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Appendix D Listings

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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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	m Verbatim Text	Body System	Of Study Med*				No. Epi.		Action	Corr. Ther.		SAE?
676.019.24505	HEADACHE	HEADACHE	^ Body as a Whole		25FEB00	1 day	No	1	MIL	NO	Yes	REL	No

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

2

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

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* 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, ModeModerate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,
STP = Drug Stopped

3

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

260

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* 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

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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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System	Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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

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

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

Days Rel Dose To Start at (Stop)

Onset Of Study Onset Dura-

Date

No. Inv. Corr. Inv.

tion Cont. Epi. Int. Action Ther. Rel. SAE?

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med*

NO DATA PRESENT

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* 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

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

Days Rel Dose To Start at (Stop)

Onset Of Study Onset Dura-

No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med*

Date

tion Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

263

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* 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,

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.001.24008 ie BACK PAIN NECK PAIN + Body as a 114 (-3) 30DEC00 19 days Yes PBU . MIL NO No No Whole **HEADACHE HEADACHES** + Body as a 08SEP00 14 days No PSR 10 1 (-116) 10 MIL NO No No Whole TRAUMA PAIN IN FEET + Body as a 20 49 (-68) 260CT00 3 days Yes MOD NO Yes UNR No FROM STRESS Whole FRACTURE RESPIRATORY UPPER + Respiratory 10 23 (-94) 30SEP00 15 days Yes . MIL NO Yes PBU No DISORDER RESPIRATORY System INFECTION 676.002.24031 i ABDOMINAL PAIN STOMACH ACHE + Body as a 6 (-106) 21FEB00 51 days Yes . MIL NO PSR No No Whole FEVER ELEVATED TEMP Body as a 7 (-105) 22FEB00 2 days Yes . MIL NO Yes UNR No Whole FEVER Body as a 08MAY00 2 days ELEVATED TEMP 30 83 (-29) Yes . MIL NO Yes UNR No Whole HEADACHE HEADACHE 05JUN00 1 day . MIL NO UNR + Body as a 111 (-1) Yes No 30 Yes Whole TRAUMA SPIDER BITE + Body as a 25APR00 15 days No 2 MIL NO UNR No 30 70 (-42) Yes Whole DECREASED DECREASED + Digestive 1 (-111) 16FEB00 1 day . MIL NO PSR No 10 Yes No APPETITE APPETITE System DIARRHEA DIARRHEA + Digestive 6 (-106) 21FEB00 1 day Yes . MIL NO PSR No Yes System DIARRHEA DIARRHEA + Digestive 30 83 (-29) 08MAY00 1 day Yes MIL NO Yes UNR No System NAUSEA QUEASY STOMACH + Digestive 10 1 (-111) 16FEB00 1 day Yes . MIL NO No PSR No System ARTHRALGIA KNEE PAIN 22APR00 42 days Yes UNR No + Musculoskel 30 67 (-45) . MIL NO Yes etal System 676.002.24034 i ABDOMINAL PAIN STOMACH ACHE + Body as a 20 69 (0) 16AUG00 1 day Yes . MIL NO No PRII Nο

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Whole

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]

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study Onset

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.002.24034 i	HEADACHE	INCREASED INTERMITTENT	+ Body as a Whole	20	25 (-44)	03JUL00	19 days	Yes		MOD	NO	Yes	PBU	No
	HOSTILITY	HEADACHES 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

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe, Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,

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]

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.003.24063 ie	HYPERNATREMIA	HYPERNATREMIA	^ Metabolic and Nutritional		-6 (-134)	17APR00	4 days	Yes		MIL		No		No
	FEVER	FEVER	Disorders + 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

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]

HEADACHE

HEADACHE

HEADACHE

HEADACHES

INTERMITTENT

CONFIDENTIAL

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

Days Rel

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

56 (-61)

87 (-30)

