days	16h 30m	REL	MOD	CNT	DST	R,W	
00051	2	PHARYNGITIS [SORE THROAT]	07MAR2001:21:30	1d 17h	12h 45m	UNR	MIL	CNT	NON	R	
00052	2	INJURY [LEFT ANKLE SPRAIN]	04APR2001:00:00	4d 00h	9h 35m	UNR	MOD	CNT	NON	R	

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no	Sess no	Preferred Term [Verbatim]	Start date and time	Duration Last Dose	Time from ion	Rel	Sev	Course	Act-	Outcome
Regimen - BRL29060 20MG UID										
00103	2	CHEST PAIN [TIGHTNESS IN CHEST]	17DEC2000:00:00	23 Days	13h 30m	PSR	MIL	CNT	NON	R
	2	HEADACHE [HEADACHE]	28DEC2000:00:00	23h 59m	12h 05m	UNR	MIL	CNT	NON	R
	2	PAIN [ACHY]	28DEC2000:00:00	23h 59m	12h 05m	UNR	MIL	CNT	NON	R
00105	2	HOT FLUSHES [HOT FLASHES]	25JAN2001:00:00	7d 00h	16h 10m	UNR	MIL	INT	NON	R
	2	HEADACHE [HEADACHE]	30JAN2001:00:00	3d 00h	16h 25m	UNR	MOD	CNT	NON	R
	2	COUGHING [COUGH]	30JAN2001:00:00	12 Days	16h 25m	UNR	MOD	CNT	NON	R
	2	RHINITIS [STUFFED NOSE]	30JAN2001:00:00	17 Days	16h 25m	UNR	MOD	CNT	NON	R
	2	FEVER [FEVER]	31JAN2001:00:00	23h 59m	15h 05m	UNR	MIL	CNT	NON	R

00201 2 NERVOUSNESS 20MAR2001:00:00
Unknown 15h 00m PSR MOD CNT NON O
[RECURRING IRRITABILITY]

2 AGGRESSIVE REACTION 24MAR2001:00:00
Unknown 15h 00m PSR MOD CNT DOR O
[OPPOSITIONAL]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no | Sess no | Preferred Term [Verbatim] | Start date and time | Duration | Time from Last Dose | Rel | Sev | Course | Act-ion | Outcome | Time to Onset

Regimen - BRL29060 20MG UID

00401 2 SOMNOLENCE 07NOV2000:12:00
Unknown 2h 30m REL MOD CNT NON O
[DAYTIME SLEEPINESS]

00502 2 HEADACHE 20NOV2000:17:15 1d
07h 23h 15m PRU MOD CNT NON R,T
[HEADACHE]

00505 2 SOMNOLENCE 10FEB2001:21:00 1d
03h 4h 05m PSR MIL CNT NON R
[SLEEPINESS]

2 HEADACHE 11FEB2001:16:30 30
min 23h 35m PSR MIL CNT NON R
[HEADACHE]

2 HEADACHE 13FEB2001:15:00 30
min 19h 46m PSR MIL CNT NON R
[HEADACHE]

2 HEADACHE 15FEB2001:17:15 30
min 22h 29m PSR MIL CNT NON R
[HEADACHE]

00506 2 CONSTIPATION 28FEB2001:08:05 13
Days 1h 29m PSR MIL 12 NON R
[CONSTIPATION]

2 FLATULENCE 28FEB2001:08:05 28
Days 1h 29m PSR MIL 27 NON R
[GAS]

2 HEADACHE 07MAR2001:13:22 1d
07h 6h 56m PSR MIL CNT NON R,T
[HEADACHES]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no | Sess no | Preferred Term [Verbatim] | Start date and time | Duration Time from Last Dose | Rel | Sev | Course | Action | Outcome | to Onset

Regimen - BRL29060 20MG UID

00509 2 ABDOMINAL PAIN 23MAR2001:00:00 2d
00h 6h 15m PSR MIL CNT NON R
[STOMACH ACHE]

2 HEADACHE 23MAR2001:16:40 20
min 22h 55m PSR MIL CNT NON R
[HEADACHE]

00510 2 SWEATING INCREASED 23MAR2001:00:00 23h
59m 5h 48m PSR MIL CNT NON R
[DIAPHORETIC]

2 HEADACHE 25MAR2001:22:30 1d
01h 4h 30m PSR MOD CNT NON R,T
[HEADACHE]

2 UPPER RESP TRACT INFECTION 28MAR2001:00:00 18 Days 5h 30m UNR MIL CNT NON R,T
[UPPER RESPIRATORY INFECTION]

00601 2 INJURY 04OCT2000:21:00 11 Days 14h 21m UNR MIL CNT NON R
[LEFT KNEE PAIN SECONDARY TO JUMPING]

00605 2 HEADACHE 11MAR2001:18:00 3h 30m 11h 00m PRU MIL CNT NON R,T
[HEADACHE]

00606 2 COUGHING 15MAR2001:21:00 1d 03h 2d 14h UNR MOD CNT NON R,T
[COUGH]

00701 2 RHINITIS 25DEC2000:09:00 2d 11h 21h 49m UNR MIL CNT NON R
[SNIFFLES]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no | Sess no | Preferred Term [Verbatim] | Start date and time | Duration Last Dose | Time from ion | Rel | Sev | Course | Act- | Outcome | to Onset

Regimen - BRL29060 20MG UID

00805 2 PAIN 02DEC2000:01:19 8 Days 17h 34m UNR MIL CNT NON R,T
[LEG ACHE]

2 PAIN 09DEC2000:23:05 17h 24m 13h 55m UNR MIL CNT NON R,T
[LEG ACHE]

2 PAIN 10DEC2000:16:30 5d 01h 7h 16m UNR MIL CNT NON R,T

[LEG ACHE]

00811 2 ABDOMINAL PAIN 27JAN2001:17:15 2d
15h 6h 55m UNR MIL CNT NON R,T
[STOMACH ACHE]

2 CONSTIPATION 29JAN2001:17:30 1h
00m 10h 30m UNR MIL CNT NON R
[CONSTIPATED]

2 ABDOMINAL PAIN 30JAN2001:08:45 1d
15h 1h 28m UNR MIL CNT NON R,T
[STOMACH ACHE]

2 HEADACHE 02FEB2001:06:34 3d
01h 20h 04m UNR MIL CNT NON R,T
[HEADACHE]

00816 2 RESPIRATORY DISORDER 07MAR2001:01:00 13
Days 16h 30m UNR MIL CNT NON R,T
[RESPIRATORY INFECTION]

00824 2 HEADACHE 11APR2001:21:30 1h
30m 14h 30m UNR MIL CNT NON R,T
[HEADACHE]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no | Sess no | Preferred Term [Verbatim] | Start date and time | Duration Last Dose | Time from ion | Rel | Sev | Course | Act- | Outcome | to Onset

Regimen - BRL29060 30MG UID

00003 3 ABDOMINAL PAIN 28DEC2000:00:00 3d
00h 14h 28m PSR MIL CNT NON R
[STOMACH ACHE]

	3	RHINITIS						08JAN2001:00:00		2d
00h	13h	00m	PRU	MIL	CNT	NON	R,T			
		[RUNNY NOSE]								
	3	RHINITIS						08JAN2001:00:00		2d
00h	13h	00m	PRU	MIL	CNT	NON	R,T			
		[NASAL CONGESTION]								
00007	3	HYPERKINESIA						17MAY2001:00:00		
Unknown	15h	34m	PSR	MOD	CNT	DOR	O,W			
		[HYPERACTIVITY]								
	3	MANIC REACTION						17MAY2001:00:00		
Unknown	15h	34m	PSR	MOD	CNT	DOR	O,W			
		[MANIA]								
00051	3	SOMNOLENCE						08MAR2001:09:15		54
Days	15	min	PRU	MOD	CNT	NON	R			
		[SEDATION]								
00103	3	HEADACHE						09JAN2001:00:00		23h
59m	16h	40m	UNR	MOD	CNT	NON	R,T			
		[HEADACHE]								
	3	FEVER						09JAN2001:00:00		23h
59m	16h	40m	UNR	MOD	CNT	NON	R			
		[FEVER]								
00105	3	HEADACHE						16FEB2001:00:00		15
Days	16h	05m	UNR	MIL	INT	NON	R			
		[INTERMITTENT HEADACHES]								

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no	Sess no	Preferred Term [Verbatim]	Start date and time	Duration Last Dose	Time from to Onset	Rel	Sev	Course	Act-ion	Outcome

Regimen - BRL29060 30MG UID

00109 3 INSOMNIA 06APR2001:00:00 17
Days 12h 30m REL MOD CNT DOR R
[INSOMNIA]

3 PERSONALITY DISORDER 06APR2001:00:00 16
Days 12h 30m REL MIL CNT DOR R
[INTERMITTENT SILLYNESS]

3 CONCENTRATION IMPAIRED 06APR2001:00:00 17
Days 12h 30m REL MIL CNT DOR R
[INTERMITTENT DISTRACTABILITY]

00503 3 UPPER RESP TRACT INFECTION 25DEC2000:00:00 4d
00h 6h 30m UNR SEV CNT NON R
[UPPER RESPIRATORY INFECTION]

3 HEADACHE 28DEC2000:17:00 6h
31m 23h 30m UNR SEV CNT NON R,T
[HEADACHE]

00506 3 HYPERKINESIA 12MAR2001:00:00
Unknown 14h 50m PSR MIL CNT NON O
[HYPERACTIVITY]

3 CONCENTRATION IMPAIRED 12MAR2001:00:00
Unknown 14h 50m PSR MIL CNT NON O
[DIFFICULTY CONCENTRATING]

3 SOMNOLENCE 12MAR2001:09:51 17
Days 3h 24m PSR MIL CNT NON R
[DROWSINESS]

3 ABDOMINAL PAIN 12MAR2001:09:51 1d
00h 3h 24m PRU MIL CNT NON R
[STOMACH ACHE]

00509 3 PHARYNGITIS 05APR2001:00:00 6d
00h 6h 51m UNR MIL CNT NON R
[SORE THROAT]

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no	Sess no	Preferred Term [Verbatim]	Start date and time	Duration Last Dose to Onset
Regimen - BRL29060 30MG UID				
00601	3	PAIN	11OCT2000:14:00	2d 17h
	7h 14m	UNR SEV CNT NON R [TOE PAIN]		
	3	INJURY	11OCT2000:14:00	1m 00s
	7h 14m	UNR MOD CNT NON R [TOE INJURY]		
	3	SGOT INCREASED	24OCT2000:06:45	14 Days
	1d 00h	PRU MIL CNT NON R [ELEVATED ASAT]		
00602	3	DIZZINESS	27DEC2000:09:00	Unknown
	2h 00m	PSR MIL CNT NON O [DIZZINESS]		
00701	3	PERSONALITY DISORDER	09JAN2001:18:30	1h 30m
	10h 56m	PSR MIL CNT NON R [INCREASED SILLYNESS]		
00805	3	PAIN	15DEC2000:17:45	2d 04h
	10h 02m	UNR MIL CNT NON R,T [LEG ACHE]		
	3	PAIN	17DEC2000:22:08	14 Days
	12h 10m	UNR MIL CNT NON R,T [LEG ACHE]		
	3	HEADACHE	23DEC2000:17:25	8 Days
	7h 13m	UNR MIL CNT NON R,T [HEADACHE]		
00824	3	HYPERKINESIA	20APR2001:08:28	20 Days
	0.0 sec	PSR MOD CNT DOR R [HYPERACTIVITY]		

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no	Sess no	Preferred Term [Verbatim]	Start date and time	Duration Last Dose	Time from ion	Rel	Sev	Course	Act-	Outcome	to Onset
Regimen - BRL29060 30MG UID											
00825	3	SOMNOLENCE [SLEEPY]	21APR2001:00:00	12 Days	16h 16m	PSR	MOD	CNT	DOR	R	
Regimen - BRL29060 20MG UID-TAPER											
00503	4	OTITIS MEDIA [EAR INFECTION]	01JAN2001:00:00	11 Days	6h 30m	UNR	SEV	CNT	NON	R,T	
00605	4	PAIN [PAIN]	03APR2001:00:00	23h 59m	17h 00m	UNR	MOD	CNT	NON	R,T	
	4	DIZZINESS [DIZZINESS]	15APR2001:09:00	6d 15h	3d 01h	PSR	MOD	CNT	NON	R	
00607	4	VERTIGO [MOTION SICKNESS]	06APR2001:10:00	13h 59m	3h 10m	UNR	MIL	CNT	NON	R,T	
00811	4	ABDOMINAL PAIN [STOMACH ACHE]	26FEB2001:13:07	17h 58m	6h 11m	UNR	MIL	CNT	NON	R,T	
	4	ABDOMINAL PAIN [STOMACH ACHE]	01MAR2001:07:02	58 min	12 min	UNR	MIL	CNT	NON	R,T	

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table DS6

ADVERSE EVENTS OF STUDY SB29060/715 - POST DOSE WITHIN 30 DAYS

Subject Group - ADOLESCENTS

Sub no	Sess no	Preferred Term [Verbatim]	Start date and time	Duration	Time from Last Dose	Rel	Sev	Course	Act-ion	Outcome to Onset
Regimen - BRL29060 10MG UID-TAPER										
00105	5	INJURY [BROKEN FINGER]	02MAR2001:00:00	21 Days	16h 03m	UNR	MOD	CNT	NON	R
00607	5	VERTIGO [MOTION SICKNESS]	12APR2001:14:30	9h 29m	8h 30m	UNR	MIL	CNT	NON	R,T
	5	HEADACHE [HEADACHE]	23APR2001:00:00	Unknown	4d 18h	PSR	MOD	CNT	NON	O

. = No data available

[ADEXL014:LIS]
[11DEC2001:11:22]

Table 10.2 Patients with Serious Adverse Events (SAEs)

PID: 715.201.00106
Protocol: 29060 715
AEGIS number: 2001006877-1
Study medication: PAROXETINE

Verbatim[preferred term]: MANIA [MANIC REACTION]

Case reference number 2001006877-1 is a clinical trial report from open-label study 29060/715 for the assessment of Paroxetine pharmacokinetics following repeat doses in children and adolescents with Obsessive-Compulsive Disorder (OCD) and/or Depression. This report refers to a 10-year-old male (patient identification number 715.201.00106).

The patient's medical history included major depressive disorder (MDD), dysthymia, attention deficit hyperactivity disorder {inattentive type}, and erythromycin allergy. The patient had no significant prior concomitant medication use.

On 25-Jan-2001, the patient began therapy with study medication, paroxetine. The patient appeared to tolerate the 10 mg and 20 mg doses well. However, following dose escalation to 30 mg UID, the patient had become more violent and out of control, with aggressive and agitated behavior toward himself. On 11-Mar-2001, 45 days after starting therapy with study medication, the patient ran away from home to his father's house, and was returned to his mother on 12-Mar-2001. On 13-Mar-2001, the patient was admitted to the Preteen Inpatient Unit of the hospital for severe mania and suicidal ideation, and was placed on suicide and escape precautions. The patient was treated for the event with prescription paroxetine (Paxil), amphetamine/dextroamphetamine (Adderall), lorazepam (Ativan), citalopram (Celexa), and quetiapine (Seroquel). On 20-Mar-2001, the patient stated that he was no longer suicidal or homicidal. He denied any hallucinations or delusions, and stated that he would not hurt himself if he went home. The patient's affect was also noted to be improved, and he was discharged home in an improved condition. The event resolved on 20-Mar-2001. The patient had been withdrawn from the study and the study medication was stopped on 12-Mar-2001 due to the event. The patient received 20 mg of study medication at the time of the events, and had completed the dose-rising phase of the study from 10 mg to 30 mg (30 mg until 09-Mar-2001). The investigator further clarified that the suicidal ideation was symptomatic of the severe mania.

The investigator reported that the severe mania was life-threatening, disabling/incapacitating, and possibly related to treatment with study medication.

Table DS12

VITAL SIGNS FLAGGING RANGES OF STUDY SB29060/715

Parameter	Position	Flagging reason
Diastolic BP	Sitting	>20mmHg decrease or >20mmHg increase from baseline
Pulse	Sitting	<35bpm or >130bpm
Systolic BP	Sitting	>30mmHg decrease or >30mmHg increase from baseline

. = No data available

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - CHILDREN
Sitting
No Dose Given

Sub no	SCR	END
Systolic BP (mmHg)		
00001	104	.
00053	104	.
00055	102	.
00101	106	.
00102	109	.
00104	100	.
00106	121	.
00107	113	.
00108	111	.
00110	105	.
00111	107	.
00112	103	.
00113	106	.
00202	114	.
00301	126	.
00303	120	103
00504	116	97
00603	120	.
00604	118	120
00702	112	.
00704	96	.
00705	ND	.
00707	116	.
00708	125	.
00709	95	100
00806	126	.
00818	108	.
Mean	111	105
SDev	8.9	10.3
n	26	4
Min	95	97
Max	126	120

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

[VITT096:TAB] [17DEC2001:15:02]

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - CHILDREN
Sitting
No Dose Given

Sub no	SCR	END
Diastolic BP (mmHg)		
00001	78	.
00053	68	.
00055	68	.
00101	61	.
00102	62	.
00104	50	.
00106	69	.
00107	64	.
00108	78	.
00110	61	.
00111	64	.
00112	55	.
00113	56	.
00202	54	.
00301	69	.
00303	55	63
00504	64	44
00603	70	.
00604	68	60
00702	64	.
00704	54	.

00705	ND	.
00707	71	.
00708	73	.
00709	54	54
00806	68	.
00818	63	.
Mean	64	55
SDev	7.5	8.4
n	26	4
Min	50	44
Max	78	63

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - CHILDREN
Sitting
No Dose Given

Sub no	SCR	END

Pulse (bpm)

00001	80	.
00053	88	.
00055	76	.
00101	76	.
00102	66	.
00104	88	.
00106	75	.
00107	94	.
00108	100	.
00110	89	.
00111	83	.
00112	62	.
00113	57	.
00202	95	.
00301	101	.
00303	68	71
00504	65	72
00603	54	.
00604	100	76
00702	80	.
00704	62	.
00705	ND	.
00707	65	.
00708	94	.
00709	ND	87
00806	74	.
00818	77	.
Mean	79	77
SDev	14.1	7.3
n	25	4
Min	54	71
Max	101	87

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

[VITT096:TAB] [17DEC2001:15:02]

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - CHILDREN
Sitting
BRL29060 10MG UID

Sub no	D1PRE	10MG PK	10PK+24
Systolic BP (mmHg)			
00001	108	112	112
00053	120	100	100
00055	102	100	ND
00101	113	104	104
00102	ND	102	122
00104	99	129	120
00106	122	112	124
00107	133	109	111
00108	120	106	ND
00110	97	102	124
00111	98	.	.
00112	100	132 H	122
00113	116	ND	ND
00202	108	98	104
00301	109	109	.
00303	108	86	101
00504	100	104	96
00603	116	84 L	80 L
00604	104	108	118
00702	125	109	.
00704	107	104	99
00705	83	94	93
00707	107	108	128
00708	126	126	114
00709	100	102	125
00806	117	117	110
00818	110	105	116
Mean	110	106	111
SDev	11.1	11.3	12.7
n	26	25	21
Min	83	84	80

Max	133	132	128

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

[VITT096:TAB] [17DEC2001:15:02]

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - CHILDREN
Sitting
BRL29060 10MG UID

Sub no	D1PRE	10MG PK	10PK+24
Diastolic BP (mmHg)			
00001	55	72	62
00053	62	70	74
00055	76	68	ND
00101	58	60	70
00102	ND	64	70
00104	64	66	46
00106	71	60	68
00107	71	76	60
00108	65	53	ND

00110	55	55	58	
00111	72	.	.	
00112	56	65	61	
00113	47	ND	ND	
00202	61	64	72	
00301	60	61	.	
00303	60	55	53	
00504	62	52	57	
00603	74	56	48	L
00604	70	70	66	
00702	70	67	.	
00704	54	64	60	
00705	53	62	56	
00707	69	65	75	
00708	71	66	66	
00709	64	52	54	
00806	63	75	65	
00818	66	48	72	
Mean	63	63	63	
SDev	7.4	7.4	8.4	
n	26	25	21	
Min	47	48	46	
Max	76	76	75	

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - CHILDREN
Sitting
BRL29060 10MG UID

Sub no	D1PRE	10MG PK	10PK+24
Pulse (bpm)			
00001	70	78	79
00053	68	60	68
00055	80	76	ND
00101	82	70	89
00102	ND	67	69
00104	88	98	83
00106	83	69	74
00107	101	74	72
00108	87	62	ND
00110	89	77	77
00111	80	.	.
00112	74	58	62
00113	62	ND	ND
00202	85	80	73
00301	86	105	.
00303	79	62	68
00504	81	64	69
00603	64	72	66
00604	70	72	82
00702	82	76	.
00704	84	77	79
00705	86	88	96
00707	79	71	72
00708	86	87	89
00709	68	78	80
00806	63	101	81
00818	87	71	74
Mean	79	76	76
SDev	9.5	12.3	8.5
n	26	25	21
Min	62	58	62
Max	101	105	96

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

[VITT096:TAB] [17DEC2001:15:02]

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - CHILDREN
Sitting
BRL29060 20MG UID

Sub no	20MG	20MG PK	20PK+24
Systolic BP (mmHg)			
00001	.	122	120
00053	.	110	100
00055	.	104	100
00101	.	108	132
00102	.	95	.
00104	.	110	108
00106	.	122	115
00107	.	107	114
00108	.	119	106
00110	.	105	100
00112	.	101	107
00202	.	90	93
00301	115	.	.
00303	.	106	109
00504	.	109	86
00603	.	90	90
00604	.	118	118
00702	102	112	103
00704	.	99	.
00705	.	101	77

00707	.	113	115
00708	.	106	112
00709	.	88	93
00806	.	114	115
00818	.	123	111
Mean	109	107	106
SDev	9.2	10.1	12.6
n	2	24	22
Min	102	88	77
Max	115	123	132

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - CHILDREN
Sitting
BRL29060 20MG UID

Sub no	20MG	20MG PK	20PK+24

Diastolic BP (mmHg)

00001	.	73	65	
00053	.	70	70	
00055	.	76	68	
00101	.	61	76	
00102	.	56	.	
00104	.	74	68	
00106	.	70	71	
00107	.	61	48	L
00108	.	74	50	
00110	.	60	60	
00112	.	51	55	
00202	.	60	40	L
00301	65	.	.	
00303	.	66	61	
00504	.	66	41	L
00603	.	60	60	
00604	.	78	74	
00702	55	71	66	
00704	.	68	.	
00705	.	58	46	
00707	.	68	68	
00708	.	74	61	
00709	.	50	51	
00806	.	65	64	
00818	.	64	54	
Mean	60	66	60	
SDev	7.1	7.7	10.4	
n	2	24	22	
Min	55	50	40	
Max	65	78	76	

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

[VITT096:TAB] [17DEC2001:15:02]

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - CHILDREN
Sitting
BRL29060 20MG UID

Sub no	20MG	20MG PK	20PK+24
Pulse (bpm)			
00001	.	82	75
00053	.	68	64
00055	.	60	64
00101	.	91	101
00102	.	65	.
00104	.	96	65
00106	.	74	81
00107	.	74	56
00108	.	73	85
00110	.	63	65
00112	.	56	55
00202	.	80	69
00301	105	.	.
00303	.	75	64
00504	.	71	83
00603	.	62	68
00604	.	76	76
00702	72	76	84
00704	.	94	.
00705	.	74	72
00707	.	80	65
00708	.	90	83
00709	.	70	61
00806	.	96	75
00818	.	70	70
Mean	89	76	72
SDev	23.3	11.3	11.0
n	2	24	22
Min	72	56	55
Max	105	96	101

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - CHILDREN
Sitting
BRL29060 30MG UID

Sub no	30MG PK	30MG PK	30PK+24
Systolic BP (mmHg)			
00001	116	.	95
00053	104	.	100
00055	100	.	102
00101	127	.	131
00102	106	103	116
00104	110	.	106
00106	113	.	117
00107	111	.	109

00108	104	.	124	
00110	119	.	99	
00112	104	.	108	
00202	123	.	101	
00301	101	.	ND	
00303	110	.	106	
00603	92	.	78	L
00604	120	.	120	
00702	112	.	123	
00704	124	110	111	
00705	102	.	97	
00707	103	.	109	
00708	106	.	117	
00709	93	.	120	
00806	100	.	108	
00818	138	.	106	
Mean	110	107	109	
SDev	11.1	4.9	11.6	
n	24	2	23	
Min	92	103	78	
Max	138	110	131	

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

[VITT096:TAB] [17DEC2001:15:02]

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - CHILDREN
Sitting
BRL29060 30MG UID

Sub no	30MG PK	30MG PK	30PK+24
Diastolic BP (mmHg)			
00001	68	.	56
00053	74	.	70
00055	80	.	70
00101	66	.	71
00102	59	54	56
00104	62	.	32 L
00106	66	.	66
00107	64	.	66
00108	59	.	54
00110	47	.	45
00112	54	.	52
00202	66	.	69
00301	53	.	ND
00303	52	.	50
00603	60	.	52 L
00604	74	.	76
00702	80	.	81
00704	64	64	64
00705	62	.	60
00707	65	.	64
00708	69	.	71
00709	57	.	68
00806	55	.	64
00818	71	.	62
Mean	64	59	62
SDev	8.5	7.1	11.0
n	24	2	23
Min	47	54	32
Max	80	64	81

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

[VITT096:TAB] [17DEC2001:15:02]

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - CHILDREN
Sitting
BRL29060 30MG UID

Sub no	30MG PK	30MG PK	30PK+24
Pulse (bpm)			
00001	82	.	87
00053	60	.	72
00055	64	.	68
00101	74	.	89
00102	74	62	67
00104	82	.	85
00106	74	.	76
00107	75	.	80
00108	79	.	85
00110	70	.	64
00112	56	.	63
00202	86	.	83
00301	81	.	ND
00303	69	.	74
00603	72	.	80
00604	76	.	80
00702	91	.	90
00704	93	74	91
00705	76	.	90

00707	60	.	92
00708	81	.	98
00709	74	.	103
00806	81	.	89
00818	70	.	91
Mean	75	68	82
SDev	9.2	8.5	10.7
n	24	2	23
Min	56	62	63
Max	93	74	103

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - CHILDREN
Sitting
BRL29060 20MG UID-TAPER

Sub 20MG TAP

no

Systolic BP (mmHg)

00055	104
00104	123
00202	86
00303	116
00702	113
00709	101
00806	102
Mean	106
SDev	12.1
n	7
Min	86
Max	123

Diastolic BP (mmHg)

00055	78
00104	69
00202	61
00303	62
00702	67
00709	57
00806	56
Mean	64
SDev	7.7
n	7
Min	56
Max	78

Pulse (bpm)

00055	70
00104	106
00202	72
00303	82
00702	82
00709	65
00806	85
Mean	80
SDev	13.5
n	7
Min	65
Max	106

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

[VITT096:TAB] [17DEC2001:15:02]

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - CHILDREN
Sitting
BRL29060 10MG UID-TAPER

Sub no	10MG TAP
Systolic BP (mmHg)	
00102	103
00107	111
00112	107
00303	110
00504	108
00603	72 L
00604	120
Mean	104
SDev	15.2
n	7
Min	72
Max	120
Diastolic BP (mmHg)	
00102	59
00107	66
00112	54
00303	55
00504	70
00603	54
00604	64
Mean	60
SDev	6.4
n	7
Min	54
Max	70

Pulse (bpm)

00102	63
00107	94
00112	70
00303	78
00504	69
00603	68
00604	72
Mean	73
SDev	10.1
n	7
Min	63
Max	94

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Sitting
No Dose Given

Sub no	SCR	END
Systolic BP (mmHg)		
00002	107	.
00003	123	.
00004	137	.
00005	132	102
00007	127	.
00051	124	.
00052	102	.

