Appendix D Listings

Page

676 PAED Listing 15.1.1 BRL 29060 - 676 Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases) 258
676 PAED Listing 15.1.2 BRL 29060 - 676 Adverse Experiences (Taper, Follow-up and Post Follow-up Phases) 362
676 PAED Listing 15.1.3.1 BRL 29060 - 676 Serious Adverse Experiences (Pre Treatment Phase) 389
676 PAED Listing 15.1.3.2 BRL 29060 - 676 Serious Adverse Experiences (Treatment Phase) 407
676 PAED Listing 15.1.3.3 BRL 29060 - 676 Serious Adverse Experiences (Taper, Follow-up and Post Follow-up Phases) 419
676 PAED Listing 15.1.4 BRL 29060 - 676 Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal 431
676 PAED Listing 15.1.5 BRL 29060 - 676 Summary of Deaths 446
676 PAED Listing 15.4.1 BRL 29060 - 676 Medical Procedures 447

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : No Therapy Dispensed, Age Group : Children
Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.019.24505	HEADACHE	HEADACHE	^ Body as a Whole	.		25FEB00	1 day	No	1	MIL	NO	Yes	REL	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : No Therapy Dispensed, Age Group : Children, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	No. Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : No Therapy Dispensed, Age Group : Children, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action Taken	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : No Therapy Dispensed, Age Group : Adolescents
Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.010.24253	HEADACHE	HEADACHE	^	Body as a Whole	.		09JAN01	1 day	Yes	.	MOD	NO	Yes	UNR	No
	NAUSEA	NAUSEA	^	Digestive System	.		08JAN01	CON	Yes	.	MIL	NO	No	UNR	No
676.103.24645	BACK PAIN	SORE BACK	^	Body as a Whole	.		15JAN01	CON	Yes	.	MOD	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : No Therapy Dispensed, Age Group : Adolescents, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : No Therapy Dispensed, Age Group : Adolescents, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.001.24008 ie	BACK PAIN	NECK PAIN	+	Body as a Whole	30	114 (-3)	30DEC00	19 days	Yes	.	MIL	NO	No	PBU	No
	HEADACHE	HEADACHES	+	Body as a Whole	10	1 (-116)	08SEP00	14 days	No	10	MIL	NO	No	PSR	No
	TRAUMA	PAIN IN FEET FROM STRESS FRACTURE	+	Body as a Whole	20	49 (-68)	26OCT00	3 days	Yes	.	MOD	NO	Yes	UNR	No
	RESPIRATORY DISORDER	UPPER RESPIRATORY INFECTION	+	Respiratory System	10	23 (-94)	30SEP00	15 days	Yes	.	MIL	NO	Yes	PBU	No
676.002.24031 i	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	10	6 (-106)	21FEB00	51 days	Yes	.	MIL	NO	No	PSR	No
	FEVER	ELEVATED TEMP	+	Body as a Whole	10	7 (-105)	22FEB00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	FEVER	ELEVATED TEMP	+	Body as a Whole	30	83 (-29)	08MAY00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	30	111 (-1)	05JUN00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	TRAUMA	SPIDER BITE	+	Body as a Whole	30	70 (-42)	25APR00	15 days	No	2	MIL	NO	Yes	UNR	No
	DECREASED APPETITE	DECREASED APPETITE	+	Digestive System	10	1 (-111)	16FEB00	1 day	Yes	.	MIL	NO	No	PSR	No
	DIARRHEA	DIARRHEA	+	Digestive System	10	6 (-106)	21FEB00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	DIARRHEA	DIARRHEA	+	Digestive System	30	83 (-29)	08MAY00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	NAUSEA	QUEASY STOMACH	+	Digestive System	10	1 (-111)	16FEB00	1 day	Yes	.	MIL	NO	No	PSR	No
	ARTHRALGIA	KNEE PAIN	+	Musculoskeletal System	30	67 (-45)	22APR00	42 days	Yes	.	MIL	NO	Yes	UNR	No
676.002.24034 i	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	20	69 (0)	16AUG00	1 day	Yes	.	MIL	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.002.24034 i	HEADACHE	INCREASED INTERMITTENT HEADACHES	+	Body as a Whole	20	25 (-44)	03JUL00	19 days	Yes	.	MOD	NO	Yes	PBU	No
	HOSTILITY	INCREASED AGGRESSION	+	Nervous System	30	50 (-19)	28JUL00	21 days	Yes	.	MOD	DCR	No	PBU	No
	INSOMNIA	INSOMNIA --INITIAL AND MIDDLE	+	Nervous System	20	29 (-40)	07JUL00	38 days	Yes	.	MOD	NO	No	UNR	No
	URINARY INCONTINENCE	INTERMITTENT BEDWETTING	+	Urogenital System	20	14 (-55)	22JUN00	7 days	Yes	.	MOD	NO	No	UNR	No
	URINARY INCONTINENCE	INTERMITTENT BED WETTING	+	Urogenital System	30	47 (-22)	25JUL00	16 days	Yes	.	MOD	NO	No	UNR	No
676.002.24039 i	INCREASED APPETITE	INCREASED APPETITE	+	Digestive System	20	16 (-12)	16FEB01	12 days	Yes	.	MIL	NO	No	PSR	No
	RESPIRATORY DISORDER	URI (UPPER RESPIRATORY INFECTION)	+	Respiratory System	10	9 (-19)	09FEB01	6 days	Yes	.	MIL	NO	Yes	UNR	No
676.003.24058 i	ALLERGIC REACTION	ALLERGIES	+	Body as a Whole	10	9 (-102)	18MAR00	3 days	Yes	.	MOD	NO	Yes	UNR	No
	NERVOUSNESS	IRRITABILITY	+	Nervous System	30	72 (-39)	20MAY00	41 days	Yes	.	MOD	DCR	No	REL	No
	CONTACT DERMATITIS	DIFFUSE RASH OVER BODY PROBABLY CONTACT RASH	+	Skin and Appendages	30	82 (-29)	30MAY00	1 day	Yes	.	MIL	NO	No	UNR	No
676.003.24059 ie	ASTHENIA	FATIGUE IN THE EVENING	+	Body as a Whole	10	9 (-111)	17MAR00	9 days	Yes	.	MOD	NO	No	PSR	No
	OTITIS MEDIA	OTITIS MEDIA	+	Special Senses	10	117 (-3)	03JUL00	8 days	Yes	.	MOD	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.003.24063 ie	HYPERNATREMIA	HYPERNATREMIA	^	Metabolic and Nutritional Disorders	.	-6 (-134)	17APR00	4 days	Yes	.	MIL		No		No
	FEVER	FEVER	+	Body as a Whole	10	2 (-126)	25APR00	3 days	Yes	.	MIL	NO	No	UNR	No
	COUGH INCREASED	COUGH	+	Respiratory System	10	2 (-126)	25APR00	3 days	Yes	.	MIL	NO	No	UNR	No
	RASH	SKIN RASH	+	Skin and Appendages	10	5 (-123)	28APR00	CON	Yes	.	MOD	NO	Yes	UNR	No
	OTITIS MEDIA	OTITIS	+	Special Senses	10	10 (-118)	03MAY00	11 days	Yes	.	MOD	NO	Yes	UNR	No
676.003.24073 i	INFECTION	STREP THROAT	+	Body as a Whole	10	34 (-30)	30APR01	8 days	Yes	.	SEV	NO	Yes	UNR	No
	ASTHMA	COUGH ASSOCIATED WITH ASTHMA	+	Respiratory System	10	36 (-28)	02MAY01	1 day	No	1	MIL	NO	Yes	UNR	No
	RESPIRATORY DISORDER	MILD URI	+	Respiratory System	10	9 (-55)	05APR01	2 days	No	1	MIL	NO	Yes	UNR	No
	OTITIS MEDIA	OTITIS MEDIA	+	Special Senses	10	34 (-30)	30APR01	3 days	No	1	MIL	NO	Yes	UNR	No
676.004.24089	HEADACHE	HEADACHE	^	Body as a Whole	.	-5 (-7)	09NOV00	1 day	Yes	.	MIL		No		No
	EPISTAXIS	NOSE BLEED	^	Respiratory System	.	-5 (-7)	09NOV00	1 day	Yes	.	MIL		No		No
676.005.24127 ie	ASTHENIA	FATIGUE	+	Body as a Whole	20	8 (-85)	10MAY01	23 days	Yes	.	MIL	NO	No	PSR	No
	ASTHENIA	FATIGUE	+	Body as a Whole	40	31 (-62)	02JUN01	15 days	Yes	.	MOD	DCR	No	PSR	No
	NERVOUSNESS	IRRITABILITY	+	Nervous System	40	30 (-63)	01JUN01	CON	Yes	.	MOD	DCR	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.007.24176 ie	OTITIS EXTERNA	OTITIS EXTERNA - LEFT EAR	+	Special Senses	20	52 (-55)	06APR00	10 days	Yes	.	MIL	NO	Yes	UNR	No
	OTITIS MEDIA	OTITIS MEDIA - LEFT EAR	+	Special Senses	20	52 (-55)	06APR00	10 days	Yes	.	MIL	NO	Yes	UNR	No
676.007.24177 ie	HOSTILITY	BEHAVIORAL DISINHIBITION	+	Nervous System	40	57 (-59)	04APR00	42 days	Yes	.	MIL	DCR	No	REL	No
676.007.24179 ie	HYPERKINESIA	HYPERACTIVATIO N	+	Nervous System	20	60 (-53)	14APR00	CON	Yes	.	MOD	DCR	No	PSR	No
	COUGH INCREASED	COUGH	+	Respiratory System	20	43 (-70)	28MAR00	6 days	Yes	.	MIL	NO	Yes	UNR	No
	SINUSITIS	SINUS CONGESTION	+	Respiratory System	10	106 (-7)	30MAY00	11 days	Yes	.	MIL	NO	Yes	UNR	No
	NAIL DISORDER	INGROWN LEFT BIG TOENAIL	+	Skin and Appendages	10	106 (-7)	30MAY00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	SWEATING	EXCESSIVE SWEATING	+	Skin and Appendages	10	1 (-112)	15FEB00	1 day	Yes	.	MIL	NO	No	PSR	No
676.007.24193 ie	PHARYNGITIS	TONSILLITIS	+	Respiratory System	50	101 (-9)	10SEP01	5 days	Yes	.	MIL	NO	Yes	UNR	No
676.009.24229 i	ABDOMINAL PAIN	STOMACH DISCOMFORT	+	Body as a Whole	10	2 (-18)	27SEP00	1 day	Yes	.	MIL	NO	No	PSR	No
676.010.24254 i	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	10	17 (-100)	01MAY00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	ALLERGIC REACTION	COMMON COLD WITH ALLERGIES	+	Body as a Whole	20	48 (-69)	01JUN00	8 days	Yes	.	MIL	NO	Yes	UNR	No
	ASTHENIA	DAYTIME FATIGUE	+	Body as a Whole	30	105 (-12)	28JUL00	CON	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	20	56 (-61)	09JUN00	1 day	Yes	.	MIL	NO	No	UNR	No
	HEADACHE	INTERMITTENT HEADACHES	+	Body as a Whole	30	87 (-30)	10JUL00	CON	Yes	.	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.010.24254 i	RESPIRATORY DISORDER	COMMON COLD WITH ALLERGIES	+	Respiratory System	20	48 (-69)	01JUN00	8 days	Yes	.	MIL	NO	Yes	UNR	No
	RESPIRATORY DISORDER	UPPER RESPIRATORY TRACT INFECTION	+	Respiratory System	20	61 (-56)	14JUN00	58 days	Yes	.	MIL	NO	Yes	UNR	No
	RESPIRATORY DISORDER	COLD WITH COUGH, ITCHY EYES, PHLEGM	+	Respiratory System	30	87 (-30)	10JUL00	CON	Yes	.	MIL	NO	No	UNR	No
	RASH	SKIN RASH ON BUTTOCKS	+	Skin and Appendages	20	43 (-74)	27MAY00	75 days	Yes	.	MIL	NO	No	PBU	No
676.012.24313 ie	INFECTION	GASTROINTESTINAL VIRUS	+	Body as a Whole	20	37 (-75)	16JUN00	3 days	Yes	.	MOD	NO	Yes	UNR	No
	SOMNOLENCE	LETHARGY	+	Nervous System	20	10 (-102)	20MAY00	18 days	Yes	.	MIL	NO	No	PSR	No
676.013.24337 ie	MACULOPAPULAR RASH	FACIAL PAPULAR RASH	^	Skin and Appendages	.	-4 (-116)	04MAR00	6 days	Yes	.	MIL		Yes		No
	NERVOUSNESS	RESTLESSNESS	+	Nervous System	10	49 (-63)	26APR00	71 days	Yes	.	MIL	NO	No	PSR	No
	CONTACT DERMATITIS	POISON IVY	+	Skin and Appendages	10	57 (-55)	04MAY00	21 days	Yes	.	MIL	NO	Yes	UNR	No
676.013.24344 ie	ABDOMINAL PAIN	STOMACHACHE	+	Body as a Whole	20	28 (-87)	12JUN00	1 day	Yes	.	MIL	NO	No	PSR	No
	WEIGHT GAIN	WEIGHT GAIN	+	Metabolic and Nutritional Disorders	30	115 (0)	07SEP00	CON	Yes	.	MIL	NO	No	PSR	No
	SOMNOLENCE	DROWSINESS	+	Nervous System	20	23 (-92)	07JUN00	CON	Yes	.	MIL	NO	No	PSR	No
676.013.24345 ie	CONCENTRATION IMPAIRED	DECREASED SCHOOL PERFORMANCE	+	Nervous System	40	109 (-10)	01OCT00	CON	Yes	.	MOD	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous, if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.013.24345 ie	NERVOUSNESS	RESTLESSNESS	+	Nervous System	10	7 (-112)	21JUN00	3 days	Yes	.	MIL	NO	No	PSR	No
	RASH	SKIN RASH ON STERNUM	+	Skin and Appendages	30	28 (-91)	12JUL00	35 days	Yes	.	MIL	NO	Yes	UNR	No
	RASH	SKIN RASH ON LEG	+	Skin and Appendages	40	89 (-30)	11SEP00	22 days	Yes	.	MIL	NO	No	UNR	No
	CONJUNCTIVITIS	BLOOD-SHOT EYES	+	Special Senses	10	13 (-106)	27JUN00	2 days	Yes	.	MIL	NO	Yes	UNR	No
676.014.24366 ie	PHARYNGITIS	SORE THROAT	+	Respiratory System	40	76 (-31)	11APR00	2 days	Yes	.	MOD	NO	Yes	UNR	No
	RESPIRATORY DISORDER	HEAD COLD	+	Respiratory System	40	68 (-39)	03APR00	2 days	Yes	.	MIL	NO	Yes	PBU	No
676.014.24377 ie	NERVOUSNESS	IRRITABILITY	+	Nervous System	40	30 (-90)	01NOV00	15 days	Yes	.	MIL	DCR	No	PSR	No
676.015.24397 ie	ALLERGIC REACTION	SEASONAL ALLERGIES	^	Body as a Whole	.	-5 (-121)	22APR00	3 days	No	1	MIL		Yes		No
	HYPERKINESIA	HYPERVERBAL HYPERACTIVE	+	Nervous System	30	35 (-81)	01JUN00	8 days	Yes	.	MIL	DCR	No	PSR	No
	SPEECH DISORDER	HYPERVERBAL HYPERACTIVE	+	Nervous System	30	35 (-81)	01JUN00	8 days	Yes	.	MIL	DCR	No	PSR	No
676.015.24403 ie	HEADACHE	HEADACHE	^	Body as a Whole	.	-4 (-125)	03JUL00	2 days	No	1	MIL		Yes		No
	ABDOMINAL PAIN	ABDOMINAL CRAMPING	+	Body as a Whole	40	113 (-8)	28OCT00	2 days	Yes	.	MIL	NO	Yes	PBU	No
	HEADACHE	HEADACHE		Body as a Whole	40	53 (-68)	29AUG00	1 day	Yes	.	MIL	NO	Yes	PBU	No
	HEADACHE	HEADACHE		Body as a Whole	40	54 (-67)	30AUG00	1 day	No	1	MIL	NO	Yes	PBU	No
	VOMITING	VOMITING	+	Digestive System	40	113 (-8)	28OCT00	1 day	Yes	.	MIL	NO	No	PBU	No
	EPISTAXIS	NOSEBLEEDS	+	Respiratory System	40	53 (-68)	29AUG00	2 days	No	2	MIL	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.015.24403 ie	EPISTAXIS	EPISTAXIS	+	Respiratory System	40	61 (-60)	06SEP00	13 days	No	.	MIL	NO	Yes	PBU	No
	SINUSITIS	SINUS HEADACHE	+	Respiratory System	20	18 (-103)	25JUL00	3 days	No	2	MIL	NO	Yes	PBU	No
676.015.24409 ie	HEADACHE	HEADACHE	^	Body as a Whole	.	-1 (-52)	04DEC00	1 day	Yes	.	MIL		Yes		No
	NAUSEA	NAUSEA	^	Digestive System	.	-1 (-52)	04DEC00	1 day	Yes	.	MIL		No		No
	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	40	34 (-17)	08JAN01	1 day	Yes	.	MIL	NO	No	PSR	No
	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	40	42 (-9)	16JAN01	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE		Body as a Whole	10	5 (-46)	10DEC00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE		Body as a Whole	20	12 (-39)	17DEC00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE		Body as a Whole	20	14 (-37)	19DEC00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HYPERKINESIA	HYPERACTIVITY	+	Nervous System	40	33 (-18)	07JAN01	11 days	Yes	.	SEV	DCR	No	REL	No
	HYPERKINESIA	HYPERACTIVITY	+	Nervous System	30	44 (-7)	18JAN01	8 days	Yes	.	SEV	STP	No	REL	No
676.015.24411 i	HYPERKINESIA	HYPERACTIVITY	+	Nervous System	30	24 (-35)	08MAR01	2 days	Yes	.	MIL	DCR	No	PSR	No
	SOMNOLENCE	SEDATED	+	Nervous System	30	16 (-43)	28FEB01	27 days	Yes	.	MIL	NO	No	REL	No
676.017.24450 ie	SYNCOPE	FAINTED AT SCIENCE FAIR	^	Cardiovascular System	.	-2 (-115)	28FEB00	1 day	Yes	.	MOD		No		No
	VASODILATATION	FEELING HOT AT NIGHT	+	Cardiovascular System	40	24 (-89)	25MAR00	37 days	Yes	.	MIL	NO	No	PBU	No
	DYSPEPSIA	HEARTBURN	+	Digestive System	50	55 (-58)	25APR00	1 day	Yes	.	MIL	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.017.24450 ie	FLATULENCE	FLATULENCE	+	Digestive System	40	24 (-89)	25MAR00	82 days	Yes	.	MOD	NO	No	PSR	No
	INSOMNIA	INSOMNIA	+	Nervous System	50	28 (-85)	29MAR00	15 days	Yes	.	MIL	NO	No	PSR	No
	RESPIRATORY DISORDER	UPPER RESPIRATORY INFECTION	+	Respiratory System	50	100 (-13)	09JUN00	42 days	Yes	.	MOD	NO	Yes	UNR	No
676.017.24453 ie	ABDOMINAL PAIN	PAINS ACROSS LOWER ABDOMEN	+	Body as a Whole	30	20 (-101)	15MAY00	2 days	Yes	.	SEV	NO	No	PSR	No
	HEADACHE	HEADACHES	+	Body as a Whole	20	11 (-110)	06MAY00	14 days	Yes	.	MIL	NO	Yes	PSR	No
	SOMNOLENCE	DROWSINESS	+	Nervous System	50	78 (-43)	12JUL00	17 days	Yes	.	MOD	NO	No	PSR	No
676.017.24455 i	HEADACHE	HEADACHE	+	Body as a Whole	10	3 (-91)	13JAN01	1 day	Yes	.	MOD	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	20	10 (-84)	20JAN01	1 day	Yes	.	MOD	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	70 (-24)	21MAR01	1 day	Yes	.	MIL	NO	No	PSR	No
	TRAUMA	BRUISES ON L. LEG (PLAYGROUND ACCIDENT)	+	Body as a Whole	40	77 (-17)	28MAR01	1 day	Yes	.	MIL	NO	No	UNR	No
	CONSTIPATION	CONSTIPATION	+	Digestive System	20	13 (-81)	23JAN01	13 days	Yes	.	MOD	NO	No	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	10	5 (-89)	15JAN01	1 day	Yes	.	MIL	NO	No	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	20	12 (-82)	22JAN01	6 days	No	3	MOD	NO	No	PSR	No
	INSOMNIA	INITIAL INSOMNIA	+	Nervous System	30	28 (-66)	07FEB01	8 days	Yes	.	MOD	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.019.24520 ie	HEADACHE	HEADACHE	+	Body as a Whole	20	23 (-89)	14APR01	6 days	Yes	.	MOD	DCR	No	PSR	No
	TRAUMA	KNEE SPRAIN	+	Body as a Whole	10	56 (-56)	17MAY01	5 days	Yes	.	MIL	NO	Yes	UNR	No
	DIARRHEA	LOOSE STOOLS	+	Digestive System	20	23 (-89)	14APR01	6 days	Yes	.	MOD	DCR	No	PSR	No
	FLATULENCE	INTESTINAL GAS	+	Digestive System	10	2 (-110)	24MAR01	CON	Yes	.	MIL	NO	No	PSR	No
	VOMITING	VOMITING	+	Digestive System	20	23 (-89)	14APR01	6 days	Yes	.	MOD	DCR	No	PSR	No
	PURPURA	BRUISED KNEE	+	Hemic and Lymphatic System	10	33 (-79)	24APR01	7 days	Yes	.	MIL	NO	No	UNR	No
	PURPURA	BRUISED STOMACH MUSCLE	+	Hemic and Lymphatic System	10	57 (-55)	18MAY01	4 days	Yes	.	MOD	NO	No	UNR	No
	MYALGIA	MUSCLE SORENESS	+	Musculoskeletal System	10	15 (-97)	06APR01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	DIZZINESS	DIZZINESS	+	Nervous System	20	23 (-89)	14APR01	6 days	Yes	.	MOD	DCR	No	PSR	No
676.020.24538 ie	ASTHMA	ASTHMA ATTACK	^	Respiratory System	.	0 (-112)	23MAR01	1 day	No	1	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	5 (-107)	28MAR01	1 day	Yes	.	MIL	NO	No	PBU	No
	VASODILATATION	HOT FLUSHES	+	Cardiovascular System	10	6 (-106)	29MAR01	1 day	Yes	.	MIL	NO	No	PBU	No
	ULCERATIVE STOMATITIS	ULCERS IN MOUTH	+	Digestive System	10	13 (-99)	05APR01	CON	Yes	.	MIL	NO	No	PBU	No
	RESPIRATORY DISORDER	COMMON COLD	+	Respiratory System	10	10 (-102)	02APR01	7 days	Yes	.	MOD	NO	No	PBU	No
	RASH	RASH ON ARM	+	Skin and Appendages	10	39 (-73)	01MAY01	3 days	Yes	.	MIL	NO	Yes	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.020.24538 ie	CONJUNCTIVITIS	PINK EYE	+	Special Senses	10	13 (-99)	05APR01	10 days	Yes	.	MOD	NO	Yes	UNR	No
676.023.17877 ie	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	10	1 (-55)	02AUG00	4 days	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	1 (-55)	02AUG00	7 days	No	3	MIL	NO	No	PSR	No
	FECAL INCONTINENCE	INCREASE IN BLADDER AND BOWEL INCONTINENCE	+	Digestive System	10	1 (-55)	02AUG00	3 days	No	3	MIL	NO	No	PSR	No
	HOSTILITY	DISINHIBITED	+	Nervous System	10	7 (-49)	08AUG00	CON	Yes	.	MOD	STP	No	REL	No
	HOSTILITY	OPPOSITIONAL	+	Nervous System	20	18 (-38)	19AUG00	CON	Yes	.	MOD	DCR	No	REL	No
	MANIC REACTION	HYPOMANIA	+	Nervous System	20	14 (-42)	15AUG00	CON	Yes	.	SEV	DCR	No	REL	No
	NEUROSIS	IMPULSIVE	+	Nervous System	20	18 (-38)	19AUG00	15 days	Yes	.	MOD	DCR	No	REL	No
	PRURITUS	ITCHY BACK	+	Skin and Appendages	10	29 (-27)	30AUG00	CON	Yes	.	MIL	STP	No	PSR	No
	RASH	RASH	+	Skin and Appendages	20	10 (-46)	11AUG00	5 days	No	1	MIL	NO	No	UNR	No
	CONJUNCTIVITIS	CONJUNCTIVITIS	+	Special Senses	10	55 (-1)	25SEP00	1 day	Yes	.	MIL	NO	No	UNR	No
	ALBUMINURIA	PROTEIN IN URINE	+	Urogenital System	10	56 (0)	26SEP00	CON	Yes	.	MIL	NO	No	UNR	No
	URINARY INCONTINENCE	INCREASE IN BLADDER AND BOWEL INCONTINENCE	+	Urogenital System	10	1 (-55)	02AUG00	3 days	No	3	MIL	NO	No	PSR	No
676.101.24622 ie	ABDOMINAL PAIN	STOMACHACHE	+	Body as a Whole	10	1 (-118)	16JUN00	3 days	No	2	MIL	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.101.24622 ie	DECREASED APPETITE	DECREASED APPETITE	+	Digestive System	30	25 (-94)	10JUL00	2 days	Yes	.	MIL	NO	No	PBU	No
	INSOMNIA	INITIAL INSOMNIA	+	Nervous System	10	1 (-118)	16JUN00	7 days	No	3	MIL	NO	No	PSR	No
676.202.24785 ie	TRAUMA	CONCUSSION DUE TO FALL FROM BIKE. SYMPTOMS: HEADACHE , NAUSEA, VOMITING. HOSPITALISED FOR TWO DAYS = SAE	^	Body as a Whole	.	-4 (-116)	07MAR00	3 days	Yes	.	SEV		Yes		Yes
	TRAUMA	LACERATIONS DUE TO FALL FROM BIKE: UPPER LEFT LEG AND CHIN	^	Body as a Whole	.	-4 (-116)	07MAR00	37 days	Yes	.	MOD		Yes		Yes
	INFECTION	LEFT LEG LACERATION FROM PREVIOUS BICYCLE ACCIDENT HAS BECOME SEPTIC	+	Body as a Whole	20	20 (-92)	31MAR00	13 days	Yes	.	SEV	NO	Yes	UNR	No
	INFECTION	FLU	+	Body as a Whole	20	32 (-80)	12APR00	4 days	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.202.24785 ie	TRAUMA	LEFT LEG LACERATION FROM PREVIOUS BICYCLE ACCIDENT HAS BECOME SEPTIC		Body as a Whole	20	20 (-92)	31MAR00	13 days	Yes	.	SEV	NO	Yes	UNR	No
	OTITIS MEDIA	OTITIS MEDIA	+	Special Senses	20	76 (-36)	26MAY00	3 days	Yes	.	MIL	NO	Yes	UNR	No
676.202.24788 ie	INSOMNIA	INSOMNIA	+	Nervous System	10	2 (-111)	02JUL00	4 days	Yes	.	MIL	NO	No	PSR	No
	LACK OF EMOTION	SOCIAL WITHDRAWAL	+	Nervous System	20	65 (-48)	03SEP00	16 days	Yes	.	MOD	NO	No	UNR	No
	URINARY INCONTINENCE	BED WETTING	+	Urogenital System	20	65 (-48)	03SEP00	CON	Yes	.	MOD	NO	No	UNR	No
676.202.24790 i	HEADACHE	HEADACHES	+	Body as a Whole	10	2 (-100)	28AUG00	3 days	Yes	.	MIL	NO	Yes	PSR	No
	INFECTION	FLU	+	Body as a Whole	10	9 (-93)	04SEP00	5 days	Yes	.	MIL	NO	Yes	UNR	No
676.203.24814 ie	INFECTION	FLU	+	Body as a Whole	10	19 (-51)	28JUN00	12 days	Yes	.	MIL	NO	Yes	UNR	No
676.204.24841 i	HEADACHE	HEADACHE	+	Body as a Whole	10	1 (-15)	31MAY00	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	6 (-10)	05JUN00	1 day	Yes	.	MIL	NO	No	PSR	No
	INFECTION	SEPTIC LEFT BIG TOE NAIL	+	Body as a Whole	10	16 (0)	15JUN00	6 days	Yes	.	MIL	NO	No	UNR	No
	TRAUMA	LACERATION TO LEFT PARIETAL AREA OF HEAD	+	Body as a Whole	10	9 (-7)	08JUN00	1 day	Yes	.	MIL	NO	No	UNR	No
	DYSPEPSIA	HEARTBURN	+	Digestive System	10	1 (-15)	31MAY00	3 days	No	3	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.206.24878 ie	HEADACHE	HEADACHE	+	Body as a Whole	10	26 (-106)	20SEP00	1 day	No	1	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	50 (-82)	14OCT00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	INSOMNIA	INSOMNIA	+	Nervous System	10	6 (-126)	31AUG00	3 days	Yes	.	MIL	NO	No	PSR	No
676.207.24898 ie	HEADACHE	HEADACHE	+	Body as a Whole	10	7 (-103)	14JUN00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	DECREASED APPETITE	LOSS OF APPETITE	+	Digestive System	20	8 (-102)	15JUN00	24 days	Yes	.	MIL	NO	No	PSR	No
	NERVOUSNESS	IRRITABILITY	+	Nervous System	40	58 (-52)	04AUG00	15 days	Yes	.	MOD	DCR	No	PSR	No
	NERVOUSNESS	RESTLESSNESS	+	Nervous System	40	58 (-52)	04AUG00	15 days	Yes	.	MOD	DCR	No	PSR	No
	RHINITIS	RHINITIS	+	Respiratory System	10	7 (-103)	14JUN00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	EAR PAIN	EARACHE	+	Special Senses	10	7 (-103)	14JUN00	1 day	Yes	.	MIL	NO	Yes	UNR	No
676.207.24909 ie	HEADACHE	HEADACHE	+	Body as a Whole	10	2 (-65)	22MAR01	1 day	No	1	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	23 (-44)	12APR01	1 day	No	1	MIL	NO	Yes	PSR	No
	FECAL INCONTINENCE	SOILING OF PANTS	+	Digestive System	40	29 (-38)	18APR01	36 days	Yes	.	MIL	NO	No	UNR	No
	COUGH INCREASED	COUGHING	+	Respiratory System	30	21 (-46)	10APR01	14 days	Yes	.	MIL	NO	Yes	UNR	No
	URINARY INCONTINENCE	NOCTURNAL BED WETTING	+	Urogenital System	40	29 (-38)	18APR01	20 days	Yes	.	MIL	NO	No	UNR	No
	URINARY INCONTINENCE	NOCTURNAL BED WETTING	+	Urogenital System	40	62 (-5)	21MAY01	CON	Yes	.	MOD	NO	No	UNR	No
676.301.25038 ie	HEADACHE	HEADACHE	+	Body as a Whole	10	3 (-109)	09SEP00	1 day	Yes	.	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.301.25038 ie	VOMITING	VOMITING	+	Digestive System	10	3 (-109)	09SEP00	1 day	No	1	MOD	NO	No	PSR	No
	NERVOUSNESS	FIDGETING	+	Nervous System	30	35 (-77)	11OCT00	CON	Yes	.	MIL	NO	No	PSR	No
	URINARY INCONTINENCE	NOCTURNAL ENURESIS	+	Urogenital System	30	44 (-68)	20OCT00	27 days	No	8	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.001.24003 ie	GASTRITIS	GASTRITIS	+	Digestive System	20	118 (-1)	12DEC00	2 days	Yes	.	SEV	NO	Yes	UNR	No
	INSOMNIA	DIFFICULTY FALLING ASLEEP (90 MINUTES INSTEAD OF 20 MINUTES)	+	Nervous System	10	2 (-117)	18AUG00	5 days	Yes	.	MIL	NO	No	PSR	No
	NERVOUSNESS	FEELS JITTERY	+	Nervous System	10	7 (-112)	23AUG00	6 days	No	30	MIL	NO	No	PSR	No
	RESPIRATORY DISORDER	UPPER RESPIRATORY INFECTION STUFFY NOSE SNEEZING COUGH	+	Respiratory System	20	79 (-40)	03NOV00	CON	Yes	.	MIL	NO	Yes	UNR	No
676.002.24032 ie	HEADACHE	HEADACHE	+	Body as a Whole	50	83 (-30)	17MAY00	1 day	Yes	.	MIL	NO	No	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	50	84 (-29)	18MAY00	1 day	Yes	.	MIL	NO	No	PBU	No
	NAUSEA	NAUSEA	+	Digestive System	50	81 (-32)	15MAY00	5 days	Yes	.	MIL	NO	No	PBU	No
	INSOMNIA	INTERMITTENT INITIAL INSOMNIA	+	Nervous System	20	9 (-104)	04MAR00	6 days	Yes	.	MIL	NO	No	PSR	No