09JUN00 1 day

10JUL00 CON

Yes

Yes

MIL NO

. MIL NO

No

No

UNR

PSR

No

No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

20

30

+ Body as a

Whole Body as a

Whole

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]

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

Dose

Days Rel To Start

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

Investigator Intensity [Inv Int]: Mil = Mild, Mod-Moderate, Sev-Severe,

20

40

and Nutritional Disorders

+ Nervous

+ Nervous

System

System

DROWSINESS

DECREASED

PERFORMANCE

SCHOOL

SOMNOLENCE

IMPAIRED

676.013.24345 ie CONCENTRATION

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]

23 (-92)

07JUN00 CON

109 (-10) 010CT00 CON

Yes

Yes

MIL NO

MOD NO

No

No

PSR

PSR

No

No

PBU

PBU

No

No

No

Nο

CONFIDENTIAL

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

Dose

Days Rel

To Start at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. 676.013.24345 ie NERVOUSNESS RESTLESSNESS 7 (-112) 21JUN00 3 days Yes PSR + Nervous 10 . MIL NO No No System RASH SKIN RASH ON + Skin and 28 (-91) 12JUL00 35 days Yes UNR . MIL NO Yes No STERNUM Appendages RASH SKIN RASH ON + Skin and 89 (-30) 11SEP00 22 days Yes . MIL NO No UNR No LEG Appendages CONJUNCTIVITIS BLOOD-SHOT + Special 13 (-106) 27JUN00 2 days Yes . MIL NO UNR No Yes EYES Senses 676.014.24366 ie PHARYNGITIS SORE THROAT + Respiratory 40 76 (-31) 11APR00 2 days Yes . MOD NO Yes UNR No System RESPIRATORY HEAD COLD + Respiratory 68 (-39) 03APR00 2 days Yes . MIL NO PBU No Yes DISORDER System 676.014.24377 ie NERVOUSNESS IRRITABILITY + Nervous 30 (-90) 01NOV00 15 days Yes . MIL DCR No PSR No System Body as a 676.015.24397 ie ALLERGIC SEASONAL -5 (-121) 22APR00 3 days No 1 MIL Yes No ALLERGIES Whole REACTION HYPERKINESIA HYPERVERBAL PSR + Nervous 30 35 (-81) 01JUN00 8 days Yes . MIL DCR No No HYPERACTIVE System SPEECH HYPERVERBAL + Nervous 01JUN00 8 days . MIL DCR PSR No 30 35 (-81) Yes No DISORDER HYPERACTIVE System 676.015.24403 ie HEADACHE HEADACHE Body as a -4 (-125) 03JUL00 2 days 1 MIL Yes No Whole ABDOMINAL PAIN ABDOMINAL + Body as a 113 (-8) 280CT00 2 days . MIL NO PBU No Yes Yes CRAMPING Whole HEADACHE HEADACHE Body as a 53 (-68) 29AUG00 1 day Yes MIL NO Yes PBU No Whole **HEADACHE HEADACHE** Body as a 40 54 (-67) 30AUG00 1 day No 1 MIL NO Yes PBU No

113 (-8)

53 (-68)

40

280CT00 1 day

29AUG00 2 days

Yes

MIL NO

2 MIL NO

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Whole

+ Digestive

+ Respiratory 40

System

System

VOMITING

EPISTAXIS

VOMITING

NOSEBLEEDS

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]

^{*} 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

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text		Body System		Of Med	Study l*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.015.24403 ie	EPISTAXIS	EPISTAXIS	+	Respiratory	40	61	(-60)	06SEP00	13 days	No		MIL	NO	Yes	PBU	No
0,0,010,11100 10	21 10 111110	21 10 111110		System		0.1	(00)	0002100	15 da ₁ 5	1.0			2.0	100	120	1.0
	SINUSITIS	SINUS HEADACHE		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	^	Cardiovascu lar System	•	-2	(-115)	28FEB00	1 day	Yes		MOD		No		No
	VASODILATATION		+	Cardiovascu lar 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

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]