00054	120	.
00103	112	.
00105	120	.
00109	100	.
00201	131	.
00401	90	.
00502	117	134
00503	116	126
00505	118	114
00506	114	.
00507	110	.
00509	116	.
00510	123	.
00601	120	110
00602	110	.
00605	100	120
00606	120	.
00607	100	110
00701	114	.
00703	109	88
00706	105	.
00804	122	.
00805	102	107
00809	135	.
00811	112	.
00816	107	.
00824	112	.
00825	126	.
Mean	115	112
SDev	10.9	13.5
n	35	9
Min	90	88
Max	137	134

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Sitting
No Dose Given

Sub no	SCR	END
Diastolic BP (mmHg)		
00002	65	.
00003	69	.
00004	80	.
00005	62	78
00007	62	.
00051	80	.
00052	68	.
00054	64	.
00103	71	.
00105	58	.
00109	63	.
00201	62	.
00401	58	.
00502	53	73
00503	69	78
00505	76	70
00506	57	.
00507	80	.
00509	56	.
00510	64	.
00601	60	76
00602	84	.
00605	70	62
00606	64	.
00607	64	68
00701	61	.
00703	61	55
00706	61	.
00804	65	.
00805	62	71
00809	58	.
00811	58	.
00816	58	.
00824	68	.
00825	73	.
Mean	65	70
SDev	7.6	7.6
n	35	9
Min	53	55
Max	84	78

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

[VITT096:TAB] [17DEC2001:15:02]

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Sitting
No Dose Given

Sub no	SCR	END
Pulse (bpm)		
00002	76	.
00003	66	.
00004	100	.
00005	80	80
00007	68	.
00051	84	.
00052	76	.
00054	76	.
00103	62	.
00105	66	.
00109	66	.
00201	75	.
00401	100	.
00502	65	77
00503	68	75
00505	87	61
00506	81	.
00507	56	.

00509	57	.
00510	72	.
00601	60	62
00602	104	.
00605	64	68
00606	72	.
00607	64	64
00701	64	.
00703	63	69
00706	71	.
00804	86	.
00805	81	97
00809	58	.
00811	97	.
00816	80	.
00824	68	.
00825	75	.
Mean	74	73
SDev	12.6	11.3
n	35	9
Min	56	61
Max	104	97

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Sitting
BRL29060 10MG UID

Sub no	D1PRE	10MG PK		10PK+24
Systolic BP (mmHg)				
00002	108	106		107
00003	99	121		92
00004	140	145		.
00005	126	104		111
00007	126	112		111
00051	118	120		120
00052	118	120		ND
00054	118	112		104
00103	116	131		110
00105	114	115		108
00109	121	107		102
00201	127	131		120
00401	88	90		88
00502	107	119		ND
00503	136	104	L	128
00505	110	108		105
00506	108	112		124
00507	118	130		126
00509	122	116		106
00510	115	124		128
00601	110	132		120
00602	110	120		116
00605	106	94		102
00606	112	116		126
00607	120	114		106
00701	111	111		100
00703	105	119		ND
00706	117	84	L	118
00804	111	96		110
00805	112	121		103
00809	117	131		137
00811	122	110		130
00816	134	131		.
00824	126	101		116
00825	122	128		109
Mean	116	115		113
SDev	10.3	13.2		11.6
n	35	35		30
Min	88	84		88
Max	140	145		137

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

[VITT096:TAB] [17DEC2001:15:02]

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Sitting
BRL29060 10MG UID

Sub no	D1PRE	10MG PK	10PK+24
Diastolic BP (mmHg)			
00002	59	52	56
00003	63	60	50
00004	80	78	.
00005	60	52	60
00007	58	53	58
00051	82	60 L	70
00052	78	68	ND
00054	70	72	78
00103	69	75	48 L
00105	58	56	64
00109	86	55 L	52 L
00201	63	69	64
00401	60	60	58
00502	59	60	ND
00503	68	64	76
00505	80	60	74
00506	58	60	68
00507	72	68	63
00509	56	62	76
00510	63	72	82
00601	58	80 H	70
00602	70	70	70
00605	64	68	64
00606	72	76	78
00607	80	80	72
00701	66	59	52
00703	45	59	ND
00706	64	64	68
00804	63	64	67

00805	62	72	63
00809	73	68	64
00811	63	78	68
00816	62	50	.
00824	67	59	68
00825	66	77	63
Mean	66	65	65
SDev	8.8	8.6	8.7
n	35	35	30
Min	45	50	48
Max	86	80	82

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Sitting
BRL29060 10MG UID

Sub no	D1PRE	10MG PK	10PK+24
Pulse (bpm)			
00002	76	62	68
00003	89	88	NA
00004	70	91	.
00005	73	70	75
00007	68	63	60
00051	88	80	76

00052	60	72	ND
00054	76	76	64
00103	81	83	73
00105	69	70	71
00109	66	74	77
00201	73	72	86
00401	80	84	80
00502	79	74	ND
00503	89	71	85
00505	84	74	64
00506	76	86	107
00507	60	86	58
00509	50	96	76
00510	80	96	81
00601	54	72	66
00602	62	66	72
00605	56	78	62
00606	68	62	62
00607	60	64	62
00701	73	85	71
00703	74	64	ND
00706	86	64	75
00804	88	76	70
00805	98	89	98
00809	74	64	72
00811	98	98	92
00816	78	66	.
00824	80	73	81
00825	88	76	81
Mean	75	76	75
SDev	11.9	10.5	11.4
n	35	35	29
Min	50	62	58
Max	98	98	107

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold

. = No data available

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Sitting
BRL29060 20MG UID

Sub no	20MG	20MG PK	20PK+24
Systolic BP (mmHg)			
00002	.	94	110
00003	.	127	98
00004	143	136	106 L
00007	.	123	122
00051	.	132	110
00052	.	120	112
00103	.	110	ND
00105	.	104	110
00109	.	87 L	96
00401	.	98	90
00502	.	105	ND
00503	.	134	.
00505	.	108	122
00506	.	115	122
00507	.	132	137
00509	.	112	114
00510	.	90	115
00601	.	104	118
00602	.	112	.
00605	.	86	100
00606	.	120	122
00607	.	110	126
00701	.	113	.
00706	.	116	111
00804	.	108	115
00805	.	123	103
00809	.	121	131
00811	.	111	103
00816	114	135	113
00824	.	118	120
00825	.	117	122
Mean	129	114	113
SDev	20.5	13.7	11.0
n	2	31	26
Min	114	86	90
Max	143	136	137

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

[VITT096:TAB] [17DEC2001:15:02]

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Sitting
BRL29060 20MG UID

Sub no	20MG	20MG PK	20PK+24
Diastolic BP (mmHg)			
00002	.	60	70
00003	.	65	56
00004	71	73	60
00007	.	62	56
00051	.	82	76
00052	.	84	70
00103	.	64	ND
00105	.	52	66
00109	.	46 L	51 L
00401	.	68	60
00502	.	62	ND
00503	.	77	.
00505	.	80	78
00506	.	56	60
00507	.	82	83
00509	.	60	60
00510	.	63	67

00601	.	74	70
00602	.	64	.
00605	.	54	60
00606	.	78	84
00607	.	68	70
00701	.	52	.
00706	.	62	68
00804	.	72	76
00805	.	79	67
00809	.	65	67
00811	.	57	53
00816	65	60	61
00824	.	68	66
00825	.	75	67
Mean	68	67	66
SDev	4.2	10.0	8.5
n	2	31	26
Min	65	46	51
Max	71	84	84

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Sitting
BRL29060 20MG UID

Sub no	20MG	20MG PK	20PK+24
Pulse (bpm)			
00002	.	60	80
00003	.	88	80
00004	85	80	70
00007	.	66	72
00051	.	72	76
00052	.	88	64
00103	.	82	ND
00105	.	66	88
00109	.	73	72
00401	.	88	80
00502	.	91	ND
00503	.	77	.
00505	.	83	69
00506	.	83	101
00507	.	50	70
00509	.	59	85
00510	.	74	105
00601	.	60	66
00602	.	60	.
00605	.	80	68
00606	.	72	66
00607	.	62	68
00701	.	73	.
00706	.	63	88
00804	.	77	84
00805	.	91	82
00809	.	79	64
00811	.	83	123
00816	65	80	70
00824	.	74	76
00825	.	72	77
Mean	75	74	79
SDev	14.1	10.7	13.9
n	2	31	26
Min	65	50	64
Max	85	91	123

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

[VITT096:TAB] [17DEC2001:15:02]

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Sitting
BRL29060 30MG UID

Sub no	30MG PK	30MG PK	30PK+24
Systolic BP (mmHg)			
00002	110	.	99
00003	98	.	135 H
00004	110	.	132
00051	110	.	110
00052	120	.	118
00103	122	.	ND
00105	104	.	104
00109	123	.	118
00401	88	.	90
00502	130	.	ND
00503	124	.	.
00506	122	.	107
00507	128	.	138
00509	ND	.	129
00510	124	.	110
00601	110	.	118
00602	106	116	110
00605	102	.	.
00606	130	.	126
00607	102	.	118
00701	99	102	104
00706	104	.	117
00804	112	.	108
00805	110	.	100
00809	108	.	129
00811	121	.	110
00816	126	.	113
00824	110	.	116

00825	129	.	136
Mean	114	109	116
SDev	11.2	9.9	12.5
n	28	2	25
Min	88	102	90
Max	130	116	138

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Sitting
BRL29060 30MG UID

Sub no	30MG PK	30MG PK	30PK+24
Diastolic BP (mmHg)			
00002	76	.	57
00003	68	.	62
00004	52 L	.	80
00051	70	.	70
00052	68	.	68

00103	75	.	ND
00105	59	.	60
00109	66	.	77
00401	58	.	60
00502	75	.	ND
00503	74	.	.
00506	54	.	53
00507	66	.	77
00509	ND	.	55
00510	66	.	67
00601	72	.	72
00602	72	78	62
00605	58	.	.
00606	78	.	80
00607	72	.	70
00701	52	55	61
00706	59	.	65
00804	69	.	70
00805	69	.	64
00809	67	.	66
00811	60	.	58
00816	55	.	54
00824	67	.	72
00825	72	.	79
Mean	66	67	66
SDev	7.6	16.3	8.3
n	28	2	25
Min	52	55	53
Max	78	78	80

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold

H = Above Potential Clinical Concern threshold
. = No data available

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Sitting
BRL29060 30MG UID

Sub no	30MG PK	30MG PK	30PK+24
Pulse (bpm)			
00002	72	.	70
00003	82	.	86
00004	85	.	84
00051	64	.	60
00052	68	.	70
00103	67	.	ND
00105	63	.	73
00109	66	.	65
00401	94	.	100
00502	81	.	ND
00503	77	.	.
00506	93	.	79
00507	63	.	60
00509	ND	.	90
00510	66	.	74
00601	70	.	72
00602	62	66	72
00605	68	.	.
00606	68	.	68
00607	60	.	68
00701	100	68	69
00706	59	.	90
00804	86	.	79
00805	72	.	78
00809	79	.	70
00811	83	.	78
00816	67	.	61
00824	78	.	83
00825	79	.	86
Mean	74	67	75
SDev	10.9	1.4	10.2
n	28	2	25
Min	59	66	60
Max	100	68	100

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

[VITT096:TAB] [17DEC2001:15:02]

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Sitting
BRL29060 20MG UID-TAPER

Subno	20MG TAP	20MG TAP	20TAP+24
Systolic BP (mmHg)			
00109	.	101	.
00503	.	130	ND
00506	.	112	.
00507	.	118	.
00605	92	108	.
00804	.	102	.
00809	.	132	.
00811	.	117	.
00824	.	110	.
00825	.	114	.
Mean	92	114	.
SDev	.	10.4	.
n	1	10	0
Min	92	101	.
Max	92	132	.

Diastolic BP (mmHg)

00109	.	68		.
00503	.	82		ND
00506	.	80	H	.
00507	.	78		.
00605	48	60		.
00804	.	63		.
00809	.	62		.
00811	.	61		.
00824	.	68		.
00825	.	73		.
Mean	48	70		.
SDev	.	8.3		.
n	1	10		0
Min	48	60		.
Max	48	82		.

Pulse (bpm)

00109	.	70		.
00503	.	81		ND
00506	.	68		.
00507	.	62		.
00605	76	84		.
00804	.	83		.
00809	.	67		.
00811	.	105		.
00824	.	83		.
00825	.	75		.
Mean	76	78		.
SDev	.	12.4		.
n	1	10		0
Min	76	62		.
Max	76	105		.

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

Table DS11

VITAL SIGNS DATA OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Sitting

BRL29060 10MG UID-TAPER

Sub no	10MG TAP
Systolic BP (mmHg)	
00005	106
00105	102
00505	109
00607	110
00805	97
Mean	105
SDev	5.4
n	5
Min	97
Max	110
Diastolic BP (mmHg)	
00005	72
00105	56
00505	67
00607	66
00805	55
Mean	63
SDev	7.4
n	5
Min	55
Max	72
Pulse (bpm)	
00005	76
00105	63
00505	56
00607	68
00805	90
Mean	71
SDev	13.1
n	5
Min	56
Max	90

Flagging performed for Sitting Systolic BP, Diastolic BP, Pulse
Key : L = Below Potential Clinical Concern threshold
H = Above Potential Clinical Concern threshold
. = No data available

Table DS34

Height and Weight Data OF STUDY SB29060/715

Subject Group - CHILDREN
Parameter - Height
(CM)

Subject No.	SCR	D1PRE	10MG PK	20MG PK	30MG PK	10MG TAP
00001	139.7	139.0	140.3	139.0	139.7	.
00053	154.9	154.9	154.9	154.9	154.9	.
00055	142.2	142.2	142.2	142.2	142.2	.
00101	138.4	141.0	141.0	139.9	141.2	.
00102	134.6	140.0	132.9	133.9	135.3	.
00104	158.8	159.0	158.1	159.7	160.2	.
00106	149.9	149.9	149.9	148.2	148.5	.
00107	148.6	152.0	152.0	152.0	152.7	.
00108	152.4	152.4	152.4	156.3	154.9	.
00110	128.9	129.0	129.0	130.0	128.7	.
00111	135.3	135.5	.	.	.	.
00112	134.6	134.6	134.6	134.6	134.6	.
00113	146.0	146.1	ND	.	.	.
00202	147.5	148.0	147.8	148.2	148.2	.
00301	125.5	122.4	122.0	.	123.4	.
00303	146.4	146.4	148.3	148.5	149.7	.
00504	130.3	130.5	130.0	129.9	.	131.0
00603	142.2	144.0	144.0	145.0	142.0	.
00604	164.0	167.0	170.0	167.0	170.0	.
00702	146.9	147.8	147.4	148.0	148.9	.
00704	131.5	131.2	131.7	132.9	134.4	.
00705	133.0	133.0	133.5	133.9	134.1	.
00707	142.3	142.0	142.7	142.8	142.1	.
00708	145.8	146.2	146.8	144.7	147.0	.
00709	135.7	134.9	136.0	135.9	136.3	.
00806	153.0	154.0	154.0	154.0	155.0	.
00818	151.0	151.0	151.0	150.5	150.5	.
n	27	27	25	24	24	1
Min	125	122	122	129	123	131
Max	164	167	170	167	170	131
Mean	142	143	143	144	144	131
SDev	9.7	10.2	10.9	10.0	10.7	.

. = No data available

[S0241035:TAB] [17DEC2001:15:05]

Table DS34

Height and Weight Data OF STUDY SB29060/715

Subject Group - CHILDREN
Parameter - Weight
(KG)

Subject No.	SCR	D1PRE	10MG PK	20MG PK	30MG PK	10MG TAP
00001	33.6	34.4	33.7	33.8	33.8	.
00053	65.5	64.5	63.6	63.6	64.5	.
00055	38.6	38.6	38.6	38.6	39.5	.
00101	40.7	40.7	40.9	41.5	41.5	.
00102	29.5	29.5	29.3	29.9	30.5	.
00104	64.1	66.4	65.9	66.6	66.7	.
00106	49.5	49.5	50.0	50.1	49.1	.
00107	61.4	63.0	63.0	63.5	62.7	.
00108	48.2	48.2	48.4	49.4	55.5	.
00110	29.8	31.4	31.5	29.6	29.6	.
00111	35.9	35.9	.	.	.	.
00112	36.1	35.5	36.0	36.2	36.0	.
00113	48.0	48.1	ND	.	.	.
00202	51.0	51.0	49.6	50.3	49.9	.
00301	26.9	26.2	26.4	.	26.3	.
00303	35.7	35.2	35.6	36.7	36.0	.
00504	29.2	30.1	29.7	30.4	.	29.7
00603	34.0	35.9	35.5	36.3	35.5	.
00604	76.5	78.0	77.0	78.2	79.0	.
00702	34.2	33.2	33.6	34.0	33.1	.
00704	25.9	26.8	25.7	26.2	27.6	.
00705	27.4	27.4	27.4	26.8	26.9	.
00707	34.2	34.4	34.1	34.0	34.1	.

00708	38.2	38.7	38.0	37.6	38.4	.
00709	34.0	34.2	35.6	31.5	36.1	.
00806	60.8	61.8	62.7	61.8	61.8	.
00818	46.8	47.6	47.7	48.1	48.6	.
n	27	27	25	24	24	1
Min	25.9	26.2	25.7	26.2	26.3	29.7
Max	76.5	78.0	77.0	78.2	79.0	29.7
Mean	42.1	42.5	42.4	43.1	43.4	29.7
SDev	13.6	13.9	14.2	14.4	14.7	.

. = No data available

[S0241035:TAB] [17DEC2001:15:05]

Table DS34

Height and Weight Data OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Parameter - Height
(CM)

Subject No.	SCR	D1PRE	10MG PK	20MG PK	30MG PK	20MG TAP

00002	157.3	157.4	157.7	158.2	157.4	.
00003	162.8	163.4	161.4	162.2	162.6	.
00004	175.8	176.5	176.6	176.6	177.3	.
00005	151.7	153.1	153.1	.	.	.
00007	172.9	172.1	172.2	172.9	.	.
00051	162.6	162.6	162.6	162.6	162.6	.
00052	190.5	190.5	190.5	190.5	190.5	.
00054	180.3	180.3	180.3	.	.	.
00103	171.5	171.5	171.5	171.5	171.5	.
00105	152.4	152.4	152.4	152.4	152.4	.
00109	171.5	171.5	167.6	169.7	170.4	.
00201	177.0	177.0	179.0	.	.	.
00401	147.3	147.3	147.3	147.3	147.3	.
00502	161.6	162.7	161.0	163.0	161.1	.
00503	174.0	174.0	173.3	173.0	.	173.0
00505	146.0	146.2	146.0	145.5	.	.
00506	156.0	156.4	156.2	157.0	157.0	.
00507	164.3	163.3	163.4	164.1	164.0	.
00509	177.3	178.0	176.4	177.0	177.5	.
00510	156.5	156.3	156.0	156.0	157.2	.
00601	172.7	173.0	169.0	169.0	169.0	.
00602	172.7	172.0	172.0	172.0	172.0	.
00605	160.0	160.0	161.0	161.0	161.0	.
00606	164.0	163.0	162.6	164.0	164.0	.
00607	129.0	165.3	173.0	165.3	172.0	.
00701	164.0	164.6	164.6	164.4	164.9	.
00703	176.2	170.3	173.2	.	.	.
00706	145.0	145.0	85.1	145.5	145.8	.
00804	167.0	167.0	167.0	167.0	167.0	.
00805	161.5	161.6	166.0	166.0	167.0	.
00809	181.6	184.0	182.0	185.0	183.0	.
00811	155.0	157.5	156.0	156.0	160.0	.
00816	159.0	161.5	160.5	162.0	163.0	.
00824	174.0	177.5	177.0	175.5	177.5	.
00825	165.0	166.0	166.0	167.0	167.5	.
n	35	35	35	31	28	1
Min	129	145	85.1	145	145	173
Max	190	190	190	190	190	173
Mean	164	165	164	165	166	173
SDev	12.3	10.7	17.0	10.4	10.0	.

. = No data available

[S0241035:TAB] [17DEC2001:15:05]

Table DS34

Height and Weight Data OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Parameter - Height
(CM)

Subject No.	10MG TAP
00002	.
00003	.
00004	.
00005	154.0
00007	.
00051	.
00052	.
00054	.
00103	.
00105	.
00109	.
00201	.
00401	.
00502	.
00503	.
00505	.
00506	.
00507	.
00509	.
00510	.
00601	.
00602	.
00605	.
00606	.
00607	.
00701	.
00703	.
00706	.
00804	.
00805	.
00809	.
00811	.
00816	.
00824	.

00825	.
n	1
Min	154
Max	154
Mean	154
SDev	.

. = No data available

Table DS34

Height and Weight Data OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Parameter - Weight
(KG)

Subject No.	SCR	D1PRE	10MG PK	20MG PK	30MG PK	20MG TAP
00002	49.8	51.0	49.4	49.5	48.6	.
00003	67.7	68.9	67.9	69.8	68.7	.
00004	85.3	86.7	81.0	85.5	85.5	.
00005	41.3	43.0	42.4	.	.	.
00007	69.7	71.4	69.9	69.6	.	.
00051	90.5	89.1	89.1	89.1	89.1	.
00052	71.4	71.4	71.4	72.7	72.7	.
00054	96.8	98.6	96.8	.	.	.
00103	57.3	57.3	57.5	57.3	57.3	.
00105	65.9	65.9	65.9	66.0	66.0	.
00109	49.3	49.3	48.9	48.0	49.3	.

00201	65.0	65.5	65.2	.	.	.
00401	30.1	30.0	30.2	30.4	30.4	.
00502	98.3	98.4	98.8	100.5	98.8	.
00503	87.8	87.8	88.3	88.0	.	86.9
00505	31.0	31.5	31.6	32.6	.	.
00506	59.4	58.6	60.4	58.8	60.3	.
00507	67.4	69.0	67.3	67.1	66.5	.
00509	61.3	61.2	63.2	63.0	63.6	.
00510	45.5	46.3	45.1	46.9	46.3	.
00601	58.6	61.0	58.0	59.4	59.5	.
00602	67.6	66.5	67.0	68.5	66.8	.
00605	53.1	54.0	54.2	52.6	53.0	.
00606	86.8	87.0	88.0	86.8	85.5	.
00607	68.0	58.4	58.5	58.5	57.5	.
00701	55.3	54.4	53.9	54.7	53.1	.
00703	63.2	65.4	63.7	.	.	.
00706	44.0	44.0	45.2	42.9	42.3	.
00804	58.6	58.7	56.8	56.2	56.2	.
00805	43.0	48.6	48.6	50.0	49.3	.
00809	141.0	143.8	143.4	144.3	142.7	.
00811	71.5	73.6	73.9	74.4	73.0	.
00816	105.4	105.7	102.7	100.7	102.2	.
00824	99.1	100.5	101.0	98.5	98.5	.
00825	80.7	81.8	82.0	82.1	81.6	.
n	35	35	35	31	28	1
Min	30.1	30.0	30.2	30.4	30.4	86.9
Max	141	143	143	144	142	86.9
Mean	68.2	68.6	68.2	68.5	68.7	86.9
SDev	22.9	23.0	22.9	23.3	23.1	.

. = No data available

Table DS34

Height and Weight Data OF STUDY SB29060/715

Subject Group - ADOLESCENTS
Parameter - Weight
(KG)

Subject No.	10MG TAP
00002	.
00003	.
00004	.
00005	42.5
00007	.
00051	.
00052	.
00054	.
00103	.
00105	.
00109	.
00201	.
00401	.
00502	.
00503	.
00505	.
00506	.
00507	.
00509	.
00510	.
00601	.
00602	.
00605	.
00606	.
00607	.
00701	.
00703	.
00706	.
00804	.
00805	.
00809	.
00811	.
00816	.
00824	.
00825	.
n	1
Min	42.5
Max	42.5
Mean	42.5
SDev	.

. = No data available

Table DS14

ECG DATA OF STUDY SB29060/715

HR (bpm)
Subject Group - CHILDREN
No Dose Given

Sub no	SCR
00001	77
00053	99
00055	57
00101	76
00102	59
00104	100
00106	76
00107	89
00108	74
00110	74
00111	79
00112	62
00113	57
00202	92
00301	101
00303	76
00504	63
00603	71
00604	85
00702	81
00704	68
00705	79
00707	63
00708	99
00709	59
00806	73
00818	71
Mean	76
SDev	13.5
n	27
Min	57
Max	101

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

HR (bpm)
Subject Group - CHILDREN

BRL29060 10MG UID

Sub no	10MG PK
00111	85
Mean	85
SDev	.
n	1
Min	85
Max	85

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

HR (bpm)
Subject Group - CHILDREN
BRL29060 30MG UID

Sub no	30MG PK
00001	82

00053	79
00055	ND
00101	80
00102	63
00104	82
00106	69
00107	78
00108	87
00110	64
00112	60
00202	81
00301	84
00303	79
00603	69
00604	71
00702	85
00704	70
00705	88
00707	72
00708	93
00709	75
00806	90
00818	81
Mean	77
SDev	8.9
n	23
Min	60
Max	93

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

HR (bpm)
Subject Group - CHILDREN
BRL29060 20MG UID-TAPER

Sub no	20MG TAP
00055	74
Mean	74
SDev	.
n	1
Min	74
Max	74

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

HR (bpm)
Subject Group - CHILDREN
BRL29060 10MG UID-TAPER

Sub no	10MG TAP
00504	62
Mean	62
SDev	.
n	1
Min	62
Max	62

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

HR (bpm)
Subject Group - ADOLESCENTS
No Dose Given

Sub no	SCR	SCRRPT	END
00002	69	.	.
00003	64	.	.
00004	83	.	.
00005	64	.	77
00007	58	65	.
00051	77	.	.
00052	60	.	.
00054	60	.	.
00103	59	.	.
00105	57	.	.
00109	60	.	.
00201	78	.	.
00401	89	.	.
00502	59	.	.
00503	73	.	.
00505	68	.	.
00506	82	.	.
00507	52	.	.
00509	60	.	.

00510	77	.	.
00601	62	.	.
00602	68	.	.
00605	71	.	.
00606	61	.	.
00607	65	.	.
00701	60	.	.
00703	59	.	66
00706	70	.	.
00804	87	.	.
00805	65	.	.
00809	54	.	.
00811	93	.	.
00816	70	.	.