	SINUSITIS	SINUS INFECTION	+	Respiratory System	40	24 (-89)	19MAR00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	SINUSITIS	SINUS DRAINAGE	+	Respiratory System	50	81 (-32)	15MAY00	7 days	Yes	.	MIL	NO	Yes	UNR	No
	CONTACT DERMATITIS	POISON IVY	+	Skin and Appendages	50	88 (-25)	22MAY00	18 days	Yes	.	MOD	NO	Yes	UNR	No
676.002.24038 ie	BACK PAIN	BACK PAIN	+	Body as a Whole	50	73 (-40)	18JAN01	2 days	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.002.24038 ie	FEVER	INCREASED TEMPERATURE	+	Body as a Whole	50	47 (-66)	23DEC00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	SOMNOLENCE	INCREASED SLEEPINESS	+	Nervous System	40	30 (-83)	06DEC00	27 days	Yes	.	MIL	NO	No	PBU	No
	RESPIRATORY DISORDER	URI	+	Respiratory System	50	46 (-67)	22DEC00	8 days	Yes	.	MOD	NO	Yes	UNR	No
676.002.24042 ie	ASTHENIA	INCREASED TIREDNESS	+	Body as a Whole	10	3 (-108)	25FEB01	95 days	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	INTERMITTENT HEADACHES	+	Body as a Whole	50	40 (-71)	03APR01	2 days	Yes	.	MIL	NO	Yes	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	50	107 (-4)	09JUN01	1 day	Yes	.	MIL	NO	Yes	PBU	No
	DECREASED APPETITE	DECREASED APPETITE	+	Digestive System	10	3 (-108)	25FEB01	75 days	Yes	.	MIL	NO	No	PSR	No
	DRY MOUTH	DRY MOUTH	+	Digestive System	40	23 (-88)	17MAR01	9 days	Yes	.	MIL	NO	No	PSR	No
676.002.24045 i	HEADACHE	HEADACHE	^	Body as a Whole	.	-3 (-85)	20MAY01	1 day	Yes	.	MOD		Yes		No
	HEADACHE	HEADACHE		Body as a Whole	50	60 (-22)	22JUL01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	RESPIRATORY DISORDER	URI	+	Respiratory System	20	11 (-71)	03JUN01	6 days	Yes	.	MIL	NO	No	UNR	No
	RESPIRATORY DISORDER	URI	+	Respiratory System	50	79 (-3)	10AUG01	CON	Yes	.	MOD	NO	Yes	UNR	No
676.003.24066 ie	INSOMNIA	INSOMNIA	+	Nervous System	20	67 (-56)	13NOV00	13 days	Yes	.	MIL	DCR	No	PSR	No
676.003.24070 ie	HEADACHE	HEADACHE	^	Body as a Whole	.	-5 (-123)	22DEC00	5 days	No	3	MOD		Yes		No
	HEADACHE	HEADACHE		Body as a Whole	10	7 (-111)	03JAN01	8 days	Yes	.	MOD	NO	Yes	PBU	No
	RESPIRATORY DISORDER	URI	+	Respiratory System	50	50 (-68)	15FEB01	4 days	Yes	.	MOD	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.003.24075 ie	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	30	104 (-7)	28AUG01	3 days	Yes	.	MOD	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	30	108 (-3)	01SEP01	1 day	No	1	MIL	NO	Yes	PSR	No
	RESPIRATORY DISORDER	URI	+	Respiratory System	10	7 (-104)	23MAY01	9 days	Yes	.	MIL	NO	Yes	UNR	No
676.004.24085 i	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	20	25 (-87)	26FEB00	1 day	Yes	.	MIL	NO	No	PSR	No
	ASTHENIA	FATIGUE	+	Body as a Whole	20	21 (-91)	22FEB00	8 days	Yes	.	MIL	NO	No	PSR	No
	FLU SYNDROME	FLU LIKE SYMPTOMS	+	Body as a Whole	10	4 (-108)	05FEB00	2 days	Yes	.	MOD	NO	Yes	PBU	No
	TRAUMA	HEAD LACERATION	+	Body as a Whole	20	53 (-59)	25MAR00	18 days	Yes	.	MOD	NO	Yes	UNR	No
	TRAUMA	BROKEN RIGHT THUMB	+	Body as a Whole	20	68 (-44)	09APR00	24 days	Yes	.	MOD	NO	Yes	UNR	No
	STOMATITIS	MOUTH PAIN	+	Digestive System	20	22 (-90)	23FEB00	1 day	Yes	.	MIL	NO	Yes	UNR	No
676.005.24114 ie	INFECTION	FLU SYMPTOMS	+	Body as a Whole	20	12 (-102)	27FEB00	2 days	Yes	.	MOD	NO	No	UNR	No
676.005.24122 ie	ASTHENIA	FATIGUE	+	Body as a Whole	50	33 (-37)	10OCT00	23 days	Yes	.	MOD	DCR	No	PSR	No
	INFECTION	FLU SYMPTOMS	+	Body as a Whole	40	49 (-21)	26OCT00	5 days	Yes	.	MIL	NO	No	UNR	No
	NERVOUSNESS	INCREASED IRRITABILITY	+	Nervous System	40	22 (-48)	29SEP00	9 days	Yes	.	MIL	NO	No	PSR	No
676.005.24124 ie	ABNORMAL DREAMS	INCREASED DREAMING	+	Nervous System	40	47 (-3)	08JAN01	4 days	Yes	.	MIL	NO	No	PSR	No
	NERVOUSNESS	INCREASED IRRITABILITY	+	Nervous System	50	30 (-20)	22DEC00	16 days	Yes	.	MOD	DCR	No	PSR	No
	NERVOUSNESS	INCREASED IRRITABILITY	+	Nervous System	40	46 (-4)	07JAN01	5 days	Yes	.	MIL	DCR	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.005.24126 ie	HYPERKALEMIA	ELEVATED POTASSIUM	+	Metabolic and Nutritional Disorders	30	119 (0)	10JUL01	4 days	Yes	.	MIL	NO	No	UNR	No
	AGITATION	AGITATION	+	Nervous System	40	49 (-70)	01MAY01	12 days	Yes	.	MOD	DCR	No	PSR	No
676.006.24142 ie	ALLERGIC REACTION	HAY FEVER	^	Body as a Whole	.	-1 (-114)	22MAY00	2 days	No	4	MIL		No		No
	NERVOUSNESS	NERVOUSNESS	^	Nervous System	.	-4 (-117)	19MAY00	7 days	Yes	.	MOD		No		No
	FEVER	INCREASED BODY TEMPERATURE	+	Body as a Whole	30	54 (-59)	16JUL00	CON	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	4 (-109)	27MAY00	1 day	No	1	MOD	NO	Yes	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	20	34 (-79)	26JUN00	4 days	Yes	.	MOD	NO	Yes	PBU	No
	INFECTION	FLU	+	Body as a Whole	20	20 (-93)	12JUN00	11 days	Yes	.	MOD	NO	Yes	PBU	No
	INFECTION	FLU	+	Body as a Whole	20	42 (-71)	04JUL00	4 days	Yes	.	SEV	NO	Yes	UNR	No
	TRAUMA	SORE NECK (CAR ACCIDENT)	+	Body as a Whole	20	31 (-82)	23JUN00	3 days	Yes	.	MOD	NO	No	UNR	No
	INCREASED APPETITE	INCREASED APPETITE	+	Digestive System	20	38 (-75)	30JUN00	CON	Yes	.	MOD	NO	No	REL	No
	PURPURA	BRUISING (EXTREMITIES)	+	Hemic and Lymphatic System	20	20 (-93)	12JUN00	7 days	Yes	.	MOD	NO	No	PSR	No
	INSOMNIA	INSOMNIA	+	Nervous System	20	9 (-104)	01JUN00	2 days	No	3	MOD	NO	No	PSR	No
	INSOMNIA	INSOMNIA	+	Nervous System	20	15 (-98)	07JUN00	12 days	No	10	MOD	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.006.24142 ie	LIBIDO DECREASED	DECREASED LIBIDO	+	Nervous System	20	20 (-93)	12JUN00	112 days	Yes	.	MOD	NO	No	REL	No
	SWEATING	NIGHT SWEATS	+	Skin and Appendages	30	54 (-59)	16JUL00	65 days	No	80	MOD	NO	No	PSR	No
676.006.24143 ie	ABDOMINAL PAIN	STOMACH CRAMPS	+	Body as a Whole	50	111 (-2)	18SEP00	5 days	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	20	21 (-92)	20JUN00	1 day	No	1	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	30	23 (-90)	22JUN00	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	53 (-60)	22JUL00	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	60 (-53)	29JUL00	1 day	Yes	.	MOD	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	50	79 (-34)	17AUG00	1 day	Yes	.	MOD	NO	Yes	PSR	No
	QT INTERVAL PROLONGED	PROLONGED QTC	+	Cardiovascular System	50	113 (0)	20SEP00	6 days	Yes	.	MIL	DCR	No	PSR	No
	DECREASED APPETITE	DECREASED APPETITE	+	Digestive System	40	46 (-67)	15JUL00	28 days	Yes	.	MIL	NO	No	PSR	No
	DECREASED APPETITE	DECREASE IN APPETITE	+	Digestive System	50	73 (-40)	11AUG00	61 days	Yes	.	MOD	NO	No	PSR	No
	DRY MOUTH	DRY MOUTH	+	Digestive System	20	8 (-105)	07JUN00	15 days	No	20	MIL	NO	No	PSR	No
	PURPURA	BRUISED FOOT	+	Hemic and Lymphatic System	40	62 (-51)	31JUL00	33 days	Yes	.	MOD	NO	No	UNR	No
	CONTACT DERMATITIS	POISON OAK RASH	+	Skin and Appendages	40	35 (-78)	04JUL00	15 days	Yes	.	SEV	NO	Yes	UNR	No
	RASH	RASH (EXTREMITIES)	+	Skin and Appendages	20	8 (-105)	07JUN00	8 days	No	10	MIL	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous, if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.006.24145 ie	HEADACHE	HEADACHE	+	Body as a Whole	10	6 (-106)	29AUG00	2 days	Yes	.	MIL	NO	No	PSR	No
	DECREASED APPETITE	DECREASE IN APPETITE	+	Digestive System	40	22 (-90)	14SEP00	27 days	Yes	.	MOD	NO	No	PSR	No
	DYSPEPSIA	INDIGESTION	+	Digestive System	30	18 (-94)	10SEP00	1 day	Yes	.	MOD	NO	Yes	UNR	No
	HOSTILITY	OPPOSITIONAL DEFIANT BEHAVIOR	+	Nervous System	50	70 (-42)	01NOV00	1 day	Yes	.	MIL	DCR	No	PBU	No
	SOMNOLENCE	DAYTIME DROWSINESS	+	Nervous System	40	22 (-90)	14SEP00	9 days	Yes	.	MIL	NO	No	PSR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	40	41 (-71)	03OCT00	2 days	Yes	.	MOD	NO	Yes	UNR	No
676.007.24170 ie	FLU SYNDROME	FLU LIKE SYMPTOMS	+	Body as a Whole	30	24 (-89)	23DEC99	10 days	Yes	.	MOD	NO	Yes	UNR	No
	INFECTION	STOMACH VIRUS	+	Body as a Whole	30	16 (-97)	15DEC99	2 days	Yes	.	MOD	NO	Yes	UNR	No
	INFECTION	STREP THROAT INFECTION WITH SCARLET FEVER	+	Body as a Whole	30	50 (-63)	18JAN00	10 days	Yes	.	MOD	NO	Yes	UNR	No
	INSOMNIA	INITIAL INSOMNIA	+	Nervous System	10	1 (-112)	30NOV99	12 days	No	11	MIL	NO	No	PSR	No
	SOMNOLENCE	DAYTIME SEDATION	+	Nervous System	10	1 (-112)	30NOV99	43 days	Yes	.	MIL	NO	No	REL	No
	ASTHMA	ASTHMA	+	Respiratory System	40	109 (-4)	17MAR00	CON	Yes	.	MOD	NO	Yes	UNR	No
	RESPIRATORY DISORDER	DEVIATED SEPTUM	+	Respiratory System	40	109 (-4)	17MAR00	CON	Yes	.	MIL	NO	No	UNR	No
	SINUSITIS	SINUSITIS	+	Respiratory System	40	70 (-43)	07FEB00	39 days	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.007.24170 ie	YAWN	YAWNING	+	Respiratory System	10	1 (-112)	30NOV99	43 days	Yes	.	MIL	NO	No	PSR	No
	CONJUNCTIVITIS	PINKEYE	+	Special Senses	20	11 (-102)	10DEC99	4 days	Yes	.	MIL	NO	Yes	UNR	No
676.007.24172 ie	FLU SYNDROME	FLU LIKE SYMPTOMS	+	Body as a Whole	20	15 (-100)	22DEC99	5 days	Yes	.	MOD	NO	Yes	UNR	No
	FLU SYNDROME	FLU LIKE SYMPTOMS	+	Body as a Whole	20	43 (-72)	19JAN00	3 days	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	INTERMITTENT HEADACHES	+	Body as a Whole	20	15 (-100)	22DEC99	11 days	Yes	.	MOD	NO	Yes	PSR	No
	SOMNOLENCE	HYPERSOMNIA	+	Nervous System	20	25 (-90)	01JAN00	101 days	Yes	.	MIL	NO	No	PSR	No
	RESPIRATORY DISORDER	HEAD COLD	+	Respiratory System	20	52 (-63)	28JAN00	7 days	Yes	.	MIL	NO	Yes	UNR	No
676.007.24188 ie	FEVER	FEVER	+	Body as a Whole	20	24 (-87)	11DEC00	5 days	Yes	.	MOD	NO	Yes	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	10	1 (-110)	18NOV00	3 days	Yes	.	MOD	NO	No	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	20	24 (-87)	11DEC00	5 days	Yes	.	MIL	NO	No	PSR	No
	SOMNOLENCE	SLEEPINESS	+	Nervous System	10	1 (-110)	18NOV00	1 day	Yes	.	MIL	NO	No	PSR	No
	RESPIRATORY DISORDER	UPPER RESPIRATORY INFECTION	+	Respiratory System	40	109 (-2)	06MAR01	5 days	Yes	.	MIL	NO	Yes	UNR	No
676.007.24192 ie	DIARRHEA	DIARRHEA	+	Digestive System	50	65 (-43)	29JUL01	13 days	No	.	MIL	NO	No	PSR	No
	DYSPEPSIA	UPSET STOMACH	+	Digestive System	50	65 (-43)	29JUL01	13 days	Yes	.	MOD	NO	Yes	PSR	No
	GASTROINTESTINAL DISORDER	REFLUX	+	Digestive System	50	65 (-43)	29JUL01	35 days	Yes	.	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.009.24227 ie	SOMNOLENCE	SLIGHT DROWSINESS	+	Nervous System	30	77 (-46)	22JUN00	13 days	No	.	MIL	NO	No	PSR	No
	RHINITIS	NASAL CONGESTION	+	Respiratory System	20	39 (-84)	15MAY00	4 days	Yes	.	MIL	NO	No	UNR	No
676.009.24232 ie	NAUSEA	NAUSEA	+	Digestive System	10	1 (-115)	19JAN01	1 day	Yes	.	MIL	NO	No	PSR	No
	HYPERKINESIA	HYPERACTIVE BEHAVIOR	+	Nervous System	20	8 (-108)	26JAN01	8 days	No	.	MOD	NO	No	PSR	No
	RHINITIS	NASAL CONGESTION	+	Respiratory System	20	108 (-8)	06MAY01	7 days	Yes	.	MIL	NO	Yes	UNR	No
676.011.24282 ie	HEADACHE	HEADACHE	+	Body as a Whole	30	33 (-8)	10APR00	CON	Yes	.	MIL	NO	No	PSR	No
	DECREASED APPETITE	DECREASED APPETITE	+	Digestive System	30	33 (-8)	10APR00	CON	Yes	.	MIL	NO	No	PSR	No
	DRY MOUTH	DRY MOUTH	+	Digestive System	30	33 (-8)	10APR00	CON	Yes	.	MIL	NO	No	PSR	No
	DYSPEPSIA	UPSET STOMACH	+	Digestive System	30	33 (-8)	10APR00	CON	Yes	.	MIL	NO	No	PSR	No
	INSOMNIA	INITIAL INSOMNIA	+	Nervous System	30	33 (-8)	10APR00	CON	Yes	.	MIL	NO	No	PSR	No
	MANIC REACTION	MANIC EPISODE	+	Nervous System	30	41 (0)	18APR00	CON	Yes	.	SEV	STP	No	REL	No
	NERVOUSNESS	RESTLESSNESS	+	Nervous System	10	10 (-31)	18MAR00	CON	Yes	.	MIL	NO	No	PSR	No
676.011.24283 ie	ASTHENIA	TIRED DURING THE DAY	+	Body as a Whole	10	1 (-110)	25JUL00	8 days	Yes	.	MIL	NO	No	PSR	No
676.012.24309 ie	MYALGIA	SORE CALF MUSCLE LEFT LEG	^	Musculoskeletal System	.	0 (-46)	21JAN00	1 day	Yes	.	MIL		No		No
	DIZZINESS	DIZZINESS WITH EXERCISE	+	Nervous System	10	6 (-40)	27JAN00	2 days	No	1	MIL	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.012.24311 ie	HEADACHE	HEADACHE	+	Body as a Whole	10	2 (-111)	25FEB00	3 days	Yes	.	MIL	NO	No	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	30	58 (-55)	21APR00	1 day	No	1	MIL	NO	Yes	UNR	No
	INFECTION	VIRUS WITH SINUS PROBLEMS	+	Body as a Whole	30	99 (-14)	01JUN00	8 days	No	1	MIL	NO	No	UNR	No
	MONILIASIS	THRUSH	+	Body as a Whole	10	9 (-104)	03MAR00	20 days	Yes	.	MIL	NO	Yes	UNR	No
	PAIN	THORACIC RIB PAIN	+	Body as a Whole	30	71 (-42)	04MAY00	CON	Yes	.	MIL	NO	No	UNR	No
	RHEUMATOID ARTHRITIS	EXACERBATION OF RHEUMATOID ARTHRITIS	+	Body as a Whole	20	28 (-85)	22MAR00	6 days	Yes	.	MOD	NO	Yes	UNR	No
	DECREASED APPETITE	DECREASED APPETITE	+	Digestive System	10	2 (-111)	25FEB00	57 days	Yes	.	MIL	NO	No	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	10	2 (-111)	25FEB00	18 days	Yes	.	MOD	NO	No	PSR	No
	VOMITING	VOMITING	+	Digestive System	10	14 (-99)	08MAR00	1 day	No	2	MIL	NO	No	UNR	No
	ABNORMAL DREAMS	NIGHTMARES	+	Nervous System	20	41 (-72)	04APR00	1 day	No	1	MIL	NO	No	UNR	No
	INSOMNIA	INSOMNIA	+	Nervous System	10	7 (-106)	01MAR00	52 days	Yes	.	MOD	NO	No	PSR	No
	MYOCLONUS	HABIT TIC	+	Nervous System	30	57 (-56)	20APR00	CON	Yes	.	MOD	NO	No	PSR	No
	SOMNOLENCE	LETHARGY	+	Nervous System	10	2 (-111)	25FEB00	CON	Yes	.	MOD	NO	No	PSR	No
	RESPIRATORY DISORDER	UPPER RESPIRATORY INFECTION	+	Respiratory System	20	23 (-90)	17MAR00	6 days	Yes	.	MIL	NO	No	UNR	No
	SINUSITIS	VIRUS WITH SINUS PROBLEMS	+	Respiratory System	30	99 (-14)	01JUN00	8 days	No	1	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.012.24311 ie	EAR PAIN	BILATERAL EARACHES	+	Special Senses	10	2 (-111)	25FEB00	3 days	Yes	.	MIL	NO	No	UNR	No
676.013.24351 ie	HEADACHE	HEADACHE	+	Body as a Whole	10	7 (-105)	16FEB01	1 day	Yes	.	MIL	NO	No	UNR	No
	VOMITING	VOMITING	+	Digestive System	40	102 (-10)	22MAY01	1 day	Yes	.	MIL	NO	No	PSR	No
	SOMNOLENCE	SOMNOLENCE	+	Nervous System	20	8 (-104)	17FEB01	135 days	Yes	.	MOD	NO	No	PSR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	10	6 (-106)	15FEB01	4 days	Yes	.	MIL	NO	No	UNR	No
	PHARYNGITIS	SWOLLEN TONSILS	+	Respiratory System	10	6 (-106)	15FEB01	4 days	Yes	.	MIL	NO	No	UNR	No
	RESPIRATORY DISORDER	COLD SYMPTOMS	+	Respiratory System	10	7 (-105)	16FEB01	18 days	Yes	.	MOD	NO	Yes	UNR	No
	RESPIRATORY DISORDER	COLD SYMPTOMS	+	Respiratory System	40	102 (-10)	22MAY01	9 days	Yes	.	MOD	NO	Yes	UNR	No
676.013.24352 ie	HEADACHE	HEADACHE	+	Body as a Whole	40	26 (-87)	24APR01	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	29 (-84)	27APR01	1 day	Yes	.	MIL	NO	No	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	50	69 (-44)	06JUN01	1 day	Yes	.	MIL	NO	Yes	PBU	No
	WEIGHT GAIN	WEIGHT GAIN	+	Metabolic and Nutritional Disorders	50	113 (0)	20JUL01	CON	Yes	.	MIL	NO	No	PSR	No
	SOMNOLENCE	DROWSINESS	+	Nervous System	10	2 (-111)	31MAR01	3 days	Yes	.	MIL	NO	No	PSR	No
676.014.24368 ie	HEADACHE	HEADACHE	+	Body as a Whole	10	1 (-109)	11FEB00	1 day	No	1	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	13 (-97)	23FEB00	1 day	No	1	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.014.24368 ie	HEADACHE	HEADACHE	+	Body as a Whole	20	51 (-59)	01APR00	2 days	Yes	.	MOD	NO	Yes	PSR	No
	VOMITING	VOMITING	+	Digestive System	10	1 (-109)	11FEB00	1 day	No	1	MIL	NO	No	PSR	No
	MYDRIASIS	MYDRIASIS	+	Special Senses	10	6 (-104)	16FEB00	3 days	Yes	.	MIL	NO	No	PSR	No
676.014.24371 i	RESPIRATORY DISORDER	HEAD COLD	^	Respiratory System	.	-5 (-33)	18FEB00	5 days	No	.	MIL		Yes		No
	SOMNOLENCE	DROWSINESS	+	Nervous System	20	10 (-18)	04MAR00	21 days	Yes	.	MIL	NO	No	PSR	No
	SINUSITIS	SINUS INFECTION	+	Respiratory System	20	16 (-12)	10MAR00	CON	Yes	.	MIL	NO	Yes	PBU	No
676.014.24374 ie	ABDOMINAL PAIN	STOMACH PAIN	+	Body as a Whole	10	2 (-110)	08JUN00	2 days	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	20	9 (-103)	15JUN00	1 day	No	1	MIL	NO	Yes	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	20	9 (-103)	15JUN00	1 day	No	1	MOD	NO	No	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	20	25 (-87)	01JUL00	4 days	Yes	.	MIL	NO	No	PSR	No
	DIZZINESS	MOTION SICKNESS	+	Nervous System	20	25 (-87)	01JUL00	1 day	Yes	.	MIL	NO	No	PSR	No
	INSOMNIA	INSOMNIA	+	Nervous System	20	25 (-87)	01JUL00	5 days	Yes	.	MOD	NO	No	PSR	No
	NERVOUSNESS	IRRITABLE	+	Nervous System	20	67 (-45)	12AUG00	9 days	Yes	.	MOD	NO	No	PSR	No
	SOMNOLENCE	DROWSINESS	+	Nervous System	20	9 (-103)	15JUN00	1 day	No	1	MIL	NO	No	PSR	No
676.014.24376 i	MYALGIA	MUSCLE DISCOMFORT	+	Musculoskeletal System	10	12 (-22)	10SEP00	3 days	Yes	.	MOD	NO	Yes	UNR	No
	ABNORMAL DREAMS	MORBID THOUGHTS	+	Nervous System	40	30 (-4)	28SEP00	CON	Yes	.	SEV	STP	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous, if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.014.24376 i	AGITATION	PANIC ATTACK	+	Nervous System	20	16 (-18)	14SEP00	1 day	No	1	MOD	INC	No	PBU	No
	AGITATION	PANIC ATTACK WORSENING	+	Nervous System	40	30 (-4)	28SEP00	1 day	No	2	SEV	STP	No	PSR	No
	EMOTIONAL LABILITY	SUICIDAL THOUGHTS	+	Nervous System	40	30 (-4)	28SEP00	CON	Yes	.	MOD	STP	No	PBU	No
676.014.24380 ie	HEADACHE	HEADACHE	+	Body as a Whole	10	7 (-76)	30MAY01	1 day	No	1	MIL	NO	Yes	UNR	No
676.015.24394 ie	HEADACHE	HEADACHE	+	Body as a Whole	20	20 (-100)	20FEB00	2 days	No	2	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	46 (-74)	17MAR00	1 day	No	1	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	49 (-71)	20MAR00	1 day	No	1	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	53 (-67)	24MAR00	1 day	No	1	MIL	NO	Yes	UNR	No
	RHINITIS	SEASONAL RHINITIS	+	Respiratory System	20	20 (-100)	20FEB00	30 days	Yes	.	MIL	NO	No	UNR	No
676.015.24399 ie	INFECTION	PARENT DIAGNOSED FLU	+	Body as a Whole	50	42 (-72)	27JUN00	4 days	Yes	.	MIL	NO	Yes	PBU	No
	MYALGIA	LEG CRAMPS FROM EXERCISE	+	Musculoskeletal System	50	113 (-1)	06SEP00	2 days	Yes	.	MIL	NO	Yes	PBU	No
	SINUSITIS	SINUSES/ALLERGIES	+	Respiratory System	10	8 (-106)	24MAY00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	SINUSITIS	SINUSES-ALLERGIES	+	Respiratory System	50	111 (-3)	04SEP00	2 days	Yes	.	MIL	NO	Yes	PBU	No
676.015.24406 i	VOMITING	NAUSEA/VOMITING	+	Digestive System	10	1 (0)	28AUG00	1 day	No	1	MIL	STP	Yes	PSR	No
676.015.24407 ie	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	20	12 (-107)	01OCT00	1 day	Yes	.	MIL	NO	No	PSR	No
	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	20	13 (-106)	02OCT00	1 day	Yes	.	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.015.24407 ie	HYPERKINESIA	HYPERACTIVE-	+	Nervous System	50	73 (-46)	01DEC00	83 days	Yes	.	MIL	DCR	No	REL	No
676.015.24414 i	ALLERGIC REACTION	NASAL ALLERGIES	+	Body as a Whole	50	110 (-7)	08JUL01	8 days	Yes	.	MIL	NO	Yes	PBU	No
	INFECTION	STOMACH FLU	+	Body as a Whole	50	41 (-76)	30APR01	3 days	Yes	.	MIL	NO	No	PBU	No
	ARTHRALGIA	JOINT PAIN	+	Musculoskeletal System	40	29 (-88)	18APR01	1 day	Yes	.	MIL	NO	Yes	PBU	No
	EPISTAXIS	BLOODY NOSE	+	Respiratory System	30	20 (-97)	09APR01	1 day	Yes	.	MIL	NO	No	PBU	No
	RHINITIS	RHINITIS	+	Respiratory System	10	4 (-113)	24MAR01	CON	Yes	.	MIL	NO	Yes	PBU	No
676.019.24508 ie	HEADACHE	HEADACHE	^	Body as a Whole	.	-2 (-121)	13MAY00	1 day	Yes	.	MIL		Yes		No
	VASODILATATION	VOMITED SECONDARY TO OVERHEATING	+	Cardiovascular System	40	54 (-65)	08JUL00	1 day	Yes	.	MIL	NO	No	UNR	No
	VOMITING	VOMITED SECONDARY TO OVERHEATING	+	Digestive System	40	54 (-65)	08JUL00	1 day	Yes	.	MIL	NO	No	UNR	No
676.019.24509 i	HEADACHE	HEADACHE	+	Body as a Whole	10	1 (-125)	16JUN00	7 days	No	4	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	53 (-73)	07AUG00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	40	46 (-80)	31JUL00	1 day	Yes	.	MIL	NO	No	PSR	No
	INSOMNIA	INITIAL INSOMNIA 2-3 TIMES A WEEK	+	Nervous System	10	1 (-125)	16JUN00	119 days	No	.	MIL	NO	No	PSR	No
	SINUSITIS	SINUSITIS	+	Respiratory System	50	105 (-21)	28SEP00	5 days	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous, if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.019.24511 ie	HEADACHE	HEADACHE	+	Body as a Whole	10	3 (-105)	26JUN00	2 days	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	20	28 (-80)	21JUL00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	30	44 (-64)	06AUG00	1 day	Yes	.	MOD	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	66 (-42)	28AUG00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	MYALGIA	MUSCLE SORENESS	+	Musculoskeletal System	40	62 (-46)	24AUG00	7 days	Yes	.	MIL	DCR	Yes	PSR	No
676.019.24518 ie	FEVER	FEVER	+	Body as a Whole	30	78 (-36)	06FEB01	3 days	Yes	.	MIL	NO	Yes	UNR	No
	FEVER	LOW GRADE FEVER	+	Body as a Whole	30	113 (-1)	13MAR01	1 day	Yes	.	MIL	NO	No	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	3 (-111)	23NOV00	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	13 (-101)	03DEC00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	20	42 (-72)	01JAN01	1 day	Yes	.	MIL	NO	Yes	PSR	No
	DIARRHEA	INCREASED BOWEL MOVEMENT	+	Digestive System	20	25 (-89)	15DEC00	4 days	Yes	.	MIL	NO	Yes	PSR	No
	DIARRHEA	DIARRHEA	+	Digestive System	20	67 (-47)	26JAN01	3 days	Yes	.	MIL	NO	Yes	UNR	No
	VOMITING	VOMIT	+	Digestive System	30	113 (-1)	13MAR01	1 day	Yes	.	MIL	NO	No	UNR	No
	ARTHRALGIA	KNEE PAIN	+	Musculoskeletal System	30	109 (-5)	09MAR01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	RESPIRATORY DISORDER	HEAD COLD	+	Respiratory System	30	78 (-36)	06FEB01	10 days	Yes	.	MOD	NO	Yes	UNR	No
	RHINITIS	STUFFY NOSE	+	Respiratory System	10	3 (-111)	23NOV00	1 day	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.020.24534 ie	ALLERGIC REACTION	ALLERGIES	+	Body as a Whole	30	48 (-99)	01JUN00	2 days	No	1	MIL	NO	Yes	UNR	No
	STOMATITIS	PAIN FROM BRACES	+	Digestive System	40	68 (-79)	21JUN00	2 days	No	1	MIL	NO	Yes	UNR	No
	ARTHRALGIA	PAIN IN ANKLES	+	Musculoskeletal System	40	94 (-53)	17JUL00	1 day	Yes	.	MIL	NO	Yes	PBU	No
676.020.24536 ie	BACK PAIN	BACK PAIN	+	Body as a Whole	30	49 (-71)	30OCT00	68 days	Yes	.	MOD	NO	No	UNR	No
	LEUKOCYTOSIS	NEUTROPHILS, ABSOLUTE 8.90 AND SEGS 78.1(ABOVE RANGE)	+	Hemic and Lymphatic System	30	120 (0)	09JAN01	CON	Yes	.	MIL	NO	No	PBU	No
	LEUKOPENIA	LYMPHOCYTES 14.5 (BELOW RANGE)	+	Hemic and Lymphatic System	30	120 (0)	09JAN01	CON	Yes	.	MIL	NO	No	PBU	No
	RESPIRATORY DISORDER	COLD	+	Respiratory System	30	118 (-2)	07JAN01	3 days	No	3	MIL	NO	Yes	UNR	No
	RHINITIS	NASAL CONGESTION	+	Respiratory System	30	120 (0)	09JAN01	CON	Yes	.	MIL	NO	No	UNR	No
676.021.24565 ie	HEADACHE	HEADACHE	+	Body as a Whole	10	14 (-106)	02OCT00	2 days	No	1	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	30	82 (-38)	09DEC00	1 day	No	1	MIL	NO	No	PSR	No
	INFECTION	FLU	+	Body as a Whole	30	101 (-19)	28DEC00	11 days	No	11	MOD	NO	Yes	PBU	No
	DECREASED APPETITE	DECREASE IN APPETITE	+	Digestive System	20	23 (-97)	11OCT00	CON	Yes	.	MIL	NO	No	PSR	No
	SOMNOLENCE	LETHARGY	+	Nervous System	30	32 (-88)	20OCT00	35 days	No	.	MIL	NO	No	PSR	No
676.022.17841 ie	ASTHENIA	FATIGUE	+	Body as a Whole	20	13 (-20)	06JUN00	2 days	No	1	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.022.17841 ie	INSOMNIA	RESTLESS SLEEP (DECREASE SLEEP TO 5 HOURS/NIGHT)	+	Nervous System	30	26 (-7)	19JUN00	6 days	Yes	.	MOD	DCR	No	PSR	No
	MANIC REACTION	BEHAVIORAL ACTIVATION/HYPOMANIA	+	Nervous System	20	23 (-10)	16JUN00	11 days	Yes	.	SEV	STP	No	PSR	No
	TREMOR	BILATERAL HAND TREMOR	+	Nervous System	30	28 (-5)	21JUN00	CON	Yes	.	MOD	DCR	No	PSR	No
	OTITIS MEDIA	PROBABLE RIGHT EAR INFECTION	+	Special Senses	20	33 (0)	26JUN00	CON	Yes	.	MIL	NO	No	UNR	No