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

HR (bpm)
Subject Group - ADOLESCENTS
No Dose Given

Sub no	SCR	SCRRPT	END
00824	70	.	.
00825	71	.	.
Mean	68	65	72
SDev	10.2	.	7.8
n	35	1	2
Min	52	65	66
Max	93	65	77

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

HR (bpm)
Subject Group - ADOLESCENTS
BRL29060 30MG UID

Sub no	30MG PK
00002	68
00003	71
00004	77
00051	68
00052	ND
00103	62
00105	59
00109	62
00401	75
00502	48
00506	91
00507	50
00509	71
00510	64
00601	68
00602	65
00606	63
00607	69
00701	71
00706	61
00804	75
00805	81
00809	60
00811	91
00816	70
00824	72
00825	79
Mean	69
SDev	10.2
n	26

Min	48
Max	91

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

HR (bpm)
Subject Group - ADOLESCENTS
BRL29060 20MG UID-TAPER

Sub no	20MG TAP
00503	64
00605	63
Mean	64
SDev	0.7
n	2
Min	63
Max	64

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

HR (bpm)
Subject Group - ADOLESCENTS
BRL29060 10MG UID-TAPER

Sub no	10MG TAP
00005	58
00505	79
Mean	69
SDev	14.8
n	2
Min	58
Max	79

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

PR (msec)
Subject Group - CHILDREN
No Dose Given

Sub no	SCR
00001	130
00053	140
00055	136
00101	136
00102	92
00104	160
00106	120
00107	152
00108	126
00110	138
00111	116
00112	128
00113	134
00202	150
00301	160
00303	130
00504	118
00603	110
00604	120
00702	128
00704	144
00705	120
00707	144
00708	136
00709	136
00806	164
00818	152
Mean	134
SDev	16.5
n	27
Min	92
Max	164

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

PR (msec)
Subject Group - CHILDREN
BRL29060 10MG UID

Sub	10MG PK

Sub no	
00111	140
Mean	140
SDev	.
n	1
Min	140
Max	140

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

PR (msec)
Subject Group - CHILDREN
BRL29060 30MG UID

Sub no	30MG PK
00001	126
00053	152
00055	ND
00101	120

00102	100
00104	160
00106	136
00107	136
00108	140
00110	136
00112	112
00202	140
00301	128
00303	130
00603	120
00604	130
00702	108
00704	100
00705	116
00707	152
00708	128
00709	140
00806	176
00818	170
Mean	133
SDev	20.0
n	23
Min	100
Max	176

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

PR (msec)
Subject Group - CHILDREN
BRL29060 20MG UID-TAPER

Sub no	20MG TAP
00055	136
Mean	136
SDev	.
n	1
Min	136
Max	136

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

PR (msec)
Subject Group - CHILDREN
BRL29060 10MG UID-TAPER

Sub no	10MG TAP
00504	126
Mean	126
SDev	.
n	1
Min	126
Max	126

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

PR (msec)
Subject Group - ADOLESCENTS
No Dose Given

Sub no	SCR	SCRRPT	END
00002	118	.	.
00003	120	.	.
00004	134	.	.
00005	130	.	140
00007	136	152	.
00051	148	.	.
00052	160	.	.
00054	180	.	.
00103	118	.	.
00105	126	.	.
00109	118	.	.
00201	140	.	.
00401	134	.	.
00502	154	.	.
00503	162	.	.
00505	122	.	.
00506	144	.	.
00507	220	.	.
00509	130	.	.
00510	190	.	.
00601	120	.	.
00602	110	.	.

00605	150	.	.
00606	120	.	.
00607	100	.	.
00701	115	.	.
00703	144	.	140
00706	108	.	.
00804	154	.	.
00805	136	.	.
00809	140	.	.
00811	148	.	.
00816	174	.	.

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

PR (msec)
Subject Group - ADOLESCENTS
No Dose Given

Sub no	SCR	SCRRPT	END
00824	152	.	.
00825	142	.	.
Mean	140	152	140
SDev	24.8	.	0.0
n	35	1	2
Min	100	152	140
Max	220	152	140

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

PR (msec)
Subject Group - ADOLESCENTS
BRL29060 30MG UID

Sub no	30MG PK
00002	108
00003	136
00004	152
00051	140
00052	ND
00103	120
00105	148
00109	128
00401	138
00502	168
00506	138
00507	236
00509	118
00510	172
00601	110
00602	130
00606	120
00607	120
00701	128
00706	108
00804	160
00805	134
00809	164
00811	152
00816	166
00824	130
00825	134
Mean	141
SDev	27.0
n	26
Min	108
Max	236

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

PR (msec)
Subject Group - ADOLESCENTS
BRL29060 20MG UID-TAPER

Sub no	20MG TAP
00503	160
00605	140
Mean	150
SDev	14.1
n	2
Min	140
Max	160

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

PR (msec)
Subject Group - ADOLESCENTS
BRL29060 10MG UID-TAPER

Sub no	10MG TAP
00005	136
00505	140
Mean	138
SDev	2.8
n	2
Min	136
Max	140

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QRS (msec)
Subject Group - CHILDREN

No Dose Given

Sub no	SCR
00001	72
00053	72
00055	80
00101	82
00102	76
00104	90
00106	92
00107	84
00108	58
00110	70
00111	74
00112	82
00113	76
00202	60
00301	98
00303	90
00504	86
00603	70
00604	100
00702	92
00704	84
00705	80
00707	100
00708	76
00709	76
00806	84
00818	100
Mean	82
SDev	11.3
n	27
Min	58
Max	100

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QRS (msec)
Subject Group - CHILDREN
BRL29060 10MG UID

Sub no	10MG PK
00111	82

Mean	82
SDev	.
n	1
Min	82
Max	82

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QRS (msec)
Subject Group - CHILDREN
BRL29060 30MG UID

Sub no	30MG PK
00001	74
00053	80
00055	ND
00101	80
00102	76
00104	84
00106	100

00107	80
00108	76
00110	76
00112	80
00202	76
00301	94
00303	74
00603	60
00604	90
00702	80
00704	76
00705	72
00707	88
00708	72
00709	84
00806	80
00818	98
Mean	80
SDev	9.0
n	23
Min	60
Max	100

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QRS (msec)
Subject Group - CHILDREN
BRL29060 20MG UID-TAPER

Sub no	20MG TAP
00055	84
Mean	84
SDev	.
n	1
Min	84
Max	84

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QRS (msec)
Subject Group - CHILDREN
BRL29060 10MG UID-TAPER

Sub no	10MG TAP
00504	84
Mean	84
SDev	.
n	1
Min	84
Max	84

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QRS (msec)
Subject Group - ADOLESCENTS
No Dose Given

Sub no	SCR	SCRRPT	END
00002	72	.	.
00003	86	.	.
00004	86	.	.
00005	86	.	84
00007	88	96	.
00051	88	.	.
00052	88	.	.
00054	84	.	.
00103	104	.	.
00105	84	.	.
00109	90	.	.
00201	80	.	.
00401	80	.	.
00502	106	.	.
00503	96	.	.
00505	72	.	.
00506	76	.	.
00507	92	.	.
00509	92	.	.
00510	86	.	.
00601	90	.	.
00602	70	.	.
00605	70	.	.
00606	90	.	.
00607	90	.	.

00701	80	.	.
00703	88	.	88
00706	76	.	.
00804	100	.	.
00805	84	.	.
00809	96	.	.
00811	100	.	.
00816	92	.	.

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QRS (msec)
Subject Group - ADOLESCENTS
No Dose Given

Subno	SCR	SCRRPT	END
00824	84	.	.
00825	92	.	.
Mean	87	96	86
SDev	9.0	.	2.8
n	35	1	2
Min	70	96	84
Max	106	96	88

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QRS (msec)
Subject Group - ADOLESCENTS
BRL29060 30MG UID

Sub no	30MG PK
00002	68
00003	92
00004	88
00051	84
00052	ND
00103	100
00105	76
00109	100
00401	80
00502	96
00506	78
00507	92
00509	90
00510	84
00601	90
00602	60
00606	90
00607	80
00701	80
00706	76
00804	100
00805	86
00809	88
00811	90
00816	86
00824	80
00825	86
Mean	85
SDev	9.5
n	26
Min	60
Max	100

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QRS (msec)
Subject Group - ADOLESCENTS
BRL29060 20MG UID-TAPER

Sub no	20MG TAP
00503	100
00605	70
Mean	85
SDev	21.2
n	2
Min	70
Max	100

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QRS (msec)
Subject Group - ADOLESCENTS
BRL29060 10MG UID-TAPER

Sub no	10MG TAP
00005	96
00505	74
Mean	85
SDev	15.6
n	2
Min	74
Max	96

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QT (msec)
Subject Group - CHILDREN
No Dose Given

Sub	SCR

Sub no	
00001	352
00053	344
00055	408
00101	390
00102	396
00104	334
00106	370
00107	328
00108	358
00110	366
00111	346
00112	390
00113	404
00202	320
00301	324
00303	364
00504	404
00603	350
00604	350
00702	372
00704	412
00705	356
00707	408
00708	356
00709	404
00806	370
00818	380
Mean	369
SDev	27.9
n	27
Min	320
Max	412

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QT (msec)
Subject Group - CHILDREN
BRL29060 10MG UID

Sub no	10MG PK
00111	336
Mean	336
SDev	.

n	1
Min	336
Max	336

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QT (msec)
Subject Group - CHILDREN
BRL29060 30MG UID

Sub no	30MG PK
00001	354
00053	360
00055	ND
00101	368
00102	384
00104	352
00106	404
00107	356
00108	348
00110	400

00112	412
00202	360
00301	348
00303	344
00603	390
00604	360
00702	344
00704	372
00705	352
00707	376
00708	364
00709	360
00806	352
00818	378
Mean	367
SDev	19.6
n	23
Min	344
Max	412

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QT (msec)
Subject Group - CHILDREN
BRL29060 20MG UID-TAPER

Sub no	20MG TAP
00055	384
Mean	384
SDev	.
n	1
Min	384
Max	384

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QT (msec)
Subject Group - CHILDREN
BRL29060 10MG UID-TAPER

Sub no	10MG TAP
00504	414
Mean	414
SDev	.
n	1
Min	414
Max	414

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QT (msec)
Subject Group - ADOLESCENTS
No Dose Given

Sub no	SCR	SCRRPT	END
00002	362	.	.
00003	406	.	.
00004	334	.	.
00005	376	.	356
00007	396	372	.
00051	352	.	.
00052	416	.	.
00054	396	.	.
00103	376	.	.
00105	452	.	.
00109	408	.	.
00201	350	.	.
00401	358	.	.
00502	398	.	.
00503	382	.	.
00505	378	.	.
00506	356	.	.
00507	434	.	.
00509	406	.	.
00510	348	.	.
00601	400	.	.
00602	400	.	.
00605	350	.	.
00606	410	.	.
00607	400	.	.
00701	408	.	.
00703	424	.	384
00706	372	.	.

00804	344	.	.
00805	380	.	.
00809	436	.	.
00811	364	.	.
00816	376	.	.

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QT (msec)
Subject Group - ADOLESCENTS
No Dose Given

Sub no	SCR	SCRRPT	END
00824	408	.	.
00825	376	.	.
Mean	387	372	370
SDev	28.9	.	19.8
n	35	1	2
Min	334	372	356
Max	452	372	384

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QT (msec)
Subject Group - ADOLESCENTS
BRL29060 30MG UID

Sub no	30MG PK
00002	374
00003	376
00004	348
00051	364
00052	ND
00103	396
00105	444
00109	412
00401	364
00502	476
00506	348
00507	438
00509	376
00510	388
00601	380
00602	400
00606	400
00607	400
00701	384
00706	388
00804	364
00805	374
00809	372
00811	342
00816	370
00824	380
00825	354
Mean	385
SDev	30.9
n	26
Min	342
Max	476

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QT (msec)
Subject Group - ADOLESCENTS
BRL29060 20MG UID-TAPER

Sub no	20MG TAP
00503	402
00605	360
Mean	381
SDev	29.7
n	2
Min	360
Max	402

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QT (msec)
Subject Group - ADOLESCENTS

BRL29060 10MG UID-TAPER

Sub no	10MG TAP
00005	392
00505	350
Mean	371
SDev	29.7
n	2
Min	350
Max	392

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QTC (msec)
Subject Group - CHILDREN
No Dose Given

Sub no	SCR
00001	398

00053	441
00055	394
00101	443
00102	396
00104	434
00106	420
00107	480
00108	398
00110	407
00111	398
00112	398
00113	396
00202	400
00301	420
00303	409
00504	413
00603	380
00604	420
00702	432
00704	438
00705	408
00707	418
00708	420
00709	397
00806	408
00818	411
Mean	414
SDev	20.8
n	27
Min	380
Max	480

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QTC (msec)
Subject Group - CHILDREN
BRL29060 10MG UID

Sub no	10MG PK
00111	399
Mean	399
SDev	.
n	1
Min	399
Max	399

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QTC (msec)
Subject Group - CHILDREN
BRL29060 30MG UID

Sub no	30MG PK
00001	413
00053	408
00055	ND
00101	423
00102	390
00104	410
00106	430
00107	403
00108	417
00110	406
00112	412
00202	414
00301	411

00303	394
00603	420
00604	390
00702	409
00704	401
00705	426
00707	411
00708	453
00709	402
00806	431
00818	439
Mean	414
SDev	15.2
n	23
Min	390
Max	453

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QTC (msec)
Subject Group - CHILDREN
BRL29060 20MG UID-TAPER

Sub no	20MG TAP
00055	422
Mean	422
SDev	.
n	1
Min	422
Max	422

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QTC (msec)
Subject Group - CHILDREN
BRL29060 10MG UID-TAPER

Sub no	10MG TAP
00504	420
Mean	420
SDev	.
n	1
Min	420
Max	420

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QTC (msec)
Subject Group - ADOLESCENTS
No Dose Given

Sub no	SCR	SCRRPT	END
00002	376	.	.
00003	419	.	.
00004	392	.	.
00005	388	.	397
00007	389	384	.
00051	393	.	.
00052	416	.	.
00054	396	.	.
00103	376	.	.
00105	443	.	.
00109	408	.	.
00201	400	.	.
00401	409	.	.
00502	394	.	.
00503	420	.	.
00505	401	.	.
00506	415	.	.
00507	403	.	.
00509	406	.	.
00510	393	.	.
00601	410	.	.
00602	430	.	.
00605	380	.	.
00606	410	.	.
00607	420	.	.
00701	408	.	.
00703	420	.	402
00706	401	.	.
00804	414	.	.
00805	392	.	.
00809	406	.	.

00811	448	.	.
00816	406	.	.

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QTC (msec)
Subject Group - ADOLESCENTS
No Dose Given

Sub no	SCR	SCRRPT	END
00824	435	.	.
00825	409	.	.
Mean	406	384	400
SDev	16.9	.	3.5
n	35	1	2
Min	376	384	397
Max	448	384	402

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QTC (msec)
Subject Group - ADOLESCENTS
BRL29060 30MG UID

Sub no	30MG PK
00002	386
00003	407
00004	388
00051	382
00052	ND
00103	402
00105	436
00109	418
00401	390
00502	425
00506	428
00507	399
00509	408
00510	400
00601	400
00602	420
00606	410
00607	430
00701	417
00706	391
00804	406
00805	434
00809	372
00811	421
00816	399
00824	416
00825	406
Mean	407
SDev	16.7
n	26
Min	372
Max	436

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QTC (msec)
Subject Group - ADOLESCENTS
BRL29060 20MG UID-TAPER

Sub no	20MG TAP
00503	414
00605	370
Mean	392
SDev	31.1
n	2
Min	370
Max	414

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS14

ECG DATA OF STUDY SB29060/715

QTC (msec)
Subject Group - ADOLESCENTS
BRL29060 10MG UID-TAPER

Sub	10MG TAP

no

00005	385
00505	401
Mean	393
SDev	11.3
n	2
Min	385
Max	401

No values of Potential Clinical Concern
. = No data available

[ECGT018:TAB]
[11DEC2001:11:20]

Table DS30

Clinical Global Impressions (CGI) Data OF STUDY SB29060/715

Subject Group - CHILDREN
SCR

Subject No.	Severity of Illness score
00001	Moderately ill
00053	Moderately ill
00055	Moderately ill
00101	Moderately ill
00102	Moderately ill
00104	Moderately ill
00106	Markedly ill
00107	Moderately ill
00108	Moderately ill
00110	Moderately ill
00111	Moderately ill
00112	Moderately ill
00113	Moderately ill
00202	Moderately ill
00301	Moderately ill
00303	Moderately ill
00504	Moderately ill
00603	Markedly ill
00604	Moderately ill
00702	Moderately ill
00704	Moderately ill
00705	Markedly ill
00707	Moderately ill
00708	Moderately ill
00709	Severely ill
00806	Moderately ill
00818	Markedly ill

. = No data available

[S0242029:TAB]
[11DEC2001:11:20]

Table DS30

Clinical Global Impressions (CGI) Data OF STUDY SB29060/715

Subject Group - CHILDREN
30MG PK DAY

Subject No.	Global Improvement score	Severity of Illness score
00001	Very much improved	Normal, not at all ill
00053	Minimally improved	Moderately ill
00055	No change	Mildly ill
00101	Very much improved	Normal, not at all ill
00102	Very much improved	Normal, not at all ill
00104	Much improved	Borderline mentally ill
00106	Much improved	Mildly ill
00107	Minimally improved	Mildly ill
00108	Much improved	Borderline mentally ill
00110	Very much improved	Borderline mentally ill
00112	Very much improved	Normal, not at all ill
00202	Minimally worse	Markedly ill
00301	No change	Moderately ill
00303	Very much improved	Borderline mentally ill
00603	Minimally worse	Markedly ill
00604	Much improved	Mildly ill
00702	Very much improved	Borderline mentally ill
00704	Much improved	Mildly ill
00705	Much improved	Mildly ill
00707	Very much improved	Mildly ill
00708	Much improved	Mildly ill
00709	Very much improved	Normal, not at all ill
00806	Much improved	Normal, not at all ill
00818	Very much improved	Borderline mentally ill

. = No data available

[S0242029:TAB]
[11DEC2001:11:20]

Table DS30

Clinical Global Impressions (CGI) Data OF STUDY SB29060/715

Subject Group - CHILDREN
10MG TAPER

Subject No.	Global Improvement score	Severity of Illness score

00504	Much improved	Borderline mentally ill

. = No data available

[S0242029:TAB]
[11DEC2001:11:20]

Table DS30

Clinical Global Impressions (CGI) Data OF STUDY SB29060/715

Subject Group - ADOLESCENTS SCR

Subject No.	Severity of Illness score
00002	Moderately ill
00003	Moderately ill
00004	Severely ill
00005	Moderately ill

00007	Moderately ill
00051	Moderately ill
00052	Moderately ill
00054	Moderately ill
00103	Moderately ill
00105	Moderately ill
00109	Moderately ill
00201	Moderately ill
00401	Markedly ill
00502	Moderately ill
00503	Moderately ill
00505	Moderately ill
00506	Moderately ill
00507	Moderately ill
00509	Moderately ill
00510	Moderately ill
00601	Moderately ill
00602	Moderately ill
00605	Moderately ill
00606	Moderately ill
00607	Moderately ill
00701	Severely ill
00703	Markedly ill
00706	Moderately ill
00804	Severely ill
00805	Moderately ill
00809	Moderately ill
00811	Moderately ill
00816	Markedly ill
00824	Moderately ill
00825	Moderately ill

. = No data available

[S0242029:TAB]
[11DEC2001:11:20]

Table DS30

Clinical Global Impressions (CGI) Data OF STUDY SB29060/715

Subject Group - ADOLESCENTS
10MG PK DAY

Subject No.	Global Improvement score	Severity of Illness score
00054	No change	Moderately ill
00703	No change	Markedly ill

. = No data available

[S0242029:TAB]
[11DEC2001:11:20]

Table DS30

Clinical Global Impressions (CGI) Data OF STUDY SB29060/715

Subject Group - ADOLESCENTS
20MG PK DAY

Subject No.	Global Improvement score	Severity of Illness score
00505	Much improved	Borderline mentally ill

. = No data available

[S0242029:TAB]
[11DEC2001:11:20]

Table DS30

Clinical Global Impressions (CGI) Data OF STUDY SB29060/715

Subject Group - ADOLESCENTS
30MG PK DAY

Subject No.	Global Improvement score	Severity of Illness score
00002	Much improved	Borderline mentally ill
00003	Much improved	Borderline mentally ill
00004	Much improved	Borderline mentally ill
00052	Minimally improved	Moderately ill
00103	Minimally improved	Moderately ill
00105	Much improved	Borderline mentally ill
00109	Much improved	Borderline mentally ill
00401	Much improved	Moderately ill
00502	Minimally improved	Mildly ill
00506	Much improved	Borderline mentally ill
00507	Much improved	Mildly ill
00509	Minimally improved	Moderately ill
00510	Much improved	Mildly ill
00601	Very much improved	Mildly ill
00602	Much improved	Mildly ill
00605	Very much improved	Normal, not at all ill
00606	Very much improved	Normal, not at all ill
00607	Much improved	Borderline mentally ill
00701	Minimally improved	Markedly ill

00706	Much improved	Mildly ill
00805	Minimally improved	Moderately ill
00809	Much improved	Mildly ill
00816	Minimally improved	Moderately ill
00825	Much improved	Mildly ill

. = No data available

[S0242029:TAB]
[11DEC2001:11:20]

Table DS30

Clinical Global Impressions (CGI) Data OF STUDY SB29060/715

Subject Group - ADOLESCENTS
20MG TAPER

Subject No.	Global Improvement score	Severity of Illness score
00051	Much improved	Borderline mentally ill
00503	Minimally improved	Mildly ill
00804	Very much improved	Borderline mentally ill
00811	Minimally improved	Moderately ill
00824	Not assessed	Borderline mentally ill

. = No data available

[S0242029:TAB]
[11DEC2001:11:20]

Table DS30

Clinical Global Impressions (CGI) Data OF STUDY SB29060/715

Subject Group - ADOLESCENTS
10MG TAPER

Subject No.	Global Improvement score	Severity of Illness score
00005	Not assessed	Not assessed

. = No data available

[S0242029:TAB]
[11DEC2001:11:20]

Table 10.3 Paroxetine steady-state Cmax [ng/mL] following once daily dosing (10, 20, 30 mg) in child patients

Patient	Gender	Age (yrs)	Weight (kg)	10 mg	20 mg	30 mg
001	M	9	33.6	25.671	38.946	96.168
053	F	10	65.5	4.540	28.002	37.617
055	M	10	38.6	1.250	19.381	28.297
101	F	9	40.7	0.286*	^	61.509*
102	M	8	29.5	29.612	81.284	192.343
104	F	11	64.1	25.803	93.985	135.200
106	M	10	49.5	5.569	53.887	106.461
107	M	10	61.4	11.414	27.967	95.579
108	F	11	48.2	8.255	27.577	81.668
110	M	9	29.8	5.571*	52.228	55.101*
112	M	11	36.1	17.891	54.391	104.008
202	M	10	51.0	8.843	20.054	72.758
301	M	8	26.9	20.250	W	W
303	M	11	35.7	20.920	56.830	131.389
504	M	8	29.2	5.945	31.895	W
603	M	11	34.0	16.233	32.133	58.834
604	M	11	76.5	19.120	47.212	120.645
702	F	11	34.2	23.712	108.747	172.136
704	M	9	25.9	35.544	115.950	193.094
705	M	9	27.4	90.851	142.367	552.601
707	M	8	34.2	21.180	66.510	99.452
708	F	8	38.2	11.335	64.032	98.156
709	M	10	34.0	8.286	33.176	59.033
806	F	10	60.8	7.256	40.916	126.989
818	M	11	46.8	29.608	110.718	147.048
N				**23**	**23**	**21**
Mean				**19.526**	**58.617**	**129.023**
SD				**18.153**	**34.529**	**106.941**
Minimum				**1.250**	**19.381**	**28.297**
Median				**17.891**	**52.228**	**104.008**
Maximum				**90.851**	**142.367**	**552.601**
Geometric mean				**14.018**	**50.029**	**105.512**
CVb(%)				**109**	**63**	**68**

* Data suspect (see text); excluded from summary statistics

^ All plasma concentrations were below the lower limit of quantification (0.1 ng/mL); excluded from summary statistics

W = patient withdrew

Table 10.4 Paroxetine steady-state Cmax [ng/mL] following once daily dosing (10, 20, 30 mg) in adolescent patients

Patient	Gender	Age (yrs)	Weight (kg)	10 mg	20 mg	30 mg
002	M	14	49.8	12.821	23.263	133.058
003	F	16	67.7	24.873	47.664	136.923
004	M	15	85.3	2.003	10.658	69.736
005	M	12	41.3	4.608	W	W
007	M	14	69.7	16.348	37.381	W
051	M	12	90.5	22.783	35.993	76.531
052	M	15	71.4	3.005	20.094	33.461
054	M	16	96.8	0.784	W	W
103	M	15	57.3	18.417	46.819	144.757
105	F	12	65.9	8.835	27.016	73.057
109	F	17	49.3	1.701*	11.599*	14.242*
201	M	12	65.0	2.084	W	W
401	F	12	30.1	36.312	85.442	139.996
502	F	16	98.3	7.440	25.702	45.020
503	F	15	87.8	0.337	11.170	W
505	M	12	31.0	10.668	41.093	W
506	M	12	59.4	14.565	35.982	65.243
507	M	12	67.4	3.951	28.425	64.754
509	M	15	61.3	3.294	29.141	72.214
510	M	12	45.5	62.838	129.896	262.925
601	M	17	58.6	5.300	26.091	54.903
602	M	15	67.6	0.792	20.663*	57.494
605	F	13	53.1	7.110	27.653	78.978
606	M	14	86.8	5.291	28.476	83.669
607	F	17	68.0	20.914	40.613	89.068
701	F	15	55.3	1.999	29.898	46.257
706	M	12	44.0	13.599	60.849	132.805
804	M	16	58.6	7.939	58.294	142.136
805	F	16	43.0	6.438	31.771	80.331
809	M	16	141.0	2.394	15.222	28.459
811	F	12	71.5	19.477	83.708	167.297
816	F	14	105.4	29.664	122.745	96.555
824	F	16	99.1	0.979	13.653	42.785
825	F	16	80.7	18.300	64.920	120.349
N				**33**	**29**	**27**
Mean				**12.005**	**42.746**	**94.028**
SD				**12.971**	**29.983**	**51.384**
Minimum				**0.337**	**10.658**	**28.459**
Median				**7.440**	**31.771**	**78.978**
Maximum				**62.838**	**129.896**	**262.925**
Geometric mean				**6.608**	**35.030**	**82.397**
CVb(%)				**191**	**70**	**56**

* Data suspect (see text); excluded from summary statistics

W = patient withdrew

Table 10.5 Paroxetine steady-state Tmax [hours] following once daily dosing (10, 20, 30 mg) in child patients

Patient	Gender	Age (yrs)	Weight (kg)	10 mg	20 mg	30 mg
001	M	9	33.6	5.00	4.97	2.00
053	F	10	65.5	5.00	5.00	12.00
055	M	10	38.6	3.00	3.00	5.00
101	F	9	40.7	0.00*	^	3.00*
102	M	8	29.5	5.00	2.97	3.00
104	F	11	64.1	3.00	3.00	5.00
106	M	10	49.5	5.08	5.42	3.00
107	M	10	61.4	3.00	3.00	3.02
108	F	11	48.2	5.00	8.00	14.13
110	M	9	29.8	12.00*	5.00	5.00*
112	M	11	36.1	5.00	5.00	5.00
202	M	10	51.0	5.00	5.00	5.00
301	M	8	26.9	3.00	W	W
303	M	11	35.7	1.92	2.92	1.83
504	M	8	29.2	12.08	5.00	W
603	M	11	34.0	8.00	5.00	3.00
604	M	11	76.5	5.00	5.08	12.00
702	F	11	34.2	3.17	2.97	3.07
704	M	9	25.9	2.92	2.00	2.00
705	M	9	27.4	2.00	8.03	3.00
707	M	8	34.2	3.12	2.98	8.00
708	F	8	38.2	5.00	2.75	8.00
709	M	10	34.0	4.88	5.05	3.08
806	F	10	60.8	2.00	5.00	3.00
818	M	11	46.8	2.00	3.00	5.02
N				**23**	**23**	**21**
Mean				**4.31**	**4.35**	**5.20**
SD				**2.26**	**1.59**	**3.59**
Minimum				**1.92**	**2.00**	**1.83**
Median				**4.88**	**5.00**	**3.08**
Maximum				**12.08**	**8.03**	**14.13**

* Data suspect (see text); excluded from summary statistics

^ All plasma concentrations were below the lower limit of quantification (0.1 ng/mL); excluded from summary statistics

W = patient withdrew

Table 10.6 Paroxetine steady-state Tmax [hours] following once daily dosing (10, 20, 30 mg) in adolescent patients

Patient	Gender	Age (yrs)	Weight (kg)	10 mg	20 mg	30 mg
002	M	14	49.8	1.98	5.00	5.00
003	F	16	67.7	5.00	5.00	2.00
004	M	15	85.3	5.00	5.08	3.00
005	M	12	41.3	5.02	W	W
007	M	14	69.7	5.00	5.00	W
051	M	12	90.5	2.00	24.00	8.00
052	M	15	71.4	5.00	8.08	5.00
054	M	16	96.8	5.00	W	W
103	M	15	57.3	11.97	3.00	3.00
105	F	12	65.9	2.00	5.00	3.00
109	F	17	49.3	7.98*	8.05*	8.00*
201	M	12	65.0	2.00	W	W
401	F	12	30.1	2.00	2.00	3.00
502	F	16	98.3	12.00	8.00	5.00
503	F	15	87.8	5.00	8.00	W
505	M	12	31.0	8.00	3.00	W
506	M	12	59.4	5.00	3.00	5.00
507	M	12	67.4	8.00	4.92	3.00
509	M	15	61.3	7.92	3.00	2.00
510	M	12	45.5	3.00	23.53	2.03
601	M	17	58.6	8.00	8.00	5.00
602	M	15	67.6	3.00	5.00*	2.00
605	F	13	53.1	3.00	7.95	12.00
606	M	14	86.8	4.92	8.00	3.33
607	F	17	68.0	7.92	3.08	12.08
701	F	15	55.3	5.00	3.00	5.00
706	M	12	44.0	12.25	3.03	3.05
804	M	16	58.6	2.98	2.02	2.00
805	F	16	43.0	8.03	8.00	5.00
809	M	16	141.0	8.02	3.00	3.00
811	F	12	71.5	5.00	8.00	5.02
816	F	14	105.4	2.97	2.00	2.98
824	F	16	99.1	5.00	3.00	5.00
825	F	16	80.7	2.00	3.02	7.78
N				**33**	**29**	**27**
Mean				**5.42**	**6.13**	**4.53**
SD				**2.96**	**5.37**	**2.70**
Minimum				**1.98**	**2.00**	**2.00**
Median				**5.00**	**5.00**	**3.33**
Maximum				**12.25**	**24.00**	**12.08**

* Data suspect (see text); excluded from summary statistics

W = patient withdrew

Table 10.7 Paroxetine steady-state AUC(0-24) [ng.h/mL] following once daily dosing (10, 20, 30 mg) in child patients

Patient	Gender	Age (yrs)	Weight (kg)	10 mg	20 mg	30 mg
001	M	9	33.6	372.21	721.35	1126.07
053	F	10	65.5	52.68	411.15	767.70
055	M	10	38.6	14.11	294.54	529.21
101	F	9	40.7	3.54*	^	897.94*
102	M	8	29.5	514.91	1045.64	2911.55
104	F	11	64.1	418.94	1531.65	2249.82
106	M	10	49.5	55.77	789.36	1612.73
107	M	10	61.4	121.46	374.77	1342.57
108	F	11	48.2	129.01	609.12	1648.09
110	M	9	29.8	91.18*	728.99	848.05*
112	M	11	36.1	254.09	715.11	1717.09
202	M	10	51.0	75.21	320.90	1190.86
301	M	8	26.9	286.16	W	W
303	M	11	35.7	256.35	810.98	1752.04
504	M	8	29.2	92.90	543.40	W
603	M	11	34.0	297.98	569.58	1075.72
604	M	11	76.5	295.61	666.40	2023.41
702	F	11	34.2	314.55	1513.71	2860.26
704	M	9	25.9	527.41	1540.62	2873.81
705	M	9	27.4	1424.04	2633.18	9017.71
707	M	8	34.2	250.64	898.37	1708.97
708	F	8	38.2	170.87	1090.57	1811.64
709	M	10	34.0	101.24	529.35	732.46
806	F	10	60.8	72.18	695.25	2411.29
818	M	11	46.8	447.87	1651.12	2343.29
N				**23**	**23**	**21**
Mean				**284.62**	**899.35**	**2081.25**
SD				**291.48**	**551.80**	**1736.71**
Minimum				**14.11**	**294.54**	**529.21**
Median				**254.09**	**721.35**	**1717.09**
Maximum				**1424.04**	**2633.18**	**9017.71**
Geometric mean				**187.84**	**771.71**	**1711.09**
CVb(%)				**131**	**60**	**66**

* Data suspect (see text); excluded from summary statistics

^ All plasma concentrations were below the lower limit of quantification (0.1 ng/mL); excluded from summary statistics

W = patient withdrew

Table 10.8 Paroxetine steady-state AUC(0-24) [ng.h/mL] following once daily dosing (10, 20, 30 mg) in adolescent patients

Patient	Gender	Age (yrs)	Weight (kg)	10 mg	20 mg	30 mg
002	M	14	49.8	138.08	340.61	1334.09
003	F	16	67.7	310.33	706.87	2709.30
004	M	15	85.3	23.15	163.65	917.76
005	M	12	41.3	56.98	W	W
007	M	14	69.7	297.23	676.45	W
051	M	12	90.5	370.91	621.69	1534.96
052	M	15	71.4	41.81	382.51	705.40
054	M	16	96.8	10.49	W	W
103	M	15	57.3	324.09	835.60	2359.48
105	F	12	65.9	78.03	311.50	861.10
109	F	17	49.3	18.90*	139.70*	160.71*
201	M	12	65.0	22.27	W	W
401	F	12	30.1	470.19	1607.52	2637.01
502	F	16	98.3	108.37	505.47	645.41
503	F	15	87.8	3.85	149.50	W
505	M	12	31.0	179.77	592.12	W
506	M	12	59.4	260.63	557.89	1232.66
507	M	12	67.4	62.10	539.83	1183.21
509	M	15	61.3	45.95	365.78	1369.93
510	M	12	45.5	1133.55	2628.33	5484.91
601	M	17	58.6	86.65	466.01	1030.36
602	M	15	67.6	9.00	233.51*	754.77
605	F	13	53.1	71.43	475.53	1642.12
606	M	14	86.8	65.33	472.23	1436.41
607	F	17	68.0	358.70	872.56	1709.59
701	F	15	55.3	25.00	382.27	691.66
706	M	12	44.0	204.36	850.54	1926.96
804	M	16	58.6	128.94	921.06	1895.08
805	F	16	43.0	107.13	544.74	1311.30
809	M	16	141.0	37.47	220.96	501.37
811	F	12	71.5	314.04	1463.14	3046.17
816	F	14	105.4	581.88	2065.15	1756.57
824	F	16	99.1	13.55	184.49	826.71
825	F	16	80.7	311.32	1349.00	2544.26
N				**33**	**29**	**27**
Mean				**189.47**	**732.86**	**1631.43**
SD				**227.05**	**581.26**	**1039.65**
Minimum				**3.85**	**149.50**	**501.37**
Median				**107.13**	**544.74**	**1369.93**
Maximum				**1133.55**	**2628.33**	**5484.91**
Geometric mean				**93.82**	**570.42**	**1394.80**
CVb(%)				**227**	**82**	**60**

* Data suspect (see text); excluded from summary statistics

W = patient withdrew

Table 10.9 Paroxetine steady-state C24 [ng/mL] following once daily dosing (10, 20, 30 mg) in child patients

Patient	Gender	Age (yrs)	Weight (kg)	10 mg	20 mg	30 mg
001	M	9	33.6	13.250	22.438	34.545
053	F	10	65.5	0.790	10.013	29.758
055	M	10	38.6	NQ	8.703	21.920
101	F	9	40.7	NQ*	^	37.578*
102	M	8	29.5	15.839	30.081	75.691
104	F	11	64.1	14.227	52.875	86.222
106	M	10	49.5	1.660	23.801	63.272
107	M	10	61.4	1.342	10.210	37.937
108	F	11	48.2	2.945	26.589	57.940
110	M	9	29.8	3.496*	24.911	28.491*
112	M	11	36.1	7.252	18.994	58.289
202	M	10	51.0	1.365	7.939	27.285
301	M	8	26.9	6.744	W	W
303	M	11	35.7	6.012	22.265	53.288
504	M	8	29.2	2.086	13.854	W
603	M	11	34.0	11.030	18.417	33.927
604	M	11	76.5	8.899	18.918	69.984
702	F	11	34.2	6.379	39.377	115.067
704	M	9	25.9	16.253	39.169	78.186
705	M	9	27.4	30.861	92.028	328.908
707	M	8	34.2	6.308	28.120	37.930
708	F	8	38.2	4.154	36.561	58.743
709	M	10	34.0	2.382	15.327	18.968
806	F	10	60.8	0.819	19.733	73.065
818	M	11	46.8	17.078	42.376	65.918
N				**23**	**23**	**21**
Mean				**7.727**	**27.074**	**67.945**
SD				**7.456**	**18.377**	**64.449**
Minimum				**NQ**	**7.939**	**18.968**
Median				**6.308**	**22.438**	**58.289**
Maximum				**30.861**	**92.028**	**328.908**
Geometric mean				**4.164**	**22.683**	**54.083**
CVb(%)				**255**	**66**	**70**

* Data suspect (see text); excluded from summary statistics

^ All plasma concentrations were below the lower limit of quantification (0.1 ng/mL); excluded from summary statistics
W = patient withdrew

NQ a value of 1/2 LLQ (0.05 ng/mL) was assigned for summary statistics calculation

Table 10.10 Paroxetine steady-state C24 [ng/mL] following once daily dosing (10, 20, 30 mg) in adolescent patients

Patient	Gender	Age (yrs)	Weight (kg)	10 mg	20 mg	30 mg
002	M	14	49.8	3.526	11.114	33.615
003	F	16	67.7	8.141	17.342	100.207
004	M	15	85.3	0.613	4.722	29.404
005	M	12	41.3	0.848	W	W
007	M	14	69.7	13.419	26.004	W
051	M	12	90.5	16.001	35.993	49.433
052	M	15	71.4	0.947	11.451	22.710
054	M	16	96.8	0.142	W	W
103	M	15	57.3	7.862	31.813	97.287
105	F	12	65.9	1.290	5.915	24.976
109	F	17	49.3	0.540*	5.263*	6.877*
201	M	12	65.0	0.340	W	W
401	F	12	30.1	15.878	44.891	98.682
502	F	16	98.3	1.260	15.754	8.726
503	F	15	87.8	NQ	3.335	W
505	M	12	31.0	5.788	17.878	W
506	M	12	59.4	8.118	21.774	43.409
507	M	12	67.4	1.225	17.294	38.979
509	M	15	61.3	1.199	9.177	56.138
510	M	12	45.5	49.440	129.896	253.522
601	M	17	58.6	2.399	12.328	42.841
602	M	15	67.6	0.132	5.678*	17.101
605	F	13	53.1	1.977	15.498	71.865
606	M	14	86.8	1.352	13.892	32.183
607	F	17	68.0	9.954	33.039	75.621
701	F	15	55.3	0.500	7.312	14.712
706	M	12	44.0	4.085	26.830	28.920
804	M	16	58.6	3.156	39.719	46.989
805	F	16	43.0	2.962	18.517	32.833
809	M	16	141.0	0.725	4.290	13.560
811	F	12	71.5	9.547	47.722	128.855
816	F	14	105.4	22.254	69.420	54.068
824	F	16	99.1	0.237	2.752	24.188
825	F	16	80.7	7.781	45.985	83.703
N				**33**	**29**	**27**
Mean				**6.156**	**25.574**	**56.464**
SD				**9.559**	**25.747**	**50.128**
Minimum				**NQ**	**2.752**	**8.726**
Median				**2.399**	**17.342**	**42.841**
Maximum				**49.440**	**129.896**	**253.522**
Geometric mean				**2.210**	**17.293**	**42.458**
CVb(%)				**366**	**116**	**88**

* Data suspect (see text); excluded from summary statistics W = patient withdrew

NQ a value of 1/2 LLQ (0.05 ng/mL) was assigned for summary statistics calculation

Table 10.11 Paroxetine steady-state CL/F [L/h] following once daily dosing (10, 20, 30 mg) in child patients

Patient	Gender	Age (yrs)	Weight (kg)	10 mg	20 mg	30 mg
001	M	9	33.6	26.87	27.73	26.64
053	F	10	65.5	189.83	48.64	39.08
055	M	10	38.6	708.72	67.90	56.69
101	F	9	40.7	2824.86*	^	33.41*
102	M	8	29.5	19.42	19.13	10.30
104	F	11	64.1	23.87	13.06	13.33
106	M	10	49.5	179.31	25.34	18.60
107	M	10	61.4	82.33	53.37	22.35
108	F	11	48.2	77.51	32.83	18.20
110	M	9	29.8	109.67*	27.44	35.38*
112	M	11	36.1	39.36	27.97	17.47
202	M	10	51.0	132.96	62.32	25.19
301	M	8	26.9	34.95	W	W
303	M	11	35.7	39.01	24.66	17.12
504	M	8	29.2	107.64	36.81	W
603	M	11	34.0	33.56	35.11	27.89
604	M	11	76.5	33.83	30.01	14.83
702	F	11	34.2	31.79	13.21	10.49
704	M	9	25.9	18.96	12.98	10.44
705	M	9	27.4	7.02	7.60	3.33
707	M	8	34.2	39.90	22.26	17.55
708	F	8	38.2	58.52	18.34	16.56
709	M	10	34.0	98.78	37.78	40.96
806	F	10	60.8	138.54	28.77	12.44
818	M	11	46.8	22.33	12.11	12.80
N				**23**	**23**	**21**
Mean				**93.26**	**29.80**	**20.58**
SD				**144.06**	**15.92**	**12.36**
Minimum				**7.02**	**7.60**	**3.33**
Median				**39.36**	**27.73**	**17.47**
Maximum				**708.72**	**67.90**	**56.69**
Geometric mean				**53.24**	**25.92**	**17.53**
CVb(%)				**131**	**60**	**66**

* Data suspect (see taxt); excluded from summary statistics

^ All plasma concentrations were below the lower limit of quantification (0.1 ng/mL); excluded from summary statistics

W = patient withdrew

Table 10.12 Paroxetine steady-state CL/F [L/h] following once daily dosing (10, 20, 30 mg) in adolescent patients

Patient	Gender	Age (yrs)	Weight (kg)	10 mg	20 mg	30 mg
002	M	14	49.8	72.42	58.72	22.49
003	F	16	67.7	32.22	28.29	11.07
004	M	15	85.3	431.97	122.21	32.69
005	M	12	41.3	175.50	W	W
007	M	14	69.7	33.64	29.57	W
051	M	12	90.5	26.96	32.17	19.54
052	M	15	71.4	239.18	52.29	42.53
054	M	16	96.8	953.29	W	W
103	M	15	57.3	30.86	23.93	12.71
105	F	12	65.9	128.16	64.21	34.84
109	F	17	49.3	529.10*	143.16*	186.67*
201	M	12	65.0	449.03	W	W
401	F	12	30.1	21.27	12.44	11.38
502	F	16	98.3	92.28	39.57	46.48
503	F	15	87.8	2597.40	133.78	W
505	M	12	31.0	55.63	33.78	W
506	M	12	59.4	38.37	35.85	24.34
507	M	12	67.4	161.03	37.05	25.35
509	M	15	61.3	217.63	54.68	21.9
510	M	12	45.5	8.82	7.61	5.47
601	M	17	58.6	115.41	42.92	29.12
602	M	15	67.6	1111.11	85.65*	39.75
605	F	13	53.1	140.00	42.06	18.27
606	M	14	86.8	153.07	42.35	20.89
607	F	17	68.0	27.88	22.92	17.55
701	F	15	55.3	400.00	52.32	43.37
706	M	12	44.0	48.93	23.51	15.57
804	M	16	58.6	77.56	21.71	15.83
805	F	16	43.0	93.34	36.71	22.88
809	M	16	141.0	266.88	90.51	59.84
811	F	12	71.5	31.84	13.67	9.85
816	F	14	105.4	17.19	9.68	17.08
824	F	16	99.1	738.01	108.41	36.29
825	F	16	80.7	32.12	14.83	11.79
N				**33**	**29**	**27**
Mean				**273.30**	**44.41**	**24.77**
SD				**495.80**	**32.34**	**13.24**
Minimum				**8.82**	**7.61**	**5.47**
Median				**93.34**	**36.71**	**21.90**
Maximum				**2597.40**	**133.78**	**59.84**
Geometric mean				**106.59**	**35.06**	**21.51**
CVb(%)				**227**	**82**	**60**

* Data suspect (see text); excluded from summary statistics

W = patient withdrew

Table 10.13 Paroxetine steady-state weight-normalized CL/F [(L/h)/kg] following once daily dosing (10, 20, 30 mg) in child patients

Patient	Gender	Age (yrs)	Weight (kg)	10 mg	20 mg	30 mg
001	M	9	33.6	0.800	0.825	0.793
053	F	10	65.5	2.898	0.743	0.597
055	M	10	38.6	18.361	1.759	1.469
101	F	9	40.7	69.407*	^	0.821*
102	M	8	29.5	0.658	0.648	0.349
104	F	11	64.1	0.372	0.204	0.208
106	M	10	49.5	3.622	0.512	0.376
107	M	10	61.4	1.341	0.869	0.364
108	F	11	48.2	1.608	0.681	0.378
110	M	9	29.8	3.680*	0.921	1.187*
112	M	11	36.1	1.090	0.775	0.484
202	M	10	51.0	2.607	1.222	0.494
301	M	8	26.9	1.299	W	W
303	M	11	35.7	1.093	0.691	0.480
504	M	8	29.2	3.686	1.261	W
603	M	11	34.0	0.987	1.033	0.820
604	M	11	76.5	0.442	0.392	0.194
702	F	11	34.2	0.930	0.386	0.307
704	M	9	25.9	0.732	0.501	0.403
705	M	9	27.4	0.256	0.277	0.122
707	M	8	34.2	1.167	0.651	0.513
708	F	8	38.2	1.532	0.480	0.434
709	M	10	34.0	2.905	1.111	1.205
806	F	10	60.8	2.279	0.473	0.205
818	M	11	46.8	0.477	0.259	0.274
N				**23**	**23**	**21**
Mean				**2.224**	**0.725**	**0.499**
SD				**3.663**	**0.373**	**0.333**
Minimum				**0.256**	**0.204**	**0.122**
Median				**1.167**	**0.681**	**0.403**
Maximum				**18.361**	**1.759**	**1.469**
Geometric mean				**1.312**	**0.636**	**0.418**
CVb(%)				**117**	**58**	**66**

* Data suspect (see text); excluded from summary statistics

^ All plasma concentrations were below the lower limit of quantification (0.1 ng/mL); excluded from summary statistics

W = patient withdrew

Table 10.14 Paroxetine steady-state weight-normalized CL/F [(L/h)/kg] following once daily dosing (10, 20, 30 mg) in adolescent patients

Patient	Gender	Age (yrs)	Weight (kg)	10 mg	20 mg	30 mg
002	M	14	49.8	1.454	1.179	0.452
003	F	16	67.7	0.476	0.418	0.164
004	M	15	85.3	5.064	1.433	0.383
005	M	12	41.3	4.249	W	W
007	M	14	69.7	0.483	0.424	W
051	M	12	90.5	0.298	0.355	0.216
052	M	15	71.4	3.350	0.732	0.596
054	M	16	96.8	9.848	W	W
103	M	15	57.3	0.539	0.418	0.222
105	F	12	65.9	1.945	0.974	0.529
109	F	17	49.3	10.732*	2.904*	3.786*
201	M	12	65.0	6.908	W	W
401	F	12	30.1	0.707	0.413	0.378
502	F	16	98.3	0.939	0.403	0.473
503	F	15	87.8	29.583	1.524	W
505	M	12	31.0	1.795	1.090	W
506	M	12	59.4	0.646	0.604	0.410
507	M	12	67.4	2.389	0.550	0.376
509	M	15	61.3	3.550	0.892	0.357
510	M	12	45.5	0.194	0.167	0.120
601	M	17	58.6	1.969	0.732	0.497
602	M	15	67.6	16.437	1.267*	0.588
605	F	13	53.1	2.637	0.792	0.344
606	M	14	86.8	1.763	0.488	0.241
607	F	17	68.0	0.410	0.337	0.258
701	F	15	55.3	7.233	0.946	0.784
706	M	12	44.0	1.112	0.534	0.354
804	M	16	58.6	1.324	0.370	0.270
805	F	16	43.0	2.171	0.854	0.532
809	M	16	141.0	1.893	0.642	0.424
811	F	12	71.5	0.445	0.191	0.138
816	F	14	105.4	0.163	0.092	0.162
824	F	16	99.1	7.447	1.094	0.366
825	F	16	80.7	0.398	0.184	0.146
N				**33**	**29**	**27**
Mean				**3.631**	**0.649**	**0.362**
SD				**5.792**	**0.375**	**0.164**
Minimum				**0.163**	**0.092**	**0.120**
Median				**1.795**	**0.550**	**0.366**
Maximum				**29.583**	**1.524**	**0.784**
Geometric mean				**1.635**	**0.537**	**0.325**
CVb(%)				**202**	**76**	**53**

* Data suspect (see text); excluded from summary statistics

W = patient withdrew

Table 10.15 CYP2D6 phenotype in child patients predicted from genotype analysis

Patient	Functional alleles	Predicted phenotype
001	1	EM
053	2	EM
055	2	EM
101	ND	ND
102	2	EM
104	1	EM
106	ND	ND
107	2	EM
108	2	EM
110	1	EM
112	1	EM
202	ND	ND
301	2	EM
303	2	EM
504	2	EM
603	1	EM
604	1	EM
702	1	EM
704	1	EM
705	1	EM
707	ND	ND
708	2	EM
709	2	EM
806	2	EM
818	1	EM

ND = not determined

Table 10.16 CYP2D6 phenotype in adolescent patients predicted from genotype analysis

Patient	Functional alleles	Predicted phenotype
002	2	EM
003	2	EM
004	1	EM
005	2	EM
007	1	EM
051	0	PM
052	2	EM
054	2	EM
103	0	PM
105	2	EM
109	2	EM
201	ND	ND
401	ND	ND
502	2	EM
503	2	EM
505	2	EM
506	1	EM
507	2	EM
509	2	EM
510	0	PM
601	2	EM
602	2	EM
605	2	EM
606	2	EM
607	1	EM
701	2	EM
706	2	EM
804	2	EM
805	2	EM
809	2	EM
811	2	EM
816	2	EM
824	2	EM
825	1	EM

ND = not determined

11 Data Source Figures

Figure 11.1 Mean steady-state paroxetine plasma concentrations [ng/mL] following once daily dosing (10, 20, 30 mg) in 56 pediatric patients (23 children and 33 adolescents)

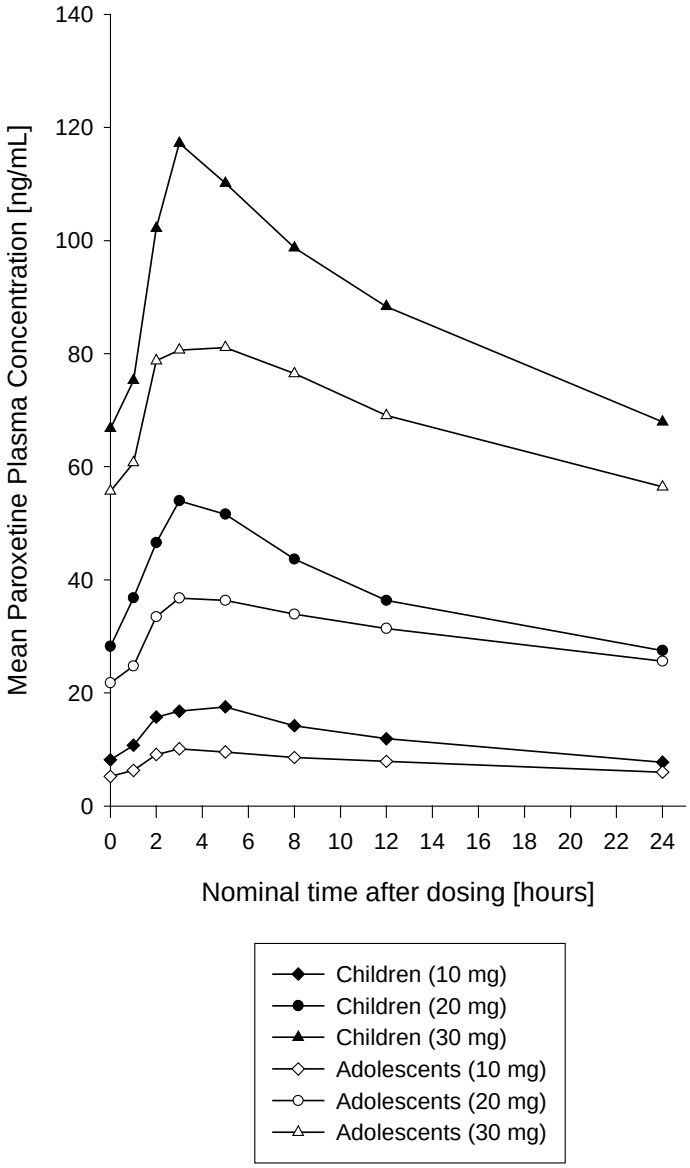
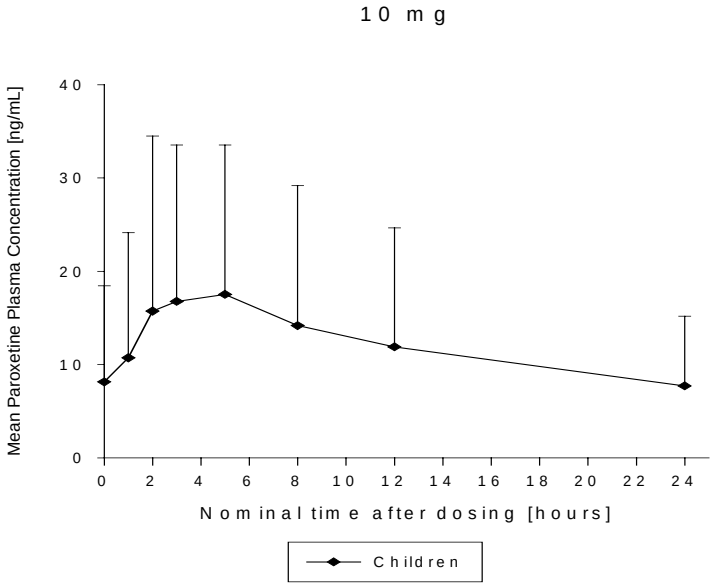


Figure 11.2 Mean (+SD) steady-state paroxetine plasma concentrations [ng/mL] following once daily dosing (10 mg) in 56 pediatric patients (23 children and 33 adolescents)