676.022.17845 ie	ASTHENIA	DROWSY/TIRED	+	Body as a Whole	10	11 (-100)	11SEP00	31 days	Yes	.	MIL	NO	No	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	1 (-110)	01SEP00	1 day	No	1	MIL	NO	No	PBU	No
	HEADACHE	FRONTAL HEADACHE	+	Body as a Whole	10	79 (-32)	18NOV00	1 day	Yes	.	MIL	NO	No	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	106 (-5)	15DEC00	1 day	Yes	.	MIL	NO	No	PBU	No
	AMNESIA	POOR CONCENTRATION MEMORY PROBLEMS	+	Nervous System	20	26 (-85)	26SEP00	81 days	Yes	.	MIL	DCR	No	PSR	No
	CONCENTRATION IMPAIRED	POOR CONCENTRATION MEMORY PROBLEMS	+	Nervous System	20	26 (-85)	26SEP00	81 days	Yes	.	MIL	DCR	No	PSR	No
	SOMNOLENCE	DROWSY/TIRED	+	Nervous System	10	11 (-100)	11SEP00	31 days	Yes	.	MIL	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.022.17849 ie	HEADACHE	HEADACHE	+	Body as a Whole	40	98 (-28)	07AUG01	1 day	No	1	MIL	NO	Yes	UNR	No
676.023.17879 i	COUGH INCREASED	SLIGHT COUGH	^	Respiratory System	.	-2 (-137)	11NOV00	CON	Yes	.	MIL		Yes		No
	ALLERGIC REACTION	SEASONAL ALLERGIES	+	Body as a Whole	20	129 (-6)	22MAR01	CON	Yes	.	MIL	NO	Yes	UNR	No
	ASTHENIA	MORE TIRED	+	Body as a Whole	10	3 (-132)	16NOV00	15 days	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	20	30 (-105)	13DEC00	1 day	No	1	MIL	NO	No	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	20	103 (-32)	24FEB01	5 days	Yes	.	MOD	NO	Yes	PSR	No
	INFECTION	STREP THROAT	+	Body as a Whole	20	30 (-105)	13DEC00	13 days	Yes	.	MOD	NO	Yes	UNR	No
	INFECTION	STREP THROAT	+	Body as a Whole	20	83 (-52)	04FEB01	6 days	Yes	.	MIL	NO	Yes	UNR	No
	DRY MOUTH	DRY MOUTH	+	Digestive System	20	15 (-120)	28NOV00	CON	Yes	.	MIL	NO	No	PSR	No
	NAUSEA	NAUSEA, VOMITING	+	Digestive System	20	49 (-86)	01JAN01	3 days	No	.	MOD	NO	No	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	20	61 (-74)	13JAN01	2 days	Yes	.	MIL	NO	No	UNR	No
	VOMITING	VOMITING	+	Digestive System	20	28 (-107)	11DEC00	3 days	No	3	MIL	NO	No	UNR	No
	VOMITING	NAUSEA, VOMITING	+	Digestive System	20	49 (-86)	01JAN01	3 days	No	.	MOD	NO	No	UNR	No
	THIRST	FEELS THIRSTY	+	Metabolic and Nutritional Disorders	20	15 (-120)	28NOV00	10 days	No	5	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.023.17879 i	HOSTILITY	AGGRESSIVE BEHAVIOR (SHOVED SCHOOLMATE)	+	Nervous System	20	87 (-48)	08FEB01	1 day	No	1	MOD	NO	No	PSR	No
	INSOMNIA	INSOMNIA	+	Nervous System	30	18 (-117)	01DEC00	CON	Yes	.	MOD	DCR	No	PBU	No
	PHARYNGITIS	THROAT IRRITATION	+	Respiratory System	20	129 (-6)	22MAR01	1 day	Yes	.	MIL	NO	No	UNR	No
	RASH	LEG RASH	+	Skin and Appendages	30	20 (-115)	03DEC00	CON	Yes	.	MIL	NO	No	PSR	No
	CONJUNCTIVITIS	CONJUNCTIVITIS	+	Special Senses	20	130 (-5)	23MAR01	4 days	Yes	.	MOD	NO	Yes	UNR	No
676.024.25150 ie	ASTHENIA	FATIGUE	+	Body as a Whole	20	11 (-30)	05MAR01	51 days	Yes	.	MOD	STP	No	PSR	No
676.024.25151 ie	HEADACHE	HEADACHE	+	Body as a Whole	20	11 (-88)	10MAR01	11 days	Yes	.	SEV	NO	No	PSR	No
676.100.24701 ie	RESPIRATORY DISORDER	COMMON COLD	^	Respiratory System	.	-7 (-121)	20JUN00	3 days	Yes	.	MIL		Yes		No
	CELLULITIS	BACTERIAL INFECTION (FACE ARMS AND TRUNK) CELLULITIS	+	Body as a Whole	50	78 (-36)	13SEP00	71 days	Yes	.	MOD	NO	Yes	UNR	No
	INFECTION	BACTERIAL INFECTION (FACE ARMS AND TRUNK) CELLULITIS	+	Body as a Whole	50	78 (-36)	13SEP00	71 days	Yes	.	MOD	NO	Yes	UNR	No
	TRAUMA	BURNED LEFT FORE FINGER	+	Body as a Whole	30	54 (-60)	20AUG00	8 days	Yes	.	MIL	NO	No	UNR	No
	DYSPEPSIA	HEARTBURN	+	Digestive System	30	54 (-60)	20AUG00	3 days	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.100.24703 ie	HEADACHE	HEADACHE	+	Body as a Whole	40	46 (-67)	19NOV00	2 days	Yes	.	MOD	NO	Yes	UNR	No
	DYSPEPSIA	HEARTBURN	+	Digestive System	20	24 (-89)	28OCT00	1 day	Yes	.	MOD	NO	Yes	UNR	No
	DYSPEPSIA	HEARTBURN	+	Digestive System	50	81 (-32)	24DEC00	1 day	Yes	.	MIL	NO	Yes	UNR	No
676.100.24705 ie	DYSPEPSIA	HEARTBURN	+	Digestive System	10	19 (-24)	04NOV00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	DEPRESSION	WORSENING DEPRESSION	+	Nervous System	20	43 (0)	28NOV00	CON	Yes	.	MOD	STP	Yes	PSR	No
	EMOTIONAL LABILITY	SELF INFLICTED SCRATCH ON RT. WRIST	+	Nervous System	20	38 (-5)	23NOV00	1 day	No	1	MIL	NO	No	PBU	No
	LACK OF EMOTION	LACK OF EMOTIONS	+	Nervous System	10	5 (-38)	21OCT00	CON	Yes	.	MIL	NO	No	PSR	No
676.100.24708 ie	TRAUMA	SLIPPED AND FELL(SLIGHT CUT TO EYEBROW AND EYEGLASSES BROKEN)	+	Body as a Whole	40	49 (-21)	10APR01	1 day	Yes	.	MOD	NO	Yes	UNR	No
	NEUROSIS	SUPERFICIAL CUTS TO THE ARMS(SELF INDUCED SCRATCHES TO GET PARENTS ATTENTION)	+	Nervous System	40	66 (-4)	27APR01	1 day	Yes	.	MOD	NO	No	PBU	No
676.100.24710 ie	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	30	33 (-85)	20MAY01	1 day	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.100.24710 ie	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	50	84 (-34)	10JUL01	1 day	Yes	.	MIL	NO	No	UNR	No
	ASTHENIA	HEAT STROKE	+	Body as a Whole	50	113 (-5)	08AUG01	1 day	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	7 (-111)	24APR01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	DYSPEPSIA	UPSET STOMACH	+	Digestive System	30	41 (-77)	28MAY01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	PURPURA	BRUISED ANKLE AND KNEE	+	Hemic and Lymphatic System	50	109 (-9)	04AUG01	3 days	Yes	.	MOD	NO	Yes	UNR	No
	EAR PAIN	EARACHE	+	Special Senses	40	54 (-64)	10JUN01	4 days	Yes	.	MOD	NO	Yes	UNR	No
676.101.24623 ie	HEADACHE	HEADACHE	+	Body as a Whole	40	63 (-47)	01SEP00	81 days	No	.	MIL	NO	No	PBU	No
	MONILIASIS	ORAL THRUSH	+	Body as a Whole	40	27 (-83)	27JUL00	7 days	Yes	.	MOD	NO	Yes	UNR	No
	INCREASED APPETITE	INCREASED APPETITE	+	Digestive System	40	36 (-74)	05AUG00	CON	Yes	.	MIL	NO	No	PBU	No
	EMOTIONAL LABILITY	MOOD LABILITY	+	Nervous System	40	21 (-89)	21JUL00	20 days	No	3	MOD	NO	No	PSR	No
	INSOMNIA	INSOMNIA	+	Nervous System	20	10 (-100)	10JUL00	31 days	Yes	.	MOD	INC	No	PBU	No
	COUGH INCREASED	COUGH	+	Respiratory System	40	104 (-6)	12OCT00	11 days	Yes	.	MOD	NO	Yes	UNR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	40	69 (-41)	07SEP00	1 day	No	1	MIL	NO	Yes	UNR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	40	104 (-6)	12OCT00	11 days	Yes	.	MOD	NO	Yes	UNR	No
	RHINITIS	RUNNY NOSE	+	Respiratory System	40	104 (-6)	12OCT00	11 days	Yes	.	MOD	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.101.24625 ie	COUGH INCREASED	COUGH	+	Respiratory System	50	84 (-31)	09JAN01	1 day	No	2	MIL	NO	No	UNR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	50	84 (-31)	09JAN01	1 day	No	1	MIL	NO	No	UNR	No
	RESPIRATORY DISORDER	HEAD COLD	+	Respiratory System	50	48 (-67)	04DEC00	8 days	Yes	.	MIL	NO	No	UNR	No
676.101.24626 ie	COUGH INCREASED	COUGH	+	Respiratory System	40	27 (-85)	07NOV00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	COUGH INCREASED	COUGH	+	Respiratory System	40	40 (-72)	20NOV00	2 days	No	1	MIL	NO	Yes	UNR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	40	40 (-72)	20NOV00	2 days	No	1	MIL	NO	Yes	UNR	No
676.101.24629 i	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	10	15 (-104)	11APR01	1 day	No	2	MIL	NO	No	PSR	No
	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	40	62 (-57)	28MAY01	1 day	Yes	.	MIL	NO	No	PBU	No
	ASTHENIA	FATIGUE/HYPOSOMNIA	+	Body as a Whole	40	39 (-80)	05MAY01	41 days	Yes	.	MOD	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	3 (-116)	30MAR01	6 days	Yes	.	MIL	STP	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	87 (-32)	22JUN01	2 days	Yes	.	MIL	NO	Yes	UNR	No
	INFECTION	FLU	+	Body as a Whole	10	4 (-115)	31MAR01	8 days	Yes	.	SEV	NO	No	PBU	No
	DIZZINESS	DIZZINESS	+	Nervous System	10	15 (-104)	11APR01	1 day	No	2	MIL	NO	No	PSR	No
	DIZZINESS	DIZZINESS	+	Nervous System	40	87 (-32)	22JUN01	2 days	Yes	.	MIL	NO	No	UNR	No
	EMOTIONAL LABILITY	THREAT OF SUICIDE	+	Nervous System	40	99 (-20)	04JUL01	1 day	No	1	MIL	NO	No	UNR	No
	INSOMNIA	FATIGUE/HYPOSOMNIA	+	Nervous System	40	39 (-80)	05MAY01	41 days	Yes	.	MOD	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.101.24629 i	COUGH INCREASED	COUGH	+	Respiratory System	10	7 (-112)	03APR01	11 days	Yes	.	MOD	NO	No	UNR	No
	EPISTAXIS	NOSE BLEED	+	Respiratory System	10	7 (-112)	03APR01	2 days	No	2	MOD	NO	No	PBU	No
	RHINITIS	SNEEZING	+	Respiratory System	40	50 (-69)	16MAY01	8 days	No	3	MIL	NO	No	UNR	No
676.102.24589 ie	ALLERGIC REACTION	HAYFEVER	+	Body as a Whole	20	14 (-119)	19JUN00	1 day	Yes	.	MIL	NO	Yes	PBU	No
	WEIGHT GAIN	9.5 % WEIGHT GAIN	+	Metabolic and Nutritional Disorders	50	133 (0)	16OCT00	CON	Yes	.	MIL	NO	No	PSR	No
	ASTHMA	ASTHMA ATTACK	+	Respiratory System	50	52 (-81)	27JUL00	1 day	No	1	MOD	NO	Yes	UNR	No
	PHARYNGITIS	THROAT INFECTION	+	Respiratory System	50	52 (-81)	27JUL00	CON	No	1	MIL	NO	Yes	UNR	No
676.103.24648 i	HEADACHE	HEADACHE	+	Body as a Whole	30	26 (-84)	10MAY00	2 days	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	30	36 (-74)	20MAY00	2 days	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	HEADACHE DUE TO CAR DOOR CLOSING ON HEAD	+	Body as a Whole	30	57 (-53)	10JUN00	19 days	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	TENSION HEADACHE	+	Body as a Whole	40	84 (-26)	07JUL00	2 days	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	TENSION HEADACHE	+	Body as a Whole	40	87 (-23)	10JUL00	CON	Yes	.	MOD	NO	No	UNR	No
	DYSPEPSIA	SLIGHT STOMACH IRRITATION (BURNING)	+	Digestive System	30	26 (-84)	10MAY00	5 days	No	3	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.103.24649 ie	FLU SYNDROME	FLU LIKE SYMPTOMS	+	Body as a Whole	40	39 (-78)	27JUN00	2 days	Yes	.	SEV	NO	Yes	PBU	No
	FLU SYNDROME	FLU LIKE SYMPTOMS GENERAL MALAISE	+	Body as a Whole	40	112 (-5)	08SEP00	4 days	Yes	.	MIL	NO	No	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	52 (-65)	10JUL00	2 days	Yes	.	MOD	NO	Yes	PBU	No
	INFECTION	EARRING HOLE INFECTED	+	Body as a Whole	20	20 (-97)	08JUN00	4 days	Yes	.	MIL	NO	Yes	UNR	No
	COUGH INCREASED	COUGH	+	Respiratory System	40	55 (-62)	13JUL00	2 days	Yes	.	MOD	NO	Yes	PBU	No
676.103.24654 i	ASTHENIA	INCREASED FATIGUE	+	Body as a Whole	10	1 (-111)	24MAR01	62 days	Yes	.	MIL	NO	No	PSR	No
	DYSPEPSIA	HEARTBURN	+	Digestive System	20	22 (-90)	14APR01	CON	Yes	.	MIL	NO	Yes	UNR	No
	WEIGHT GAIN	WEIGHT GAIN	+	Metabolic and Nutritional Disorders	30	69 (-43)	31MAY01	CON	Yes	.	MIL	DCR	No	PSR	No
676.200.24729 ie	MIGRAINE	MIGRAINE	+	Cardiovascular System	20	10 (-103)	16MAR00	2 days	No	1	MOD	NO	Yes	PBU	No
	MIGRAINE	MIGRAINE	+	Cardiovascular System	40	67 (-46)	12MAY00	1 day	Yes	.	MOD	NO	Yes	UNR	No
	MIGRAINE	MIGRAINE	+	Cardiovascular System	50	105 (-8)	19JUN00	1 day	No	1	MIL	NO	No	UNR	No
676.200.24733 ie	DEPRESSION	ONSET OF DEPRESSION	+	Nervous System	40	74 (-19)	01JUL00	CON	Yes	.	MOD	NO	No	PBU	No
	RESPIRATORY DISORDER	VIRAL UPPER RESPIRATORY TRACT INFECTION	+	Respiratory System	40	48 (-45)	05JUN00	9 days	Yes	.	MOD	NO	No	REL	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.200.24733 ie	RHINITIS	VIRAL CORYZA	+	Respiratory System	30	42 (-51)	30MAY00	1 day	No	1	MIL	INC	Yes	UNR	No
676.200.24735 ie	TOOTH DISORDER	TOOTHACHE AND WISDOM TEETH EXTRACTION; PATIENT EXPERIENCED CONTINOUS TOOTHACHE FOR A PERIOD TWO WEEKS PRIOR TO EXTRACTION.	+	Digestive System	20	14 (-98)	30MAY00	29 days	Yes	.	MOD	NO	Yes	UNR	No
676.200.24742 i	ASTHENIA	FATIGUE / TIREDNESS	+	Body as a Whole	10	1 (-108)	27SEP00	CON	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	78 (-31)	13DEC00	1 day	No	1	MIL	NO	Yes	PSR	No
	INFECTION	INFECTED FOOT		Body as a Whole	.	110 (1)	14JAN01	6 days	Yes	.	MOD	STP	Yes	UNR	No
676.200.24743 ie	HEADACHE	HEADACHES	+	Body as a Whole	20	9 (-109)	20OCT00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	20	10 (-108)	21OCT00	2 days	Yes	.	MIL	NO	No	PSR	No
	SOMNOLENCE	DROWSINESS	+	Nervous System	10	4 (-114)	15OCT00	6 days	Yes	.	MOD	NO	No	REL	No
676.200.24748 ie	RHINITIS	VIRAL CORYZA	+	Respiratory System	20	22 (-91)	24APR01	5 days	No	1	MIL	NO	Yes	UNR	No
676.201.24762 ie	SOMNOLENCE	SOMNOLENCE	+	Nervous System	10	2 (-112)	17OCT00	18 days	No	18	MIL	NO	No	PSR	No
676.202.24789 ie	INFECTION	FLU	^	Body as a Whole	.	-4 (-135)	22AUG00	4 days	Yes	.	MIL		No		No
	ASTHENIA	TIREDNESS	+	Body as a Whole	10	1 (-130)	27AUG00	8 days	Yes	.	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.202.24798 ie	HEADACHE	HEADACHE	+	Body as a Whole	30	29 (-84)	10MAR01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	DECREASED APPETITE	POOR APPETITE	+	Digestive System	30	45 (-68)	26MAR01	15 days	Yes	.	MOD	DCR	No	PSR	No
676.202.24799 ie	INFECTION	FLU WITH HEADACHE	+	Body as a Whole	20	77 (-38)	01MAY01	11 days	Yes	.	MIL	NO	Yes	UNR	No
676.203.24813 ie	ABDOMINAL PAIN	STOMACHACHE	+	Body as a Whole	10	72 (-38)	21MAY00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	43 (-67)	22APR00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	INFECTION	FLU	+	Body as a Whole	10	28 (-82)	07APR00	8 days	Yes	.	MIL	NO	Yes	UNR	No
	INFECTION	FLU	+	Body as a Whole	10	65 (-45)	14MAY00	6 days	No	1	MIL	NO	Yes	UNR	No
	TRAUMA	SOFT TISSUE INJURY (R) HIP	+	Body as a Whole	10	38 (-72)	17APR00	3 days	Yes	.	MIL	NO	Yes	UNR	No
	INSOMNIA	INSOMNIA	+	Nervous System	10	1 (-109)	11MAR00	10 days	Yes	.	MIL	NO	No	PSR	No
	INSOMNIA	INSOMNIA	+	Nervous System	20	16 (-94)	26MAR00	14 days	Yes	.	MOD	DCR	No	REL	No
	BRONCHITIS	BRONCHITIS	+	Respiratory System	10	80 (-30)	29MAY00	6 days	Yes	.	MIL	NO	Yes	UNR	No
	URINARY FREQUENCY	FREQUENCY OF URINE (NIGHT AND DAYTIME)	+	Urogenital System	20	16 (-94)	26MAR00	25 days	Yes	.	MOD	DCR	No	REL	No
676.204.24844 i	ABDOMINAL PAIN	ABDOMINAL CRAMPS	+	Body as a Whole	20	25 (-80)	23JUL00	11 days	Yes	.	MIL	NO	Yes	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	1 (-104)	29JUN00	2 days	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	4 (-101)	02JUL00	1 day	Yes	.	MIL	NO	Yes	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.204.24844 i	HEADACHE	HEADACHE	+	Body as a Whole	20	19 (-86)	17JUL00	1 day	Yes	.	MIL	NO	Yes	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	20	20 (-85)	18JUL00	1 day	Yes	.	MIL	NO	No	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	30	42 (-63)	09AUG00	3 days	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	54 (-51)	21AUG00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	59 (-46)	26AUG00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	63 (-42)	30AUG00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	INFECTION	FLU	+	Body as a Whole	50	103 (-2)	09OCT00	7 days	Yes	.	MIL	NO	Yes	UNR	No
	PAIN	PAINFUL LEFT ARM	+	Body as a Whole	40	70 (-35)	06SEP00	3 days	Yes	.	MIL	NO	Yes	UNR	No
	DIARRHEA	DIARRHEA	+	Digestive System	20	25 (-80)	23JUL00	8 days	Yes	.	MIL	NO	Yes	PBU	No
	DIARRHEA	DIARRHOEA	+	Digestive System	30	47 (-58)	14AUG00	2 days	No	2	MIL	NO	Yes	PSR	No
	RECTAL DISORDER	PRURITUS ANI	+	Digestive System	20	32 (-73)	30JUL00	6 days	Yes	.	MIL	NO	Yes	UNR	No
	DIZZINESS	DIZZINESS	+	Nervous System	10	2 (-103)	30JUN00	1 day	Yes	.	MIL	NO	No	PSR	No
676.204.24845 ie	INFECTION	FLU	+	Body as a Whole	40	34 (-81)	03AUG00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	50	115 (0)	23OCT00	1 day	Yes	.	MIL	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.204.24845 ie	DIZZINESS	LIGHTHEADED ASSOCIATED WITH MENSTRUAL CYCLE	+	Nervous System	50	79 (-36)	17SEP00	2 days	Yes	.	MIL	NO	No	UNR	No
	DIZZINESS	DIZZY	+	Nervous System	50	80 (-35)	18SEP00	3 days	Yes	.	MIL	NO	No	PSR	No
	DIZZINESS	DIZZY	+	Nervous System	50	115 (0)	23OCT00	1 day	Yes	.	MIL	NO	No	PBU	No
676.204.24849 ie	ABDOMINAL PAIN	ABDOMINAL CRAMPS	+	Body as a Whole	30	20 (-93)	30JAN01	1 day	Yes	.	MIL	NO	Yes	PSR	No
	ABDOMINAL PAIN	ABDOMINAL CRAMPS	+	Body as a Whole	50	70 (-43)	21MAR01	2 days	Yes	.	MIL	NO	No	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	50	70 (-43)	21MAR01	2 days	Yes	.	MIL	NO	No	PSR	No
676.204.24851 ie	HEADACHE	HEADACHE	+	Body as a Whole	10	1 (-111)	15FEB01	1 day	Yes	.	MIL	NO	No	REL	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	2 (-110)	16FEB01	1 day	Yes	.	MIL	NO	Yes	REL	No
	HEADACHE	HEADACHE	+	Body as a Whole	20	14 (-98)	28FEB01	1 day	Yes	.	MIL	NO	Yes	PBU	No
	INFECTION	FLU SYMPTOMS	+	Body as a Whole	50	44 (-68)	30MAR01	2 days	Yes	.	MIL	NO	Yes	PBU	No
	RESPIRATORY DISORDER	UPPER RESPIRATORY TRACT INFECTION	+	Respiratory System	50	108 (-4)	02JUN01	CON	Yes	.	MIL	NO	Yes	UNR	No
	YAWN	YAWNING	+	Respiratory System	10	2 (-110)	16FEB01	7 days	Yes	.	MIL	NO	No	REL	No
	HERPES SIMPLEX	HERPES STOMATITIS	+	Skin and Appendages	50	108 (-4)	02JUN01	10 days	Yes	.	MIL	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.205.24982 ie	HEADACHE	HEADACHE	+	Body as a Whole	30	56 (-56)	25MAY00	57 days	Yes	.	MOD	DCR	No	PSR	No
	INFECTION	FLU	+	Body as a Whole	40	68 (-44)	06JUN00	5 days	Yes	.	MIL	NO	Yes	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	40	71 (-41)	09JUN00	4 days	No	4	MOD	DCR	No	PSR	No
676.205.24985 i	INFECTION	FLU	+	Body as a Whole	10	18 (-8)	25FEB01	5 days	Yes	.	MIL	NO	Yes	UNR	No
	ANEMIA	ANAEMIA	+	Hemic and Lymphatic System	20	25 (-1)	04MAR01	3 days	No	2	SEV	STP	Yes	UNR	Yes
676.205.24988 ie	INFECTION	FLU	+	Body as a Whole	40	97 (-16)	06JUN01	4 days	Yes	.	MIL	NO	Yes	UNR	No
	DECREASED APPETITE	LOSS OF EVENING APPETITE	+	Digestive System	20	23 (-90)	24MAR01	32 days	Yes	.	MIL	NO	No	PSR	No
676.206.24870 ie	INFECTION	FLU	+	Body as a Whole	20	15 (-95)	01APR00	3 days	Yes	.	MIL	NO	No	UNR	No
676.206.24871 ie	ASTHENIA	FATIGUE	+	Body as a Whole	20	10 (-106)	10APR00	8 days	Yes	.	MOD	NO	Yes	PSR	No
	TRAUMA	SORE FOOT AFTER FALL	+	Body as a Whole	30	84 (-32)	23JUN00	38 days	Yes	.	MIL	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.206.24871 ie	HYPOTENSION	PATIENT EXPERIENCED A BLACK OUT ON THE EVENING OF 22-06-00.SHE HURT HER HEAD,IT LASTED A FEW MINUTES. SHE COULD NOT REMEMBER ANYTHING THE NEXT DAY.DIAGNOSIS: SYNCOPE BECAUSE OF HYPOTENSION.	+	Cardiovascular System	30	83 (-33)	22JUN00	1 day	No	1	MOD	NO	Yes	PBU	No
	NAUSEA	NAUSEA,ONCE ON 13-05-00 FOR 15MINUTES	+	Digestive System	30	43 (-73)	13MAY00	1 day	No	1	MIL	NO	No	UNR	No
	INSOMNIA	INSOMNIA	+	Nervous System	20	13 (-103)	13APR00	2 days	Yes	.	MIL	NO	No	PSR	No
	CONJUNCTIVITIS	ITCHING OF EYES	+	Special Senses	10	5 (-111)	05APR00	1 day	Yes	.	MIL	NO	Yes	PSR	No
676.206.24875 ie	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	10	1 (-109)	24JUL00	2 days	Yes	.	MIL		Yes		No
	RESPIRATORY DISORDER	COLD (COMMON)	+	Respiratory System	10	54 (-56)	15SEP00	4 days	Yes	.	MIL	NO	Yes	UNR	No
	RESPIRATORY DISORDER	COLD (COMMON)	+	Respiratory System	10	84 (-26)	15OCT00	5 days	Yes	.	MIL	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.206.24875 ie	RHINITIS	RUNNY NOSE	+	Respiratory System	10	28 (-82)	20AUG00	1 day	No	1	MIL	NO	Yes	UNR	No
676.206.24877 ie	HEADACHE	HEADACHE	+	Body as a Whole	10	4 (-127)	29AUG00	2 days	No	2	MIL	NO	No	PSR	No
676.206.24882 ie	HEADACHE	ELECTIVE SURGERY L EFT AND RIGHT TM JOINT	+	Body as a Whole	10	3 (-111)	10FEB01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	INFECTION	FLU	+	Body as a Whole	40	68 (-46)	16APR01	5 days	Yes	.	MIL	NO	Yes	UNR	No
	INFECTION	FLU	+	Body as a Whole	40	114 (0)	01JUN01	8 days	Yes	.	MIL	NO	Yes	UNR	No
	INSOMNIA	INSOMNIA	+	Nervous System	20	13 (-101)	20FEB01	CON	Yes	.	MOD	INC	No	PSR	No
676.207.24900 ie	ASTHENIA	TIREDNESS	+	Body as a Whole	30	16 (-97)	19JUL00	1 day	Yes	.	MOD	DCR	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	20	112 (-1)	23OCT00	1 day	No	1	MIL	NO	Yes	PBU	No
	DEPERSONALIZATION	DEJA VU	+	Nervous System	30	16 (-97)	19JUL00	1 day	Yes	.	MOD	DCR	No	PSR	No
	NERVOUSNESS	EDGY FEELING	+	Nervous System	30	16 (-97)	19JUL00	1 day	Yes	.	MOD	DCR	No	PSR	No
676.207.24901 ie	HEADACHE	HEADACHE	+	Body as a Whole	10	1 (-111)	19OCT00	1 day	No	1	MOD	NO	No	PSR	No
	KETOSIS	KETONES(+) IN URINE	+	Metabolic and Nutritional Disorders	20	15 (-97)	02NOV00	14 days	Yes	.	MIL	NO	No	UNR	No
	ALBUMINURIA	PROTEIN IN URINE (+)	+	Urogenital System	20	15 (-97)	02NOV00	98 days	Yes	.	MIL	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.207.24901 ie	URINE ABNORMALITY	TRACE UROBILINOGEN URINE	+	Urogenital System	20	28 (-84)	15NOV00	3 days	Yes	.	MIL	NO	No	UNR	No
676.207.24906 ie	ASTHENIA	DAYTIME TIREDNESS	+	Body as a Whole	20	12 (-100)	26FEB01	15 days	Yes	.	MOD	NO	No	PSR	No
	INFECTION	INFLUENZA	+	Body as a Whole	10	2 (-110)	16FEB01	3 days	Yes	.	MIL	NO	Yes	UNR	No
	TRAUMA	SPRAIN TO LEFT ANKLE	+	Body as a Whole	30	52 (-60)	07APR01	4 days	Yes	.	MIL	NO	No	UNR	No
	DECREASED APPETITE	LOSS OF APPETITE	+	Digestive System	30	75 (-37)	30APR01	13 days	Yes	.	MIL	NO	No	PSR	No
	SOMNOLENCE	DAYTIME DROWSINESS	+	Nervous System	30	41 (-71)	27MAR01	2 days	Yes	.	MOD	NO	No	PSR	No
	TREMOR	TREMOR OF HANDS	+	Nervous System	20	16 (-96)	02MAR01	15 days	Yes	.	MIL	NO	No	PSR	No
	SWEATING	INCREASED SWEATING	+	Skin and Appendages	20	16 (-96)	02MAR01	11 days	Yes	.	MIL	NO	No	PSR	No
676.207.24907 i	ASTHENIA	TIREDNESS	+	Body as a Whole	10	3 (-29)	19FEB01	CON	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	1 (-31)	17FEB01	1 day	Yes	.	MIL	NO	No	PSR	No
	DECREASED APPETITE	DECREASED APPETITE	+	Digestive System	10	2 (-30)	18FEB01	22 days	Yes	.	MIL	NO	No	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	10	4 (-28)	20FEB01	2 days	Yes	.	MIL	NO	No	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	10	10 (-22)	26FEB01	1 day	No	1	MOD	NO	No	PSR	No
	WEIGHT LOSS	WEIGHT LOSS (1KG)	+	Metabolic and Nutritional Disorders	10	3 (-29)	19FEB01	CON	Yes	.	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.207.24907 i	DEPRESSION	DEPRESSED MOOD	+	Nervous System	20	17 (-15)	05MAR01	5 days	Yes	.	MIL	NO	No	PSR	No
	DIZZINESS	DIZZINESS	+	Nervous System	10	1 (-31)	17FEB01	1 day	Yes	.	MIL	NO	No	PSR	No
	INSOMNIA	INITIAL INSOMNIA	+	Nervous System	10	5 (-27)	21FEB01	10 days	Yes	.	MIL	NO	No	PSR	No
	NERVOUSNESS	IRRITABILITY	+	Nervous System	20	17 (-15)	05MAR01	7 days	Yes	.	MIL	NO	No	PSR	No
	YAWN	INCREASED YAWNING	+	Respiratory System	10	1 (-31)	17FEB01	CON	Yes	.	MIL	NO	No	PSR	No
	RASH	SKIN RASH	+	Skin and Appendages	20	15 (-17)	03MAR01	11 days	Yes	.	MIL	NO	No	PSR	No
676.207.24911 ie	ABDOMINAL PAIN	STOMACH CRAMPS	+	Body as a Whole	40	111 (-2)	21AUG01	2 days	Yes	.	MIL	NO	Yes	PBU	No
	ASTHENIA	DAYTIME TIREDNESS	+	Body as a Whole	20	10 (-103)	12MAY01	7 days	Yes	.	MIL	NO	No	PSR	No
	ASTHENIA	DAYTIME TIREDNESS	+	Body as a Whole	30	24 (-89)	26MAY01	8 days	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	20	19 (-94)	21MAY01	1 day	No	1	SEV	NO	Yes	PSR	No
	INCREASED APPETITE	INCREASE IN APPETITE	+	Digestive System	30	24 (-89)	26MAY01	CON	Yes	.	MIL	NO	No	PSR	No
	VOMITING	VOMITING	+	Digestive System	40	111 (-2)	21AUG01	2 days	Yes	.	MIL	NO	No	PBU	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	10	7 (-106)	09MAY01	3 days	Yes	.	MIL	NO	Yes	PBU	No
	RHINITIS	RHINITIS	+	Respiratory System	10	8 (-105)	10MAY01	8 days	Yes	.	MIL	NO	Yes	PBU	No
	ACNE	ACNE (FACE)	+	Skin and Appendages	30	31 (-82)	02JUN01	CON	Yes	.	MIL	NO	Yes	PSR	No