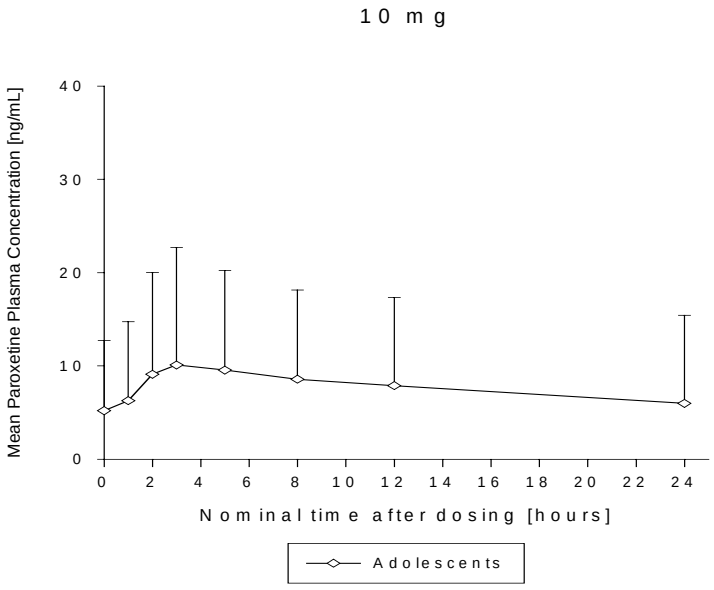
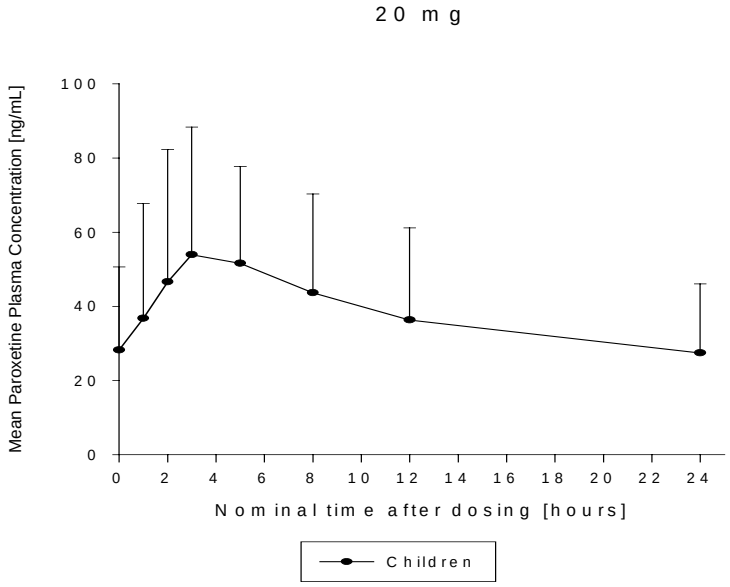


Figure 11.3 Mean (+SD) steady-state paroxetine plasma concentrations [ng/mL] following once daily dosing (20 mg) in 52 pediatric patients (23 children and 29 adolescents)



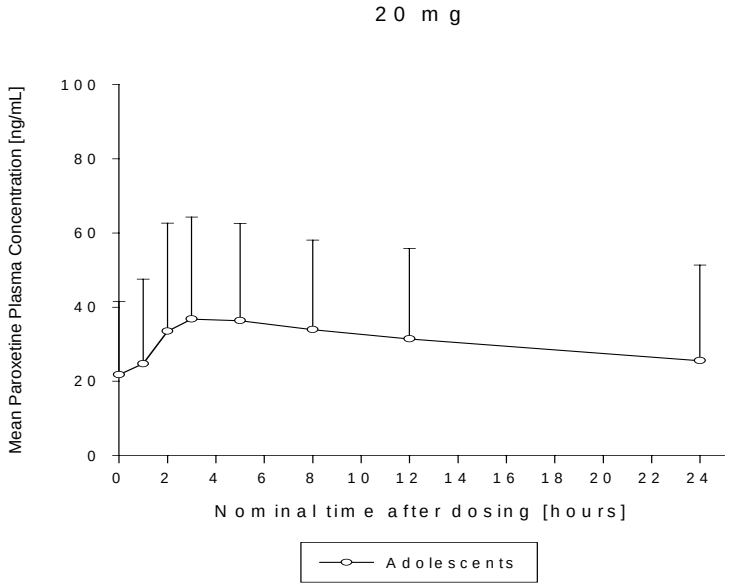
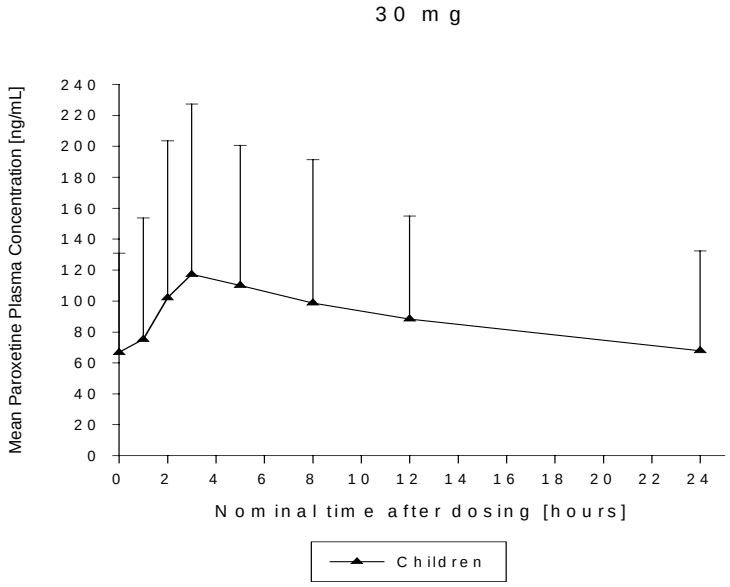


Figure 11.4 Mean (+SD) steady-state paroxetine plasma concentrations [ng/mL] following once daily dosing (30 mg) in 48 pediatric patients (21 children and 27 adolescents)



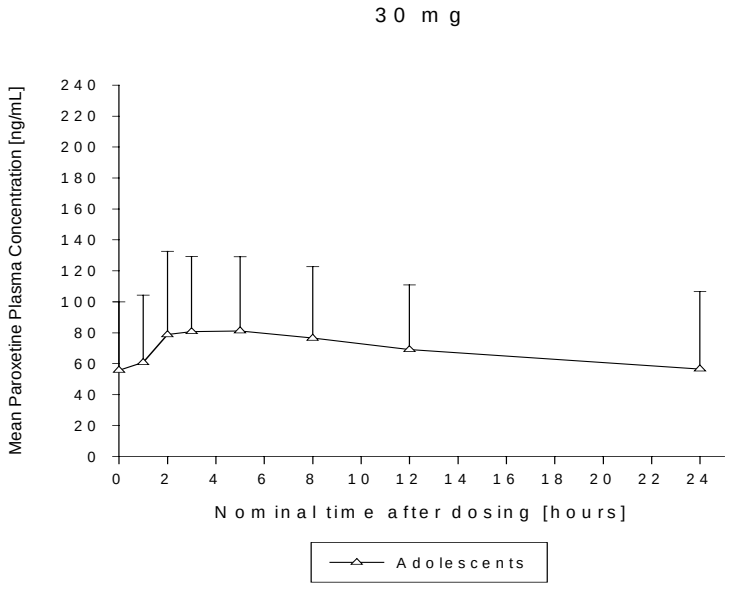
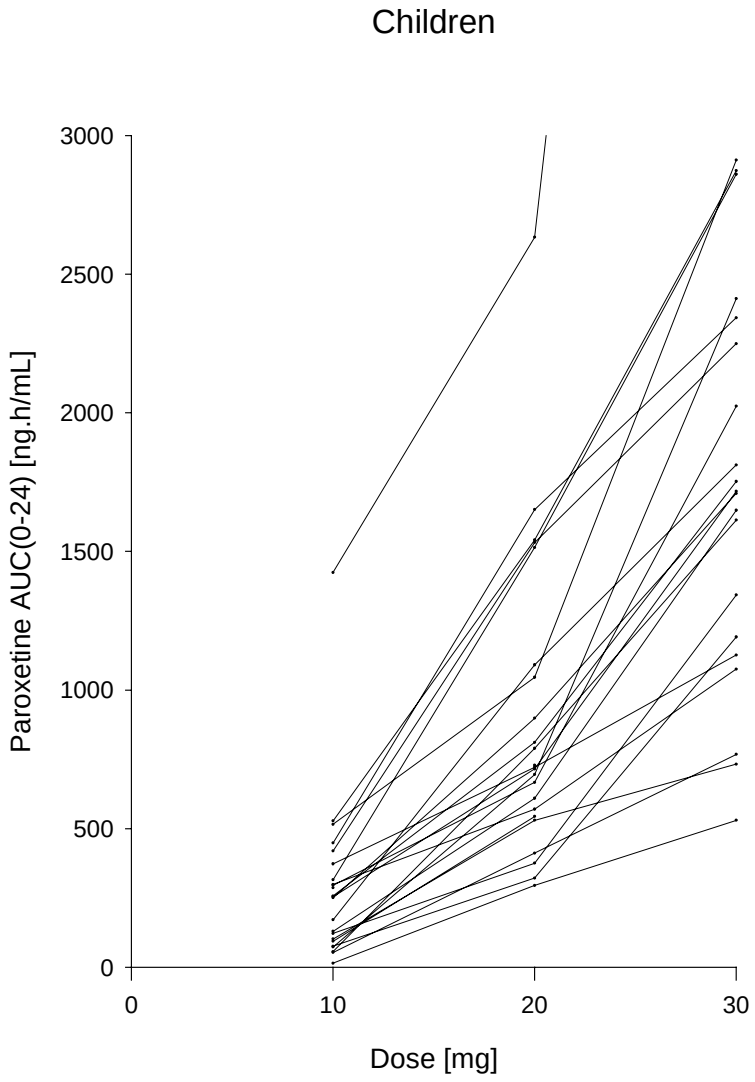
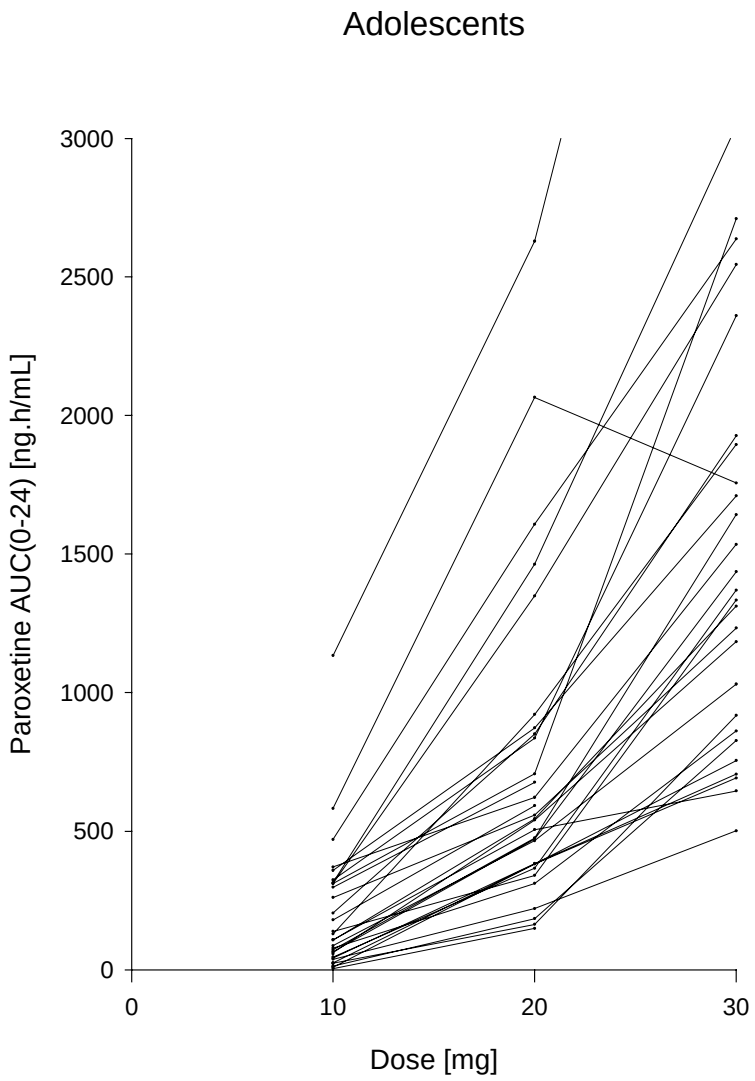


Figure 11.5 Relationship between paroxetine steady state AUC(0-24) and dose (10, 20, 30 mg/day) in child patients



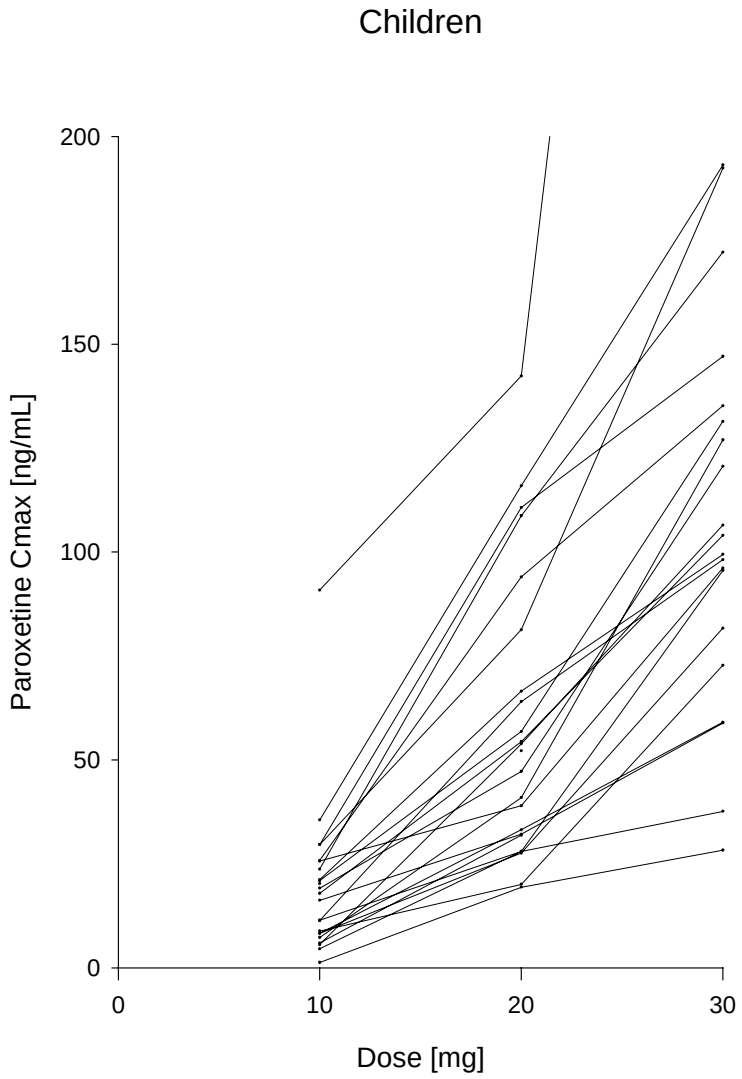
The off-scale value (30 mg, Patient 705) was 9018 ng.h/mL.

Figure 11.6 Relationship between paroxetine steady state AUC(0-24) and dose (10, 20, 30 mg/day) in adolescent patients



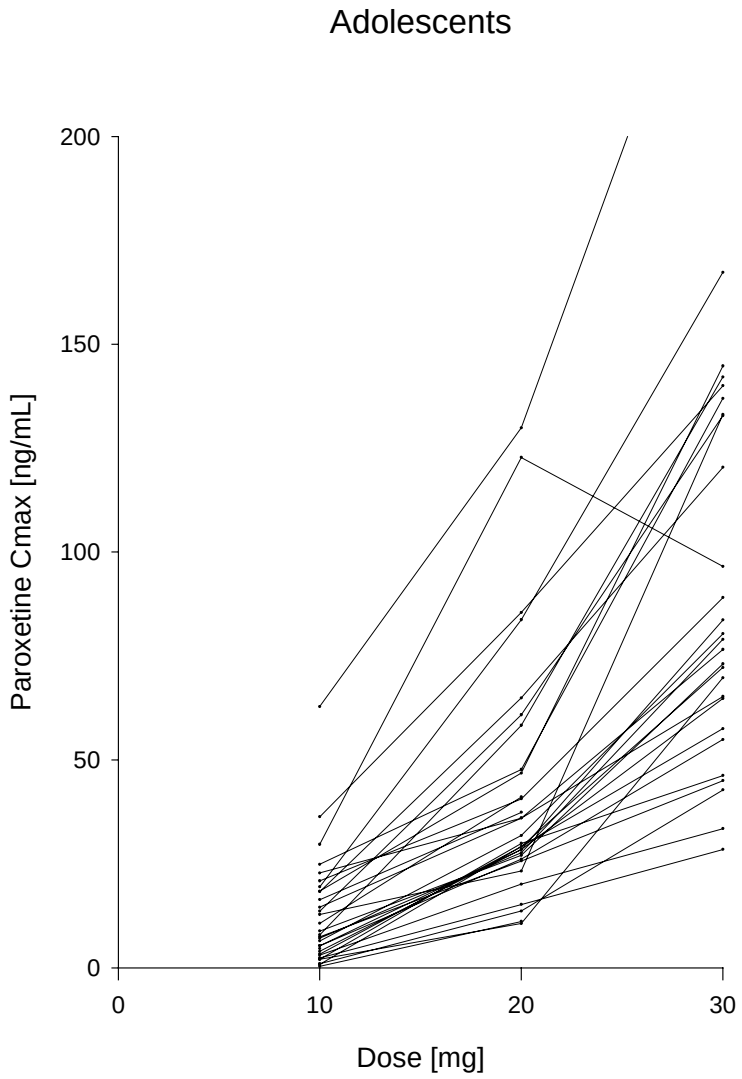
The off-scale values (30 mg, Patient 510 and Patient 811) were 5485 ng.h/mL and 3046 ng.h/mL, respectively.

Figure 11.7 Relationship between paroxetine steady state Cmax and dose (10, 20, 30 mg/day) in child patients



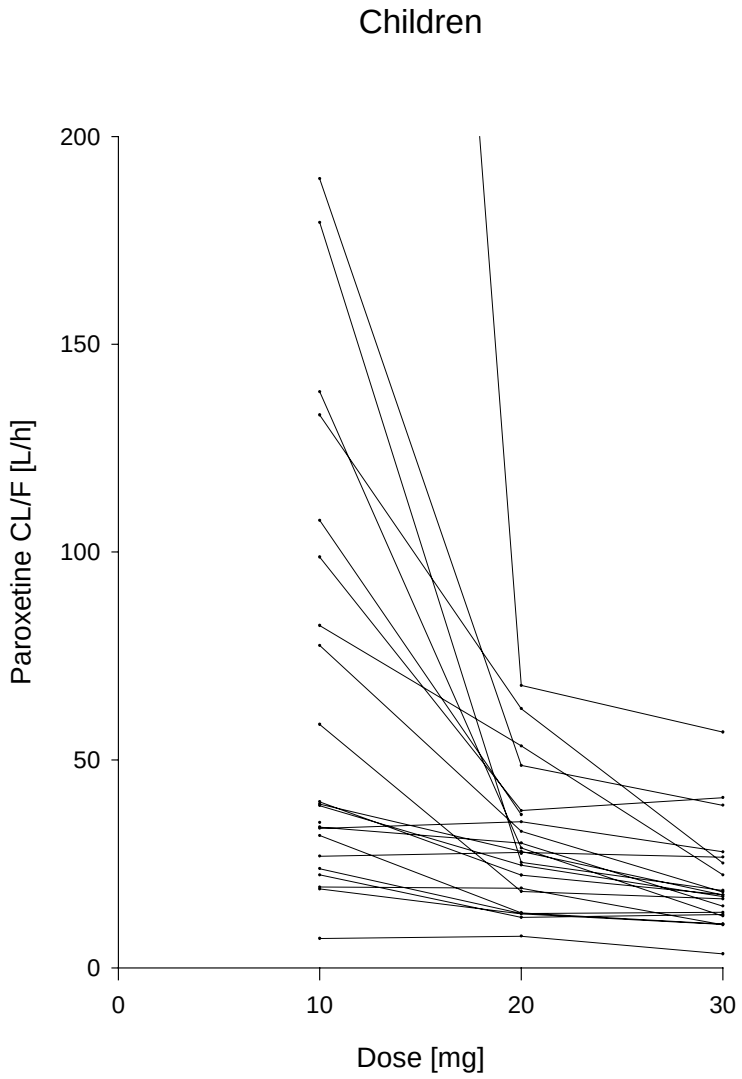
The off-scale value (30 mg, Patient 705) was 553 ng/mL.

Figure 11.8 Relationship between paroxetine steady state Cmax and dose (10, 20, 30 mg/day) in adolescent patients



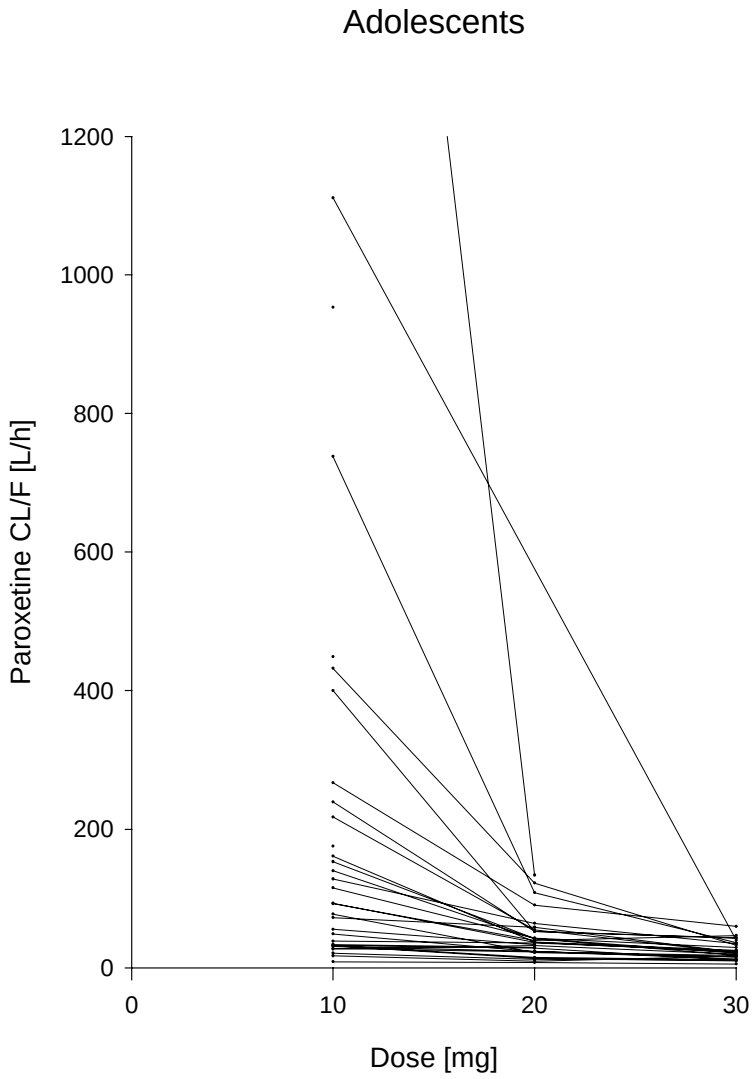
The off-scale value (30 mg, Patient 510) was 263 ng/mL.

Figure 11.9 Relationship between paroxetine steady state CL/F and dose (10, 20, 30 mg/day) in child patients



The off-scale value (10 mg, Patient 055) was 709 L/h.

Figure 11.10 Relationship between paroxetine steady state CL/F and dose (10, 20, 30 mg/day) in adolescent patients



The off-scale value (10 mg, Patient 503) was 2597 L/h.

Figure 11.11 Relationship between paroxetine steady state AUC(0-24) and gender in pediatric patients (10 mg/day)

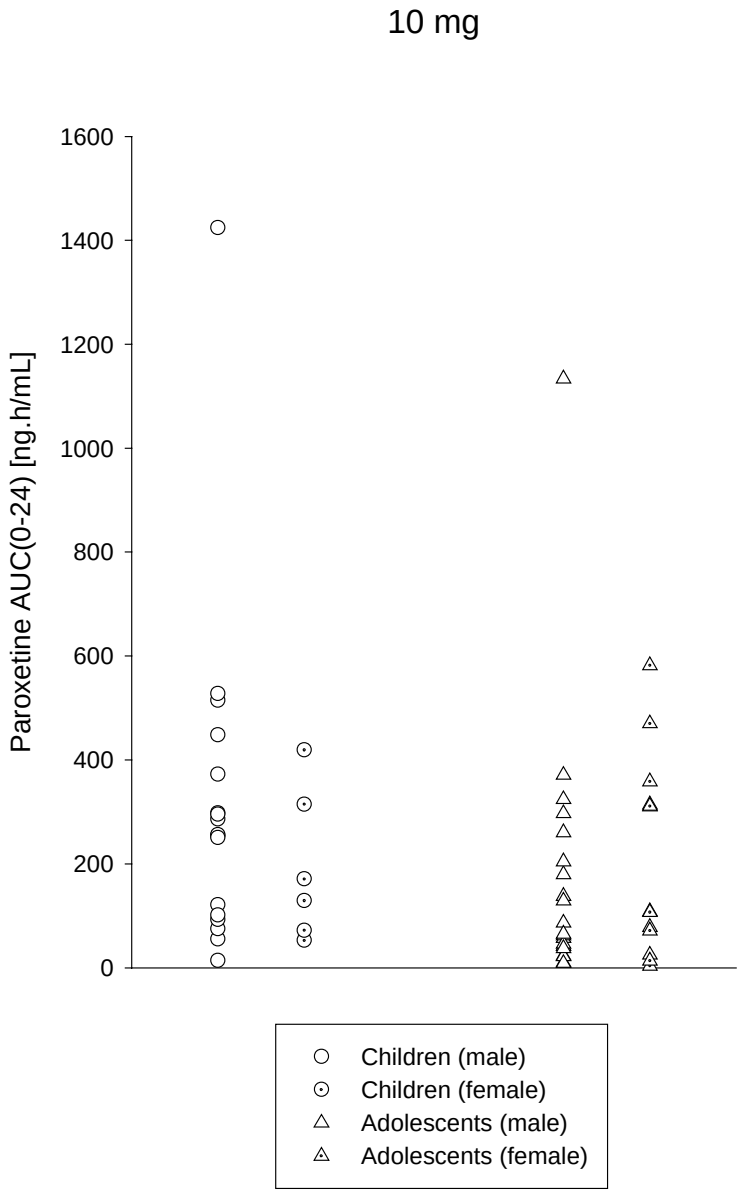


Figure 11.12 Relationship between paroxetine steady state AUC(0-24) and gender in pediatric patients (20 mg/day)