676.209.24954 ie	ABDOMINAL PAIN	STOMACH CRAMPS	+	Body as a Whole	10	112 (-2)	15AUG00	1 day	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.209.24954 ie	HEADACHE	HEADACHE (DUE TO SMOKE INHALATION)	+	Body as a Whole	10	83 (-31)	17JUL00	1 day	Yes	.	MIL	NO	No	UNR	No
	TRAUMA	HEADACHE (DUE TO SMOKE INHALATION)	+	Body as a Whole	10	83 (-31)	17JUL00	1 day	Yes	.	MIL	NO	No	UNR	No
	COUGH INCREASED	COUGHING	+	Respiratory System	10	46 (-68)	10JUN00	14 days	Yes	.	MIL	NO	Yes	UNR	No
	PHARYNGITIS	PHARYNGITIS	+	Respiratory System	20	10 (-104)	05MAY00	2 days	No	1	MIL	NO	Yes	UNR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	10	28 (-86)	23MAY00	4 days	Yes	.	MIL	NO	Yes	UNR	No
	RESPIRATORY DISORDER	UPPER RESPIRATORY TRACT INFECTION	+	Respiratory System	10	18 (-96)	13MAY00	4 days	Yes	.	MIL	NO	No	UNR	No
	RHINITIS	RHINITIS	+	Respiratory System	10	25 (-89)	20MAY00	7 days	Yes	.	MIL	NO	Yes	UNR	No
676.209.24956 ie	ASTHENIA	TIREDNESS	+	Body as a Whole	10	3 (-108)	14MAY00	8 days	Yes	.	MIL	NO	No	PSR	No
	INFECTION	FLU	+	Body as a Whole	30	30 (-81)	10JUN00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	DIARRHEA	DIARRHEA	+	Digestive System	10	13 (-98)	24MAY00	3 days	Yes	.	MIL	NO	No	PBU	No
	BRONCHITIS	BRONCHITIS	+	Respiratory System	30	78 (-33)	28JUL00	10 days	Yes	.	MOD	NO	Yes	UNR	No
676.209.24959 ie	ABDOMINAL PAIN	ABDOMINAL CRAMPS	+	Body as a Whole	10	1 (-111)	01AUG00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	ABDOMINAL PAIN	EPIGASTRIC PAIN	+	Body as a Whole	10	1 (-111)	01AUG00	1 day	Yes	.	MIL	NO	Yes	PBU	No
	ASTHENIA	TIREDNESS (FATIGUE)	+	Body as a Whole	20	21 (-91)	21AUG00	32 days	Yes	.	SEV	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.209.24959 ie	ASTHENIA	TIREDNESS (FATIGUE)	+	Body as a Whole	50	73 (-39)	12OCT00	CON	Yes	.	SEV	NO	No	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	14 (-98)	14AUG00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	30	28 (-84)	28AUG00	2 days	No	2	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	50 (-62)	19SEP00	1 day	Yes	.	MOD	NO	Yes	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	10	1 (-111)	01AUG00	50 days	Yes	.	MIL	NO	Yes	PSR	No
	MYALGIA	BACKACHE(MUSCLE PAIN)	+	Musculoskeletal System	30	29 (-83)	29AUG00	1 day	Yes	.	MIL	NO	Yes	UNR	No
676.209.24961 i	ALLERGIC REACTION	BEE STING-SWOLLEN (L) FOOT	+	Body as a Whole	20	20 (-63)	30OCT00	3 days	Yes	.	MOD	NO	Yes	UNR	No
	ASTHENIA	FATIGUE DURING DAY	+	Body as a Whole	10	1 (-82)	11OCT00	16 days	Yes	.	MIL	NO	No	REL	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	3 (-80)	13OCT00	5 days	Yes	.	MIL	NO	Yes	REL	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	51 (-32)	30NOV00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	DYSPEPSIA	HEARTBURN	+	Digestive System	40	49 (-34)	28NOV00	33 days	Yes	.	SEV	NO	Yes	REL	No
676.209.24964 ie	AGITATION	PANIC ATTACK	+	Nervous System	10	4 (-123)	21OCT00	1 day	Yes	.	MIL	NO	No	PSR	No
	AGITATION	PANIC ATTACK	+	Nervous System	10	7 (-120)	24OCT00	1 day	No	1	MIL	NO	No	PSR	No
	DIZZINESS	DIZZINESS	+	Nervous System	40	41 (-86)	27NOV00	7 days	Yes	.	MIL	NO	Yes	UNR	No
676.209.24966 ie	RHINITIS	ALLERGIC RHINITIS	^	Respiratory System	.	-1 (-121)	05FEB01	1 day	Yes	.	MIL		Yes		No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.209.24966 ie	INFECTION	HEADACHE (DUE TO INFLUENZA)	+	Body as a Whole	10	13 (-107)	19FEB01	4 days	Yes	.	MOD	NO	Yes	UNR	No
	INFECTION	INFLUENZA	+	Body as a Whole	10	13 (-107)	19FEB01	4 days	Yes	.	MOD	NO	Yes	UNR	No
	TRAUMA	SOFT TISSUE INJURY NECK	+	Body as a Whole	10	32 (-88)	10MAR01	38 days	Yes	.	SEV	NO	Yes	UNR	No
	MYALGIA	MYALGIA	+	Musculoskeletal System	10	13 (-107)	19FEB01	3 days	Yes	.	MIL	NO	No	UNR	No
	SOMNOLENCE	DROWSINESS	+	Nervous System	10	5 (-115)	11FEB01	5 days	Yes	.	MIL	NO	No	PSR	No
	RHINITIS	RHINITIS	+	Respiratory System	10	13 (-107)	19FEB01	3 days	Yes	.	MOD	NO	Yes	UNR	No
	VESICULOBULLOUS RASH	SKIN RASH (R) ARM - SINGLE BLISTER	+	Skin and Appendages	10	92 (-28)	09MAY01	CON	Yes	.	MIL	NO	No	UNR	No
676.209.24968 ie	BILIRUBINEMIA	GILBERT'S SYNDROME (START DATE UNKNOWN - DATE OF DIAGNOSIS INDICATED)	^	Metabolic and Nutritional Disorders	.	-6 (-121)	20FEB01	CON	Yes	.	MIL		No		No
	HEADACHE	HEADACHE	+	Body as a Whole	10	26 (-89)	24MAR01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	38 (-77)	05APR01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	54 (-61)	21APR01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	TREMOR	TREMOR IN BOTH HANDS	+	Nervous System	10	1 (-114)	27FEB01	4 days	Yes	.	MOD	NO	No	PSR	No
	RESPIRATORY DISORDER	COUGHING (URTI)	+	Respiratory System	10	19 (-96)	17MAR01	2 days	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous, if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.209.24969 ie	GINGIVITIS	GINGIVITIS DUE TO ORTHODONTIC PROCEDURE	+	Digestive System	20	78 (-36)	19JUN01	CON	Yes	.	MIL	NO	Yes	UNR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	20	24 (-90)	26APR01	5 days	Yes	.	MIL	NO	No	UNR	No
	EAR PAIN	PAINFUL (L) EAR (EAR ACHE)	+	Special Senses	20	30 (-84)	02MAY01	3 days	Yes	.	MIL	NO	No	UNR	No
676.300.25013 i	INFECTION	GRIPPE	+	Body as a Whole	30	79 (-33)	01SEP00	10 days	Yes	.	MOD	NO	Yes	PBU	No
676.301.25039 ie	GASTROINTESTINAL DISORDER	STOMACH COMPLAINTS	^	Digestive System	.	-7 (-126)	26SEP00	4 days	Yes	.	MIL		No		No
	RESPIRATORY DISORDER	COLD	^	Respiratory System	.	-3 (-122)	30SEP00	12 days	Yes	.	MOD		Yes		No
	HEADACHE	HEADACHE	+	Body as a Whole	40	109 (-10)	20JAN01	6 days	Yes	.	MOD	NO	No	PBU	No
	INFECTION	MYCOSIS (HAND/FEET)	+	Body as a Whole	30	42 (-77)	14NOV00	14 days	Yes	.	MIL	NO	Yes	PBU	No
	INCREASED APPETITE	INCREASED APPETITE	+	Digestive System	20	14 (-105)	17OCT00	15 days	Yes	.	MIL	NO	No	PSR	No
	INCREASED APPETITE	INCREASED APPETITE	+	Digestive System	30	34 (-85)	06NOV00	18 days	Yes	.	MIL	NO	No	PBU	No
	BRONCHITIS	BRONCHITIS	+	Respiratory System	30	53 (-66)	25NOV00	6 days	Yes	.	MOD	NO	Yes	UNR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	40	109 (-10)	20JAN01	6 days	Yes	.	MOD	NO	No	PBU	No
	RESPIRATORY DISORDER	COLD		Respiratory System	30	81 (-38)	23DEC00	13 days	Yes	.	MIL	NO	Yes	PBU	No
	RHINITIS	RHINITIS	+	Respiratory System	30	45 (-74)	17NOV00	4 days	Yes	.	MIL	NO	No	UNR	No
	SWEATING	DYSHYDROSIS	+	Skin and Appendages	30	26 (-93)	29OCT00	17 days	Yes	.	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.301.25041 ie	SYNCOPE	WEAK (LIPOTHYMIA)	+	Cardiovascular System	40	118 (-2)	18SEP01	4 days	Yes	.	MOD	NO	No	PBU	No
	RHINITIS	RHINITIS	+	Respiratory System	20	11 (-109)	03JUN01	7 days	Yes	.	MIL	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.006.24142 ie	ABNORMAL EJACULATION	DELAYED EJACULATION	+	Urogenital System	20	20 (-93)	12JUN00	CON	Yes	.	MOD	NO	No	REL	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.002.24045 i	DYSMENORRHEA	MENSTRUAL CRAMPS	+ Urogenital System	20	19 (-63)	11JUN01	2 days	Yes	.	MOD	NO	Yes	UNR	No
676.005.24118 ie	DYSMENORRHEA	MENSTRUAL CRAMPS	+ Urogenital System	50	75 (-44)	16JUL00	1 day	Yes	.	MOD	NO	Yes	UNR	No
676.006.24145 ie	DYSMENORRHEA	MENSTRUAL CRAMPS	+ Urogenital System	30	20 (-92)	12SEP00	1 day	Yes	.	SEV	NO	Yes	UNR	No
	DYSMENORRHEA	MENSTRUAL CRAMPS	+ Urogenital System	40	55 (-57)	17OCT00	1 day	Yes	.	SEV	NO	Yes	UNR	No
	DYSMENORRHEA	MENSTRUAL CRAMPS	+ Urogenital System	40	96 (-16)	27NOV00	2 days	Yes	.	MIL	NO	Yes	UNR	No
676.015.24399 ie	DYSMENORRHEA	MENSTRUAL CRAMPING	+ Urogenital System	10	8 (-106)	24MAY00	3 days	No	2	MIL	NO	Yes	UNR	No
676.022.17845 ie	AMENORRHEA	POSSIBLE AMENORRHEA	+ Urogenital System	10	1 (-110)	01SEP00	124 days	Yes	.	MIL	NO	No	PBU	No
676.023.17879 i	DYSMENORRHEA	MENSTRUAL CRAMPS	+ Urogenital System	20	26 (-109)	09DEC00	1 day	No	.	MOD	NO	Yes	UNR	No
	DYSMENORRHEA	MENSTRUAL CRAMPS	+ Urogenital System	20	51 (-84)	03JAN01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	DYSMENORRHEA	MENSTRUAL CRAMPS	+ Urogenital System	20	61 (-74)	13JAN01	1 day	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.001.24012 i	DIARRHEA	NAUSEA, VOMITING, DIARRHEA	+	Digestive System	0	21 (-97)	28DEC00	2 days	No	1	MOD	NO	No	PBU	No
	NAUSEA	NAUSEA, VOMITING, DIARRHEA	+	Digestive System	0	21 (-97)	28DEC00	2 days	No	1	MOD	NO	No	PBU	No
	VOMITING	NAUSEA, VOMITING, DIARRHEA	+	Digestive System	0	21 (-97)	28DEC00	2 days	No	1	MOD	NO	No	PBU	No
	RESPIRATORY DISORDER	UPPER RESPIRATORY ILLNESS (COUGH)	+	Respiratory System	0	6 (-112)	13DEC00	2 days	Yes	.	MOD	NO	Yes	PBU	No
676.003.24067 ie	INFECTION	FLU	+	Body as a Whole	0	2 (-119)	29SEP00	2 days	Yes	.	MOD	NO	Yes	UNR	No
	INFECTION	FLU	+	Body as a Whole	0	50 (-71)	16NOV00	1 day	Yes	.	MOD	NO	Yes	UNR	No
	DYSPEPSIA	UPSET STOMACH	+	Digestive System	0	110 (-11)	15JAN01	CON	Yes	.	MIL	NO	Yes	UNR	No
676.003.24069 i	TRAUMA	BUMP ON LEFT KNEE	+	Body as a Whole	0	26 (-87)	21JAN01	CON	Yes	.	MIL	NO	No	UNR	No
676.005.24113 ie	CONSTIPATION	CONSTIPATION	+	Digestive System	0	39 (-93)	20MAR00	CON	Yes	.	MIL	NO	No	PSR	No
676.005.24123 ie	INFECTION	FLU SYMPTOMS	+	Body as a Whole	0	5 (-107)	27NOV00	4 days	Yes	.	MOD	NO	Yes	UNR	No
	NERVOUSNESS	INCREASED IRRITABILITY	+	Nervous System	0	49 (-63)	10JAN01	16 days	Yes	.	MOD	DCR	No	PSR	No
676.007.24175 i	PHARYNGITIS	THROAT INFECTION	+	Respiratory System	0	12 (-14)	16FEB00	2 days	Yes	.	MIL	NO	Yes	UNR	No
676.007.24178 ie	FEVER	FEVER	+	Body as a Whole	0	37 (-47)	15MAR00	2 days	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.007.24178 ie	FEVER	FEVER	+	Body as a Whole	0	82 (-2)	29APR00	4 days	No	.	MIL	NO	No	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	1 (-83)	08FEB00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	13 (-71)	20FEB00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	INFECTION	INFLUENZA	+	Body as a Whole	0	22 (-62)	29FEB00	5 days	Yes	.	MIL	NO	Yes	UNR	No
	INFECTION	HEAD LICE	+	Body as a Whole	0	32 (-52)	10MAR00	6 days	Yes	.	MIL	NO	Yes	UNR	No
676.007.24182 ie	DIARRHEA	DIARRHEA	+	Digestive System	0	85 (-33)	24MAY00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	SINUSITIS	SINUS CONGESTION	+	Respiratory System	0	62 (-56)	01MAY00	42 days	Yes	.	MIL	NO	Yes	UNR	No
	SINUSITIS	SINUSITIS	+	Respiratory System	0	104 (-14)	12JUN00	CON	Yes	.	MOD	NO	Yes	UNR	No
676.010.24259 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	4 (-106)	15AUG00	9 days	No	6	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	17 (-93)	28AUG00	1 day	No	1	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	18 (-92)	29AUG00	1 day	No	1	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	24 (-86)	04SEP00	1 day	No	1	MIL	NO	Yes	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	45 (-65)	25SEP00	4 days	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	67 (-43)	17OCT00	1 day	Yes	.	MIL	NO	Yes	PBU	No
	TRAUMA	SKINNED KNEES	+	Body as a Whole	0	33 (-77)	13SEP00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	0	45 (-65)	25SEP00	4 days	Yes	.	MOD	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.012.24310 ie	ABDOMINAL PAIN	STOMACH CRAMPS	+	Body as a Whole	0	30 (-85)	27FEB00	4 days	No	4	MOD	NO	No	PSR	No
	DIARRHEA	DIARRHEA	+	Digestive System	0	30 (-85)	27FEB00	4 days	No	4	MOD	NO	No	PSR	No
	GASTROENTERITIS	VIRAL GASTROENTERITIS	+	Digestive System	0	48 (-67)	16MAR00	2 days	Yes	.	MOD	NO	No	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	0	24 (-91)	21FEB00	1 day	Yes	.	MIL	NO	No	PBU	No
	NAUSEA	NAUSEA	+	Digestive System	0	26 (-89)	23FEB00	4 days	Yes	.	MIL	NO	No	PBU	No
	NAUSEA	NAUSEA	+	Digestive System	0	30 (-85)	27FEB00	4 days	No	4	MOD	NO	No	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	0	48 (-67)	16MAR00	2 days	Yes	.	MOD	NO	No	UNR	No
	DIZZINESS	DIZZINESS	+	Nervous System	0	30 (-85)	27FEB00	4 days	No	4	MOD	NO	No	PSR	No
	INSOMNIA	INSOMNIA	+	Nervous System	0	30 (-85)	27FEB00	4 days	No	4	MOD	NO	No	PSR	No
	SOMNOLENCE	LETHARGY	+	Nervous System	0	48 (-67)	16MAR00	2 days	Yes	.	MOD	NO	No	UNR	No
	RESPIRATORY DISORDER	VIRAL UPPER RESPIRATORY INFECTION	+	Respiratory System	0	3 (-112)	31JAN00	4 days	Yes	.	MIL	NO	No	UNR	No
676.012.24316 ie	INSOMNIA	INSOMNIA	+	Nervous System	0	104 (0)	02MAY01	3 days	No	2	MOD	NO	No	PSR	No
	NERVOUSNESS	NERVOUSNESS	+	Nervous System	0	42 (-62)	01MAR01	CON	Yes	.	MIL	DCR	No	PSR	No
676.013.24353 ie	COUGH INCREASED	COUGH	^	Respiratory System	.	-2 (-59)	30APR01	13 days	No	.	MIL	NO	No	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	56 (-1)	27JUN01	1 day	Yes	.	MOD	NO	Yes	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.013.24353 ie	TRAUMA	ABRASION LEFT LOWER LEG	+	Body as a Whole	0	43 (-14)	14JUN01	7 days	Yes	.	MIL	NO	No	UNR	No
	HYPONATREMIA	HYPONATREMIA	+	Metabolic and Nutritional Disorders	0	57 (0)	28JUN01	6 days	Yes	.	MIL	NO	No	PSR	No
	SOMNOLENCE	SOMNOLENCE	+	Nervous System	0	2 (-55)	04MAY01	29 days	No	.	MIL	NO	No	PBU	No
676.014.24369 ie	SOMNOLENCE	SLEEPINESS	+	Nervous System	0	2 (-111)	11FEB00	1 day	Yes	.	MIL	NO	No	PSR	No
676.015.24398 ie	GASTROENTERITIS	GASTROENTERITIS/MOTHERS REPORT	+	Digestive System	0	31 (-25)	12JUN00	2 days	Yes	.	MIL	NO	Yes	PBU	No
676.015.24405 ie	TRAUMA	FX RADIAL HEAD LEFT ARM	^	Body as a Whole	.	-4 (-123)	20JUL00	CON	Yes	.	MIL		Yes		No
	HEADACHE	HEADACHE	+	Body as a Whole	0	50 (-69)	12SEP00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	61 (-58)	23SEP00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	PHARYNGITIS	PHARYNGITIS	+	Respiratory System	0	118 (-1)	19NOV00	2 days	Yes	.	MIL	NO	Yes	UNR	No
676.015.24410 i	RHINITIS	RHINITIS	+	Respiratory System	0	36 (-36)	14MAR01	17 days	Yes	.	MIL	NO	No	UNR	No
	RHINITIS	RHINITIS	+	Respiratory System	0	67 (-5)	14APR01	CON	Yes	.	MIL	NO	No	UNR	No
676.017.24456 ie	ALLERGIC REACTION	SEASONAL ALLERGIES	+	Body as a Whole	0	17 (-95)	04MAY01	12 days	Yes	.	MOD	NO	Yes	UNR	No
	CHEST PAIN	CHEST PAIN	+	Body as a Whole	0	55 (-57)	11JUN01	1 day	Yes	.	MOD	NO	No	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	10 (-102)	27APR01	1 day	Yes	.	MIL	NO	Yes	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.017.24456 ie	ARTHRALGIA	PAINFUL R. ELBOW	+	Musculoskeletal System	0	42 (-70)	29MAY01	3 days	Yes	.	MOD	NO	No	UNR	No
	EAR PAIN	EARACHE (LEFT)	+	Special Senses	0	82 (-30)	08JUL01	23 days	Yes	.	SEV	NO	Yes	UNR	No
676.019.24507 i	ALLERGIC REACTION	SINUS CONGESTION DUE TO SEASONAL ALLERGY	+	Body as a Whole	0	26 (-86)	20MAR00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	2 (-110)	25FEB00	1 day	Yes	.	MIL	NO	Yes	REL	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	84 (-28)	17MAY00	1 day	Yes	.	MIL	NO	No	UNR	No
	INFECTION	STREP THROAT	+	Body as a Whole	0	35 (-77)	29MAR00	2 days	Yes	.	MOD	NO	Yes	UNR	No
	COUGH INCREASED	COUGH	+	Respiratory System	0	34 (-78)	28MAR00	3 days	Yes	.	MIL	NO	No	UNR	No
	RHINITIS	RHINITIS	+	Respiratory System	0	20 (-92)	14MAR00	17 days	Yes	.	MIL	NO	No	UNR	No
	RHINITIS	RHINITIS	+	Respiratory System	0	74 (-38)	07MAY00	7 days	Yes	.	MIL	NO	No	UNR	No
	SINUSITIS	SINUS HEADACHE	+	Respiratory System	0	21 (-91)	15MAR00	6 days	No	2	MIL	NO	Yes	UNR	No
676.019.24514 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	46 (-72)	18SEP00	1 day	Yes	.	MOD	NO	Yes	PBU	No
	CONCENTRATION IMPAIRED	CONCENTRATION PROBLEMS	+	Nervous System	0	25 (-93)	28AUG00	2 days	Yes	.	MIL	NO	No	PSR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	0	8 (-110)	11AUG00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	RHINITIS	NASAL CONGESTION	+	Respiratory System	0	16 (-102)	19AUG00	1 day	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.019.24514 ie	RHINITIS	NASAL CONGESTION	+	Respiratory System	0	48 (-70)	20SEP00	8 days	Yes	.	MIL	NO	Yes	PBU	No
676.020.24533 ie	ABDOMINAL PAIN	STOMACH HURTS WHEN PATIENT TAKES MEDICATION ON AN EMPTY STOMACH	+	Body as a Whole	0	77 (-37)	10JUL00	1 day	No	1	MIL	NO	No	PBU	No
	DECREASED APPETITE	EATING LESS	+	Digestive System	0	34 (-80)	28MAY00	CON	Yes	.	MIL	NO	No	PBU	No
	EPISTAXIS	NOSEBLEED	+	Respiratory System	0	7 (-107)	01MAY00	6 days	No	6	MIL	NO	No	PBU	No
	RASH	ALLERGIC REACTION (RASH) TO PLANT	+	Skin and Appendages	0	18 (-96)	12MAY00	CON	Yes	.	MIL	NO	Yes	UNR	No
676.023.17878 i	FLU SYNDROME	FLU-LIKE ILLNESS	^	Body as a Whole	.	-7 (-47)	05SEP00	2 days	Yes	.	MIL		No		No
	PAIN	FOOT PAIN	^	Body as a Whole	.	-13 (-53)	30AUG00	CON	No	42	MOD		No		No
	CONJUNCTIVITIS	CONJUNCTIVITIS	^	Special Senses	.	-3 (-43)	09SEP00	4 days	Yes	.	MIL		Yes		No
	DECREASED APPETITE	DECREASED APPETITE	+	Digestive System	0	11 (-29)	23SEP00	8 days	Yes	.	MIL	NO	No	PSR	No
	AGITATION	AGITATION	+	Nervous System	0	28 (-12)	10OCT00	15 days	Yes	.	MOD	STP	No	REL	No
	SOMNOLENCE	DROWSINESS (FELL ASLEEP AT SCHOOL)	+	Nervous System	0	23 (-17)	05OCT00	1 day	No	1	MOD	NO	No	PSR	No
	COUGH INCREASED	COUGH	+	Respiratory System	0	4 (-36)	16SEP00	CON	Yes	.	MOD	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous, if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.023.17878 i	RHINITIS	RUNNING NOSE	+	Respiratory System	0	4 (-36)	16SEP00	CON	Yes	.	MOD	NO	No	UNR	No
676.100.24709 ie	RESPIRATORY DISORDER	COMMON COLD	+	Respiratory System	0	78 (-36)	06JUN01	8 days	Yes	.	MOD	NO	Yes	UNR	No
676.101.24627 ie	HEADACHE	HEADACHE	^	Body as a Whole	.	-4 (-123)	16OCT00	1 day	No	1	MIL		No		No
	HEADACHE	HEADACHE		Body as a Whole	0	28 (-91)	17NOV00	1 day	No	1	MIL	NO	Yes	UNR	No
	TRAUMA	LEG INJURY	+	Body as a Whole	0	27 (-92)	16NOV00	2 days	No	1	MIL	NO	No	UNR	No
	DYSPEPSIA	UPSET STOMACH	+	Digestive System	0	18 (-101)	07NOV00	2 days	No	5	MOD	NO	No	PSR	No
	INSOMNIA	INITIAL INSOMNIA	+	Nervous System	0	18 (-101)	07NOV00	4 days	No	3	MOD	NO	No	PSR	No
	RHINITIS	STUFFY NOSE	+	Respiratory System	0	10 (-109)	30OCT00	2 days	Yes	.	MIL	NO	Yes	UNR	No
676.202.24786 ie	INFECTION	FLU	+	Body as a Whole	0	81 (-29)	07JUN00	6 days	Yes	.	MIL	NO	Yes	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	0	5 (-105)	23MAR00	1 day	Yes	.	MIL	NO	No	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	0	14 (-96)	01APR00	1 day	Yes	.	MIL	NO	No	PSR	No
	VOMITING	NAUSEA AND VOMITING	+	Digestive System	0	25 (-85)	12APR00	1 day	Yes	.	MOD	NO	No	PSR	No
676.202.24787 i	FECAL INCONTINENCE	ENCOPRESIS	+	Digestive System	0	2 (-53)	27MAR00	21 days	Yes	.	MIL	NO	No	PBU	No
676.202.24794 i	ABDOMINAL PAIN	ABDOMINAL PAIN	+	Body as a Whole	0	3 (-93)	29AUG00	1 day	Yes	.	MIL	NO	Yes	PSR	No
676.204.24852 ie	ABDOMINAL PAIN	ABDOMINAL PAIN	+	Body as a Whole	0	13 (-92)	12MAR01	1 day	Yes	.	MIL	NO	No	PSR	No
	PAIN	PAINFUL TOE	+	Body as a Whole	0	2 (-103)	01MAR01	3 days	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.204.24852 ie	DIARRHEA	DIARRHEA	+	Digestive System	0	13 (-92)	12MAR01	1 day	Yes	.	MIL	NO	No	PSR	No
676.205.24989 ie	INFECTION	WORM INFECTION	+	Body as a Whole	0	7 (-49)	14MAR01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	INFECTION	FLU SYMPTOMS	+	Body as a Whole	0	28 (-28)	04APR01	8 days	Yes	.	MIL	NO	Yes	UNR	No
	COUGH INCREASED	COUGHING	+	Respiratory System	0	14 (-42)	21MAR01	9 days	Yes	.	MIL	NO	Yes	UNR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	0	12 (-44)	19MAR01	11 days	Yes	.	MIL	NO	Yes	UNR	No
	URINARY RETENTION	URINE RETENTION	+	Urogenital System	0	12 (-44)	19MAR01	57 days	Yes	.	MOD	STP	No	PSR	No
676.206.24869 ie	INFECTION	FLU	+	Body as a Whole	0	3 (-108)	13MAR00	7 days	Yes	.	MIL	NO	Yes	UNR	No
	INFECTION	FLU	+	Body as a Whole	0	80 (-31)	29MAY00	5 days	Yes	.	MIL	NO	Yes	UNR	No
	INCOORDINATION	CLUMSY	+	Nervous System	0	1 (-110)	11MAR00	2 days	Yes	.	MIL	NO	No	PSR	No
	RHINITIS	RUNNY NOSE	+	Respiratory System	0	3 (-108)	13MAR00	CON	Yes	.	MIL	NO	Yes	UNR	No
676.206.24872 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	40 (-78)	19JUL00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	INFECTION	FLU	+	Body as a Whole	0	62 (-56)	10AUG00	5 days	Yes	.	MIL	NO	Yes	UNR	No
	COUGH INCREASED	COUGH DRY NON-PRODUCTIVE	+	Respiratory System	0	18 (-100)	27JUN00	3 days	Yes	.	MIL	NO	Yes	UNR	No
	ECZEMA	RASH INSIDE OF THE ELBOWS AND CHEST (ECZEMA)	+	Skin and Appendages	0	55 (-63)	03AUG00	33 days	Yes	.	MIL	NO	Yes	UNR	No
676.206.24879 i	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	0	5 (-103)	30AUG00	1 day	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.206.24879 i	PHARYNGITIS	TONSILLITIS	+	Respiratory System	0	11 (-97)	05SEP00	9 days	Yes	.	SEV	NO	Yes	UNR	No
676.207.24899 ie	NAUSEA	NAUSEA	^	Digestive System	.	-5 (-116)	10JUN00	1 day	No	1	MIL		Yes		No
	BACK PAIN	LOW BACKACHE	+	Body as a Whole	0	99 (-12)	22SEP00	19 days	Yes	.	MIL	NO	No	PBU	No
	HEADACHE	HEADACHES	+	Body as a Whole	0	65 (-46)	19AUG00	2 days	No	2	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	84 (-27)	07SEP00	4 days	Yes	.	MIL	NO	No	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	99 (-12)	22SEP00	19 days	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	109 (-2)	02OCT00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	NAUSEA	NAUSEA		Digestive System	0	5 (-106)	20JUN00	1 day	No	1	MIL	NO	No	PSR	No
	NAUSEA	NAUSEA		Digestive System	0	18 (-93)	03JUL00	1 day	No	1	MIL	NO	No	PSR	No
	NAUSEA	NAUSEA		Digestive System	0	65 (-46)	19AUG00	7 days	Yes	.	MIL	NO	No	PSR	No
	NAUSEA	NAUSEA		Digestive System	0	84 (-27)	07SEP00	4 days	Yes	.	MIL	NO	No	PSR	No
	NAUSEA	NAUSEA		Digestive System	0	99 (-12)	22SEP00	19 days	Yes	.	MIL	NO	No	PSR	No
	TOOTH CARIES	DENTAL CARIES	+	Digestive System	0	47 (-64)	01AUG00	1 day	No	1	MIL	NO	No	UNR	No
	TOOTH DISORDER	TOOTHACHE	+	Digestive System	0	3 (-108)	18JUN00	1 day	No	1	MIL	NO	Yes	UNR	No
	TOOTH DISORDER	TOOTHACHE	+	Digestive System	0	29 (-82)	14JUL00	18 days	Yes	.	MOD	NO	Yes	UNR	No
	CONCENTRATION IMPAIRED	IMPAIRED CONCENTRATION	+	Nervous System	0	1 (-110)	16JUN00	7 days	Yes	.	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.207.24899 ie	SOMNOLENCE	LETHARGY	+	Nervous System	0	1 (-110)	16JUN00	8 days	Yes	.	MIL	NO	No	PSR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	0	65 (-46)	19AUG00	7 days	Yes	.	MIL	NO	No	PSR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	0	83 (-28)	06SEP00	5 days	Yes	.	MIL	NO	No	PBU	No
	PHOTOSENSITIVITY	PHOTOSENSITIVITY	+	Skin and Appendages	0	99 (-12)	22SEP00	CON	Yes	.	MIL	NO	No	PBU	No
	HAEMATURIA	TRACE OF BLOOD IN URINE		Urogenital System	.	112 (1)	05OCT00	CON	Yes	.	MIL	NO	No	UNR	No
676.208.24926 ie	EOSINOPHILIA	RAISED EOSINOPHILS	^	Hemic and Lymphatic System	.	-7 (-122)	04APR00	CON		.	MIL		No		No
	RHINITIS	RUNNY NOSE AND EYES (ALLERGIC RHINITIS)	^	Respiratory System	.	-4 (-119)	07APR00	13 days	Yes	.	MOD		Yes		No
676.209.24953 ie	INFECTION	INFLUENZA	^	Body as a Whole	.	-6 (-120)	19APR00	4 days	Yes	.	MIL		No		No
	HEADACHE	HEADACHE	+	Body as a Whole	0	42 (-72)	06JUN00	1 day	Yes	.	MIL	NO	No	UNR	No
	COUGH INCREASED	COUGHING	+	Respiratory System	0	52 (-62)	16JUN00	13 days	Yes	.	MIL	NO	Yes	UNR	No
	RHINITIS	RHINITIS	+	Respiratory System	0	52 (-62)	16JUN00	13 days	Yes	.	MIL	NO	Yes	UNR	No
	RHINITIS	RHINITIS	+	Respiratory System	0	113 (-1)	16AUG00	1 day	Yes	.	MIL	NO	Yes	UNR	No
676.209.24958 i	ABNORMAL LABORATORY VALUE	UNINTENTIONAL OVERDOSE OF STUDY MEDICATION	+	Body as a Whole	0	42 (-70)	11SEP00	11 days	Yes	.	MIL	NO	No	REL	Yes