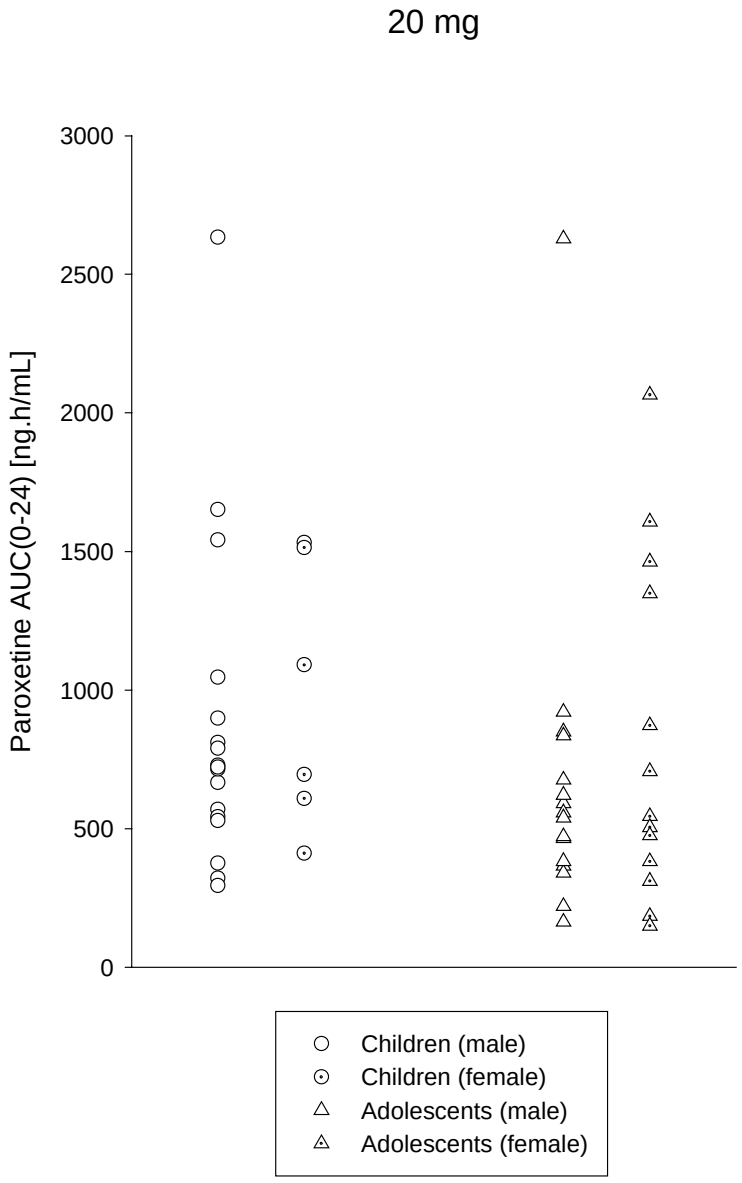


Figure 11.13 Relationship between paroxetine steady state AUC(0-24) and gender in pediatric patients (30 mg/day)

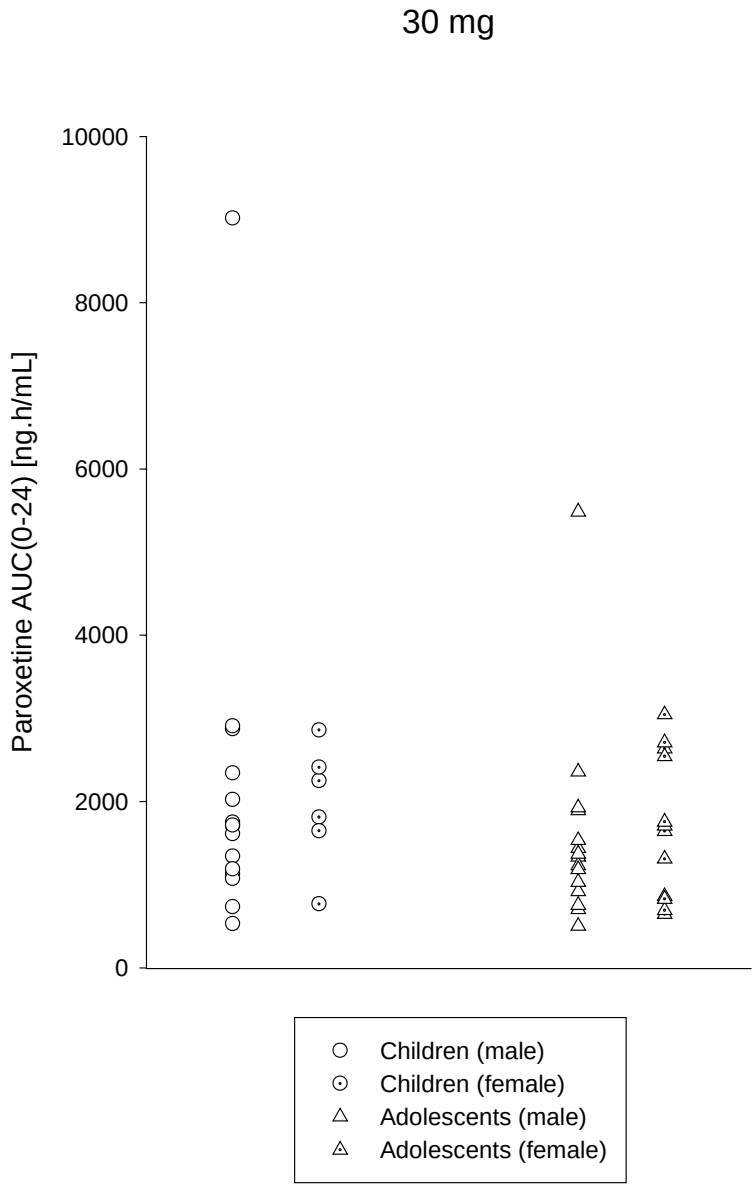


Figure 11.14 Relationship between paroxetine steady state Cmax and gender in pediatric patients (10 mg/day)

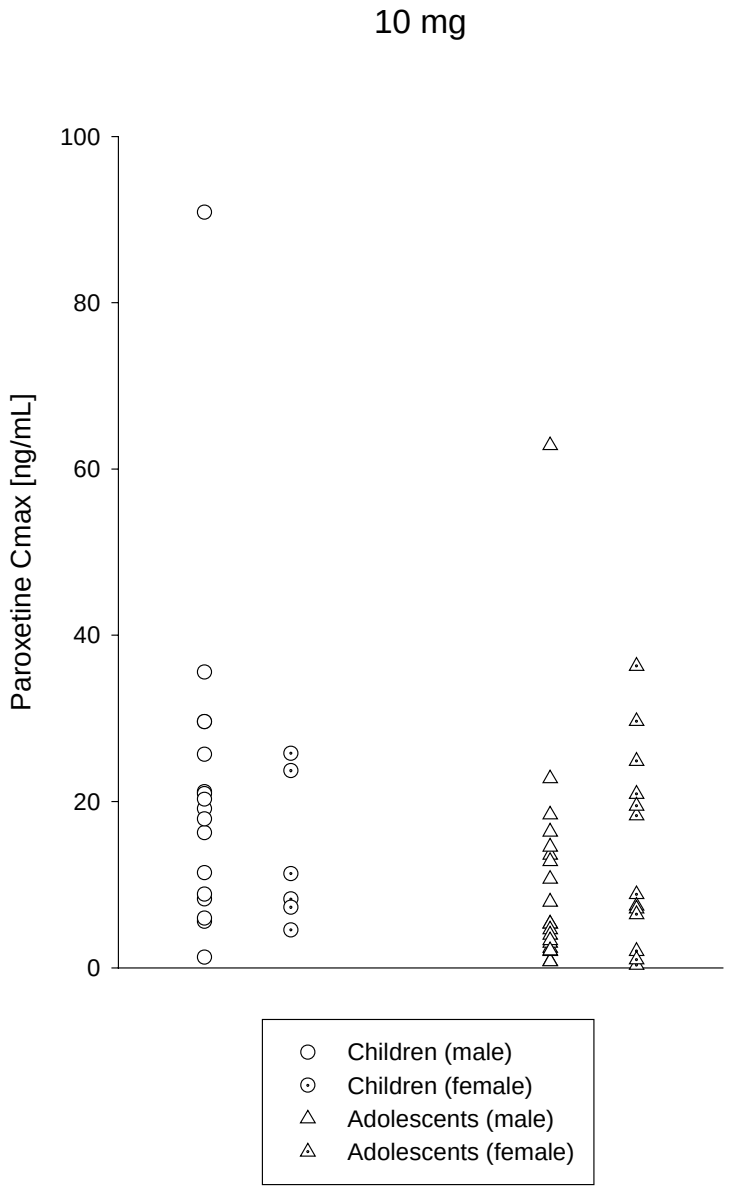


Figure 11.15 Relationship between paroxetine steady state Cmax and gender in pediatric patients (20 mg/day)

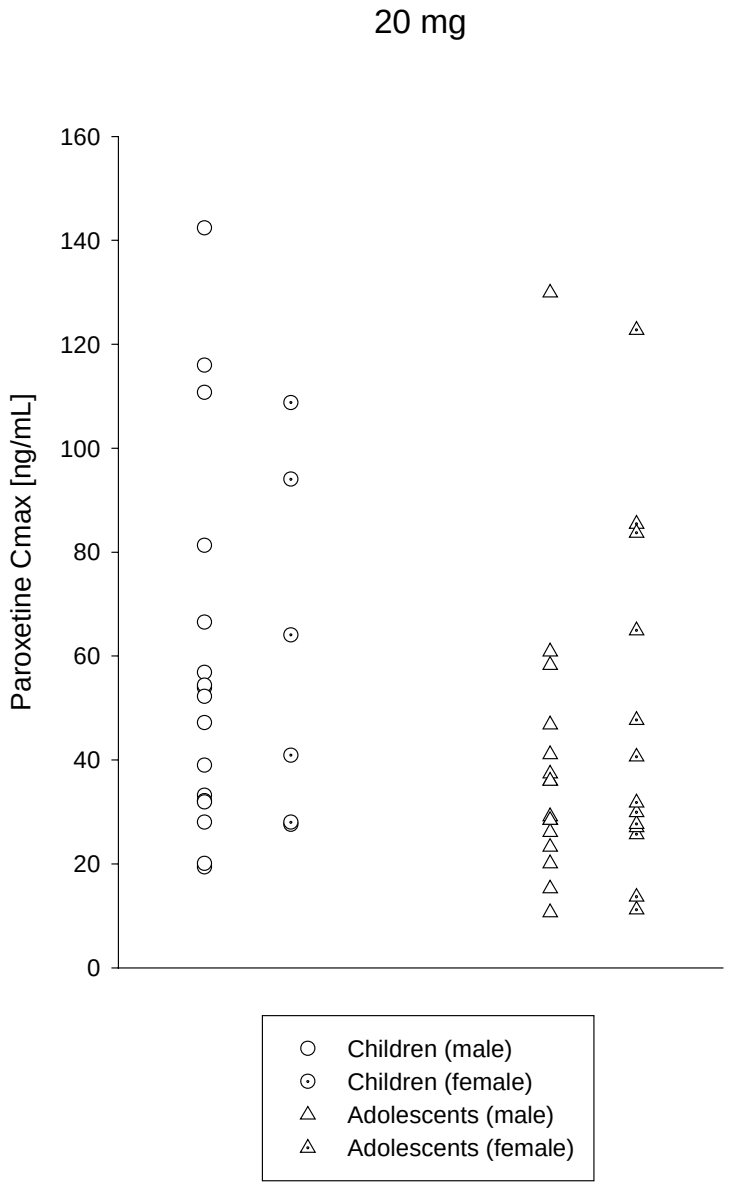


Figure 11.16 Relationship between paroxetine steady state Cmax and gender in pediatric patients (30 mg/day)

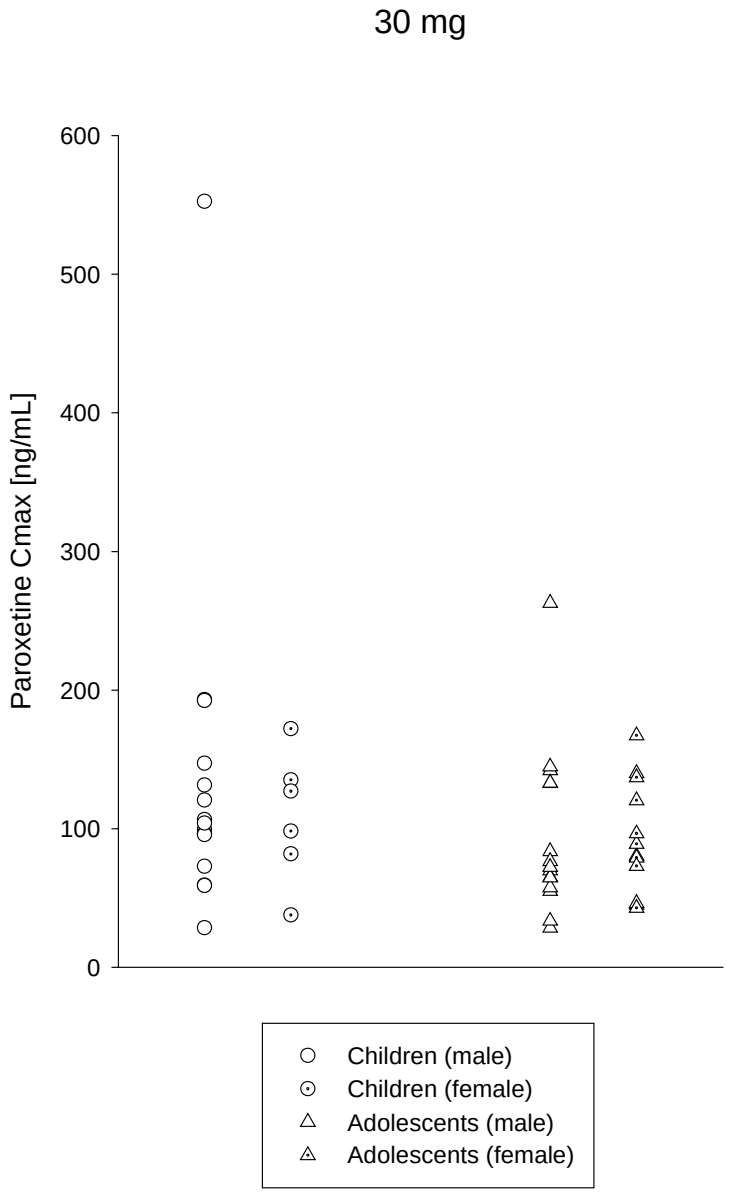


Figure 11.17 Relationship between paroxetine steady state CL/F and gender in pediatric patients (10 mg/day)

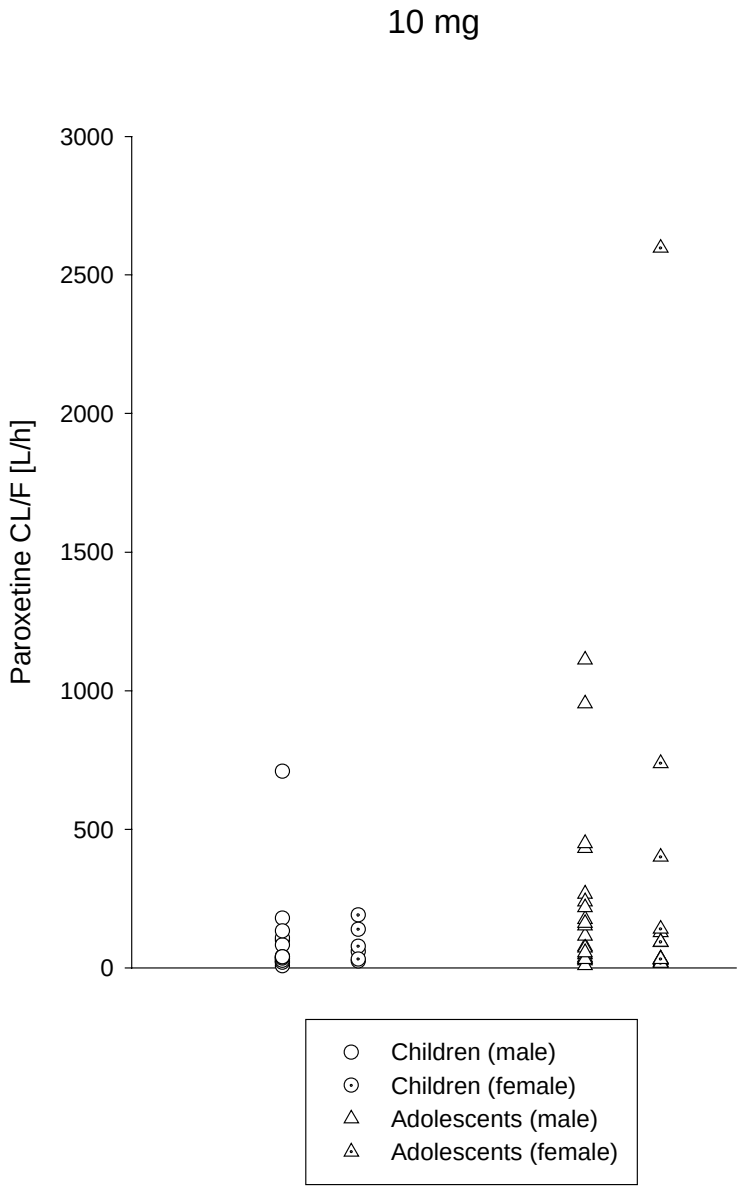


Figure 11.18 Relationship between paroxetine steady state CL/F and gender in pediatric patients (20 mg/day)

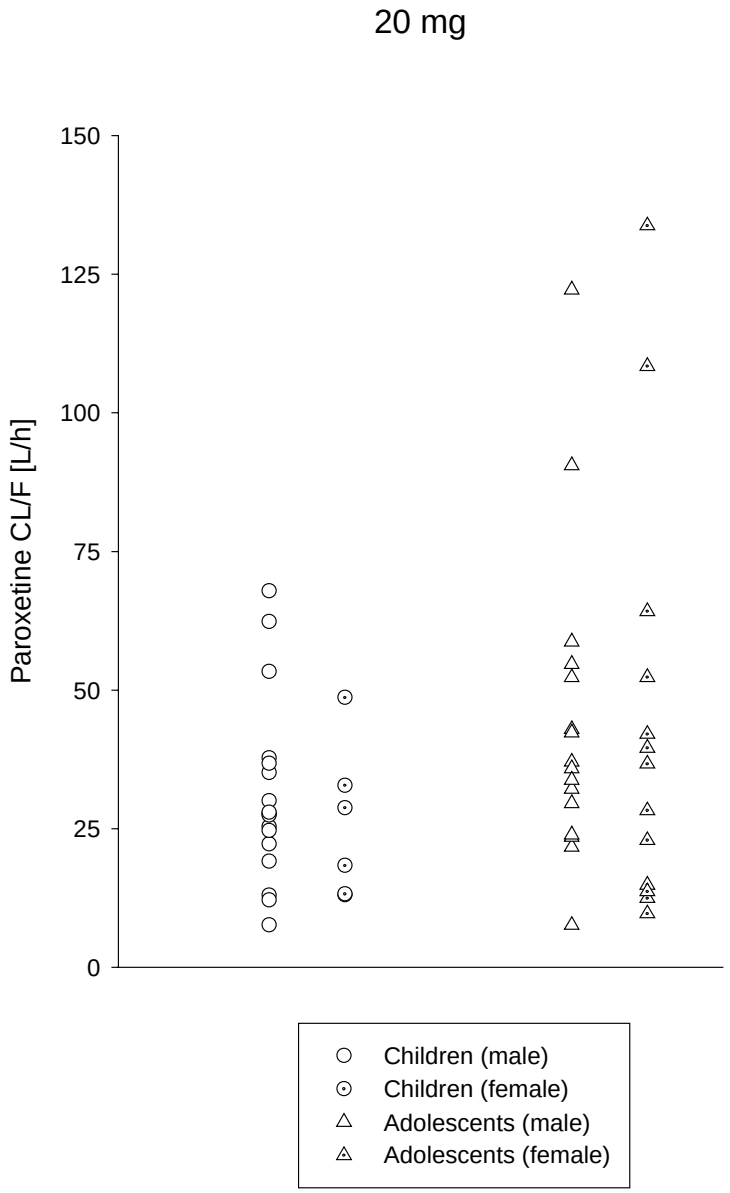


Figure 11.19 Relationship between paroxetine steady state CL/F and gender in pediatric patients (30 mg/day)

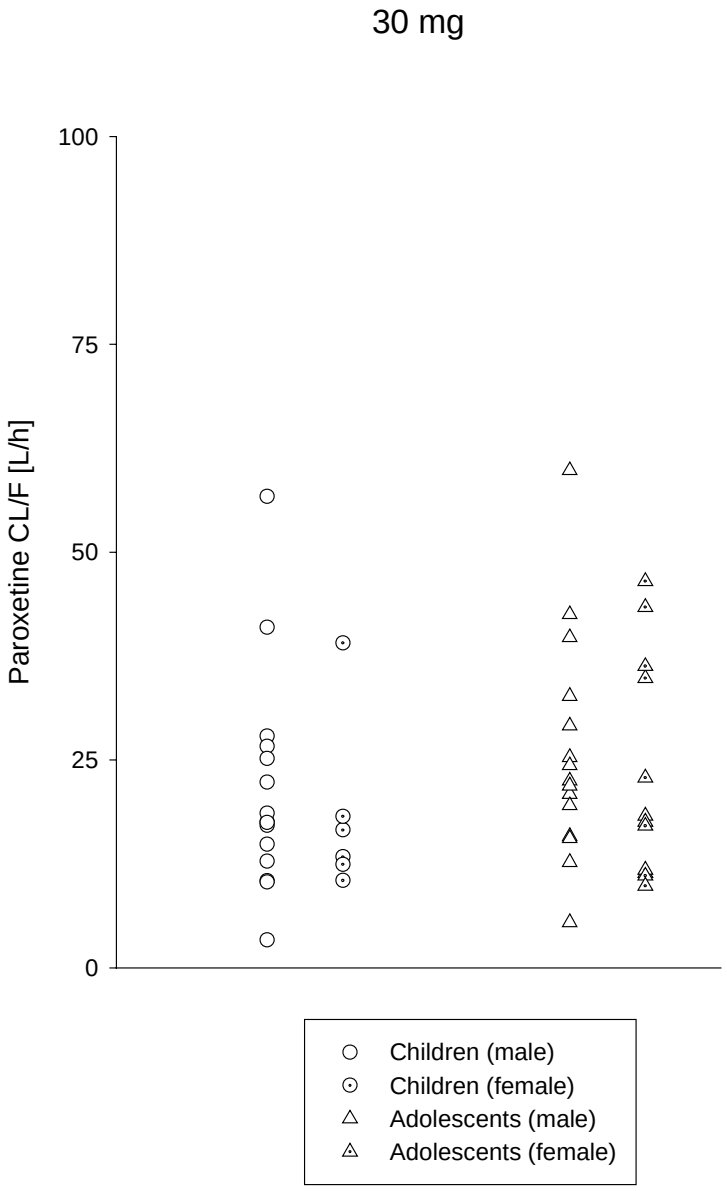


Figure 11.20 Relationship between paroxetine steady state AUC(0-24) and age in pediatric patients (10 mg/day)

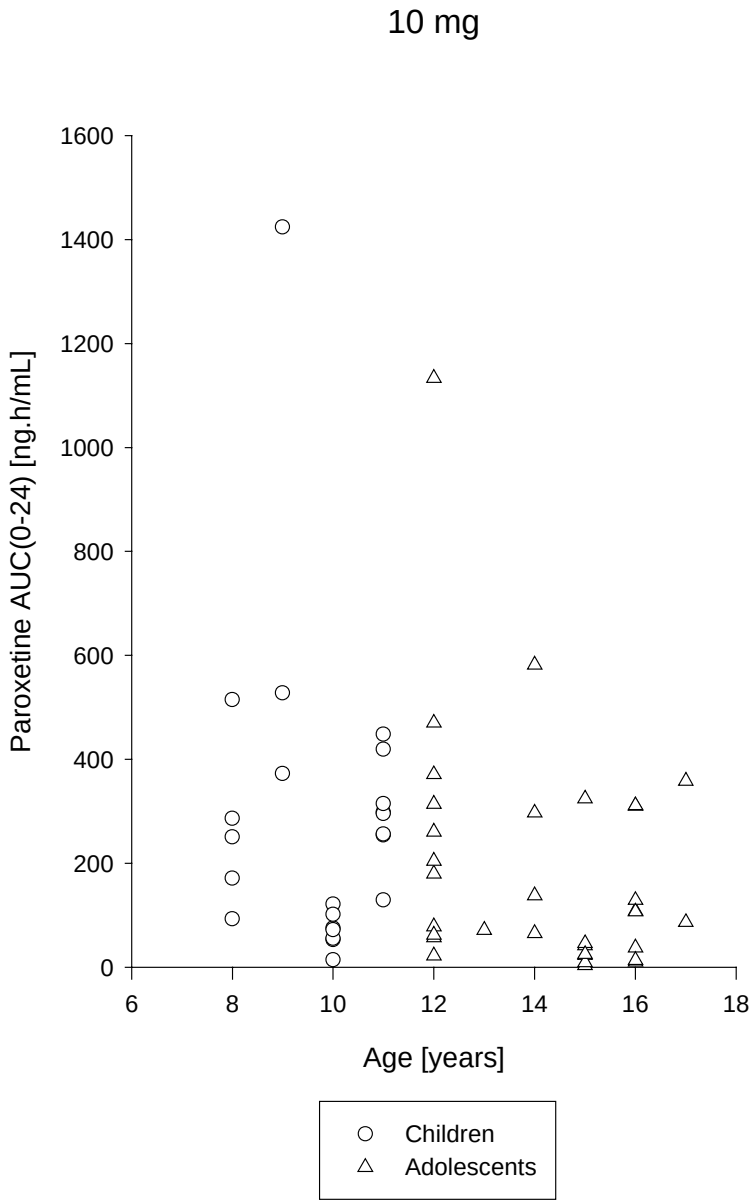


Figure 11.21 Relationship between paroxetine steady state AUC(0-24) and age in pediatric patients (20 mg/day)

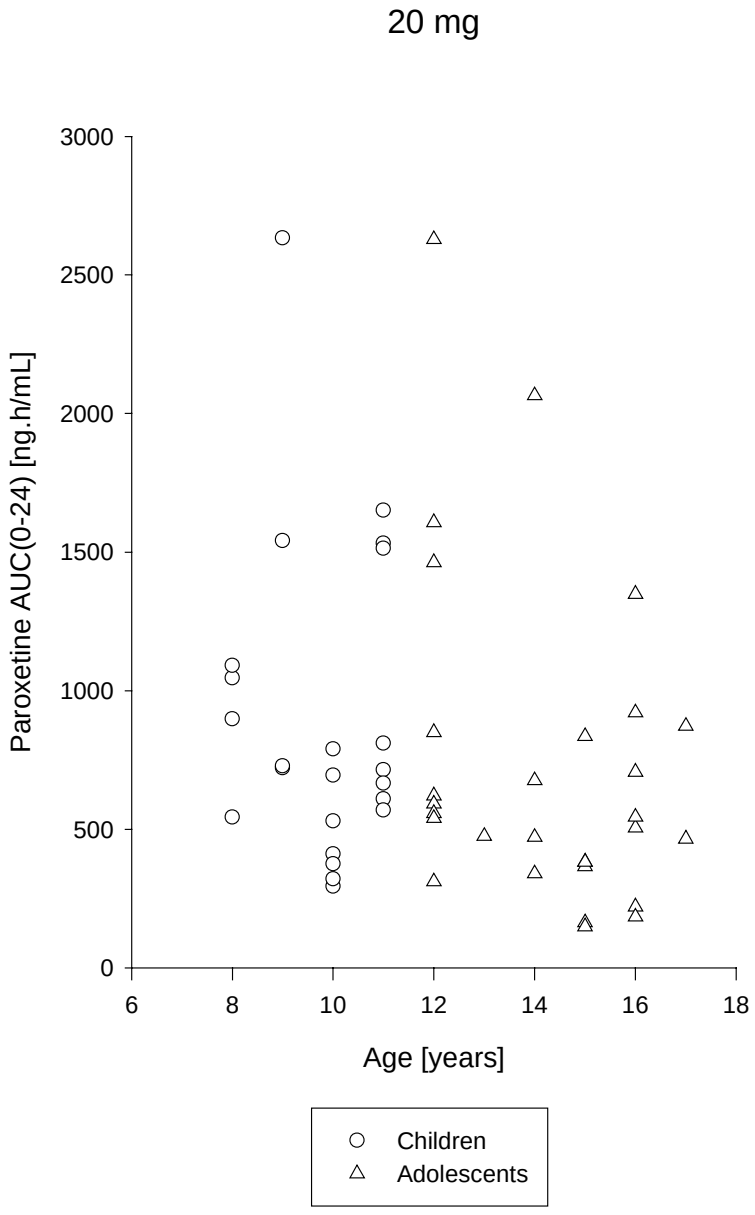


Figure 11.22 Relationship between paroxetine steady state AUC(0-24) and age in pediatric patients (30 mg/day)