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.209.24958 i	ASTHENIA	FATIGUE AND TIREDNESS IN THE AFTERNOONS	+	Body as a Whole	0	23 (-89)	23AUG00	25 days	Yes	.	MOD	NO	No	PSR	No
	TACHYCARDIA	INCREASED PULSE RATE	+	Cardiovascular System	0	21 (-91)	21AUG00	33 days	Yes	.	MIL	NO	No	PSR	No
	NAUSEA	NAUSEA (PATIENT DRANK A TIN OF WARM COOLDRINK).	+	Digestive System	0	30 (-82)	30AUG00	1 day	Yes	.	MIL	NO	No	UNR	No
	FUNGAL DERMATITIS	FUNGAL INFECTION (IN GROIN)	+	Skin and Appendages	0	28 (-84)	28AUG00	14 days	Yes	.	MOD	NO	Yes	UNR	No
676.209.24960 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	24 (-89)	02SEP00	1 day	Yes	.	MIL	NO	No	UNR	No
	BRONCHITIS	BRONCHITIS	+	Respiratory System	0	7 (-106)	16AUG00	4 days	Yes	.	MOD	NO	Yes	UNR	No
	SINUSITIS	SINUSITIS	+	Respiratory System	0	7 (-106)	16AUG00	6 days	No	1	MOD	NO	Yes	UNR	No
	RASH	SKIN RASH (BOTH ARMS AND TRUNK).	+	Skin and Appendages	0	51 (-62)	29SEP00	14 days	Yes	.	MIL	NO	Yes	UNR	No
	OTITIS MEDIA	OTITIS MEDIA (L) EAR.	+	Special Senses	0	62 (-51)	10OCT00	6 days	Yes	.	MOD	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.001.24004 ie	ALLERGIC REACTION	SEASONAL ALLERGIES	+	Body as a Whole	0	72 (-39)	26OCT00	10 days	Yes	.	MIL	NO	Yes	PBU	No
	SOMNOLENCE	DROWSINESS AROUND 2 PM	+	Nervous System	0	38 (-73)	22SEP00	11 days	No	10	MOD	NO	No	PSR	No
	RESPIRATORY DISORDER	UPPER RESPIRATORY ILLNESS	+	Respiratory System	0	52 (-59)	06OCT00	20 days	Yes	.	MOD	NO	Yes	UNR	No
676.002.24030 ie	ASTHENIA	INCREASED TIREDNESS	+	Body as a Whole	0	25 (-91)	06MAR00	25 days	Yes	.	MIL	NO	No	PSR	No
	DYSPEPSIA	UPSET STOMACH	+	Digestive System	0	6 (-110)	16FEB00	1 day	Yes	.	MIL	NO	No	PBU	No
	WEIGHT LOSS	WEIGHT LOSS	+	Metabolic and Nutritional Disorders	0	97 (-19)	17MAY00	CON	Yes	.	MOD	NO	No	PBU	No
676.002.24033 ie	RESPIRATORY DISORDER	URI	^	Respiratory System	.	-1 (-112)	02MAY00	2 days	Yes	.	MIL		Yes		No
	ASTHENIA	INCREASED TIREDNESS	+	Body as a Whole	0	8 (-103)	11MAY00	17 days	Yes	.	MIL	NO	No	PSR	No
	ASTHENIA	INCREASED TIREDNESS	+	Body as a Whole	0	40 (-71)	12JUN00	3 days	Yes	.	MIL	NO	No	PBU	No
676.002.24037 ie	WEIGHT GAIN	WEIGHT GAIN	+	Metabolic and Nutritional Disorders	0	35 (-76)	23NOV00	117 days	Yes	.	MIL	NO	No	PBU	No
	DIZZINESS	DIZZINESS	+	Nervous System	0	1 (-110)	20OCT00	2 days	Yes	.	MIL	NO	No	PSR	No
	EMOTIONAL LABILITY	INCREASED MOODINESS	+	Nervous System	0	18 (-93)	06NOV00	7 days	Yes	.	MIL	NO	No	UNR	No
	NERVOUSNESS	INCREASED IRRITABILITY	+	Nervous System	0	18 (-93)	06NOV00	7 days	Yes	.	MIL	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.002.24037 ie	URINARY TRACT INFECTION	URINARY TRACT INFECTION	+	Urogenital System	0	10 (-101)	29OCT00	7 days	Yes	.	MOD	NO	Yes	UNR	No
676.002.24040 ie	BACK PAIN	NECK PAIN	+	Body as a Whole	0	81 (-37)	28APR01	8 days	Yes	.	MOD	NO	No	UNR	No
	BACK PAIN	BACK PAIN	+	Body as a Whole	0	81 (-37)	28APR01	54 days	Yes	.	MOD	NO	Yes	UNR	No
	BACK PAIN	NECK PAIN	+	Body as a Whole	0	111 (-7)	28MAY01	14 days	Yes	.	MIL	NO	No	UNR	No
	FLU SYNDROME	FLU-LIKE SYMPTOMS	+	Body as a Whole	0	1 (-117)	07FEB01	15 days	Yes	.	SEV	NO	Yes	UNR	No
	INFECTION	YEAST INFECTION	+	Body as a Whole	0	11 (-107)	17FEB01	6 days	Yes	.	MIL	NO	Yes	UNR	No
	PAIN	ARM PAIN	+	Body as a Whole	0	81 (-37)	28APR01	6 days	Yes	.	MIL	NO	No	UNR	No
	ARTHROSIS	NECK AND BACK STIFFNESS	+	Musculoskeletal System	0	82 (-36)	29APR01	6 days	Yes	.	MOD	NO	Yes	UNR	No
	MYALGIA	CHEST PAIN MUSCULAR	+	Musculoskeletal System	0	81 (-37)	28APR01	4 days	Yes	.	MIL	NO	No	UNR	No
	INSOMNIA	MIDDLE INSOMNIA	+	Nervous System	0	41 (-77)	19MAR01	38 days	Yes	.	MOD	NO	Yes	PBU	No
	INSOMNIA	INITIAL INSOMNIA	+	Nervous System	0	52 (-66)	30MAR01	13 days	Yes	.	MOD	NO	Yes	PBU	No
	NERVOUSNESS	INCREASED IRRITABILITY	+	Nervous System	0	48 (-70)	26MAR01	31 days	Yes	.	MOD	NO	No	PBU	No
	RESPIRATORY DISORDER	URI	+	Respiratory System	0	108 (-10)	25MAY01	3 days	Yes	.	MIL	NO	Yes	UNR	No
676.002.24044 ie	RESPIRATORY DISORDER	UPPER RESPIRATORY INFECTION	+	Respiratory System	0	6 (-106)	27FEB01	10 days	Yes	.	MOD	NO	Yes	UNR	No
676.002.24046 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	5 (-110)	06JUN01	1 day	Yes	.	MIL	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.002.24046 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	55 (-60)	26JUL01	1 day	Yes	.	MOD	NO	Yes	PBU	No
	TRAUMA	RIGHT HAND SOFT TISSUE INJURY	+	Body as a Whole	0	26 (-89)	27JUN01	4 days	Yes	.	MIL	NO	Yes	UNR	No
	COUGH INCREASED	COUGH	+	Respiratory System	0	25 (-90)	26JUN01	6 days	Yes	.	MOD	NO	Yes	UNR	No
676.003.24057 ie	INFECTION	VIRAL ILLNESS	+	Body as a Whole	0	2 (-124)	03MAR00	7 days	Yes	.	MOD	NO	Yes	UNR	No
	INFECTION	FLU	+	Body as a Whole	0	8 (-118)	09MAR00	7 days	Yes	.	MOD	NO	Yes	UNR	No
	RESPIRATORY DISORDER	URI	+	Respiratory System	0	15 (-111)	16MAR00	8 days	Yes	.	MOD	NO	Yes	UNR	No
676.003.24074 ie	BACK PAIN	BACK PAIN	+	Body as a Whole	0	23 (-91)	02MAY01	2 days	No	1	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	48 (-66)	27MAY01	12 days	No	3	MOD	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	108 (-6)	26JUL01	1 day	Yes	.	MOD	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	113 (-1)	31JUL01	2 days	Yes	.	MOD	NO	Yes	PSR	No
	DYSPEPSIA	GI DISTRESS	+	Digestive System	0	12 (-102)	21APR01	1 day	No	1	MIL	NO	Yes	PSR	No
	ABNORMAL VISION	BLURRED VISION	+	Special Senses	0	56 (-58)	04JUN01	24 days	Yes	.	MIL	DCR	No	PSR	No
676.004.24087 ie	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	0	11 (-59)	25MAR00	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	8 (-62)	22MAR00	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	46 (-24)	29APR00	1 day	Yes	.	MIL	NO	Yes	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.004.24087 ie	STOMATITIS	MOUTH PAIN	+	Digestive System	0	25 (-45)	08APR00	2 days	Yes	.	MIL	NO	No	UNR	No
676.005.24116 ie	ASTHENIA	FATIGUE	+	Body as a Whole	0	3 (-135)	09APR00	129 days	Yes	.	MIL	NO	No	PSR	No
	DECREASED APPETITE	DECREASED APPETITE	+	Digestive System	0	3 (-135)	09APR00	3 days	Yes	.	MIL	NO	No	PSR	No
676.005.24119 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	26 (-91)	30MAY00	2 days	Yes	.	MIL	NO	No	UNR	No
676.005.24125 ie	INFECTION	FLU SYMPTOMS	+	Body as a Whole	0	2 (-39)	01DEC00	3 days	Yes	.	MOD	NO	Yes	UNR	No
	SINUSITIS	SINUS INFECTION	+	Respiratory System	0	25 (-16)	24DEC00	10 days	Yes	.	MOD	NO	Yes	UNR	No
676.005.24128 i	ASTHENIA	FATIGUE	+	Body as a Whole	0	8 (-13)	10MAY01	6 days	Yes	.	MIL	NO	No	PSR	No
676.006.24141 ie	ASTHENIA	FATIGUE	+	Body as a Whole	0	16 (-98)	09MAR00	13 days	No	15	MIL	NO	No	PSR	No
	CHILLS	CHILLS, NAUSEA (WHILE SWIMMING)	+	Body as a Whole	0	42 (-72)	04APR00	1 day	No	1	SEV	NO	No	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	21 (-93)	14MAR00	1 day	Yes	.	SEV	NO	Yes	PSR	No
	DRY MOUTH	DRY MOUTH	+	Digestive System	0	4 (-110)	26FEB00	5 days	No	10	MIL	NO	No	PSR	No
	DRY MOUTH	CHAPPED LIPS	+	Digestive System	0	4 (-110)	26FEB00	24 days	No	5	MIL	NO	No	UNR	No
	DRY MOUTH	DRY MOUTH	+	Digestive System	0	22 (-92)	15MAR00	15 days	Yes	.	MOD	NO	No	PSR	No
	DRY MOUTH	CHAPPED LIPS	+	Digestive System	0	60 (-54)	22APR00	10 days	Yes	.	MIL	NO	No	PSR	No
	NAUSEA	CHILLS, NAUSEA (WHILE SWIMMING)	+	Digestive System	0	42 (-72)	04APR00	1 day	No	1	SEV	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.006.24141 ie	DIZZINESS	DIZZY (UPON STANDING)	+	Nervous System	0	16 (-98)	09MAR00	11 days	No	10	MIL	NO	No	PSR	No
	DIZZINESS	DIZZY (UPON STANDING)	+	Nervous System	0	29 (-85)	22MAR00	28 days	No	10	MIL	NO	No	PSR	No
	DIZZINESS	DIZZY (UPON STANDING)	+	Nervous System	0	60 (-54)	22APR00	4 days	No	5	SEV	NO	No	PSR	No
	DIZZINESS	DIZZY (UPON STANDING)	+	Nervous System	0	64 (-50)	26APR00	52 days	No	30	MIL	NO	No	PSR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	0	29 (-85)	22MAR00	3 days	Yes	.	MIL	NO	No	UNR	No
676.006.24144 ie	ABDOMINAL PAIN	STOMACHACHE	+	Body as a Whole	0	17 (-96)	17JUN00	3 days	No	3	SEV	NO	No	PBU	No
	BACK PAIN	BACKACHE	+	Body as a Whole	0	1 (-112)	01JUN00	17 days	Yes	.	SEV	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	11 (-102)	11JUN00	1 day	No	1	MOD	NO	No	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	42 (-71)	12JUL00	1 day	Yes	.	MOD	NO	Yes	PSR	No
	TRAUMA	SUNBURN	+	Body as a Whole	0	14 (-99)	14JUN00	4 days	Yes	.	MOD	NO	Yes	UNR	No
	DRY MOUTH	DRY MOUTH	+	Digestive System	0	11 (-102)	11JUN00	1 day	No	1	MIL	NO	No	PSR	No
	DYSPEPSIA	HEARTBURN	+	Digestive System	0	19 (-94)	19JUN00	4 days	No	10	MOD	NO	Yes	PBU	No
	NAUSEA	NAUSEA	+	Digestive System	0	4 (-109)	04JUN00	1 day	No	1	MIL	NO	No	PBU	No
	INSOMNIA	INSOMNIA	+	Nervous System	0	33 (-80)	03JUL00	18 days	No	10	MOD	NO	No	PSR	No
	RHINITIS	NASAL CONGESTION	+	Respiratory System	0	93 (-20)	01SEP00	31 days	Yes	.	MIL	NO	Yes	UNR	No
676.007.24169 ie	FLU SYNDROME	FLU LIKE SYMPTOMS	+	Body as a Whole	0	18 (-94)	17DEC99	9 days	Yes	.	MOD	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.007.24169 ie	INFECTION	INFLUENZA	+	Body as a Whole	0	44 (-68)	12JAN00	CON	Yes	.	MIL	NO	No	REL	No
	INFECTION	STOMACH VIRUS	+	Body as a Whole	0	67 (-45)	04FEB00	2 days	Yes	.	MIL	NO	Yes	UNR	No
676.007.24173 i	RESPIRATORY DISORDER	HEAD COLD	+	Respiratory System	0	22 (-89)	21JAN00	5 days	Yes	.	MIL	NO	Yes	UNR	No
676.007.24187 ie	INFECTION	INFLUENZA	+	Body as a Whole	0	68 (-44)	02JAN01	6 days	Yes	.	MOD	NO	No	UNR	No
676.007.24189 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	20 (-93)	30JAN01	2 days	Yes	.	MIL	NO	Yes	UNR	No
	HOSTILITY	INCREASED AGGRESSION	+	Nervous System	0	20 (-93)	30JAN01	3 days	Yes	.	MOD	NO	No		No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	0	14 (-99)	24JAN01	2 days	Yes	.	MIL	NO	Yes	UNR	No
	RHINITIS	NASAL CONGESTION	+	Respiratory System	0	14 (-99)	24JAN01	2 days	Yes	.	MIL	NO	No	UNR	No
	SINUSITIS	SINUS CONGESTION	+	Respiratory System	0	20 (-93)	30JAN01	2 days	Yes	.	MIL	NO	No	UNR	No
	SINUSITIS	SINUS CONGESTION	+	Respiratory System	0	35 (-78)	14FEB01	29 days	Yes	.	MOD	NO	Yes	UNR	No
676.009.24225 ie	RESPIRATORY DISORDER	URI	^	Respiratory System	.	-5 (-119)	09FEB00	5 days	Yes	.	MOD		Yes		No
	DRY MOUTH	DRY MOUTH	+	Digestive System	0	35 (-79)	20MAR00	13 days	Yes	.	MIL	NO	No	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	0	9 (-105)	23FEB00	2 days	Yes	.	SEV	NO	No	PBU	No
	VOMITING	VOMITING	+	Digestive System	0	9 (-105)	23FEB00	2 days	Yes	.	MOD	NO	No	PBU	No
	URINARY TRACT INFECTION	UTI	+	Urogenital System	0	86 (-28)	10MAY00	10 days	Yes	.	MIL	NO	Yes	UNR	No
676.009.24228 ie	TRAUMA	WHIPLASH	+	Body as a Whole	0	33 (-31)	06JUN00	6 days	Yes	.	MOD	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.009.24230 i	RESPIRATORY DISORDER	UPPER RESPIRATORY INFECTION	+	Respiratory System	0	45 (-72)	03FEB01	11 days	Yes	.	MOD	NO	Yes	UNR	No
676.009.24231 ie	ASTHENIA	FATIGUE	^	Body as a Whole	.	-3 (-112)	01FEB01	CON	Yes	.	MIL		No		No
	NAUSEA	NAUSEA	^	Digestive System	.	-2 (-111)	02FEB01	CON	Yes	.	MOD		No		No
	PHARYNGITIS	SORE THROAT	^	Respiratory System	.	-2 (-111)	02FEB01	CON	Yes	.	MOD		No		No
	HEADACHE	HEADACHE	+	Body as a Whole	0	32 (-77)	08MAR01	7 days	No	3	MOD	NO	Yes	UNR	No
	INFECTION	FLU SYNDROME	+	Body as a Whole	0	7 (-102)	11FEB01	10 days	Yes	.	MOD	NO	Yes	UNR	No
	ARTHRALGIA	LEFT HIP PAIN	+	Musculoskeletal System	0	48 (-61)	24MAR01	7 days	Yes	.	MIL	NO	Yes	UNR	No
	ARTHRALGIA	LEFT HIP PAIN	+	Musculoskeletal System	0	78 (-31)	23APR01	CON	Yes	.	MIL	NO	Yes	UNR	No
	VERTIGO	VERTIGO	+	Nervous System	0	17 (-92)	21FEB01	5 days	Yes	.	MOD	NO	Yes	UNR	No
	VERTIGO	VERTIGO	+	Nervous System	0	22 (-87)	26FEB01	9 days	Yes	.	MIL	NO	Yes	UNR	No
676.012.24312 ie	HYPERTONIA	STIFF NECK	+	Nervous System	0	42 (-77)	12JUN00	CON	Yes	.	MIL	NO	Yes	UNR	No
676.012.24314 i	DECREASED APPETITE	DECREASED APPETITE	+	Digestive System	.	125 (0)	02NOV00	CON	Yes	.	MIL	NO	No	PSR	No
676.013.24339 ie	HEADACHE	HEADACHE	^	Body as a Whole	.	-1 (-110)	23MAR00	1 day	Yes	.	MIL		No		No
	ABDOMINAL PAIN	STOMACHACHE	+	Body as a Whole	0	9 (-100)	02APR00	1 day	Yes	.	MIL	NO	No	PBU	No
	ABDOMINAL PAIN	STOMACHACHE	+	Body as a Whole	0	21 (-88)	14APR00	1 day	Yes	.	MIL	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.013.24339 ie	ABDOMINAL PAIN	STOMACHACHE	+	Body as a Whole	0	41 (-68)	04MAY00	2 days	Yes	.	MIL	NO	No	PBU	No
	HEADACHE	HEADACHE		Body as a Whole	0	28 (-81)	21APR00	1 day	Yes	.	MIL	NO	Yes	PBU	No
	MYALGIA	MUSCLE ACHES	+	Musculoskeletal System	0	9 (-100)	02APR00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	NERVOUSNESS	RESTLESSNESS	+	Nervous System	0	2 (-107)	26MAR00	6 days	Yes	.	MIL	NO	No	PSR	No
	SOMNOLENCE	DROWSINESS	+	Nervous System	0	2 (-107)	26MAR00	4 days	Yes	.	MIL	NO	No	PSR	No
	RESPIRATORY DISORDER	COMMON COLD SYMPTOMS	+	Respiratory System	0	13 (-96)	06APR00	10 days	Yes	.	MIL	NO	Yes	UNR	No
	RESPIRATORY DISORDER	COMMON COLD SYMPTOMS	+	Respiratory System	0	64 (-45)	27MAY00	6 days	Yes	.	MOD	NO	Yes	UNR	No
	HERPES SIMPLEX	COLD SORE	+	Skin and Appendages	0	13 (-96)	06APR00	10 days	Yes	.	MIL	NO	No	UNR	No
676.013.24342 ie	HEADACHE	HEADACHE	^	Body as a Whole	.	-2 (-125)	26APR00	1 day	Yes	.	MIL		No		No
	HEADACHE	HEADACHE		Body as a Whole	0	3 (-120)	01MAY00	1 day	Yes	.	MIL	NO	No	UNR	No
	HEADACHE	HEADACHE		Body as a Whole	0	4 (-119)	02MAY00	1 day	Yes	.	MIL	NO	No	UNR	No
	HEADACHE	INTERMITTENT HEADACHES		Body as a Whole	0	11 (-112)	09MAY00	3 days	Yes	.	MIL	NO	No	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	15 (-108)	13MAY00	1 day	Yes	.	MOD	NO	No	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	18 (-105)	16MAY00	1 day	Yes	.	MOD	NO	Yes	PBU	No
	HEADACHE	HEADACHE		Body as a Whole	0	24 (-99)	22MAY00	1 day	Yes	.	MIL	NO	No	UNR	No
	HEADACHE	HEADACHE		Body as a Whole	0	39 (-84)	06JUN00	1 day	Yes	.	MIL	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.013.24342 ie	DECREASED APPETITE	DECREASED APPETITE	+	Digestive System	0	13 (-110)	11MAY00	21 days	Yes	.	MIL	NO	No	PSR	No
	DIARRHEA	DIARRHEA	+	Digestive System	0	11 (-112)	09MAY00	1 day	Yes	.	MIL	NO	No	UNR	No
	TOOTH DISORDER	IMPACTED WISDOM TEETH	+	Digestive System	0	70 (-53)	07JUL00	1 day	Yes	.	MOD	NO	Yes	UNR	No
	SOMNOLENCE	DROWSINESS	+	Nervous System	0	14 (-109)	12MAY00	15 days	Yes	.	MIL	NO	No	PSR	No
676.013.24346 ie	WEIGHT GAIN	WEIGHT GAIN	+	Metabolic and Nutritional Disorders	0	42 (-12)	04AUG00	CON	Yes	.	MIL	NO	No	PSR	No
676.013.24349 ie	RESPIRATORY DISORDER	COMMON COLD SYMPTOMS	^	Respiratory System	.	-8 (-50)	02NOV00	3 days	Yes	.	MIL		No		No
	ASTHENIA	FATIGUE	+	Body as a Whole	0	6 (-36)	16NOV00	2 days	Yes	.	MOD	NO	No	UNR	No
	FEVER	ELEVATED TEMPERATURE	+	Body as a Whole	0	6 (-36)	16NOV00	2 days	Yes	.	MOD	NO	No	UNR	No
	INFECTION	FLU SYMPTOMS	+	Body as a Whole	0	6 (-36)	16NOV00	2 days	Yes	.	MOD	NO	No	UNR	No
	DYSPEPSIA	INCREASED SEVERITY OF HEARTBURN	+	Digestive System	0	16 (-26)	26NOV00	1 day	Yes	.	MOD	NO	Yes	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	0	6 (-36)	16NOV00	2 days	Yes	.	MOD	NO	No	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	0	14 (-28)	24NOV00	2 days	Yes	.	MIL	NO	No	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	0	19 (-23)	29NOV00	1 day	Yes	.	MIL	NO	No	REL	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.013.24349 ie	THIRST	INCREASED THIRST	+	Metabolic and Nutritional Disorders	0	40 (-2)	20DEC00	CON	Yes	.	MIL	NO	No	PSR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	0	7 (-35)	17NOV00	10 days	Yes	.	MOD	NO	No	UNR	No
	RHINITIS	RHINITIS	+	Respiratory System	0	15 (-27)	25NOV00	2 days	Yes	.	MIL	NO	No	UNR	No
676.014.24365 ie	ASTHMA	ASTHMA	+	Respiratory System	0	101 (-7)	05MAY00	8 days	No	2	MIL	NO	Yes	PBU	No
676.014.24370 i	HEADACHE	HEADACHE	^	Body as a Whole	.	-1 (-99)	21FEB00	2 days	Yes	.	MOD		Yes		No
	HEADACHE	HEADACHE		Body as a Whole	0	24 (-74)	17MAR00	1 day	Yes	.	MIL	NO	Yes	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	65 (-33)	27APR00	3 days	Yes	.	SEV	NO	Yes	PBU	No
	GINGIVITIS	SORE GUMS	+	Digestive System	0	8 (-90)	01MAR00	7 days	Yes	.	MOD	NO	Yes	UNR	No
	ECZEMA	ECZEMA	+	Skin and Appendages	0	38 (-60)	31MAR00	CON	Yes	.	MOD	NO	Yes	UNR	No
676.014.24373 i	NERVOUSNESS	IRRITABILITY	+	Nervous System	0	31 (-26)	09JUN00	CON	Yes	.	MOD	NO	No	PBU	No
676.014.24378 ie	TRAUMA	FRACTURE OF 2ND AND 1ST METATARSAL BONE OF THE RIGHT FOOT	+	Body as a Whole	0	12 (-38)	26NOV00	CON	Yes	.	MOD	NO	No	UNR	No
676.015.24395 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	105 (-11)	26JUN00	2 days	No	2	MIL	NO	Yes	PBU	No
	PNEUMONIA	PNEUMONIA	+	Respiratory System	0	12 (-104)	25MAR00	13 days	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.015.24408 ie	PHARYNGITIS	SORE THROAT	+	Respiratory System	0	32 (-34)	07NOV00	2 days	Yes	.	MIL	NO	No	UNR	No
	PHARYNGITIS	PHARYNGITIS	+	Respiratory System	0	40 (-26)	15NOV00	CON	Yes	.	MIL	NO	Yes	UNR	No
	RHINITIS	RHINITIS	+	Respiratory System	0	40 (-26)	15NOV00	CON	Yes	.	MIL	NO	No	UNR	No
676.015.24412 i	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	0	32 (-31)	01APR01	1 day	Yes	.	MIL	NO	No	PSR	No
	RHINITIS	RHINITIS	+	Respiratory System	0	6 (-57)	06MAR01	CON	Yes	.	MIL	NO	No	UNR	No
676.015.24413 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	2 (-115)	09MAR01	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	22 (-95)	29MAR01	1 day	Yes	.	MIL	NO	Yes	PSR	No
	NERVOUSNESS	IRRITABILITY	+	Nervous System	0	77 (-40)	23MAY01	17 days	Yes	.	MIL	DCR	No	REL	No
	RHINITIS	NASAL CONGESTION	+	Respiratory System	0	115 (-2)	30JUN01	CON	Yes	.	MIL	NO	Yes	PSR	No
676.017.24451 ie	NAUSEA	SICK TO THE STOMACH (NAUSEA)	^	Digestive System	.	-2 (-121)	26MAR00	1 day	Yes	.	MIL		No		No
	TRAUMA	STUBBED TOE	+	Body as a Whole	0	114 (-5)	20JUL00	2 days	Yes	.	SEV	NO	No	UNR	No
	RESPIRATORY DISORDER	UPPER RESPIRATORY INFECTION	+	Respiratory System	0	24 (-95)	21APR00	4 days	Yes	.	MIL	NO	Yes	UNR	No
676.017.24452 i	INFECTION	INCREASED ACNE (STAPH. INFECTION)	+	Body as a Whole	0	8 (-40)	03MAY00	CON	Yes	.	MOD	NO	Yes	PBU	No
	HOSTILITY	INCREASED ANGER	+	Nervous System	0	8 (-40)	03MAY00	CON	Yes	.	MIL	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.017.24452 i	NERVOUSNESS	INCREASED IRRITABILITY	+	Nervous System	0	8 (-40)	03MAY00	CON	Yes	.	MIL	NO	No	PBU	No
	ACNE	INCREASED ACNE (STAPH. INFECTION)	+	Skin and Appendages	0	8 (-40)	03MAY00	CON	Yes	.	MOD	NO	Yes	PBU	No
	OTITIS EXTERNA	OTITIS EXTERNA	+	Special Senses	0	22 (-26)	17MAY00	15 days	Yes	.	MOD	NO	Yes	UNR	No
676.019.24510 ie	HEADACHE	HEADACHE	^	Body as a Whole	.	-2 (-54)	17JUN00	1 day	Yes	.	MIL		Yes		No
	HEADACHE	HEADACHE		Body as a Whole	0	11 (-41)	30JUN00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE		Body as a Whole	0	45 (-7)	03AUG00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	52 (0)	10AUG00	1 day	Yes	.	MOD	NO	No	PSR	No
	INSOMNIA	INSOMNIA, EARLY AND MIDDLE, SECONDARY TO WITNESSING TRAUMATIC EVENT	+	Nervous System	0	14 (-38)	03JUL00	1 day	Yes	.	MOD	NO	Yes	UNR	No
	INSOMNIA	INITIAL INSOMNIA (2 - 3 TIMES A WEEK), SECONDARY TO WITNESSING TRAUMATIC EVENT	+	Nervous System	0	21 (-31)	10JUL00	CON	No	.	MIL	NO	Yes	PSR	No
676.019.24516 i	ALLERGIC REACTION	NASAL ALLERGY	+	Body as a Whole	0	21 (-2)	20NOV00	1 day	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.019.24516 i	COUGH INCREASED	COUGH	+	Respiratory System	0	15 (-8)	14NOV00	6 days	Yes	.	MIL	NO	Yes	UNR	No
	COUGH INCREASED	STUFFY NOSE SECONDARY TO COUGH	+	Respiratory System	0	15 (-8)	14NOV00	6 days	Yes	.	MIL	NO	Yes	UNR	No
	RHINITIS	STUFFY NOSE SECONDARY TO COUGH	+	Respiratory System	0	15 (-8)	14NOV00	6 days	Yes	.	MIL	NO	Yes	UNR	No
676.019.24519 i	ABDOMINAL PAIN	ABDOMINAL PAIN	+	Body as a Whole	0	5 (-123)	27FEB01	1 day	Yes	.	MIL	NO	No	UNR	No
	INFECTION	STREPTOCOCCAL THROAT	+	Body as a Whole	0	74 (-54)	07MAY01	7 days	Yes	.	MIL	NO	Yes	UNR	No
	RHINITIS	NASAL CONGESTION	+	Respiratory System	0	55 (-73)	18APR01	8 days	Yes	.	MIL	NO	Yes	UNR	No
676.020.24535 ie	BACK PAIN	BACK PAIN	+	Body as a Whole	0	3 (-42)	04MAY00	CON	Yes	.	MOD	NO	No	PBU	No
	BACK PAIN	NECK PAIN	+	Body as a Whole	0	7 (-38)	08MAY00	1 day	No	1	MOD	NO	No	UNR	No
	NEOPLASM	LUMPS AND BUMPS ON ARM-UNDERLYING CONDITION IS UNKNOWN	+	Body as a Whole	0	26 (-19)	27MAY00	CON	Yes	.	MIL	NO	No	PBU	No
	NEOPLASM	LUMPS AND BUMPS ON HANDS AND FEET-UNDERLYIN G CAUSE UNKNOWN	+	Body as a Whole	0	26 (-19)	27MAY00	CON	Yes	.	MIL	NO	No	PBU	No
	ARTHRALGIA	RIGHT SHOULDER AND ARM PAIN	+	Musculoskel etal System	0	7 (-38)	08MAY00	CON	Yes	.	MOD	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.020.24535 ie	RASH	SPOTS ON FACE	+	Skin and Appendages	0	10 (-35)	11MAY00	CON	Yes	.	MIL		No		No
	ALBUMINURIA	PROTEIN IN URINE	+	Urogenital System	0	45 (0)	15JUN00	CON		.	MIL	NO	No	UNR	No
676.020.24537 i	POLYCYTHEMIA	RED BLOOD CELL COUNT OUT OF RANGE.	+	Hemic and Lymphatic System	0	126 (0)	16MAR01	CON	Yes	.	MIL	NO	No	PBU	No
676.021.24564 ie	ALLERGIC REACTION	ALLERGIES	^	Body as a Whole	.	0 (-113)	10AUG00	CON	Yes	.	MIL		Yes		No
	DRY MOUTH	DRY MOUTH	+	Digestive System	0	28 (-85)	07SEP00	103 days	No	90	MIL	NO	No	PSR	No
	DIZZINESS	DIZZINESS	+	Nervous System	0	21 (-92)	31AUG00	23 days	No	92	MIL	NO	No	PSR	No
	INSOMNIA	DECREASED SLEEP	+	Nervous System	0	26 (-87)	05SEP00	82 days	No	80	MIL	NO	No	PSR	No
	SOMNOLENCE	LETHARGY	+	Nervous System	0	25 (-88)	04SEP00	CON	Yes	.	MIL	NO	No	PSR	No
	RHINITIS	NASAL CONGESTION	+	Respiratory System	0	29 (-84)	08SEP00	CON	Yes	.	MIL	NO	Yes	PBU	No
	RHINITIS	NASAL CONGESTION	+	Respiratory System	0	78 (-35)	27OCT00	2 days	No	1	MIL	NO	Yes	PBU	No
	SWEATING	INCREASED SWEATING	+	Skin and Appendages	0	7 (-106)	17AUG00	CON	Yes	.	MOD	NO	No	PSR	No
676.022.17843 ie	TRAUMA	BACK STRAIN	+	Body as a Whole	0	23 (-90)	07SEP00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	BRONCHITIS	BRONCHIAL INFECTION	+	Respiratory System	0	41 (-72)	25SEP00	14 days	No	1	MIL	NO	No	UNR	No
	OTITIS MEDIA	OTITIS MEDIA	+	Special Senses	0	41 (-72)	25SEP00	14 days	Yes	.	MIL	NO	Yes	UNR	No
676.022.17862 ie	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	0	30 (-96)	19APR01	1 day	No	1	MOD	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.022.17862 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	1 (-125)	21MAR01	1 day	Yes	.	MOD	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	9 (-117)	29MAR01	1 day	Yes	.	MIL	NO	No	UNR	No
	RESPIRATORY DISORDER	COMMON COLD	+	Respiratory System	0	35 (-91)	24APR01	4 days	No	1	MIL	NO	Yes	UNR	No
	RESPIRATORY DISORDER	COMMON COLD	+	Respiratory System	0	44 (-82)	03MAY01	3 days	No	1	MIL	NO	Yes	UNR	No
	ACNE	ACNE	+	Skin and Appendages	0	126 (0)	24JUL01	CON	Yes	.	MIL	NO	No	UNR	No
676.100.24702 i	HEADACHE	HEADACHE	^	Body as a Whole	.	0 (-99)	09AUG00	1 day	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	HEADACHE		Body as a Whole	0	52 (-47)	30SEP00	1 day	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	HEADACHE		Body as a Whole	0	78 (-21)	26OCT00	1 day	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	HEADACHE		Body as a Whole	0	79 (-20)	27OCT00	2 days	Yes	.	MOD	NO	Yes	UNR	No
	WEIGHT GAIN	WEIGHT GAIN	+	Metabolic and Nutritional Disorders	0	6 (-93)	15AUG00	CON	Yes	.	MIL	NO	No	PBU	No
	INSOMNIA	INSOMNIA	+	Nervous System	0	55 (-44)	03OCT00	CON	Yes	.	MIL	NO	No	UNR	No
	RESPIRATORY DISORDER	COMMON COLD	+	Respiratory System	0	7 (-92)	16AUG00	7 days	Yes	.	MOD	NO	Yes	UNR	No
676.100.24704 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	46 (-67)	18NOV00	8 days	Yes	.	MIL	NO	No	UNR	No
	ARTHRALGIA	JOINT PAIN	+	Musculoskeletal System	0	46 (-67)	18NOV00	8 days	Yes	.	MIL	NO	No	UNR	No
676.100.24706 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	84 (-28)	16JAN01	1 day	Yes	.	MOD	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.100.24706 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	109 (-3)	10FEB01	1 day	Yes	.	MOD	NO	Yes	UNR	No
	DIZZINESS	DIZZINESS	+	Nervous System	0	4 (-108)	28OCT00	4 days	Yes	.	MIL	NO	No	UNR	No
676.100.24707 ie	INFECTION	INFLUENZA	^	Body as a Whole	.	-2 (-114)	17DEC00	6 days	Yes	.	MIL	NO	Yes	UNR	No
	ASTHENIA	INCREASED TIREDNESS	+	Body as a Whole	0	1 (-111)	20DEC00	56 days	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHES	+	Body as a Whole	0	1 (-111)	20DEC00	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	13 (-99)	01JAN01	1 day	Yes	.	MIL	NO	No	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	14 (-98)	02JAN01	1 day	Yes	.	MIL	NO	No	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	15 (-97)	03JAN01	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	109 (-3)	07APR01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	INFECTION	FLU		Body as a Whole	0	80 (-32)	09MAR01	4 days	Yes	.	MIL	NO	No	UNR	No
	TRAUMA	RIB SPACE TENDERNESS(CARTILAGE TYPE)	+	Body as a Whole	0	103 (-9)	01APR01	CON	Yes	.	MOD	NO	No	UNR	No
	INCREASED APPETITE	INCREASED HUNGER	+	Digestive System	0	1 (-111)	20DEC00	56 days	Yes	.	MIL	NO	No	PSR	No
	MYALGIA	MUSCLE CRAMPS TO MID BACK	+	Musculoskeletal System	0	10 (-102)	29DEC00	47 days	Yes	.	MIL	NO	No	PSR	No
	DIZZINESS	DIZZINESS	+	Nervous System	0	1 (-111)	20DEC00	56 days	Yes	.	MIL	NO	No	PSR	No
	EMOTIONAL LABILITY	BAD MOOD	+	Nervous System	0	15 (-97)	03JAN01	7 days	No	10	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.100.24707 ie	ALBUMINURIA	PROTEINURIA	+	Urogenital System	0	69 (-43)	26FEB01	CON	Yes	.	MIL	NO	No	PBU	No
	CYSTITIS	BLADDER INFECTION	+	Urogenital System	0	62 (-50)	19FEB01	9 days	Yes	.	MOD	NO	Yes	PBU	No
676.101.24617 ie	TRAUMA	STRAINED ELBOW	^	Body as a Whole	.	-9 (-108)	15MAY00	8 days	No	1	MIL		Yes		No
	HEADACHE	HEADACHE	^	Body as a Whole	.	-3 (-102)	21MAY00	2 days	No	1	MOD		Yes		No
	ASTHENIA	FATIGUE	+	Body as a Whole	0	5 (-94)	29MAY00	45 days	No	4	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE		Body as a Whole	0	71 (-28)	03AUG00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE		Body as a Whole	0	95 (-4)	27AUG00	2 days	No	1	MIL	NO	Yes	UNR	No
	INFECTION	INFLUENZA	+	Body as a Whole	0	40 (-59)	03JUL00	2 days	Yes	.	MOD	NO	No	UNR	No
	SOMNOLENCE	SEDATION	+	Nervous System	0	38 (-61)	01JUL00	12 days	Yes	.	MIL	NO	No	PBU	No
	RHINITIS	SNEEZING	+	Respiratory System	0	98 (-1)	30AUG00	1 day	No	1	MIL	NO	Yes	UNR	No
	CONJUNCTIVITIS	CONJUNCTIVITIS (LEFT EYE)	+	Special Senses	0	76 (-23)	08AUG00	13 days	Yes	.	MIL	NO	No	UNR	No
676.102.24590 i	RESPIRATORY DISORDER	CHEST COLD AND SORE THROAT	+	Respiratory System	0	5 (-22)	13SEP00	3 days	No	1	MOD	NO	Yes	PBU	No
	SINUSITIS	SINUS INFECTION	+	Respiratory System	0	21 (-6)	29SEP00	CON	No	1	MIL	NO	Yes	PBU	No
676.102.24593 ie	RESPIRATORY DISORDER	COLD VIRUS	+	Respiratory System	0	40 (-78)	28FEB01	CON	Yes	.	MIL	NO	Yes	PBU	No
	RASH	RASH UNDER BOTH ARMS	+	Skin and Appendages	0	9 (-109)	28JAN01	CON	Yes	.	MIL	NO	Yes	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.103.24647 ie	ASTHENIA	FATIGUE	+	Body as a Whole	0	31 (-84)	11MAY00	4 days	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	72 (-43)	21JUN00	2 days	Yes	.	MOD	NO	Yes	PBU	No
	DRY MOUTH	DRY MOUTH	+	Digestive System	0	31 (-84)	11MAY00	4 days	Yes	.	MIL	NO	No	PSR	No
676.103.24650 ie	FEVER	FEVER	+	Body as a Whole	0	71 (-46)	19AUG00	2 days	Yes	.	MIL	NO	Yes	UNR	No
676.103.24652 ie	BACK PAIN	SORE BACK	+	Body as a Whole	0	77 (-43)	15JAN01	CON	Yes	.	MOD	NO	Yes	UNR	No
	FLU SYNDROME	FLU-LIKE SYMPTOMS	+	Body as a Whole	0	106 (-14)	13FEB01	15 days	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	17 (-103)	16NOV00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	22 (-98)	21NOV00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	39 (-81)	08DEC00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	MYALGIA	BACK SPASM	+	Musculoskeletal System	0	24 (-96)	23NOV00	2 days	Yes	.	MOD	NO	Yes	UNR	No
676.200.24731 ie	RHINITIS	VIRAL CORYZA	+	Respiratory System	0	20 (-93)	16APR00	2 days	No	1	MIL	NO	Yes	UNR	No
676.200.24732 ie	RHINITIS	VIRAL CORYZA	+	Respiratory System	0	68 (-45)	10JUN00	2 days	No	1	MIL	INC	Yes	UNR	No
676.200.24736 ie	GASTROENTERITIS	GASTROENTERITIS AND VOMITING	+	Digestive System	0	6 (-102)	12JUN00	2 days	Yes	.	MIL	NO	Yes	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.200.24736 ie	LIVER FUNCTION TESTS ABNORMAL	EOSINOPHILS ABSOLUTE0.63 HIGHER THAN RANGE; NEUTROPHILS1.7 2 LOWER THAN RANGE;EOSINOPH ILS11.8 HIGHER THAN RANGE; UREA NITROGEN2.3 LOWER THAN RANGE; BILIRUBIN 26 HIGHER THAN RANGE	+	Digestive System	0	108 (0)	22SEP00	CON	No	1	MIL	NO	No	UNR	No
	EOSINOPHILIA	EOSINOPHILS ABSOLUTE0.63 HIGHER THAN RANGE; NEUTROPHILS1.7 2 LOWER THAN RANGE;EOSINOPH ILS11.8 HIGHER THAN RANGE; UREA NITROGEN2.3 LOWER THAN RANGE; BILIRUBIN 26 HIGHER THAN RANGE	+	Hemic and Lymphatic System	0	108 (0)	22SEP00	CON	No	1	MIL	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.200.24736 ie	LEUKOPENIA	EOSINOPHILS ABSOLUTE0.63 HIGHER THAN RANGE; NEUTROPHILS1.7 2 LOWER THAN RANGE;EOSINOPH ILS11.8 HIGHER THAN RANGE; UREA NITROGEN2.3 LOWER THAN RANGE; BILIRUBIN 26 HIGHER THAN RANGE	+	Hemic and Lymphatic System	0	108 (0)	22SEP00	CON	No	1	MIL	NO	No	UNR	No
	BILIRUBINEMIA	EOSINOPHILS ABSOLUTE0.63 HIGHER THAN RANGE; NEUTROPHILS1.7 2 LOWER THAN RANGE;EOSINOPH ILS11.8 HIGHER THAN RANGE; UREA NITROGEN2.3 LOWER THAN RANGE; BILIRUBIN 26 HIGHER THAN RANGE	+	Metabolic and Nutritional Disorders	0	108 (0)	22SEP00	CON	No	1	MIL	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous, if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.200.24736 ie	BRONCHITIS	VIRAL CORYZA/BRONCHITIS	+	Respiratory System	0	17 (-91)	23JUN00	9 days	Yes	.	MIL	NO	Yes	UNR	No
	RHINITIS	VIRAL CORYZA/BRONCHITIS	+	Respiratory System	0	17 (-91)	23JUN00	9 days	Yes	.	MIL	NO	Yes	UNR	No
676.200.24737 ie	ABDOMINAL PAIN	ABDOMINAL DISCOMFORT AFTER EATING	+	Body as a Whole	0	7 (-104)	01AUG00	CON	Yes	.	MIL	NO	No	PSR	No
	RHINITIS	ALLERGIC RHINITIS	+	Respiratory System	0	92 (-19)	25OCT00	CON	Yes	.	MIL	NO	Yes	PBU	No
	ACNE	ACNE VULGARIS	+	Skin and Appendages	0	88 (-23)	21OCT00	CON	Yes	.	MIL	NO	Yes	PBU	No
676.200.24744 ie	HEADACHE	HEADACHES	+	Body as a Whole	0	23 (-90)	30NOV00	37 days	No	5	MOD	NO	Yes	PSR	No
	SOMNOLENCE	DROWSINESS	+	Nervous System	0	19 (-94)	26NOV00	19 days	No	10	MOD	NO	No	PSR	No
676.200.24746 ie	NAUSEA	NAUSEA	+	Digestive System	0	1 (-111)	28FEB01	6 days	Yes	.	MIL	NO	No	REL	No
	DIZZINESS	DIZZINESS	+	Nervous System	0	1 (-111)	28FEB01	4 days	No	1	MIL	NO	No	PSR	No
	SOMNOLENCE	DROWSINESS	+	Nervous System	0	1 (-111)	28FEB01	6 days	Yes	.	MOD	NO	No	PSR	No
676.200.24747 i	RHINITIS	VIRAL CORYZA	+	Respiratory System	0	50 (-62)	09MAY01	2 days	Yes	.	MIL	NO	Yes	UNR	No
676.201.24761 ie	INFECTION	INFLUENZA	+	Body as a Whole	0	7 (-64)	16OCT00	4 days	No	1	MIL	NO	No	UNR	No
676.203.24816 i	HEADACHE	HEADACHE	^	Body as a Whole	.	-3 (-62)	29MAR00	2 days	Yes	.	MIL		Yes		No
	HEADACHE	HEADACHE	+	Body as a Whole	0	2 (-57)	03APR00	1 day	Yes	.	MOD	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.203.24816 i	HEADACHE	HEADACHE	+	Body as a Whole	0	7 (-52)	08APR00	1 day	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	HEADACHE		Body as a Whole	0	15 (-44)	16APR00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE		Body as a Whole	0	22 (-37)	23APR00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE		Body as a Whole	0	35 (-24)	06MAY00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE		Body as a Whole	0	44 (-15)	15MAY00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE		Body as a Whole	0	55 (-4)	26MAY00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	INFECTION	FLU	+	Body as a Whole	0	30 (-29)	01MAY00	3 days	Yes	.	MIL	NO	Yes	UNR	No
676.203.24819 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	69 (-35)	05OCT00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	INFECTION	FLU	+	Body as a Whole	0	17 (-87)	14AUG00	9 days	Yes	.	MIL	NO	No	UNR	No
	SINUSITIS	SINUSITIS	+	Respiratory System	0	25 (-79)	22AUG00	CON	Yes	.	MOD	NO	Yes	UNR	No
676.204.24842 ie	COUGH INCREASED	NOCTURNAL COUGH	+	Respiratory System	0	21 (-21)	28JUN00	15 days	Yes	.	MIL	NO	No	UNR	No
	RESPIRATORY DISORDER	UPPER RESPIRATORY TRACT INFECTION	+	Respiratory System	0	5 (-37)	12JUN00	5 days	Yes	.	MIL	NO	Yes	UNR	No
	RHINITIS	BLOCKED NOSE	+	Respiratory System	0	21 (-21)	28JUN00	15 days	Yes	.	MIL	NO	No	UNR	No
676.204.24843 i	INCREASED APPETITE	INCREASED APPETITE	+	Digestive System	0	17 (-95)	01JUL00	47 days	Yes	.	MIL	NO	No	PSR	No
	DIZZINESS	DIZZINESS	+	Nervous System	0	53 (-59)	06AUG00	1 day	Yes	.	MIL	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.204.24843 i	NERVOUSNESS	IRRITABILITY	+	Nervous System	0	70 (-42)	23AUG00	15 days	Yes	.	MIL	DCR	No	PSR	No
676.204.24846 ie	HEADACHE	HEADACHES	+	Body as a Whole	0	1 (-110)	27JUL00	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	3 (-108)	29JUL00	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	4 (-107)	30JUL00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	5 (-106)	31JUL00	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	8 (-103)	03AUG00	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	9 (-102)	04AUG00	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	25 (-86)	20AUG00	2 days	Yes	.	MIL	NO	No	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	30 (-81)	25AUG00	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	63 (-48)	27SEP00	1 day	Yes	.	MIL	NO	No	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	102 (-9)	05NOV00	1 day	Yes	.	MIL	NO	Yes	PBU	No
676.204.24847 i	HEADACHE	HEADACHE	+	Body as a Whole	0	2 (-109)	01SEP00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	4 (-107)	03SEP00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	5 (-106)	04SEP00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	9 (-102)	08SEP00	1 day	Yes	.	MIL	NO	Yes	PBU	No
	INFECTION	FLU	+	Body as a Whole	0	27 (-84)	26SEP00	28 days	Yes	.	MIL	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.204.24847 i	INFECTION	FLU	+	Body as a Whole	0	83 (-28)	21NOV00	CON	Yes	.	MIL	NO	No	UNR	No
	TRAUMA	INJURY TO LEFT HAND	+	Body as a Whole	0	104 (-7)	12DEC00	2 days	Yes	.	MOD	NO	Yes	UNR	No
	DIARRHEA	DIARRHOEA	+	Digestive System	0	52 (-59)	21OCT00	1 day	Yes	.	MIL	NO	Yes	PBU	No
	NAUSEA	NAUSEA	+	Digestive System	0	36 (-75)	05OCT00	6 days	Yes	.	MIL	DCR	No	REL	No
	ULCERATIVE STOMATITIS	MOUTH ULCERS	+	Digestive System	0	25 (-86)	24SEP00	14 days	Yes	.	MIL	NO	Yes	UNR	No
	EXTRAPYRAMIDAL SYNDROME	EXTRAPYRAMIDAL SIDE EFFECTS (THICK TONGUE & QUIVERING JAW)	+	Nervous System	0	36 (-75)	05OCT00	7 days	No	3	MOD	DCR	Yes	REL	No
	INSOMNIA	MIDDLE INSOMNIA	+	Nervous System	0	16 (-95)	15SEP00	48 days	Yes	.	MIL	NO	No	PSR	No
	RESPIRATORY DISORDER	UPPER RESPIRATORY TRACT INFECTION	+	Respiratory System	0	55 (-56)	24OCT00	6 days	Yes	.	MIL	NO	Yes	UNR	No
	YAWN	YAWNING	+	Respiratory System	0	36 (-75)	05OCT00	6 days	No	3	MIL	DCR	No	REL	No
676.204.24850 i	ABDOMINAL PAIN	PAINFUL ABDOMEN	^	Body as a Whole	.	0 (-51)	25JAN01	1 day	Yes	.	MIL		No		No
	PHARYNGITIS	PAINFUL THROAT	^	Respiratory System	.	0 (-51)	25JAN01	1 day	Yes	.	MIL		No		No
	NAUSEA	NAUSEA	+	Digestive System	0	12 (-39)	06FEB01	1 day	Yes	.	MIL	NO	No	PSR	No
676.205.24987 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	3 (-109)	25FEB01	1 day	No	1	MIL	NO	Yes	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.205.24987 ie	AGITATION	AGITATION	+	Nervous System	0	14 (-98)	08MAR01	CON	Yes	.	MOD	NO	No	PBU	No
676.206.24874 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	2 (-108)	10JUL00	5 days	No	5	MIL	NO	No	PSR	No
	COUGH INCREASED	COUGH	+	Respiratory System	0	21 (-89)	29JUL00	14 days	Yes	.	MOD	NO	Yes	UNR	No
	RESPIRATORY DISORDER	COLD(COMMON)	+	Respiratory System	0	12 (-98)	20JUL00	6 days	Yes	.	MOD	NO	Yes	UNR	No
676.206.24876 ie	INFECTION	FLU	+	Body as a Whole	0	21 (-109)	15SEP00	12 days	Yes	.	MOD	NO	Yes	UNR	No
676.206.24880 ie	INFECTION	FLU	+	Body as a Whole	0	50 (-64)	10MAR01	6 days	Yes	.	MOD	NO	Yes	UNR	No
	HYPOTENSION	DIZZINESS-DUE TO LOW BLOOD PRESSURE	+	Cardiovascular System	0	7 (-107)	26JAN01	CON	Yes	.	MIL	NO	No	PBU	No
676.207.24897 ie	RESPIRATORY DISORDER	COMMON COLD	+	Respiratory System	0	52 (-33)	23APR00	9 days	Yes	.	MIL	NO	No	UNR	No
	RHINITIS	RHINITIS DUE TO ALLERGY	+	Respiratory System	0	12 (-73)	14MAR00	13 days	Yes	.	MOD	NO	Yes	UNR	No
676.207.24902 ie	DIZZINESS	DIZZINESS	+	Nervous System	0	1 (-111)	20OCT00	6 days	Yes	.	MIL	NO	No	PSR	No
676.207.24904 ie	ASTHENIA	TIREDNESS	+	Body as a Whole	0	11 (-101)	13FEB01	32 days	Yes	.	MIL	NO	No	PSR	No
	ASTHENIA	TIREDNESS	+	Body as a Whole	0	84 (-28)	27APR01	37 days	Yes	.	MOD	NO	No	PSR	No
	BACK PAIN	BACKACHE	+	Body as a Whole	0	95 (-17)	08MAY01	2 days	Yes	.	SEV	NO	Yes	PBU	No
	DIARRHEA	DIARRHOEA	+	Digestive System	0	87 (-25)	30APR01	6 days	Yes	.	MOD	NO	Yes	PBU	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	0	90 (-22)	03MAY01	2 days	Yes	.	MIL	NO	Yes	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.207.24904 ie	PHARYNGITIS	SORE THROAT	+	Respiratory System	0	100 (-12)	13MAY01	2 days	Yes	.	MIL	NO	Yes	PBU	No
676.207.24910 ie	ABDOMINAL PAIN	ABDOMINAL PAIN	+	Body as a Whole	0	20 (-92)	25APR01	1 day	No	1	MIL	NO	Yes	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	5 (-107)	10APR01	1 day	No	1	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	23 (-89)	28APR01	1 day	No	1	MIL	NO	No	PSR	No
	VASODILATATION	HOT FLUSHES	+	Cardiovascular System	0	28 (-84)	03MAY01	15 days	Yes	.	MIL	NO	No	PSR	No
	ANXIETY	INCREASED ANXIETY	+	Nervous System	0	77 (-35)	21JUN01	36 days	Yes	.	MIL	NO	No	PSR	No
	DIZZINESS	DIZZINESS	+	Nervous System	0	40 (-72)	15MAY01	1 day	No	1	MIL	NO	No	PBU	No
	SOMNOLENCE	DROWSINESS	+	Nervous System	0	2 (-110)	07APR01	2 days	Yes	.	MIL	NO	No	PSR	No
676.209.24957 i	RASH	RASH RIGHT ARM DUE TO MICROPORE	^	Skin and Appendages	.	-6 (-117)	05MAY00	CON	Yes	.	MIL		No		No
	INFECTION	INFLUENZA	+	Body as a Whole	0	4 (-107)	15MAY00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	0	1 (-110)	12MAY00	1 day	Yes	.	MIL	NO	No	PSR	No
676.209.24962 ie	ASTHENIA	FATIGUE DURING DAYTIME	+	Body as a Whole	0	1 (-61)	11OCT00	27 days	Yes	.	MIL	NO	No	REL	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	32 (-30)	11NOV00	1 day	Yes	.	MIL	NO	Yes	UNR	No
676.209.24963 ie	ABDOMINAL PAIN	ABDOMINAL DISCOMFORT	+	Body as a Whole	0	7 (-120)	24OCT00	1 day	No	1	MIL	NO	No	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	31 (-96)	17NOV00	1 day	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.209.24963 ie	MYALGIA	MUSCLE PAIN IN RIGHT SHOULDER	+	Musculoskeletal System	0	28 (-99)	14NOV00	2 days	Yes	.	MIL	NO	Yes	UNR	No
676.209.24965 ie	GASTROENTERITIS	GASTROENTERITIS (NAUSEA AND VOMITING)	+	Digestive System	0	14 (-103)	01NOV00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	GASTROENTERITIS	NAUSEA/VOMITING/DIARRHOEA.	+	Digestive System	0	69 (-48)	26DEC00	5 days	Yes	.	MOD	NO	Yes	UNR	No
	COUGH INCREASED	COUGHING	+	Respiratory System	0	1 (-116)	19OCT00	13 days	Yes	.	MIL	NO	Yes	UNR	No
	PHOTOPHOBIA	LIGHT SENSITIVITY	+	Special Senses	0	3 (-114)	21OCT00	12 days	Yes	.	MIL	NO	No	UNR	No
	URINARY FREQUENCY	URINARY FREQUENCY	+	Urogenital System	0	35 (-82)	22NOV00	15 days	Yes	.	MIL	NO	No	UNR	No
676.209.24967 i	HEADACHE	HEADACHE	+	Body as a Whole	0	3 (-87)	24FEB01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	12 (-78)	05MAR01	1 day	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	52 (-38)	14APR01	2 days	Yes	.	MIL	NO	Yes	UNR	No
	PHARYNGITIS	PHARYNGITIS	+	Respiratory System	0	16 (-74)	09MAR01	3 days	Yes	.	MIL	NO	Yes	UNR	No
	RESPIRATORY DISORDER	URTI (SORE THROAT, DIZZINESS, NAUSEA)	+	Respiratory System	0	83 (-7)	15MAY01	8 days	Yes	.	MOD	NO	Yes	UNR	No
676.300.25010 ie	SYNCOPE	SYNCOPE	+	Cardiovascular System	0	111 (-3)	22AUG00	1 day	No	2	MOD	NO	No	PSR	No
676.300.25011 i	TREMOR	TREMBLING	^	Nervous System	.	-5 (-103)	11MAY00	CON	Yes	.	MOD		No		No
	HYPOTENSION	HYPOTENSION	+	Cardiovascular System	0	3 (-95)	19MAY00	1 day	Yes	.	MOD	NO	Yes	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.300.25011 i	SYNCOPE	LIPOTHYMIA	+	Cardiovascular System	0	15 (-83)	31MAY00	CON	No	1	MOD	NO	No	UNR	No
	PHARYNGITIS	RHINOPHARYNGITIS	+	Respiratory System	0	13 (-85)	29MAY00	8 days	Yes	.	MOD	NO	Yes	UNR	No
676.301.25037 ie	ABDOMINAL PAIN	STOMACHACHE	+	Body as a Whole	0	45 (-68)	20OCT00	20 days	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	41 (-72)	16OCT00	24 days	Yes	.	MIL	NO	Yes	PBU	No
	RHINITIS	RHINITIS	+	Respiratory System	0	42 (-71)	17OCT00	7 days	Yes	.	MIL	NO	Yes	PBU	No
676.301.25040 i	COUGH INCREASED	COUGH	+	Respiratory System	0	11 (-93)	29APR01	8 days	Yes	.	MIL	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	No. Cont.	Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.		.						