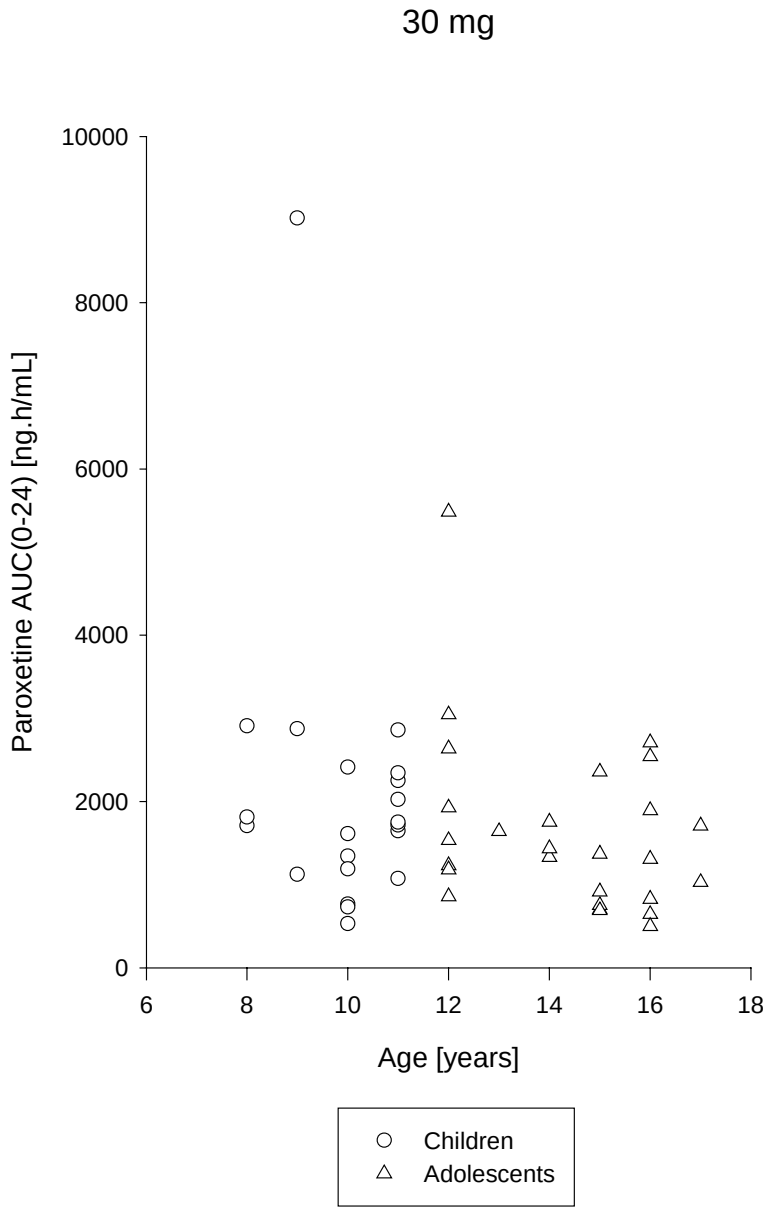


Figure 11.23 Relationship between paroxetine steady state Cmax and age in pediatric patients (10 mg/day)

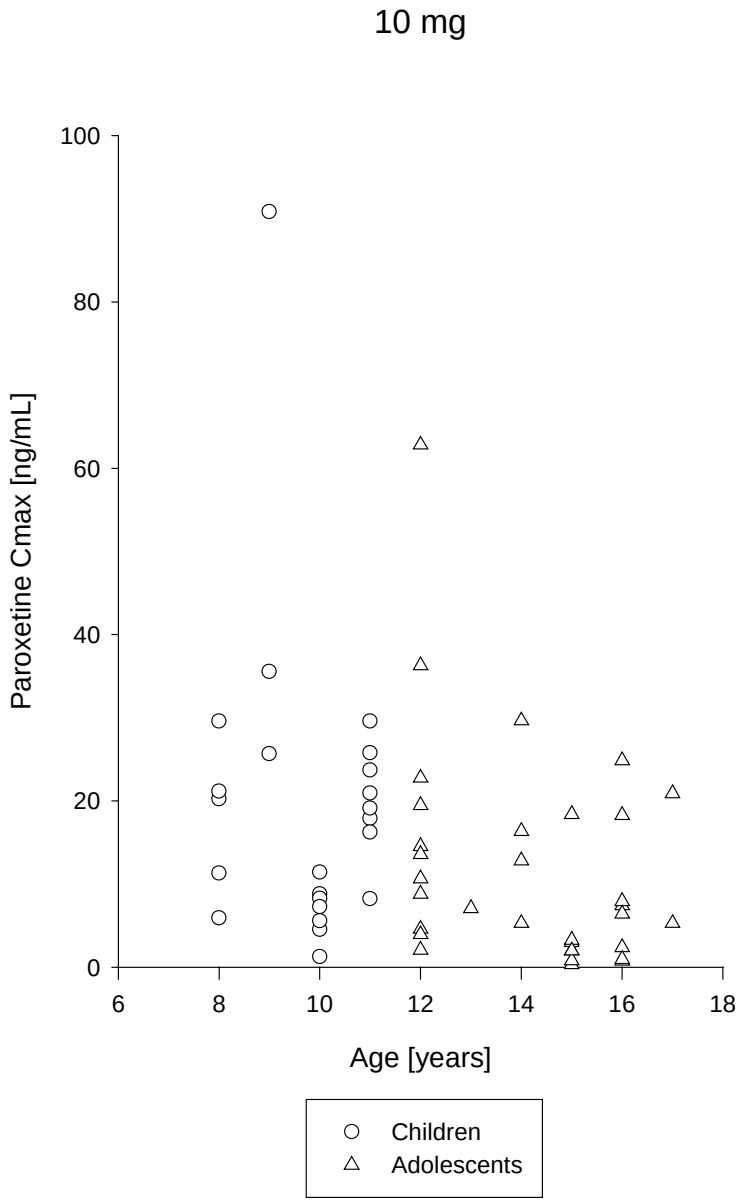


Figure 11.24 Relationship between paroxetine steady state Cmax and age in pediatric patients (20 mg/day)

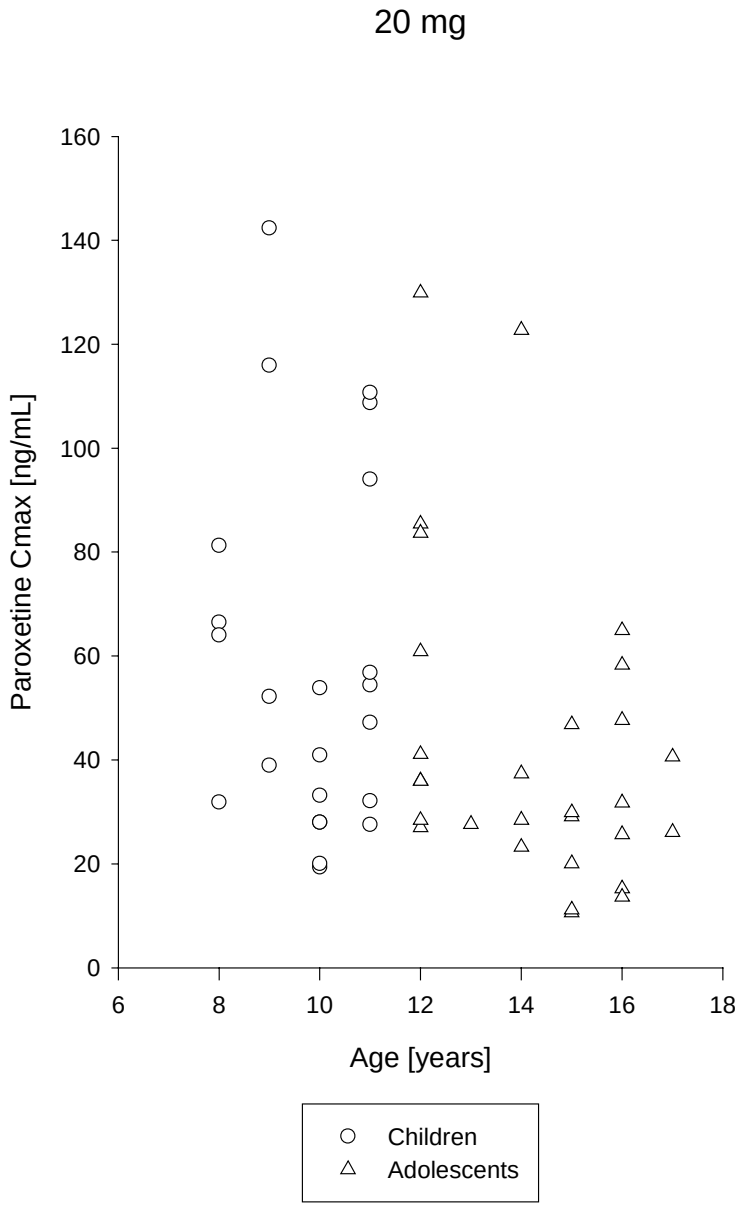


Figure 11.25 Relationship between paroxetine steady state Cmax and age in pediatric patients (30 mg/day)

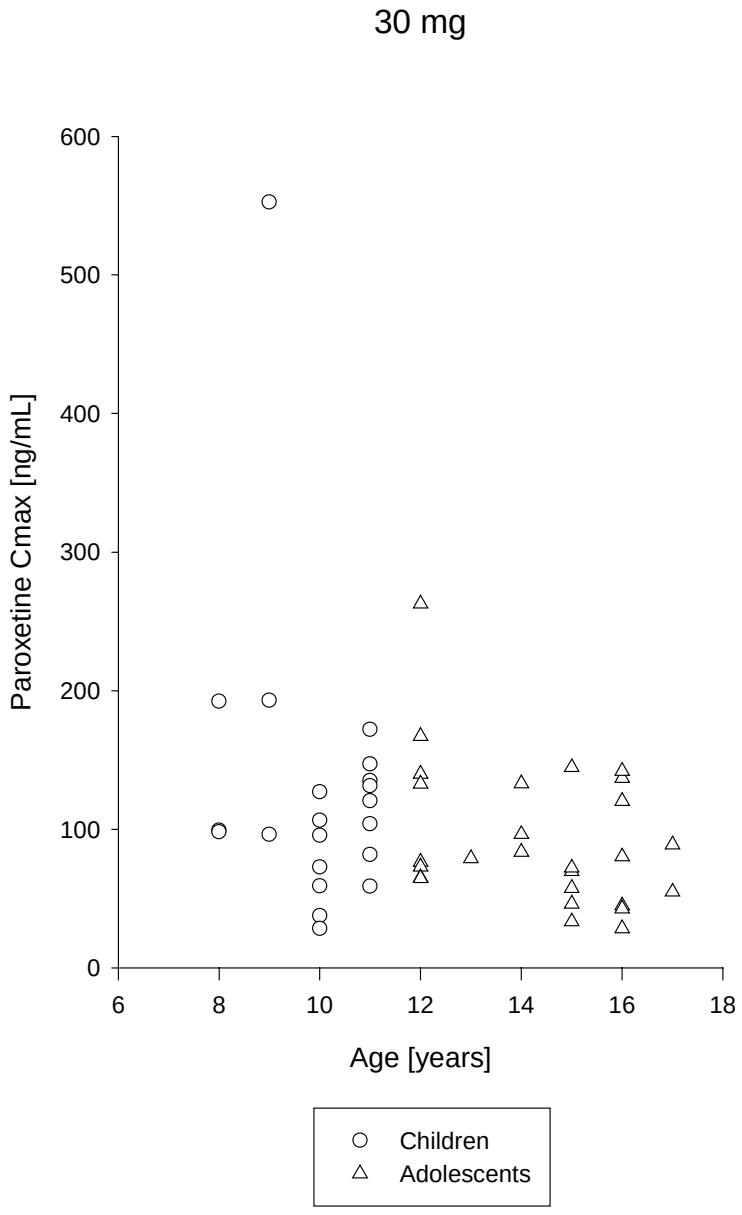


Figure 11.26 Relationship between paroxetine steady state CL/F and age in pediatric patients (10 mg/day)

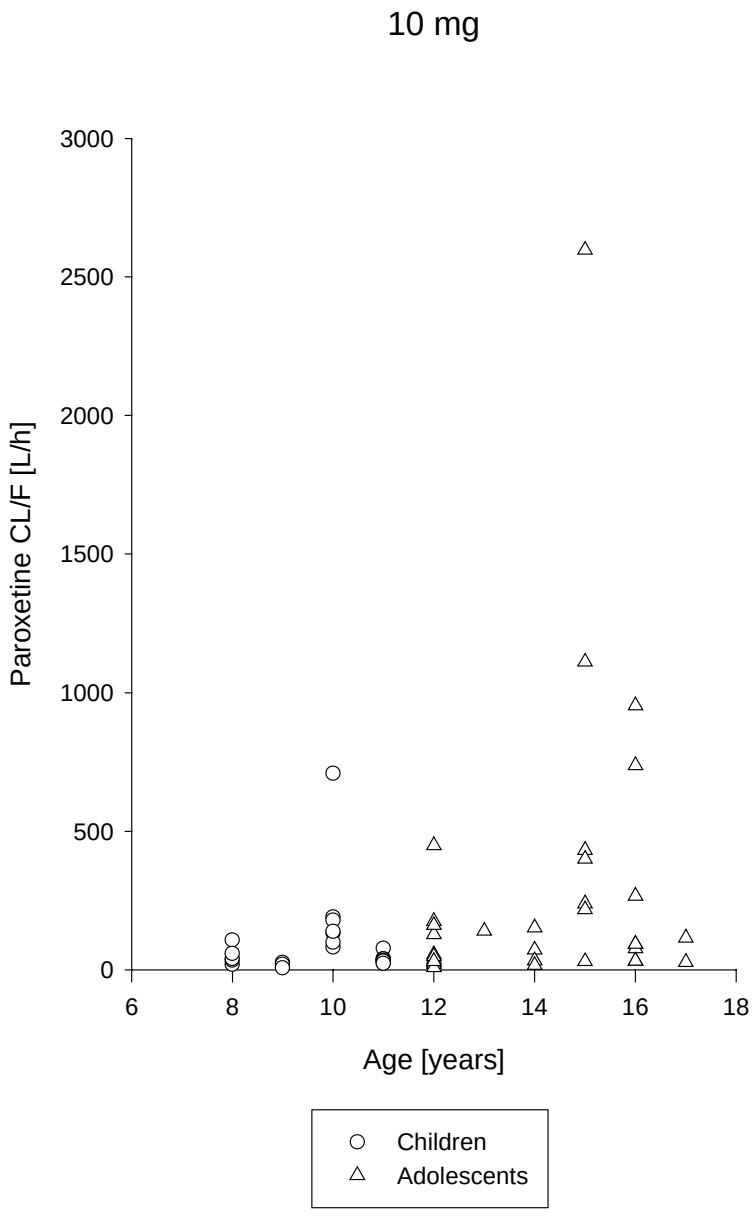


Figure 11.27 Relationship between paroxetine steady state CL/F and age in pediatric patients (20 mg/day)

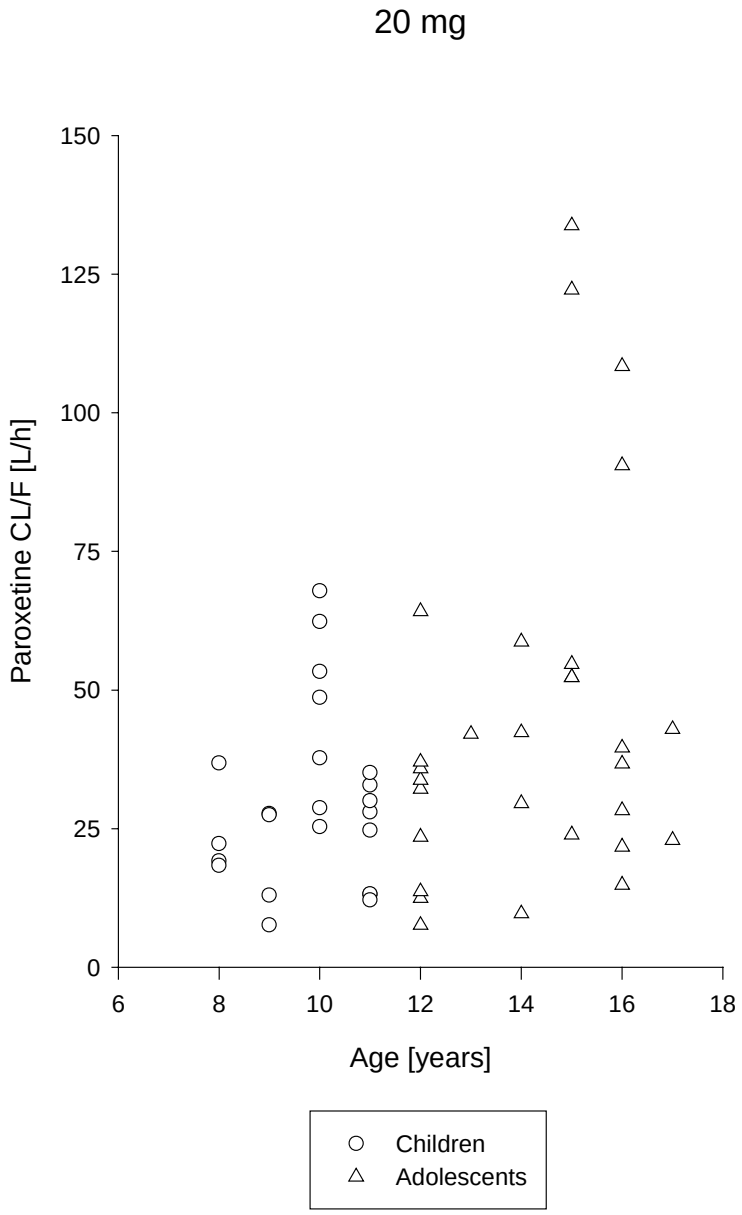


Figure 11.28 Relationship between paroxetine steady state CL/F and age in pediatric patients (30 mg/day)

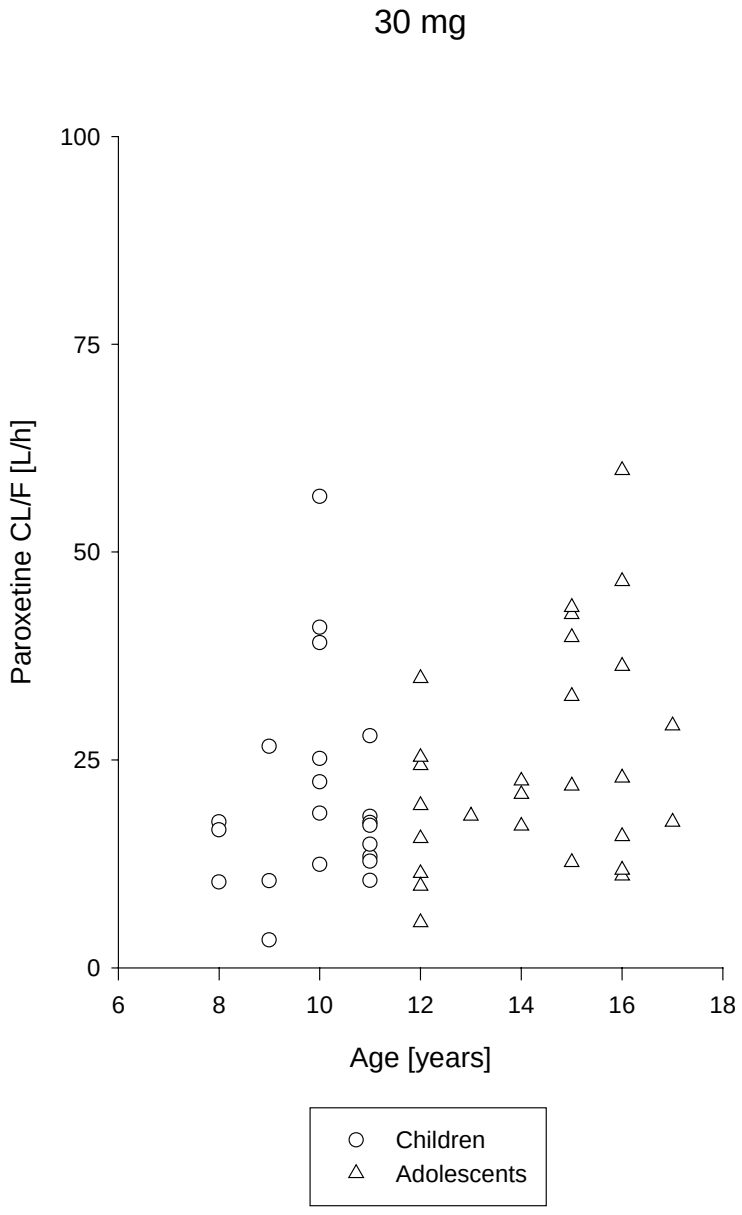


Figure 11.29 Relationship between paroxetine steady state AUC(0-24) and weight in pediatric patients (10 mg/day)

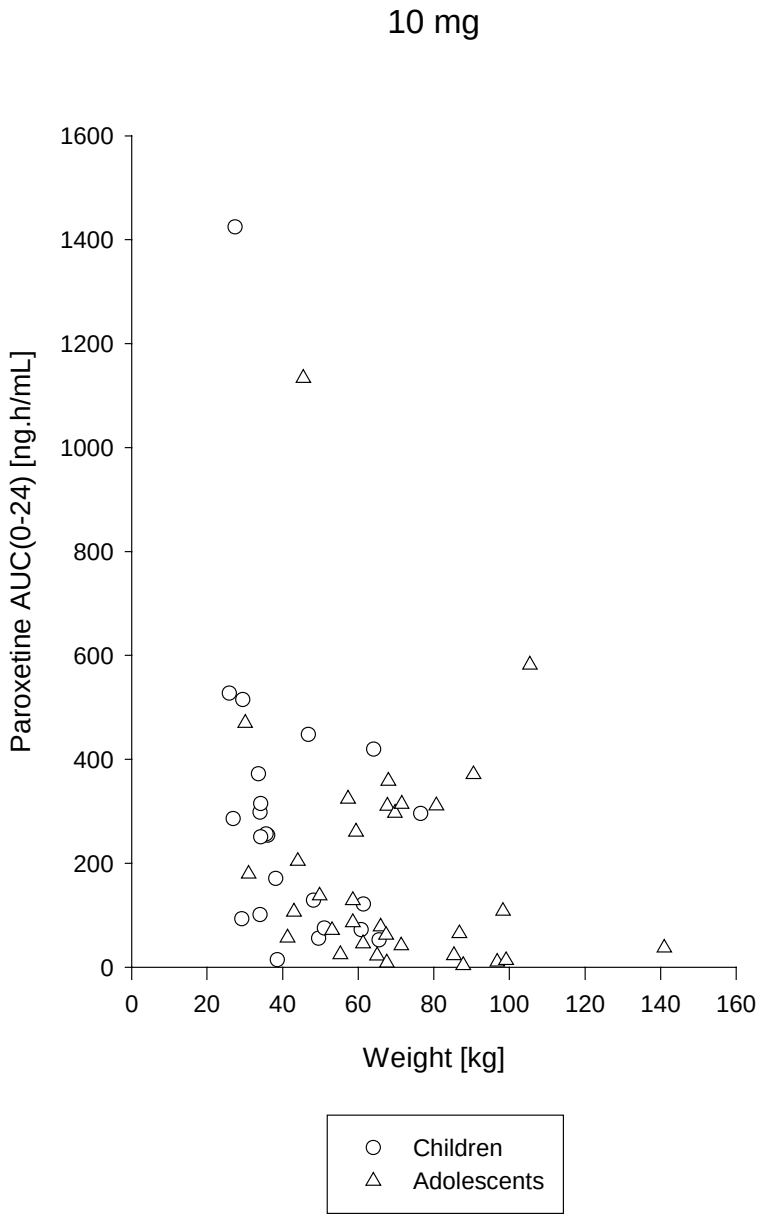


Figure 11.30 Relationship between paroxetine steady state AUC(0-24) and weight in pediatric patients (20 mg/day)

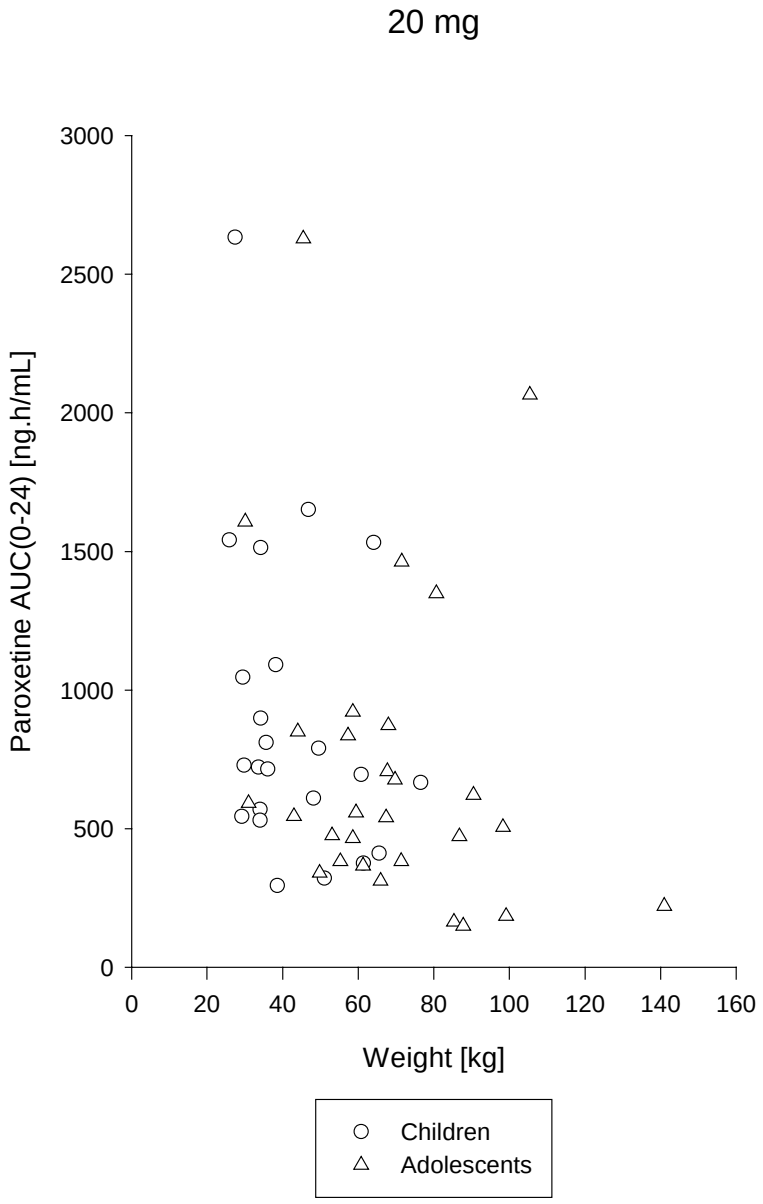


Figure 11.31 Relationship between paroxetine steady state AUC(0-24) and weight in pediatric patients (30 mg/day)