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.1

Adverse Experiences (Excl. Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.009.24231 ie	DYSMENORRHEA	MENSTRUAL CRAMPS	+	Urogenital System	0	40 (-69)	16MAR01	3 days	Yes	.	MOD	NO	Yes	UNR	No
676.012.24312 ie	DYSMENORRHEA	MENSTRUAL CRAMPS	+	Urogenital System	0	6 (-113)	07MAY00	CON	Yes	.	MIL	NO	Yes	UNR	No
676.015.24413 ie	DYSMENORRHEA	MENSTRUAL CRAMPS	+	Urogenital System	0	83 (-34)	29MAY01	3 days	Yes	.	MIL	NO	Yes	PSR	No
676.301.25040 i	DYSMENORRHEA	PAINFULL PERIODS	+	Urogenital System	0	25 (-79)	13MAY01	3 days	Yes	.	MOD	NO	Yes	UNR	No
	DYSMENORRHEA	PAINFUL PERIODS	+	Urogenital System	0	84 (-20)	11JUL01	3 days	Yes	.	MOD	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, + =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continuous,
if No then No. Epi = Number Of Episodes
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.001.24008 ie	RESPIRATORY DISORDER	UPPER RESPIRATORY INFECTION (URI)	+	Respiratory System	.	137 (20)	22JAN01	CON	Yes	.	MOD	NO	Yes	PBU	No
676.002.24031 i	DIARRHEA	DIARRHEA	+	Digestive System	20	118 (6)	12JUN00	2 days	Yes	.	MOD	NO	Yes	UNR	No
	DYSPEPSIA	UPSET STOMACH	+	Digestive System	.	136 (24)	30JUN00	3 days	Yes	.	MIL	NO	No	UNR	No
676.003.24071 i	ABDOMINAL PAIN	STOMACH PAIN	+	Body as a Whole	.	114 (3)	02JUN01	4 days	No	1	MIL	NO	No	UNR	No
	VOMITING	VOMITING	+	Digestive System	.	114 (3)	02JUN01	4 days	No	1	MIL	NO	No	UNR	No
676.003.24073 i	DYSPEPSIA	UPSET STOMACH	+	Digestive System	.	66 (2)	01JUN01	4 days	No	1	MIL	NO	Yes	PSR	No
	ASTHMA	ASTHMA	+	Respiratory System	.	67 (3)	02JUN01	CON	Yes	.	MIL	NO	Yes	UNR	No
676.007.24193 ie	HEADACHE	HEADACHE	+	Body as a Whole	40	138 (28)	17OCT01	8 days	Yes	.	MOD	NO	Yes	PBU	No
676.010.24254 i	INSOMNIA	INSOMNIA	+	Nervous System	20	128 (11)	20AUG00	CON	Yes	.	MIL	NO	No	PBU	No
	CONSTIPATION	CONSTIPATION		Digestive System	.	151 (34)	12SEP00	1 day	Yes	.	MIL	NO	Yes	UNR	No
676.013.24337 ie	FLU SYNDROME	FLU LIKE SYMPTOMS	+	Body as a Whole	.	115 (3)	01JUL00	2 days	Yes	.	MIL	NO	No	REL	No
676.013.24344 ie	RHINITIS	RHINITIS	+	Respiratory System	20	118 (3)	10SEP00	CON	Yes	.	MIL	NO	No	UNR	No
	ABDOMINAL PAIN	STOMACHACHE	+	Body as a Whole	.	126 (11)	18SEP00	3 days	Yes	.	MIL	NO	No	REL	No
676.013.24345 ie	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	30	136 (17)	28OCT00	10 days	Yes	.	MIL	NO	No	PSR	No
	FLU SYNDROME	FLU LIKE SYMPTOMS	+	Body as a Whole	30	129 (10)	21OCT00	3 days	Yes	.	MOD	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.013.24345 ie	HEADACHE	INTERMITTENT HEADACHES	+	Body as a Whole	30	124 (5)	16OCT00	22 days	Yes	.	MOD	NO	Yes	PSR	No
	DIZZINESS	INTERMITTENT DIZZINESS	+	Nervous System	30	136 (17)	28OCT00	7 days	Yes	.	MIL	NO	No	PSR	No
676.014.24366 ie	HEADACHE	HEADACHE	+	Body as a Whole	30	131 (24)	05JUN00	1 day	Yes	.	MOD	NO	Yes	PSR	No
	FEVER	FEVER	+	Body as a Whole	.	139 (32)	13JUN00	1 day	Yes	.	MOD	NO	Yes	PBU	No
	HEADACHE	HEADACHE	+	Body as a Whole	.	135 (28)	09JUN00	CON	Yes	.	MOD	NO	Yes	PSR	No
676.015.24409 ie	INFECTION	FLU SYMPTOMS	+	Body as a Whole	.	61 (10)	04FEB01	8 days	Yes	.	MIL	NO	No	PSR	No
676.015.24411 i	HEADACHE	NAUSEA AND HEADACHE	+	Body as a Whole	.	61 (2)	14APR01	3 days	Yes	.	MIL	NO	Yes	PSR	No
	NAUSEA	NAUSEA AND HEADACHE	+	Digestive System	.	61 (2)	14APR01	3 days	Yes	.	MIL	NO	Yes	PSR	No
676.017.24450 ie	NAUSEA	NAUSEA	+	Digestive System	40	140 (27)	19JUL00	2 days	Yes	.	MIL	NO	No	PSR	No
676.017.24453 ie	TRAUMA	FRACTURED RIGHT WRIST	+	Body as a Whole	40	140 (19)	12SEP00	1 day	Yes	.	MOD	NO	Yes	UNR	No
	SINUSITIS	SINUS INFECTION	+	Respiratory System	40	129 (8)	01SEP00	7 days	Yes	.	SEV	NO	No	PBU	No
	VOMITING	VOMITING	+	Digestive System	.	149 (28)	21SEP00	4 days	Yes	.	MOD	NO	No	PBU	No
676.017.24455 i	HEADACHE	HEADACHE		Body as a Whole	.	117 (23)	07MAY01	1 day	Yes	.	MIL	NO	Yes	PBU	No
676.020.24538 ie	TRAUMA	CUT ON LEG	+	Body as a Whole	10	120 (8)	21JUL01	CON	Yes	.	MIL	NO	Yes	UNR	No
	EAR PAIN	EARACHE	+	Special Senses	.	129 (17)	30JUL01	CON	Yes	.	MOD	NO	Yes	UNR	No
676.203.24814 ie	HEADACHE	HEADACHE	+	Body as a Whole	.	71 (1)	19AUG00	CON	Yes	.	MIL	NO	No	REL	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.203.24814 ie	NAUSEA	NAUSEA	+	Digestive System	.	71 (1)	19AUG00	7 days	Yes	.	MOD	NO	No	REL	No
	INSOMNIA	INSOMNIA	+	Nervous System	.	74 (4)	22AUG00	CON	Yes	.	MOD	NO	No	REL	No
	TREMOR	TREMBLING	+	Nervous System	.	71 (1)	19AUG00	7 days	Yes	.	MOD	NO	No	REL	No
676.206.24878 ie	HEADACHE	HEADACHE	+	Body as a Whole	.	138 (6)	10JAN01	3 days	Yes	.	MIL	NO	No	PSR	No
676.207.24898 ie	NERVOUSNESS	IRRITABILITY	+	Nervous System	20	113 (3)	28SEP00	33 days	Yes	.	MOD	NO	No	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	.	125 (15)	10OCT00	1 day	Yes	.	MIL	NO	Yes	UNR	No
676.301.25038 ie	VOMITING	VOMITING	+	Digestive System	.	130 (18)	14JAN01	1 day	No	1	MIL	NO	Yes	PSR	No
	DIZZINESS	DIZZINESS	+	Nervous System	.	128 (16)	12JAN01	4 days	Yes	.	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.023.17877 ie	DYSMENORRHEA	MENSTRUAL CRAMPS	Urogenital System	.	165 (109)	13JAN01	1 day	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.001.24003 ie	THYROID DISORDER	ELEVATED TSH LEVEL (6.8), NORMAL LIMITS 0.4-5.5		Endocrine System	.	156 (37)	19JAN01	CON	Yes	.	MIL	NO	No	PBU	No
	DEPRESSION	SADNESS, IRRITABILITY, AND LACK OF MOTIVATION	+	Nervous System	.	140 (21)	03JAN01	CON	Yes	.	MOD	NO	No	PSR	No
	LACK OF EMOTION	SADNESS, IRRITABILITY, AND LACK OF MOTIVATION	+	Nervous System	.	140 (21)	03JAN01	CON	Yes	.	MOD	NO	No	PSR	No
	NERVOUSNESS	SADNESS, IRRITABILITY, AND LACK OF MOTIVATION	+	Nervous System	.	140 (21)	03JAN01	CON	Yes	.	MOD	NO	No	PSR	No
676.002.24032 ie	HEADACHE	HEADACHE	+	Body as a Whole	40	128 (15)	01JUL00	5 days	Yes	.	MOD	NO	Yes	UNR	No
	INFECTION	STREP THROAT	+	Body as a Whole	40	128 (15)	01JUL00	13 days	Yes	.	MOD	NO	Yes	UNR	No
	ASTHENIA	INCREASED TIREDNESS	+	Body as a Whole	.	144 (31)	17JUL00	5 days	Yes	.	MOD	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	.	144 (31)	17JUL00	7 days	Yes	.	MOD	NO	Yes	PSR	No
	DIARRHEA	DIARRHEA	+	Digestive System	.	144 (31)	17JUL00	1 day	Yes	.	MIL	NO	No	PBU	No
	NAUSEA	NAUSEA	+	Digestive System	.	144 (31)	17JUL00	7 days	Yes	.	MOD	NO	No	PSR	No
	MYALGIA	MUSCLE ACHES	+	Musculoskeletal System	.	144 (31)	17JUL00	CON	Yes	.	MIL	NO	No	PBU	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	.	149 (36)	22JUL00	2 days	Yes	.	MIL	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.002.24038 ie	DIZZINESS	DIZZINESS	+	Nervous System	40	138 (25)	24MAR01	8 days	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	.	145 (32)	31MAR01	2 days	Yes	.	MIL	NO	Yes	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	.	144 (31)	30MAR01	3 days	Yes	.	MIL	NO	No	PSR	No
	DIZZINESS	DIZZINESS	+	Nervous System	.	145 (32)	31MAR01	2 days	Yes	.	MOD	NO	No	PSR	No
	DIZZINESS	INTERMITTENT DIZZINESS	+	Nervous System	.	147 (34)	02APR01	7 days	Yes	.	MIL	NO	No	PSR	No
676.002.24042 ie	HEADACHE	HEADACHE	+	Body as a Whole	40	117 (6)	19JUN01	1 day	Yes	.	MIL	NO	Yes	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	.	144 (33)	16JUL01	1 day	Yes	.	MIL	NO	No	PSR	No
	LYMPHADENOPATHY	NECK PAIN WITH SWOLLEN LYMPH NODES	+	Hemic and Lymphatic System	.	144 (33)	16JUL01	CON	Yes	.	MIL	NO	Yes	UNR	No
	DIZZINESS	DIZZINESS	+	Nervous System	.	143 (32)	15JUL01	6 days	Yes	.	MOD	NO	No	PSR	No
676.003.24075 ie	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	.	125 (14)	18SEP01	CON	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	.	117 (6)	10SEP01	11 days	No	4	MIL	NO	Yes	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	.	120 (9)	13SEP01	8 days	Yes	.	MIL	NO	No	UNR	No
	DIZZINESS	DIZZINESS	+	Nervous System	.	120 (9)	13SEP01	CON	Yes	.	MIL	NO	No	UNR	No
	SINUSITIS	SINUS PRESSURE	+	Respiratory System	.	117 (6)	10SEP01	CON	Yes	.	MIL	NO	No	UNR	No
676.004.24085 i	HEADACHE	ALLERGY HEADACHE	+	Body as a Whole	10	120 (8)	31MAY00	2 days	Yes	.	MIL	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.004.24085 i	HYPERKINESIA	ATTENTION DEFICIT HYPERACTIVITY DISORDER.	+	Nervous System	.	126 (14)	06JUN00	CON	Yes	.	MOD	NO	Yes	UNR	No
676.005.24122 ie	ANXIETY	HOSPITALIZATION DUE TO HIS FEARS AND DEP DISEASE UNDER STUDY	+	Nervous System	.	84 (14)	30NOV00	5 days	Yes	.	MOD	NO	Yes	UNR	Yes
	DEPRESSION	HOSPITALIZATION DUE TO HIS FEARS AND DEP DISEASE UNDER STUDY	+	Nervous System	.	84 (14)	30NOV00	5 days	Yes	.	MOD	NO	Yes	UNR	Yes
676.006.24143 ie	RESPIRATORY DISORDER	UPPER RESPIRATORY INFECTION	+	Respiratory System	40	124 (11)	01OCT00	5 days	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	.	141 (28)	18OCT00	CON	No	5	MOD	NO	Yes	PSR	No
676.006.24145 ie	DIZZINESS	DIZZINESS	+	Nervous System	30	119 (7)	20DEC00	14 days	Yes	.	SEV	NO	Yes	REL	No
	MYOCLONUS	MYOCLONIC JERKS	+	Nervous System	30	119 (7)	20DEC00	19 days	No	25	MOD	NO	No	REL	No
	DIZZINESS	DIZZINESS	+	Nervous System	.	133 (21)	03JAN01	5 days	Yes	.	MIL	NO	No	REL	No
	MYOCLONUS	MYOCLONIC JERKS	+	Nervous System	.	138 (26)	08JAN01	2 days	No	5	MIL	NO	No	REL	No
676.007.24172 ie	ABDOMINAL PAIN	STOMACH CRAMPS	+	Body as a Whole	.	124 (9)	09APR00	8 days	No	.	MOD	NO	No	PSR	No
	ASTHENIA	FATIGUE	+	Body as a Whole	.	125 (10)	10APR00	7 days	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHES	+	Body as a Whole	.	123 (8)	08APR00	4 days	No	.	MOD	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.007.24172 ie	DIZZINESS	DIZZINESS	+	Nervous System	.	124 (9)	09APR00	8 days	No	.	MIL	NO	Yes	PSR	No
676.007.24192 ie	SINUSITIS	SINUS DRAINAGE	+	Respiratory System	40	124 (16)	26SEP01	19 days	Yes	.	MIL	NO	Yes	UNR	No
676.009.24227 ie	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	.	143 (20)	27AUG00	7 days	No	.	MOD	NO	No	PSR	No
	DIZZINESS	DIZZINESS	+	Nervous System	.	143 (20)	27AUG00	7 days	No	.	MOD	NO	No	PSR	No
	RHINITIS	NASAL CONGESTION	+	Respiratory System	.	145 (22)	29AUG00	2 days	Yes	.	MOD	NO	Yes	UNR	No
676.011.24283 ie	EMOTIONAL LABILITY	VAGUE SUICIDAL IDEATION	+	Nervous System	.	112 (1)	13NOV00	1 day	Yes	.	MIL	NO	No	UNR	No
676.013.24351 ie	ALLERGIC REACTION	ALLERGY SYMPTOMS (NASAL CONGESTION, SNEEZING)	+	Body as a Whole	30	114 (2)	03JUN01	2 days	Yes	.	MIL	NO	Yes	UNR	No
	DIZZINESS	LIGHTHEADEDNESS	+	Nervous System	.	139 (27)	28JUN01	9 days	No	.	MIL	NO	No	PSR	No
676.013.24352 ie	ASTHENIA	FATIGUE	+	Body as a Whole	40	117 (4)	24JUL01	4 days	Yes	.	MOD	NO	No	PSR	No
676.014.24368 ie	SOMNOLENCE	SLEEPINESS	+	Nervous System	10	112 (2)	01JUN00	5 days	Yes	.	MIL	NO	No	PSR	No
676.014.24374 ie	NERVOUSNESS	IRRITABILITY	+	Nervous System	30	117 (5)	01OCT00	CON	Yes	.	MOD	NO	No	PSR	No
676.014.24376 i	INSOMNIA	SLEEP DISTURBANCE	+	Nervous System	.	42 (8)	10OCT00	CON	Yes	.	SEV	NO	No	PBU	No
676.015.24394 ie	ANXIETY	SOCIAL ANXIETY	+	Nervous System	.	151 (31)	30JUN00	CON	Yes	.	MOD	NO	Yes	REL	No
676.015.24407 ie	TRAUMA	FRACTURED ARM	+	Body as a Whole	30	139 (20)	05FEB01	CON	Yes	.	SEV	NO	Yes	UNR	Yes

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.015.24407 ie	TRAUMA	PAIN FROM BROKEN ARM	+	Body as a Whole	.	152 (33)	18FEB01	1 day	Yes	.	MIL	NO	Yes	UNR	No
676.015.24414 i	ANXIETY	EXACERBATION OF SOCIAL ANXIETY	+	Nervous System	.	154 (37)	21AUG01	CON	Yes	.	MIL	NO	Yes	REL	No
	DIZZINESS	DIZZINESS	+	Nervous System	.	151 (34)	18AUG01	CON	Yes	.	MIL	NO	No	PSR	No
	EMOTIONAL LABILITY	MOODINESS	+	Nervous System	.	151 (34)	18AUG01	3 days	Yes	.	MIL	NO	No	PSR	No
676.020.24534 ie	ABDOMINAL PAIN	STOMACH PAIN	+	Body as a Whole	30	148 (1)	09SEP00	CON	Yes	.	MIL	NO	Yes	PBU	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	30	158 (11)	19SEP00	CON	Yes	.	MIL	NO	Yes	UNR	No
676.020.24536 ie	HEADACHE	HEADACHE	+	Body as a Whole	20	129 (9)	18JAN01	1 day	No	1	MIL	NO	Yes	PBU	No
	FLATULENCE	GAS	+	Digestive System	.	142 (22)	31JAN01	1 day	Yes	.	MIL	NO	Yes	PBU	No
676.100.24705 ie	HEADACHE	HEADACHE	+	Body as a Whole	.	56 (13)	11DEC00	1 day	Yes	.	MOD	NO	Yes	UNR	No
676.100.24710 ie	HEADACHE	HEADACHE	+	Body as a Whole	40	130 (12)	25AUG01	29 days	Yes	.	MOD	NO	Yes	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	40	130 (12)	25AUG01	29 days	Yes	.	MOD	NO	Yes	PSR	No
	DIZZINESS	DIZZINESS	+	Nervous System	40	130 (12)	25AUG01	29 days	Yes	.	MOD	NO	No	PSR	No
676.101.24623 ie	TRAUMA	WRIST INJURY		Body as a Whole	.	167 (57)	14DEC00	5 days	Yes	.	MOD	NO	Yes	UNR	No
676.101.24629 i	DYSPEPSIA	UPSET STOMACH (ANXIETY)		Digestive System	.	183 (64)	26SEP01	1 day	No	1	MOD	NO	No	UNR	No
	ANXIETY	UPSET STOMACH (ANXIETY)		Nervous System	.	183 (64)	26SEP01	1 day	No	1	MOD	NO	No	UNR	No
676.103.24649 ie	RESPIRATORY DISORDER	COLD	+	Respiratory System	.	147 (30)	13OCT00	CON	Yes	.	MIL	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.103.24654 i	HEADACHE	HEADACHE	+	Body as a Whole	.	120 (8)	21JUL01	6 days	No	6	MOD	NO	Yes	REL	No
	DIZZINESS	LIGHTHEADEDNESS	+	Nervous System	.	120 (8)	21JUL01	6 days	No	6	MOD	NO	No	REL	No
676.202.24789 ie	HEADACHE	HEADACHES	+	Body as a Whole	.	139 (8)	12JAN01	2 days	Yes	.	SEV	NO	No	PSR	No
676.202.24798 ie	ANXIETY	TEARFULL AND IRRITABLE DUE TO SOCIAL ANXIETY DISORDER	+	Nervous System	.	129 (16)	18JUN01	12 days	Yes	.	MIL	NO	Yes	PSR	No
676.202.24799 ie	WITHDRAWAL SYNDROME	NAUSEA WITH HEADACHE(WITHDRAWAL SYMPTOMS)	+	Nervous System	.	125 (10)	18JUN01	4 days	Yes	.	MOD	NO	Yes	PSR	No
676.203.24813 ie	HEADACHE	HEADACHE	+	Body as a Whole	.	113 (3)	01JUL00	5 days	Yes	.	MOD	NO	Yes	REL	No
	NAUSEA	NAUSEA	+	Digestive System	.	113 (3)	01JUL00	5 days	Yes	.	MOD	NO	Yes	REL	No
676.204.24844 i	ABNORMAL VISION	MYOPIA	+	Special Senses	40	119 (14)	25OCT00	CON	Yes	.	MIL	NO	No	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	.	134 (29)	09NOV00	3 days	Yes	.	MIL	NO	No	PSR	No
	DIZZINESS	DIZZINESS	+	Nervous System	.	134 (29)	09NOV00	3 days	Yes	.	MIL	NO	No	PSR	No
676.204.24845 ie	ACNE	FACIAL PIMPLES		Skin and Appendages	.	168 (53)	15DEC00	CON	Yes	.	MIL	NO	No	UNR	No
676.204.24851 ie	SOMNOLENCE	AFTERNOON SLEEPINESS	+	Nervous System	40	125 (13)	19JUN01	11 days	Yes	.	MIL	NO	No	PSR	No
	RESPIRATORY DISORDER	UPPER RESPIRATORY TRACT INFECTION	+	Respiratory System	.	137 (25)	01JUL01	CON	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.205.24983 ie	ASTHENIA	MOOD IRRITABLE, TIRED, TEARFUL DUE TO STOPPING TREATMENT.	+	Body as a Whole	.	149 (28)	23NOV00	CON	Yes	.	MOD	NO	No	PSR	No
	EMOTIONAL LABILITY	MOOD IRRITABLE, TIRED, TEARFUL DUE TO STOPPING TREATMENT.	+	Nervous System	.	149 (28)	23NOV00	CON	Yes	.	MOD	NO	No	PSR	No
	NERVOUSNESS	MOOD IRRITABLE, TIRED, TEARFUL DUE TO STOPPING TREATMENT.	+	Nervous System	.	149 (28)	23NOV00	CON	Yes	.	MOD	NO	No	PSR	No
676.205.24985 i	HYPOCHROMIC ANEMIA	IRON DEFICIENCY ANAEMIA-ADMITTED FOR PARENTERAL IRON THERAPY	+	Hemic and Lymphatic System	.	27 (1)	06MAR01	5 days	No	1	MIL	NO	Yes	UNR	No
676.206.24870 ie	DECREASED APPETITE	FELT NAUSEOUS AND HAD NO APPETITE	+	Digestive System	.	121 (11)	16JUL00	5 days	No	1	MIL	NO	No	PSR	No
	NAUSEA	FELT NAUSEOUS AND HAD NO APPETITE	+	Digestive System	.	121 (11)	16JUL00	5 days	No	1	MIL	NO	No	PSR	No
676.206.24871 ie	HYPOTENSION	DIZZINESS RELATED TO HYPOTENSION	+	Cardiovascular System	20	117 (1)	26JUL00	19 days	Yes	.	MIL	NO	Yes	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.206.24871 ie	HEADACHE	HEADACHE	+	Body as a Whole	.	130 (14)	08AUG00	6 days	No	4	MIL	NO	Yes	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	.	131 (15)	09AUG00	1 day	Yes	.	MIL	NO	Yes	PSR	No
676.206.24875 ie	NERVOUSNESS	IRRITABLE	+	Nervous System	.	115 (5)	15NOV00	CON	Yes	.	MIL	NO	No	PSR	No
676.206.24877 ie	ASTHENIA	TIREDNESS	+	Body as a Whole	.	144 (13)	16JAN01	4 days	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	.	144 (13)	16JAN01	4 days	Yes	.	MIL	NO	No	PSR	No
676.206.24882 ie	HEADACHE	HEADACHE	+	Body as a Whole	.	138 (24)	25JUN01	8 days	No	8	MIL	NO	Yes	PSR	No
676.207.24900 ie	NERVOUSNESS	IRRITABLE	+	Nervous System	20	118 (5)	29OCT00	CON	Yes	.	MIL	NO	No	PBU	No
676.207.24901 ie	NAUSEA	NAUSEA	+	Digestive System	30	131 (19)	26FEB01	3 days	Yes	.	MIL	NO	Yes	UNR	No
676.207.24906 ie	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	30	135 (23)	29JUN01	4 days	Yes	.	MIL	NO	No	PSR	No
676.207.24907 i	INFECTION	FLU SYMPTOMS	+	Body as a Whole	.	39 (7)	27MAR01	CON	Yes	.	MOD	NO	No	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	.	33 (1)	21MAR01	3 days	Yes	.	MIL	NO	No	PSR	No
	SOMNOLENCE	LETHARGY	+	Nervous System	.	33 (1)	21MAR01	3 days	Yes	.	MIL	NO	No	PSR	No
	SWEATING	SWEATING	+	Skin and Appendages	.	33 (1)	21MAR01	3 days	Yes	.	MIL	NO	No	PSR	No
676.209.24954 ie	DIZZINESS	DIZZINESS	+	Nervous System	.	115 (1)	18AUG00	8 days	Yes	.	MIL	NO	No	PSR	No
676.209.24968 ie	PALPITATION	PALPITATIONS	+	Cardiovascular System	.	118 (3)	24JUN01	8 days	Yes	.	MOD	NO	No	UNR	No
	DIZZINESS	DIZZINESS	+	Nervous System	.	118 (3)	24JUN01	8 days	Yes	.	MOD	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.300.25012 ie	ABDOMINAL PAIN	STOMACH CRAMPS	+	Body as a Whole	20	125 (9)	20SEP00	CON	Yes	.	MOD	NO	Yes	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	20	125 (9)	20SEP00	CON	Yes	.	MOD	NO	Yes	PSR	No
	VERTIGO	VERTIGO	+	Nervous System	20	125 (9)	20SEP00	CON	No	.	MOD	NO	No	PSR	No
676.301.25039 ie	DIZZINESS	DIZZINESS	+	Nervous System	30	143 (24)	23FEB01	16 days	Yes	.	MIL	NO	No	PSR	No
	EMOTIONAL LABILITY	TEARFUL	+	Nervous System	30	143 (24)	23FEB01	14 days	Yes	.	MIL	NO	No	PSR	No
	NERVOUSNESS	IRRITABLE	+	Nervous System	30	143 (24)	23FEB01	CON	Yes	.	MIL	NO	No	PSR	No
	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	.	144 (25)	24FEB01	5 days	Yes	.	MIL	NO	Yes	PSR	No
676.301.25041 ie	SYNCOPE	WEAK (SLEPT A LOT) (LIPOTHYMIA)	+	Cardiovascular System	.	142 (22)	12OCT01	7 days	Yes	.	MOD	NO	No	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Female Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.010.24259 ie	PHARYNGITIS	SORE THROAT	+	Respiratory System	0	121 (11)	10DEC00	5 days	Yes	.	MIL	NO	Yes	UNR	No
	RHINITIS	NASAL CONGESTION	+	Respiratory System	0	121 (11)	10DEC00	5 days	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	.	151 (41)	09JAN01	1 day	Yes	.	MOD	NO	Yes	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	.	150 (40)	08JAN01	CON	Yes	.	MIL	NO	No	UNR	No
676.013.24353 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	81 (24)	22JUL01	1 day	Yes	.	MIL	NO	Yes	PSR	No
	INFECTION	VIRAL SYNDROME	+	Body as a Whole	.	93 (36)	03AUG01	8 days	Yes	.	MOD	NO	Yes	UNR	No
676.015.24398 ie	ANXIETY	SOCIAL ANXIETY	+	Nervous System	0	88 (32)	08AUG00	CON	Yes	.	MOD	NO	Yes	REL	No
676.015.24405 ie	HEADACHE	HEADACHE	+	Body as a Whole	.	138 (19)	09DEC00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	.	139 (20)	10DEC00	1 day	Yes	.	MIL	NO	Yes	PSR	No
676.020.24533 ie	CONTACT DERMATITIS	POISON IVY	+	Skin and Appendages	.	125 (11)	27AUG00	2 days	No	1	MIL	NO	Yes	UNR	No
676.100.24709 ie	HEADACHE	HEADACHE	+	Body as a Whole	.	148 (34)	15AUG01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	.	152 (38)	19AUG01	1 day	Yes	.	MIL	NO	Yes	UNR	No
676.101.24627 ie	RESPIRATORY DISORDER	COLD SYMPTOMS (RUNNY NOSE AND COUGH)	+	Respiratory System	0	148 (29)	17MAR01	2 days	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE		Body as a Whole	.	161 (42)	30MAR01	1 day	No	1	MIL	NO	Yes	UNR	No
676.204.24852 ie	COUGH INCREASED	NIGHT TIME COUGHING	+	Respiratory System	0	114 (9)	21JUN01	16 days	Yes	.	MIL	NO	Yes	UNR	No
	INFECTION	INFLUENZA	+	Body as a Whole	.	122 (17)	29JUN01	9 days	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.205.24989 ie	URINARY FREQUENCY	URINARY FREQUENCY AND ENURESES	+	Urogenital System	.	58 (2)	04MAY01	11 days	No	1	MOD	NO	No	UNR	No
	URINARY INCONTINENCE	URINARY FREQUENCY AND ENURESES	+	Urogenital System	.	58 (2)	04MAY01	11 days	No	1	MOD	NO	No	UNR	No
676.207.24899 ie	PYURIA	LEUCOCYTES IN URINE (+)	+	Urogenital System	0	140 (29)	02NOV00	15 days	Yes	.	MIL	NO	No	UNR	No
	URINARY TRACT INFECTION	URINARY TRACT INFECTION	+	Urogenital System	.	141 (30)	03NOV00	5 days	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Male Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.001.24004 ie	RESPIRATORY DISORDER	UPPER RESPIRATORY ILLNESS	+	Respiratory System	.	123 (12)	16DEC00	9 days	Yes	.	MOD	NO	Yes	PBU	No
676.002.24030 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	145 (29)	04JUL00	1 day	Yes	.	MIL	NO	Yes	UNR	No
676.002.24033 ie	COUGH INCREASED	COUGH	+	Respiratory System	0	132 (21)	12SEP00	10 days	Yes	.	MIL	NO	Yes	UNR	No
676.002.24037 ie	RESPIRATORY DISORDER	URI	+	Respiratory System	0	120 (9)	16FEB01	8 days	Yes	.	MOD	NO	Yes	UNR	No
676.002.24040 ie	HEADACHE	HEADACHE	+	Body as a Whole	.	157 (39)	13JUL01	4 days	Yes	.	MIL	NO	Yes	UNR	No
	VOMITING	EMESIS	+	Digestive System	.	157 (39)	13JUL01	1 day	No	3	MOD	NO	No	UNR	No
	DIZZINESS	DIZZINESS	+	Nervous System	.	158 (40)	14JUL01	8 days	Yes	.	MOD	NO	No	UNR	No
676.003.24074 ie	INFECTION	YEAST INFECTION	+	Body as a Whole	.	127 (13)	14AUG01	1 day	No	1	SEV	NO	Yes	UNR	No
676.004.24087 ie	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	0	86 (16)	08JUN00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	0	84 (14)	06JUN00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	.	105 (35)	27JUN00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	.	105 (35)	27JUN00	1 day	Yes	.	MIL	NO	Yes	UNR	No
676.009.24231 ie	PAIN	JAW PAIN		Body as a Whole	.	134 (25)	18JUN01	11 days	Yes	.	SEV	NO	Yes	UNR	No
676.012.24314 i	HEADACHE	HEADACHE	+	Body as a Whole	0	131 (6)	08NOV00	1 day	Yes	.	MIL	NO	Yes	UNR	No
	NERVOUSNESS	INCREASED IRRITABILITY	+	Nervous System	0	132 (7)	09NOV00	CON	Yes	.	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.013.24339 ie	TRAUMA	STRAINED LIGAMENT IN FOOT	+	Body as a Whole	0	134 (25)	05AUG00	CON	Yes	.	MOD	NO	Yes	UNR	No
676.013.24342 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	147 (24)	22SEP00	4 days	Yes	.	MOD	NO	Yes	UNR	No
	LARYNX DISORDER	LARYNGITIS	+	Respiratory System	0	138 (15)	13SEP00	4 days	Yes	.	MIL	NO	No	UNR	No
	RESPIRATORY DISORDER	COLD SYMPTOMS	+	Respiratory System	0	133 (10)	08SEP00	9 days	Yes	.	MOD	NO	Yes	UNR	No
	HEADACHE	INTERMITTENT HEADACHES		Body as a Whole	.	155 (32)	30SEP00	15 days	Yes	.	MIL	NO	No	UNR	No
	NAUSEA	NAUSEA	+	Digestive System	.	155 (32)	30SEP00	15 days	Yes	.	MIL	NO	No	PSR	No
	SOMNOLENCE	DROWSINESS	+	Nervous System	.	155 (32)	30SEP00	15 days	Yes	.	MIL	NO	No	PSR	No
676.013.24346 ie	PHARYNGITIS	SORE THROAT	+	Respiratory System	.	79 (25)	10SEP00	2 days	Yes	.	MOD	NO	Yes	UNR	No
	RHINITIS	NASAL CONGESTION	+	Respiratory System	.	79 (25)	10SEP00	2 days	Yes	.	MOD	NO	No	UNR	No
676.013.24349 ie	ABDOMINAL PAIN	STOMACHACHE	+	Body as a Whole	0	45 (3)	25DEC00	1 day	Yes	.	MIL	NO	No	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	.	68 (26)	17JAN01	1 day	Yes	.	MIL	NO	No	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	.	69 (27)	18JAN01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as a Whole	.	70 (28)	19JAN01	1 day	Yes	.	MIL	NO	No	UNR	No
	DIZZINESS	DIZZINESS	+	Nervous System	.	59 (17)	08JAN01	CON	Yes	.	MIL	NO	Yes	UNR	No
	TREMOR	SHAKINESS	+	Nervous System	.	60 (18)	09JAN01	CON	Yes	.	MIL	NO	No	UNR	No
676.014.24365 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	112 (4)	16MAY00	1 day	Yes	.	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.015.24408 ie	ANXIETY	SOCIAL ANXIETY WORSENING	+	Nervous System	.	96 (30)	10JAN01	CON	Yes	.	MOD	NO	Yes	REL	No
676.015.24412 i	DRY MOUTH	DRY MOUTH	+	Digestive System	.	96 (33)	04JUN01	5 days	Yes	.	MIL	NO	No	PSR	No
	NAUSEA	NAUSEA	+	Digestive System	.	96 (33)	04JUN01	5 days	Yes	.	MIL	NO	No	PSR	No
676.015.24413 ie	ANXIETY	EXACERBATION OF SOCIAL ANXIETY	+	Nervous System	0	140 (23)	25JUL01	CON	Yes	.	MIL	NO	Yes	REL	No
676.017.24451 ie	RESPIRATORY DISORDER	URI	+	Respiratory System	.	155 (36)	30AUG00	1 day	Yes	.	MIL	NO	Yes	UNR	No
676.019.24516 i	PHARYNGITIS	ENLARGED TONSILS	+	Respiratory System	.	37 (14)	06DEC00	CON	Yes	.	MIL	NO	No	UNR	No
676.021.24562 i	AGITATION	INCREASED AGITATION	+	Nervous System	.	9 (7)	16FEB00	7 days	No	1	MOD	STP	No	PSR	No
676.100.24706 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	137 (25)	10MAR01	1 day	Yes	.	MOD	NO	Yes	UNR	No
676.101.24617 ie	ASTHENIA	FATIGUED	+	Body as a Whole	0	106 (7)	07SEP00	CON	Yes	.	MIL	NO	No	PSR	No
	RESPIRATORY DISORDER	HEAD COLD	+	Respiratory System	0	104 (5)	05SEP00	2 days	No	1	MIL	NO	Yes	UNR	No
676.103.24650 ie	INFECTION	STREP THROAT	+	Body as a Whole	0	125 (8)	12OCT00	8 days	Yes	.	MOD	NO	Yes	UNR	No
676.103.24652 ie	MYALGIA	SORE FOREARMS	+	Musculoskeletal System	.	146 (26)	25MAR01	6 days	Yes	.	MIL	NO	Yes	UNR	No
676.202.24797 ie	GINGIVITIS	DENTAL ABSCESS	+	Digestive System	.	130 (18)	30MAY01	CON	Yes	.	SEV	NO	No	UNR	No
676.203.24819 ie	HEADACHE	HEADACHE	+	Body as a Whole	.	116 (12)	21NOV00	4 days	Yes	.	MOD	NO	No	PSR	No
	INSOMNIA	INSOMNIA	+	Nervous System	.	115 (11)	20NOV00	CON	Yes	.	MOD	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.204.24842 ie	ASTHENIA	TIREDNESS	+	Body as a Whole	.	50 (8)	27JUL00	2 days	Yes	.	MIL	NO	No	UNR	No
	ASTHENIA	TIREDNESS	+	Body as a Whole	.	54 (12)	31JUL00	5 days	Yes	.	MIL	NO	No	UNR	No
	ASTHENIA	TIREDNESS	+	Body as a Whole	.	61 (19)	07AUG00	CON	Yes	.	MIL	NO	No	UNR	No
	DECREASED APPETITE	REDUCED APPETITE	+	Digestive System	.	50 (8)	27JUL00	CON	Yes	.	MIL	NO	No	UNR	No
676.204.24843 i	RESPIRATORY DISORDER	UPPER RESPIRATORY TRACT INFECTION	+	Respiratory System	.	140 (28)	01NOV00	3 days	Yes	.	MIL	NO	Yes	UNR	No
676.204.24847 i	RHINITIS	RHINITIS	+	Respiratory System	.	139 (28)	16JAN01	CON	Yes	.	MIL	NO	Yes	UNR	No
676.207.24910 ie	LARYNX DISORDER	LARYNGITIS	+	Respiratory System	0	137 (25)	20AUG01	3 days	Yes	.	MIL	NO	No	UNR	No
676.209.24957 i	TRAUMA	MULTIPLE ABRASIONS - HANDS, FOREHEAD, (L)KNEE, LACERATION LIP. PATIENT FELL OF A BICYCLE.	+	Body as a Whole	.	120 (9)	08SEP00	8 days	Yes	.	SEV	NO	Yes	UNR	No
676.209.24962 ie	HEADACHE	HEADACHE	+	Body as a Whole	0	77 (15)	26DEC00	1 day	Yes	.	SEV	NO	Yes	UNR	No
676.209.24963 ie	BACK PAIN	BACKACHE	+	Body as a Whole	0	153 (26)	19MAR01	18 days	Yes	.	MIL	NO	Yes	UNR	No
676.209.24967 i	HEADACHE	HEADACHE		Body as a Whole	.	111 (21)	12JUN01	1 day	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.301.25037 ie	MALAISE	SLUMP (IN COMBINATION WITH COUGH)	Body as a Whole	.	159 (46)	11FEB01	2 days	Yes	.	MIL	NO	Yes	PBU	No
	COUGH INCREASED	COUGH	Respiratory System	.	159 (46)	11FEB01	CON	Yes	.	MIL	NO	No	PBU	No
	COUGH INCREASED	SLUMP (IN COMBINATION WITH COUGH)	Respiratory System	.	159 (46)	11FEB01	2 days	Yes	.	MIL	NO	Yes	PBU	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.2

Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.013.24349 ie	DYSMENORRHEA	MENSTRUAL CRAMPS	+	Urogenital System	.	70 (28)	19JAN01	CON	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : No Therapy Dispensed, Age Group : Children
Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT			.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : No Therapy Dispensed, Age Group : Children, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT				.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : No Therapy Dispensed, Age Group : Children, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT				.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : No Therapy Dispensed, Age Group : Adolescents
Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT				.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : No Therapy Dispensed, Age Group : Adolescents, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT				.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : No Therapy Dispensed, Age Group : Adolescents, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	No. Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT				.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
676.202.24785 ie	TRAUMA	CONCUSSION DUE TO FALL FROM BIKE. SYMPTOMS: HEADACHE , NAUSEA, VOMITING. HOSPITALISED FOR TWO DAYS = SAE	^ Body as a Whole	.	-4 (-116)	07MAR00	3 days	Yes	.	SEV		Yes	
	TRAUMA	LACERATIONS DUE TO FALL FROM BIKE: UPPER LEFT LEG AND CHIN	^ Body as a Whole	.	-4 (-116)	07MAR00	37 days	Yes	.	MOD		Yes	

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : Paroxetine, Age Group : Children, Male Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	No. Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT			.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : Paroxetine, Age Group : Children, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT				.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT				.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : Paroxetine, Age Group : Adolescents, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT				.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : Paroxetine, Age Group : Adolescents, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	No. Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT				.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	No. Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT			.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : Placebo, Age Group : Children, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT				.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : Placebo, Age Group : Children, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT				.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	No. Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT			.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : Placebo, Age Group : Adolescents, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT				.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

Treatment Group : Placebo, Age Group : Adolescents, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.
NO DATA PRESENT				.		.			.				

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

Treatment Group : Paroxetine, Age Group : Children, Male Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

Treatment Group : Paroxetine, Age Group : Children, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.205.24985 i	ANEMIA	ANAEMIA	+	Hemic and Lymphatic System	20	25 (-1)	04MAR01	3 days	No	2	SEV	STP	Yes	UNR	Yes

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

Treatment Group : Paroxetine, Age Group : Adolescents, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

Treatment Group : Paroxetine, Age Group : Adolescents, Female Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.209.24958 i	ABNORMAL LABORATORY VALUE	UNINTENTIONAL OVERDOSE OF STUDY MEDICATION	+	Body as a Whole	0	42 (-70)	11SEP00	11 days	Yes	.	MIL	NO	No	REL	Yes

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

Treatment Group : Placebo, Age Group : Children, Male Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	No. Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

Treatment Group : Placebo, Age Group : Children, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

Treatment Group : Placebo, Age Group : Adolescents, Male Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

Treatment Group : Placebo, Age Group : Adolescents, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.3

Serious Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.3

Serious Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Male Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.3

Serious Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Children, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.3

Serious Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.005.24122 ie	ANXIETY	HOSPITALIZATION DUE TO HIS FEARS AND DEP DISEASE UNDER STUDY	+	Nervous System	.	84 (14)	30NOV00	5 days	Yes	.	MOD	NO	Yes	UNR	Yes
	DEPRESSION	HOSPITALIZATION DUE TO HIS FEARS AND DEP DISEASE UNDER STUDY	+	Nervous System	.	84 (14)	30NOV00	5 days	Yes	.	MOD	NO	Yes	UNR	Yes
676.015.24407 ie	TRAUMA	FRACTURED ARM	+	Body as a Whole	30	139 (20)	05FEB01	CON	Yes	.	SEV	NO	Yes	UNR	Yes

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.3

Serious Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.3

Serious Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Paroxetine, Age Group : Adolescents, Female Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.3

Serious Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.3

Serious Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Male Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.3

Serious Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Children, Female Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.3

Serious Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.3

Serious Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Male Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.3.3

Serious Adverse Experiences (Taper, Follow-up and Post Follow-up Phases)

Treatment Group : Placebo, Age Group : Adolescents, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
+ = Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.4

Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.015.24409 ie	HEADACHE	HEADACHE	^	Body as a Whole	.	-1 (-52)	04DEC00	1 day	Yes	.	MIL		Yes		No
	NAUSEA	NAUSEA	^	Digestive System	.	-1 (-52)	04DEC00	1 day	Yes	.	MIL		No		No
	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	40	34 (-17)	08JAN01	1 day	Yes	.	MIL	NO	No	PSR	No
	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	40	42 (-9)	16JAN01	1 day	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE		Body as a Whole	10	5 (-46)	10DEC00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE		Body as a Whole	20	12 (-39)	17DEC00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HEADACHE	HEADACHE		Body as a Whole	20	14 (-37)	19DEC00	1 day	Yes	.	MIL	NO	Yes	PSR	No
	HYPERKINESIA	HYPERACTIVITY	+	Nervous System	40	33 (-18)	07JAN01	11 days	Yes	.	SEV	DCR	No	REL	No
	HYPERKINESIA	HYPERACTIVITY	+	Nervous System	30	44 (-7)	18JAN01	8 days	Yes	.	SEV	STP	No	REL	No
	INFECTION	FLU SYMPTOMS	+	Body as a Whole	.	61 (10)	04FEB01	8 days	Yes	.	MIL	NO	No	PSR	No
676.023.17877 ie	ABDOMINAL PAIN	STOMACH ACHE	+	Body as a Whole	10	1 (-55)	02AUG00	4 days	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	10	1 (-55)	02AUG00	7 days	No	3	MIL	NO	No	PSR	No
	FECAL INCONTINENCE	INCREASE IN BLADDER AND BOWEL INCONTINENCE	+	Digestive System	10	1 (-55)	02AUG00	3 days	No	3	MIL	NO	No	PSR	No
	HOSTILITY	DISINHIBITED	+	Nervous System	10	7 (-49)	08AUG00	CON	Yes	.	MOD	STP	No	REL	No
	HOSTILITY	OPPOSITIONAL	+	Nervous System	20	18 (-38)	19AUG00	CON	Yes	.	MOD	DCR	No	REL	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent,+ =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.4

Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal

Treatment Group : Paroxetine, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.023.17877 ie	MANIC REACTION	HYPOMANIA	+	Nervous System	20	14 (-42)	15AUG00	CON	Yes	.	SEV	DCR	No	REL	No
	NEUROSIS	IMPULSIVE	+	Nervous System	20	18 (-38)	19AUG00	15 days	Yes	.	MOD	DCR	No	REL	No
	PRURITUS	ITCHY BACK	+	Skin and Appendages	10	29 (-27)	30AUG00	CON	Yes	.	MIL	STP	No	PSR	No
	RASH	RASH	+	Skin and Appendages	20	10 (-46)	11AUG00	5 days	No	1	MIL	NO	No	UNR	No
	CONJUNCTIVITIS	CONJUNCTIVITIS	+	Special Senses	10	55 (-1)	25SEP00	1 day	Yes	.	MIL	NO	No	UNR	No
	ALBUMINURIA	PROTEIN IN URINE	+	Urogenital System	10	56 (0)	26SEP00	CON	Yes	.	MIL	NO	No	UNR	No
	URINARY INCONTINENCE	INCREASE IN BLADDER AND BOWEL INCONTINENCE	+	Urogenital System	10	1 (-55)	02AUG00	3 days	No	3	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent,+ =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.4

Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal

Treatment Group : Paroxetine, Age Group : Children, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent,+ =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.4

Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal

Treatment Group : Paroxetine, Age Group : Children, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.023.17877 ie	DYSMENORRHEA	MENSTRUAL CRAMPS	Urogenital System	.	165 (109)	13JAN01	1 day	Yes	.	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent,+ =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.4

Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.011.24282 ie	HEADACHE	HEADACHE	+	Body as a Whole	30	33 (-8)	10APR00	CON	Yes	.	MIL	NO	No	PSR	No
	DECREASED APPETITE	DECREASED APPETITE	+	Digestive System	30	33 (-8)	10APR00	CON	Yes	.	MIL	NO	No	PSR	No
	DRY MOUTH	DRY MOUTH	+	Digestive System	30	33 (-8)	10APR00	CON	Yes	.	MIL	NO	No	PSR	No
	DYSPEPSIA	UPSET STOMACH	+	Digestive System	30	33 (-8)	10APR00	CON	Yes	.	MIL	NO	No	PSR	No
	INSOMNIA	INITIAL INSOMNIA	+	Nervous System	30	33 (-8)	10APR00	CON	Yes	.	MIL	NO	No	PSR	No
	MANIC REACTION	MANIC EPISODE	+	Nervous System	30	41 (0)	18APR00	CON	Yes	.	SEV	STP	No	REL	No
	NERVOUSNESS	RESTLESSNESS	+	Nervous System	10	10 (-31)	18MAR00	CON	Yes	.	MIL	NO	No	PSR	No
676.014.24376 i	MYALGIA	MUSCLE DISCOMFORT	+	Musculoskeletal System	10	12 (-22)	10SEP00	3 days	Yes	.	MOD	NO	Yes	UNR	No
	ABNORMAL DREAMS	MORBID THOUGHTS	+	Nervous System	40	30 (-4)	28SEP00	CON	Yes	.	SEV	STP	No	PBU	No
	AGITATION	PANIC ATTACK	+	Nervous System	20	16 (-18)	14SEP00	1 day	No	1	MOD	INC	No	PBU	No
	AGITATION	PANIC ATTACK WORSENING	+	Nervous System	40	30 (-4)	28SEP00	1 day	No	2	SEV	STP	No	PSR	No
	EMOTIONAL LABILITY	SUICIDAL THOUGHTS	+	Nervous System	40	30 (-4)	28SEP00	CON	Yes	.	MOD	STP	No	PBU	No
	INSOMNIA	SLEEP DISTURBANCE	+	Nervous System	.	42 (8)	10OCT00	CON	Yes	.	SEV	NO	No	PBU	No
676.015.24406 i	VOMITING	NAUSEA/VOMITING	+	Digestive System	10	1 (0)	28AUG00	1 day	No	1	MIL	STP	Yes	PSR	No
676.022.17841 ie	ASTHENIA	FATIGUE	+	Body as a Whole	20	13 (-20)	06JUN00	2 days	No	1	MIL	NO	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent,+ =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.4

Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.022.17841 ie	INSOMNIA	RESTLESS SLEEP (DECREASE SLEEP TO 5 HOURS/NIGHT)	+	Nervous System	30	26 (-7)	19JUN00	6 days	Yes	.	MOD	DCR	No	PSR	No
	MANIC REACTION	BEHAVIORAL ACTIVATION/HYPOMANIA	+	Nervous System	20	23 (-10)	16JUN00	11 days	Yes	.	SEV	STP	No	PSR	No
	TREMOR	BILATERAL HAND TREMOR	+	Nervous System	30	28 (-5)	21JUN00	CON	Yes	.	MOD	DCR	No	PSR	No
	OTITIS MEDIA	PROBABLE RIGHT EAR INFECTION	+	Special Senses	20	33 (0)	26JUN00	CON	Yes	.	MIL	NO	No	UNR	No
676.024.25150 ie	ASTHENIA	FATIGUE	+	Body as a Whole	20	11 (-30)	05MAR01	51 days	Yes	.	MOD	STP	No	PSR	No
676.100.24705 ie	DYSPEPSIA	HEARTBURN	+	Digestive System	10	19 (-24)	04NOV00	2 days	Yes	.	MIL	NO	Yes	UNR	No
	DEPRESSION	WORSENING DEPRESSION	+	Nervous System	20	43 (0)	28NOV00	CON	Yes	.	MOD	STP	Yes	PSR	No
	EMOTIONAL LABILITY	SELF INFLICTED SCRATCH ON RT. WRIST	+	Nervous System	20	38 (-5)	23NOV00	1 day	No	1	MIL	NO	No	PBU	No
	LACK OF EMOTION	LACK OF EMOTIONS	+	Nervous System	10	5 (-38)	21OCT00	CON	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	.	56 (13)	11DEC00	1 day	Yes	.	MOD	NO	Yes	UNR	No
676.200.24742 i	ASTHENIA	FATIGUE / TIREDNESS	+	Body as a Whole	10	1 (-108)	27SEP00	CON	Yes	.	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as a Whole	40	78 (-31)	13DEC00	1 day	No	1	MIL	NO	Yes	PSR	No
	INFECTION	INFECTED FOOT		Body as a Whole	.	110 (1)	14JAN01	6 days	Yes	.	MOD	STP	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent,+ =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.4

Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal

Treatment Group : Paroxetine, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.205.24985 i	INFECTION	FLU	+	Body as a Whole	10	18 (-8)	25FEB01	5 days	Yes	.	MIL	NO	Yes	UNR	No
	ANEMIA	ANAEMIA	+	Hemic and Lymphatic System	20	25 (-1)	04MAR01	3 days	No	2	SEV	STP	Yes	UNR	Yes
	HYPOCHROMIC ANEMIA	IRON DEFICIENCY ANAEMIA-ADMITTED FOR PARENTERAL IRON THERAPY	+	Hemic and Lymphatic System	.	27 (1)	06MAR01	5 days	No	1	MIL	NO	Yes	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent,+ =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.4

Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal

Treatment Group : Paroxetine, Age Group : Adolescents, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent,+ =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.4

Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal

Treatment Group : Paroxetine, Age Group : Adolescents, Female Specific Adverse Experiences

Patient / Flag	Preferred Term Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT			.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent,+ =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

Listing 15.1.4

Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal

Treatment Group : Placebo, Age Group : Children, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text		Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.023.17878 i	FLU SYNDROME	FLU-LIKE ILLNESS	^	Body as a Whole	.	-7 (-47)	05SEP00	2 days	Yes	.	MIL		No		No
	PAIN	FOOT PAIN	^	Body as a Whole	.	-13 (-53)	30AUG00	CON	No	42	MOD		No		No
	CONJUNCTIVITIS	CONJUNCTIVITIS	^	Special Senses	.	-3 (-43)	09SEP00	4 days	Yes	.	MIL		Yes		No
	DECREASED APPETITE	DECREASED APPETITE	+	Digestive System	0	11 (-29)	23SEP00	8 days	Yes	.	MIL	NO	No	PSR	No
	AGITATION	AGITATION	+	Nervous System	0	28 (-12)	10OCT00	15 days	Yes	.	MOD	STP	No	REL	No
	SOMNOLENCE	DROWSINESS (FELL ASLEEP AT SCHOOL)	+	Nervous System	0	23 (-17)	05OCT00	1 day	No	1	MOD	NO	No	PSR	No
	COUGH INCREASED	COUGH	+	Respiratory System	0	4 (-36)	16SEP00	CON	Yes	.	MOD	NO	No	UNR	No
	RHINITIS	RUNNING NOSE	+	Respiratory System	0	4 (-36)	16SEP00	CON	Yes	.	MOD	NO	No	UNR	No
676.205.24989 ie	INFECTION	WORM INFECTION	+	Body as a Whole	0	7 (-49)	14MAR01	1 day	Yes	.	MIL	NO	Yes	UNR	No
	INFECTION	FLU SYMPTOMS	+	Body as a Whole	0	28 (-28)	04APR01	8 days	Yes	.	MIL	NO	Yes	UNR	No
	COUGH INCREASED	COUGHING	+	Respiratory System	0	14 (-42)	21MAR01	9 days	Yes	.	MIL	NO	Yes	UNR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System	0	12 (-44)	19MAR01	11 days	Yes	.	MIL	NO	Yes	UNR	No
	URINARY RETENTION	URINE RETENTION	+	Urogenital System	0	12 (-44)	19MAR01	57 days	Yes	.	MOD	STP	No	PSR	No
	URINARY FREQUENCY	URINARY FREQUENCY AND ENURESES	+	Urogenital System	.	58 (2)	04MAY01	11 days	No	1	MOD	NO	No	UNR	No
	URINARY INCONTINENCE	URINARY FREQUENCY AND ENURESES	+	Urogenital System	.	58 (2)	04MAY01	11 days	No	1	MOD	NO	No	UNR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent,+ =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.4

Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal

Treatment Group : Placebo, Age Group : Children, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent,+ =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.4

Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal

Treatment Group : Placebo, Age Group : Children, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent,+ =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.4

Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal

Treatment Group : Placebo, Age Group : Adolescents, Gender Non Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
676.021.24562 i	AGITATION	INCREASED AGITATION	+ Nervous System	.	9 (7)	16FEB00	7 days	No	1	MOD	STP	No	PSR	No

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent,+ =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.4

Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal

Treatment Group : Placebo, Age Group : Adolescents, Male Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent,+ =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.4

Adverse Experiences For Patients with an Adverse Experience(s) Leading to Withdrawal

Treatment Group : Placebo, Age Group : Adolescents, Female Specific Adverse Experiences

Patient / Flag	Preferred Term	Verbatim Text	Body System	Dose at Onset (mg)	Days Rel To Start (Stop) Of Study Med*	Onset Date	Dura-tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.	Inv. Rel.	SAE?
NO DATA PRESENT				.		.			.					

* Rel Days from AE Onset Date to Start of Rand. Study Med. + 1 (Rel Days from AE Onset Date to End of Rand. Study Med. Excl Taper)
^=Pre-Treatment Emergent,+ =Treatment Emergent, Duration : CON = Continuing, Cont. : Yes = AE Course Continous,
if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,STP = Drug Stopped
Corrective Therapy [Corr Ther]. Investigator Relationship [Inv Rel]: PBU = Probably Unrelated,
PSR = Possibly Related, REL = Related, UNR = Unrelated
Serious AE as Judged by SB Criteria (Investigator) [SAE]
Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.1.5

Summary of Deaths

NO DATA AVAILABLE FOR THIS REPORT

BRL 29060 - 676

Listing 15.4.1

Medical Procedures

Treatment Group: No Therapy Dispensed Age Group: Children

Patient/Flag	Procedure text	Indication	Procedure Start Date	Procedure End Date
	NO MEDICAL PROCEDURES FOR THIS TREATMENT AND AGE GROUP		.	.

Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.4.1

Medical Procedures

Treatment Group: No Therapy Dispensed Age Group: Adolescents

Patient/Flag	Procedure text	Indication	Procedure Start Date	Procedure End Date
	NO MEDICAL PROCEDURES FOR THIS TREATMENT AND AGE GROUP		.	.

Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

BRL 29060 - 676

Listing 15.4.1

Medical Procedures

Treatment Group: Paroxetine Age Group: Children

Patient/Flag	Procedure text	Indication	Procedure Start Date	Procedure End Date
676.002.24034 i	URINE ANALYSIS - RESULTS NEGATIVE	BEDWETTING	10AUG2000	10AUG2000
676.007.24179 ie	INGROWN LEFT BIG TOENAIL CLIPPED	INGROWN TOENAIL	30MAY2000	30MAY2000
676.015.24403 ie	NOSEBLEEDS	NOSE BLEEDS	12SEP2000	12SEP2000
676.017.24455 i	VISIT SCHOOL NURSE BANDAGE BRUISES	BRUISES ON L. LEG	28MAR2001	28MAR2001
676.019.24520 ie	ABDOMINAL X-RAY	BRUISED STOMACH MUSCLE	18MAY2001	18MAY2001
676.202.24785 ie	LACERATION CHIN AND LEFT LEG SUTURED	DUE TO FALL FROM HIS BIKE	07MAR2000	09MAR2000

Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

Listing 15.4.1

Medical Procedures

Treatment Group: Paroxetine Age Group: Adolescents

Patient/Flag	Procedure text	Indication	Procedure Start Date	Procedure End Date
676.004.24085 i	RIGHT HAND X-RAY	BROKEN RIGHT THUMB	02MAY2000	02MAY2000
	BRACES TIGHTENED {ORTHODONTIA}	ROUTINE	23FEB2000	23FEB2000
		ROUTINE	08MAR2000	08MAR2000
		ROUTINE	22MAR2000	22MAR2000
	DERMATOLOGICAL EXAMINATION	FACIAL ANCE	08MAR2000	08MAR2000
	EYE EXAM	ROUTINE	10MAR2000	10MAR2000
	HAND EXAMINATION	BROKEN RIGHT THUMB	10APR2000	10APR2000
	ORTHODONTIC BRACES TIGHTENED	ROUTINE	17MAY2000	17MAY2000
	STAPLES IN HEAD X3	HEAD LACERATION	25MAR2000	25MAR2000
	STAPLES REMOVED FROM HEAD	HEAD LACERATION	05APR2000	05APR2000
676.007.24170 ie	MAGNETIC RESONANCE IMAGING	POSSIBLE DEVIATED SEPTUM	06MAR2000	06MAR2000
	PULMONARY FUNCTION TESTS	POSSIBLE ASTHMA	13MAR2000	13MAR2000
676.014.24380 ie	TIGHTENING OF THE{MOUTH} BRACES	MISSALIGNED TEATH	30MAY2001	30MAY2001
676.015.24407 ie	SURGERY/ HOSPITALIZATION {FRACTURED LEFT ARM}	FRACTURE LEFT ARM	05FEB2001	05FEB2001
676.019.24518 ie	DENTAL BRACES TIGHTENED	ROUTINE	20DEC2000	20DEC2000
676.020.24534 ie	BRACES	HAD BRACES PUT ON	23MAY2000	23MAY2000
	INSERTION OF DENTAL SEPARATORS	FILLING OF BRACES	10MAY2000	10MAY2000
	INSERTIONS OF DENTAL SEPARATORS	PREPARATION FORT BRACES	10MAY2000	10MAY2000
676.023.17879 i	STREPTOCOCCAL TEST (THROAT CULTURE)	SORE THROAT	14DEC2000	14DEC2000
	STREPTOCOCCUS TEST	STREP THROAT	04FEB2001	04FEB2001
	THROAT CULTURE	THROAT IRRITATION	22MAR2001	22MAR2001
676.100.24710 ie	EAR IRRIGATION	EARACHE	10JUN2001	10JUN2001
676.101.24629 i	PSYCHOEDUCATIONAL TESTING	RULE OUT LEARNING DISABILITY	11JUN2001	11JUN2001
		RULE OUT LEARNING DISABILITY	04JUL2001	04JUL2001
676.200.24735 ie	WISDOM TEETH EXTRACTED UNDER GENERAL ANAESTHETIC.	IMPACTED WISDOM TEETH	20JUN2000	20JUN2000
676.204.24844 i	DENTAL EXTRACTIONS	DENTAL CARIES	31AUG2000	31AUG2000
	DENTAL FILLINGS	DENTAL CARIES	21AUG2000	21AUG2000
		DENTAL CARIES	31AUG2000	31AUG2000
676.205.24985 i	ELECTROENCEPHALOGRAM	POSSIBLE TEMPORAL LOBE EPILEPSY	05MAR2001	05MAR2001
	MAGNETIC RESONANCE IMAGING	POSSIBLE TEMPORAL LOBE EPILEPSY	05MAR2001	05MAR2001
676.206.24871 ie	EEG	BLACK OUT - HYPOTENSION	23JUN2000	23JUN2000

Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

Listing 15.4.1

Medical Procedures

Treatment Group: Paroxetine Age Group: Adolescents

Patient/Flag	Procedure text	Indication	Procedure Start Date	Procedure End Date
676.206.24871 ie	HEART ULTRASONOGRAPHY	SYNCOPE- HYPOTENSION	23JUN2000	23JUN2000
676.206.24882 ie	ELECTIVE SURGERY RIGHT AND LEFT TEMPOROMANDIBULAR JOINTS	HEADACHE	10FEB2001	10FEB2001
676.207.24900 ie	BLOOD COLLECTION	ABNORMAL SCREEN VALUES	18JUL2000	18JUL2000
676.207.24901 ie	URINE DIPSTICK	POSITIVE AT WEEK 3 - KETONES + AND PROTEIN +	15NOV2000	15NOV2000
676.209.24966 ie	X RAY OF NECK	SOFT TISSUE INJURY NECK	10MAR2001	10MAR2001
676.209.24969 ie	ORTHODONTIC PROCEDURE TO TEETH	TO APPLY BRACES	26JUN2001	26JUN2001
		TO RECTIFY TEETH APPLY ELASTIC BANDS FOR BRACES	19JUN2001	19JUN2001
676.301.25039 ie	CLINICAL EXAMINATION BY GENERAL PRACTITIONER	BRONCHITIS	27NOV2000	27NOV2000
		MYCOSIS (HAND/FEET)	14NOV2000	14NOV2000
	PHYSICAL EXAMINATION BY GENERAL PRACTITIONER	COLD	01OCT2000	01OCT2000
		SORE THROAT	22JAN2001	22JAN2001
		STOMACHACHE	24FEB2001	24FEB2001

Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

Listing 15.4.1

Medical Procedures

Treatment Group: Placebo Age Group: Children

Patient/Flag	Procedure text	Indication	Procedure Start Date	Procedure End Date
676.001.24012 i	TOOTH EXTRACTION	ORTHODONTIC WORK	26DEC2000	26DEC2000
676.003.24069 i	X-RAY	BUMP ON LEFT KNEE	04APR2001	04APR2001
676.010.24259 ie	THROAT AND NASAL CULTURE	SORE THROAT	26SEP2000	26SEP2000
676.012.24310 ie	ORAL BRACES (PLACED)	OVERBITE	08MAY2000	08MAY2000
676.013.24353 ie	THROAT CULTURE	VIRAL SYNDROME	07AUG2001	07AUG2001
676.015.24405 ie	IMMOBILIZER/SLING LEFT ARM	FRACTURE L ARM	20JUL2000	20JUL2000
	X-RAY LEFT ARM	FRACTURE L ARM	20JUL2000	20JUL2000
676.017.24456 ie	X-RAY OF RIGHT ELBOW	PAIN ON EXTENSION	29MAY2001	29MAY2001
676.023.17878 i	AUDIOLOGY EXAMINATION	TALKING LOUD	11OCT2000	11OCT2000
	FOOT X-RAY	FOOT PAIN	30AUG2000	30AUG2000
676.100.24709 ie	CHEST EXAM BY FAMILY DOCTOR	COMMON COLD	08JUN2001	08JUN2001
676.207.24899 ie	DENTAL EXTRACTION	DENTAL CARIES	01AUG2000	01AUG2000

Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population

Listing 15.4.1

Medical Procedures

Treatment Group: Placebo Age Group: Adolescents

Patient/Flag	Procedure text	Indication	Procedure Start Date	Procedure End Date
676.002.24040 ie	BACK X-RAY	BACK PAIN	04MAY2001	04MAY2001
	NECK X-RAY	NECK PAIN	01MAY2001	01MAY2001
	PHYSICAL THERAPY	BACK AND NECK PAIN	31MAY2001	02JUN2001
676.003.24074 ie	EYE EXAM	BLURRED VISION	13JUN2001	13JUN2001
676.004.24087 ie	ORTHODONTIA BRACES TIGHTENED	ROUTINE	08APR2000	08APR2000
	ORTHODONTIC BRACES TIGHTENED	ROUTINE	02JUN2000	02JUN2000
676.006.24144 ie	HEATING PAD	BACK PAIN	01JUN2000	08JUN2000
676.009.24228 ie	X-RAY OF THE NECK	WHIPLASH	06JUN2000	06JUN2000
676.013.24342 ie	WISDOM TEETH EXTRACTION	IMPACTED WISDOM TEETH	07JUL2000	07JUL2000
676.014.24370 i	GUM SURGERY	PERIODONTOSIS	01MAR2000	01MAR2000
676.014.24378 ie	X-RAYS OF RIGHT FOOT	FRACTURE OF METHATARSAL BONES/INJURY	26NOV2000	26NOV2000
676.021.24564 ie	PHYSICAL EXAM	ROUTINE FOR HIGHSCHOOL SPORTS	04SEP2000	04SEP2000
676.100.24702 i	PAP SMEAR	ANNUAL CHECK UP	24NOV2000	24NOV2000
676.100.24707 ie	VISIT TO DOCTOR	BLADDER INFECTION	27FEB2001	27FEB2001
676.101.24617 ie	CARDIOLOGY CONSULT	PVCS	24MAY2000	24MAY2000
	PHYSIOTHERAPY	STRAINED ELBOW	15MAY2000	15MAY2000
676.102.24593 ie	DERMATOLOGIST ASSESSMENT	SKIN ERUPTION (RASH) UNDER ARMS	08FEB2001	08FEB2001
676.204.24847 i	5 SUTURES TO LEFT HAND	LACERATION OF LEFT HAND	12DEC2000	12DEC2000

Population Flag: i = Intention-To-Treat Population, e = Per-Protocol Population