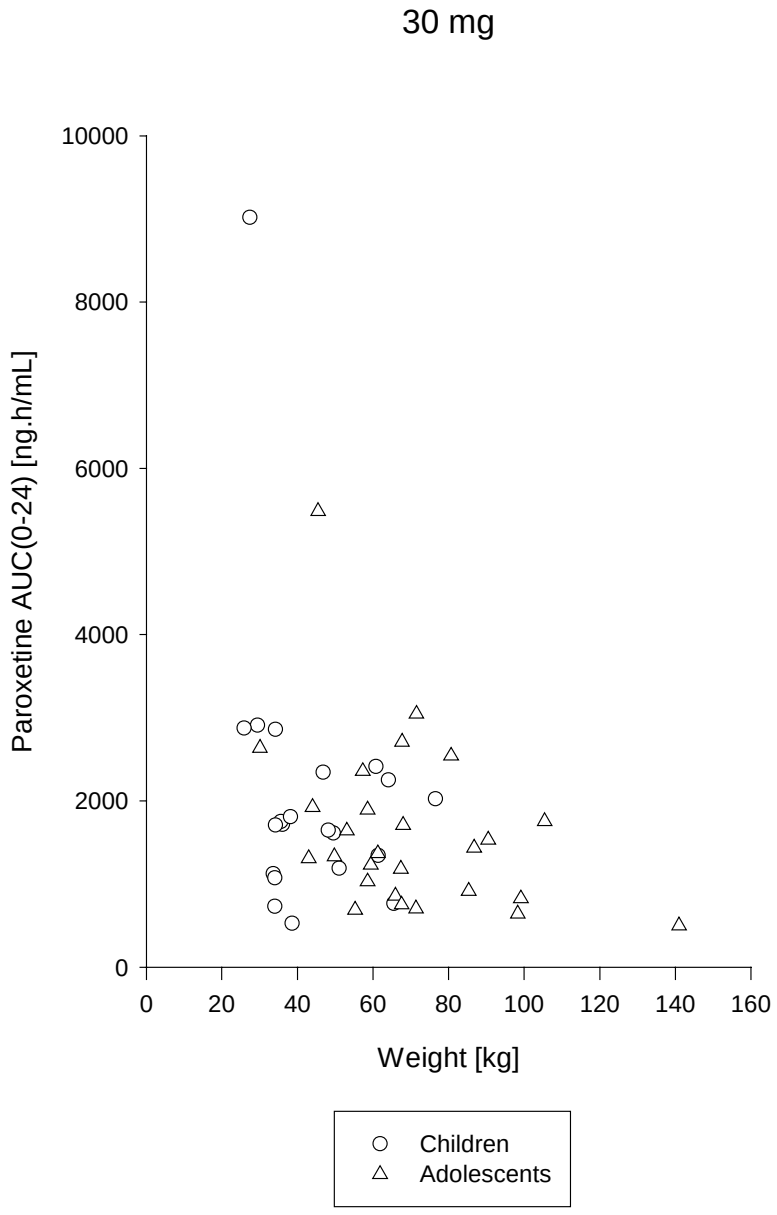


Figure 11.32 Relationship between paroxetine steady state Cmax and weight in pediatric patients (10 mg/day)

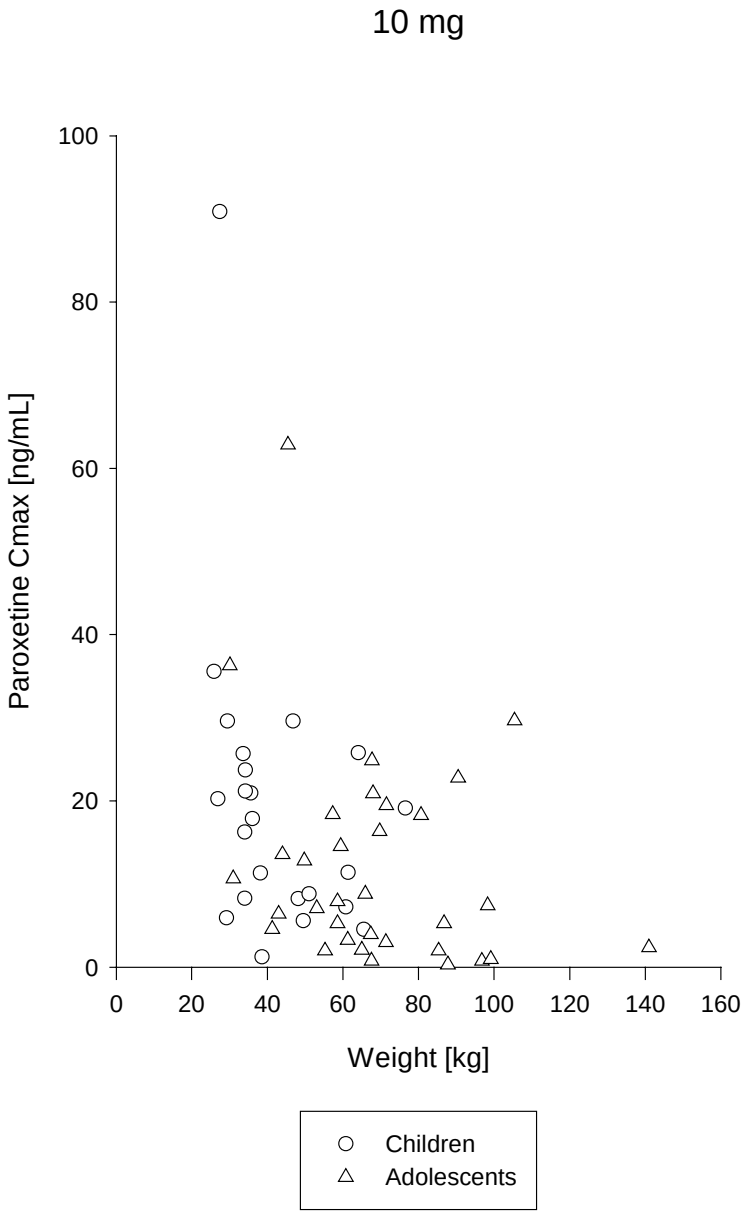


Figure 11.33 Relationship between paroxetine steady state Cmax and weight in pediatric patients (20 mg/day)

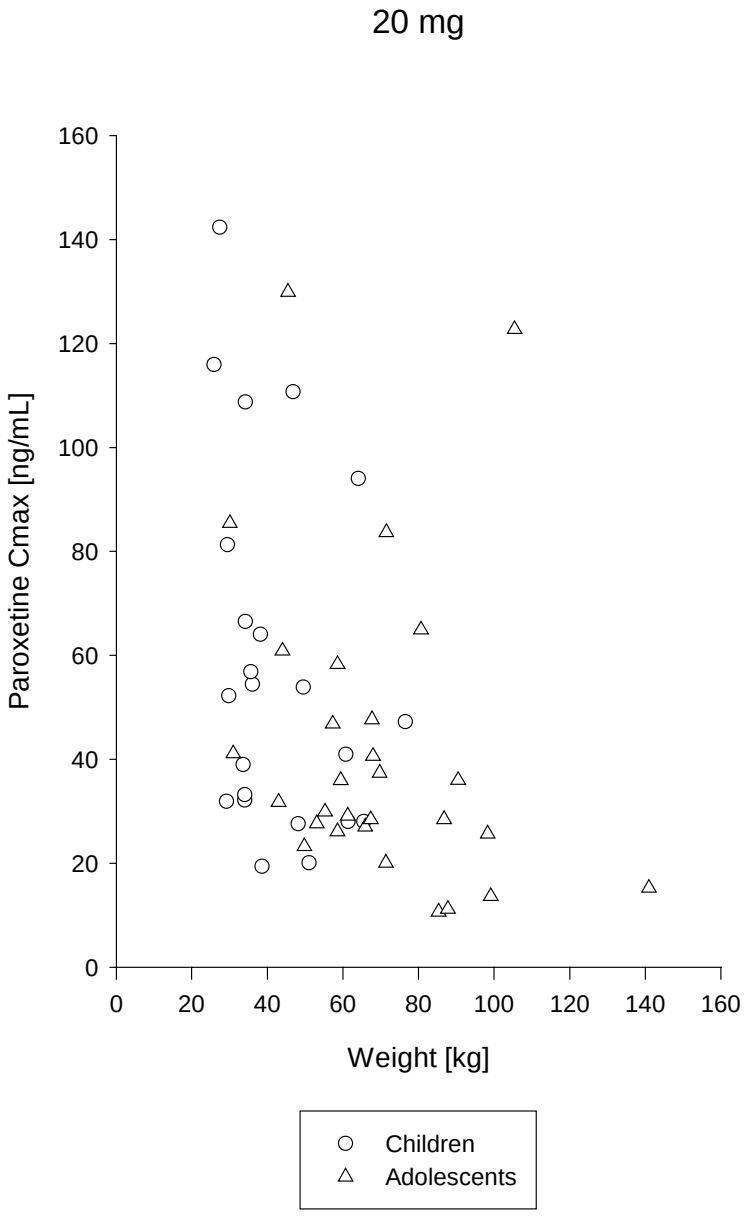


Figure 11.34 Relationship between paroxetine steady state Cmax and weight in pediatric patients (30 mg/day)

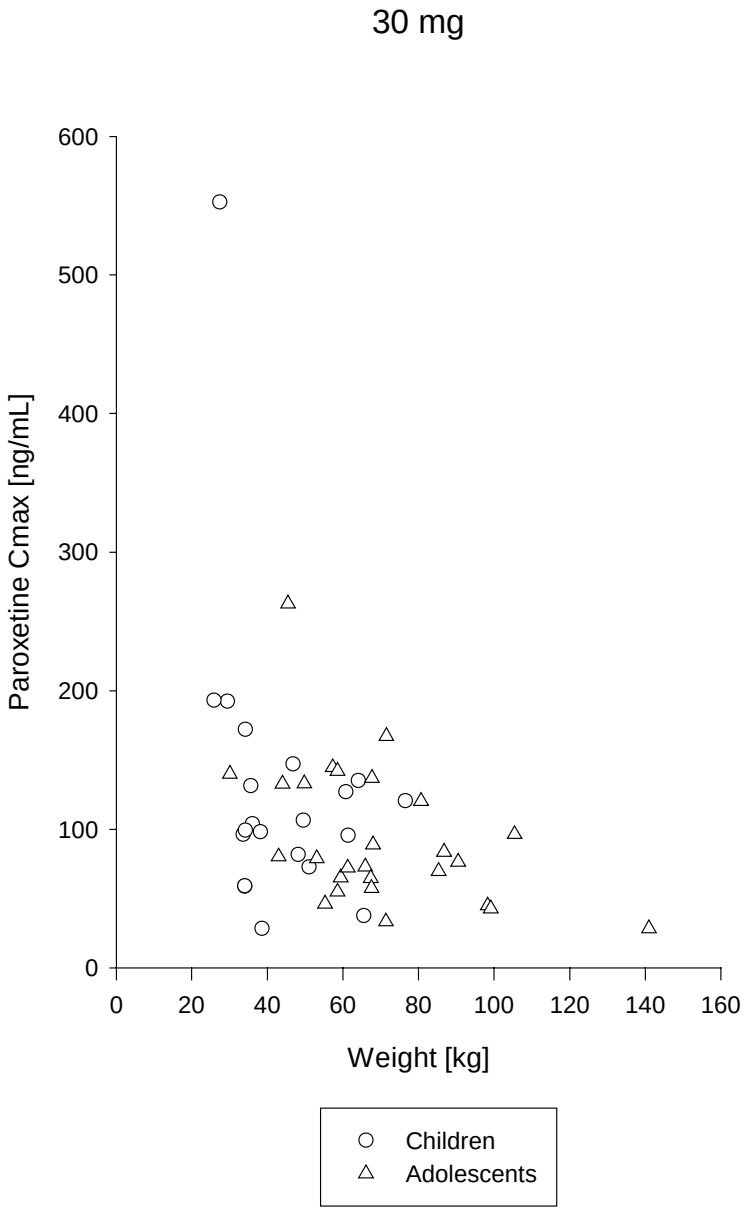


Figure 11.35 Relationship between paroxetine steady state CL/F and weight in pediatric patients (10 mg/day)

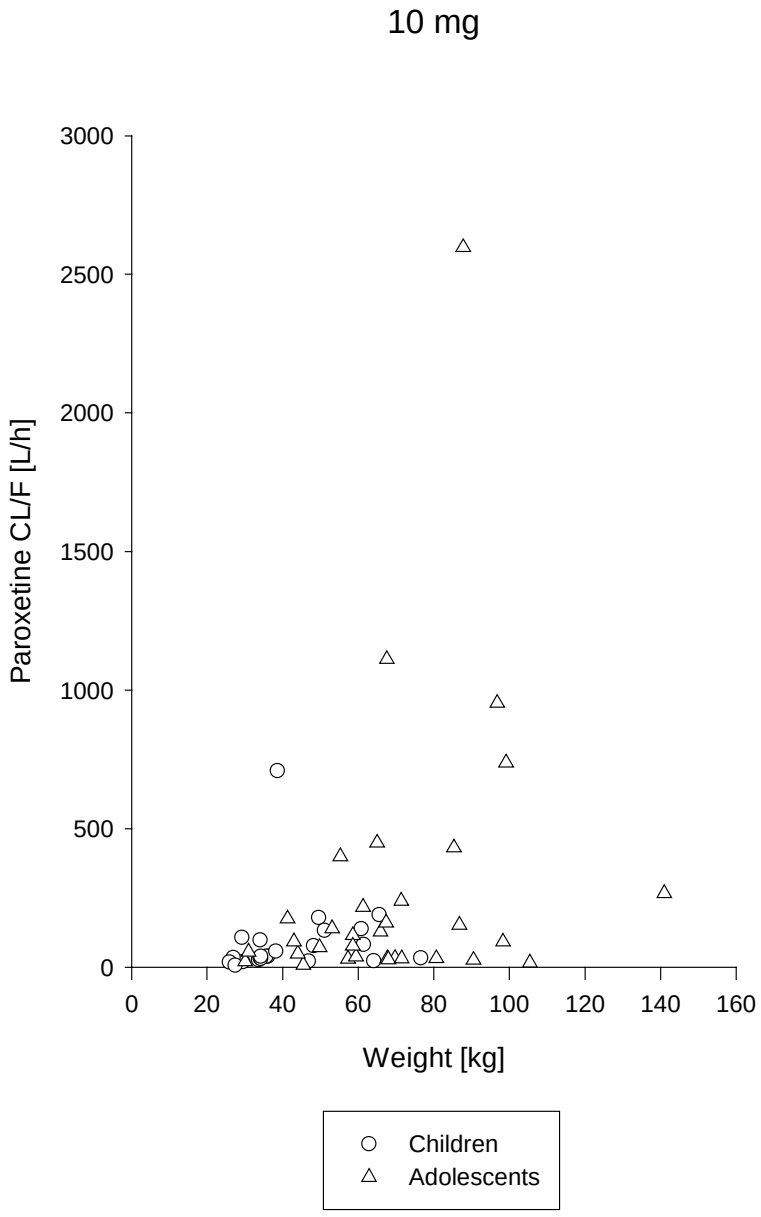


Figure 11.36 Relationship between paroxetine steady state CL/F and weight in pediatric patients (20 mg/day)

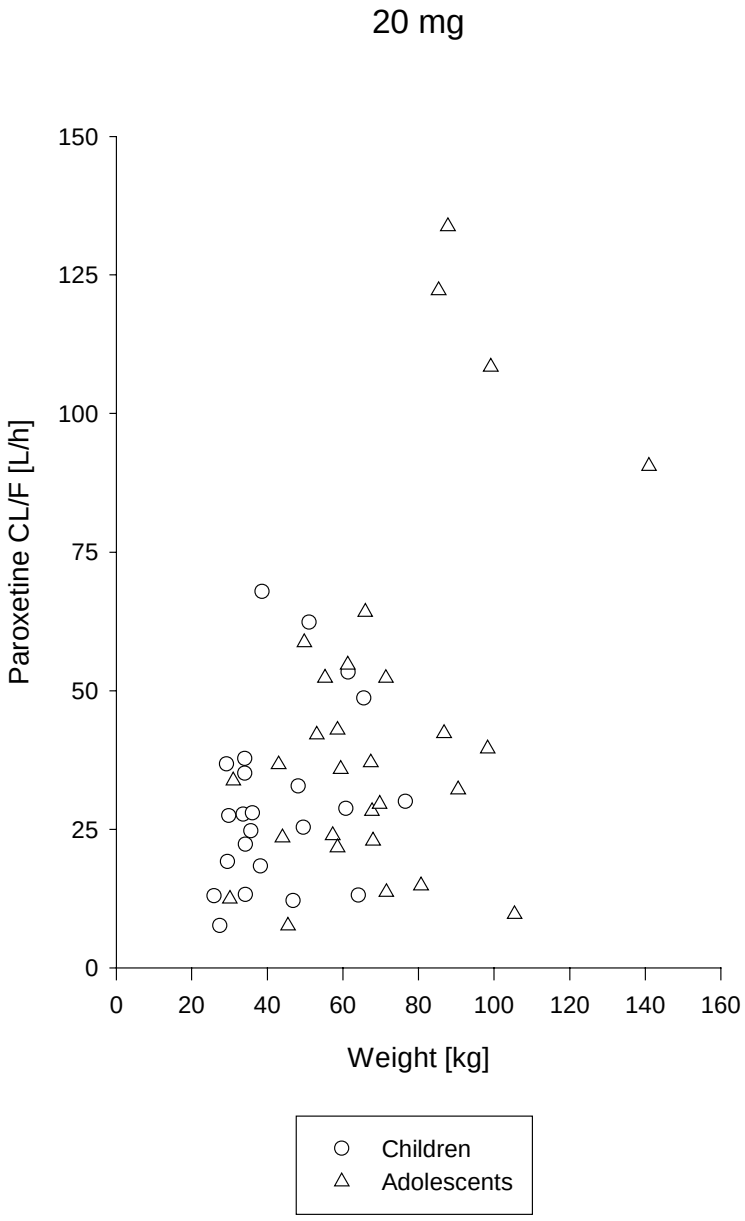


Figure 11.37 Relationship between paroxetine steady state CL/F and weight in pediatric patients (30 mg/day)

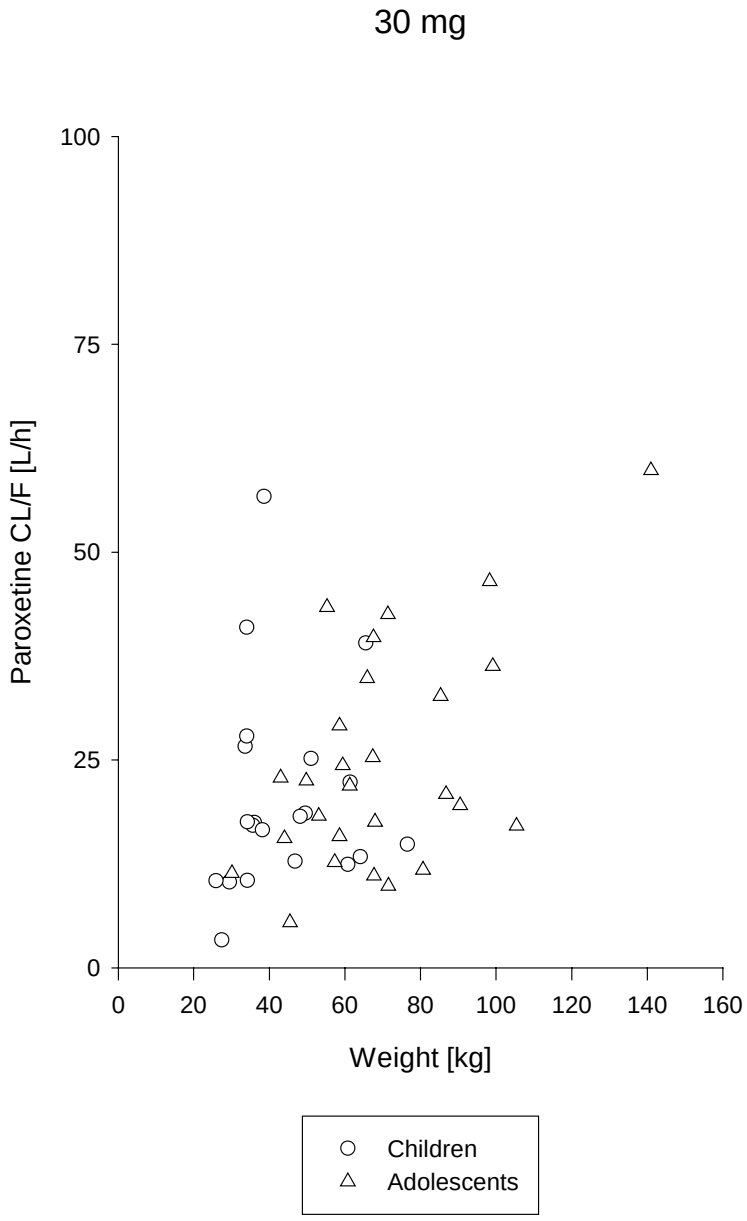


Figure 11.38 Relationship between paroxetine steady state weight-normalized CL/F [(L/h)/kg] and age in pediatric patients (10 mg/day)

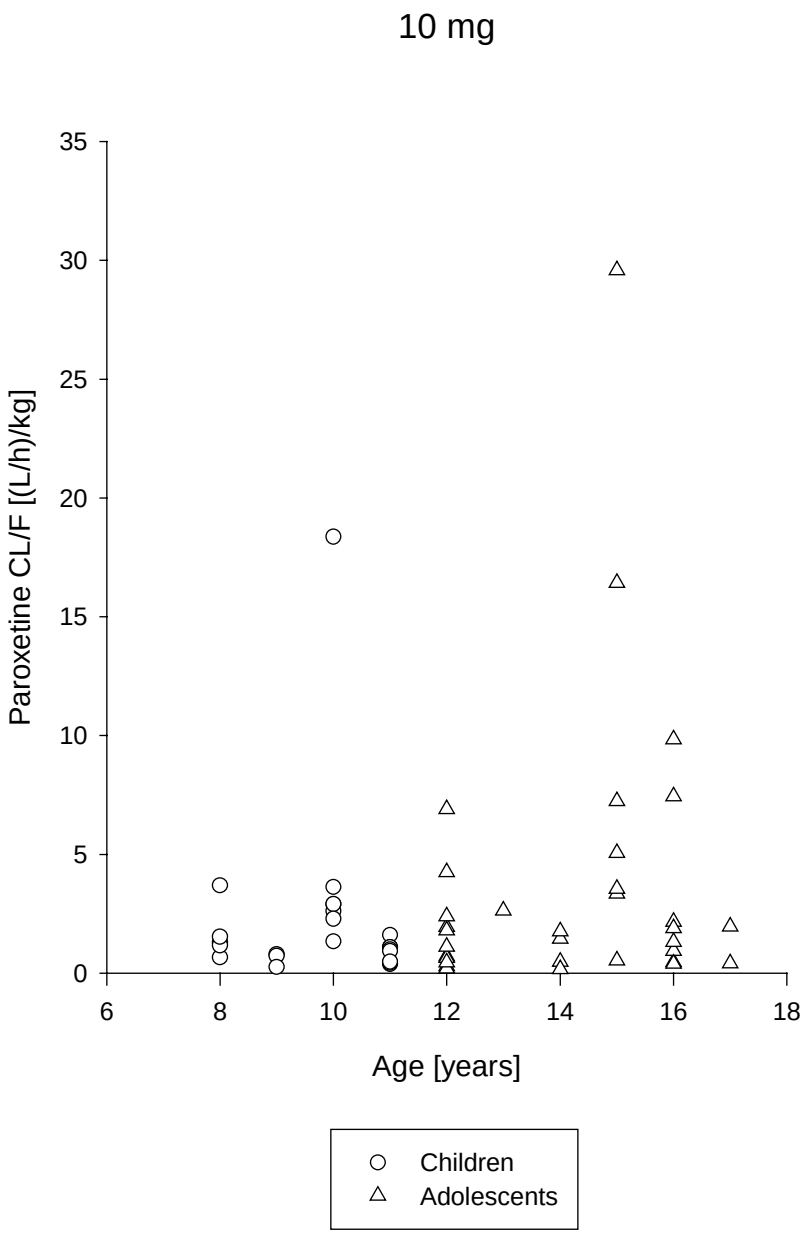


Figure 11.39 Relationship between paroxetine steady state weight-normalized CL/F [(L/h)/kg] and age in pediatric patients (20 mg/day)

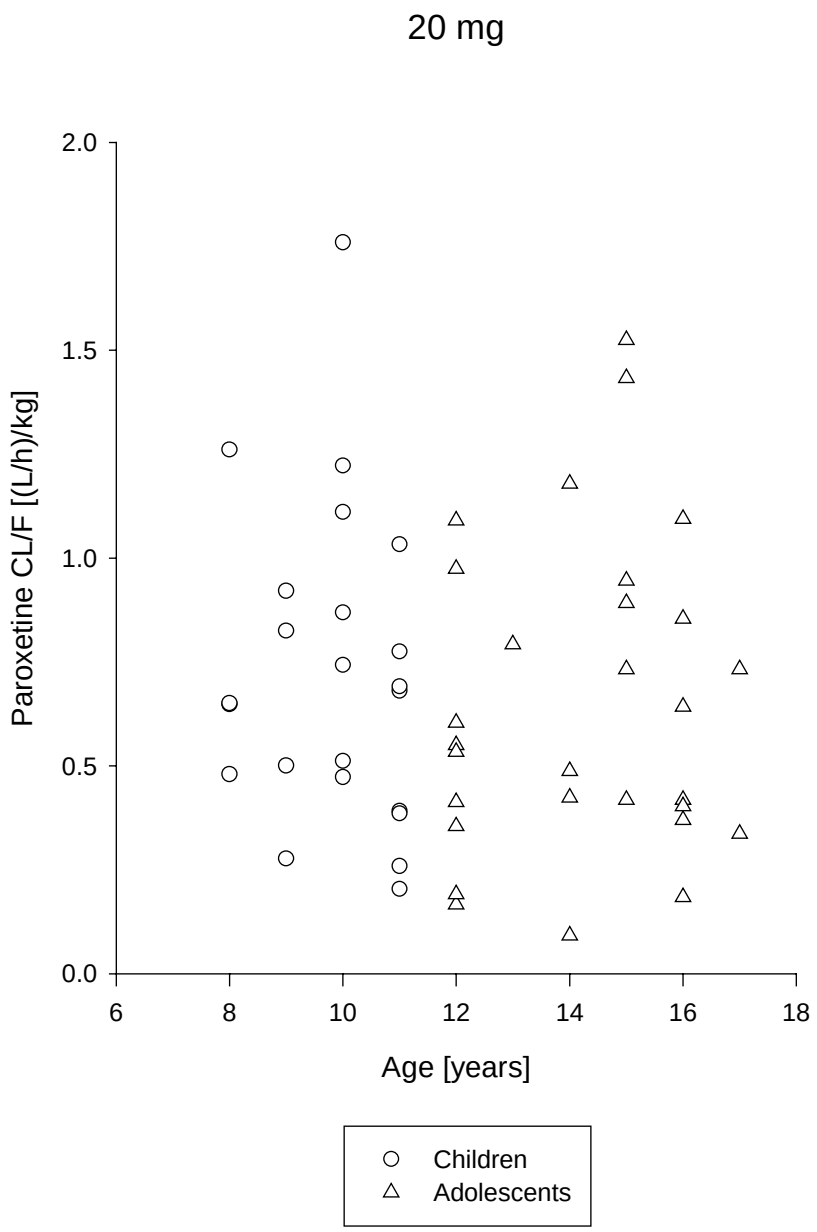


Figure 11.40 Relationship between paroxetine steady state weight-normalized CL/F [(L/h)/kg] and age in pediatric patients (30 mg/day)