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

Days Rel

To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.017.24450 ie FLATULENCE FLATULENCE + Digestive 24 (-89) 25MAR00 82 days Yes 40 . MOD NO No PSR No System INSOMNIA INSOMNIA + Nervous 50 29MAR00 15 days Yes PSR 28 (-85) . MIL NO No No System RESPIRATORY UPPER + Respiratory 50 100 (-13) 09JUN00 42 days Yes . MOD NO Yes UNR No DISORDER RESPIRATORY System INFECTION 676.017.24453 ie ABDOMINAL PAIN PAINS ACROSS + Body as a 20 (-101) 15MAY00 2 days Yes SEV NO No PSR No LOWER ABDOMEN Whole HEADACHE HEADACHES + Body as a 11 (-110) 06MAY00 14 days Yes PSR . MIL NO Yes No Whole SOMNOLENCE DROWSINESS + Nervous 78 (-43) 12JUL00 17 days Yes . MOD NO No PSR No System 676.017.24455 i HEADACHE **HEADACHE** + Body as a 3 (-91) 13JAN01 1 day PSR 10 Yes MOD NO Yes No Whole HEADACHE HEADACHE + Body as a 20JAN01 1 day 2.0 10 (-84) Yes MOD NO PSR No Nο Whole HEADACHE HEADACHE + Body as a 21MAR01 1 day PSR 40 70 (-24) Yes MIL NO No No Whole TRAUMA BRUISES ON L. + Body as a 77 (-17) 28MAR01 1 day Yes . MIL NO No UNR No LEG Whole (PLAYGROUND ACCIDENT) CONSTIPATION CONSTIPATION + Digestive 13 (-81) 23JAN01 13 days Yes PSR No . MOD NO No System NAUSEA NAUSEA + Digestive 10 5 (-89) 15JAN01 1 day Yes MIL NO No PSR No System NAUSEA NAUSEA + Digestive 20 12 (-82) 22JAN01 6 days No 3 MOD NO No PSR No

28 (-66)

07FEB01 8 days Yes

MOD NO

No

PSR

No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None

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System + Nervous

System

INSOMNIA

INITIAL

INSOMNIA

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]

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text		Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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	+		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	+	Musculoskel etal 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		Cardiovascu lar 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

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]

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

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

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = No.

Whole

Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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	٠	-4 (-116)	07MAR00	3 days	Yes	٠	SEV		Yes		Yes
	TRAUMA	LACERATIONS DUE TO FALL FROM BIKE: UPPER LEFT LEG AND CHIN	^ Body as a Whole	٠	-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	٠	SEV	NO	Yes	UNR	No
	INFECTION	FLU	+ Body as a Whole	20	32 (-80)	12APR00	4 days	Yes	•	MIL	NO	Yes	UNR	No

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

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Corr. Inv.

CONFIDENTIAL

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

Days Rel

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

676.202.24785 ie	TRAUMA	LEFT LEG LACERATION FROM PREVIOUS BICYCLE		Body as a Whole	20	20 (-92)	31MAR00 13 day	s Yes	•	SEV	NO	Yes	UNR	No
		ACCIDENT HAS BECOME SEPTIC												
	OTITIS MEDIA	OTITIS MEDIA		Special Senses	20	76 (-36)	26MAY00 3 days	Yes	٠	MIL	NO	Yes	UNR	No
676.202.24788 ie	INSOMNIA	INSOMNIA	+ N	Jervous System	10	2 (-111)	02JUL00 4 days	Yes	٠	MIL	NO	No	PSR	No
	LACK OF EMOTION	SOCIAL WITHDRAWAL	+ N	Jervous System	20	65 (-48)	03SEP00 16 day	s Yes		MOD	NO	No	UNR	No
	URINARY INCONTINENCE	BED WETTING	+ U	Jrogenital System	20	65 (-48)	03SEP00 CON	Yes	•	MOD	NO	No	UNR	No
676.202.24790 i	HEADACHE	HEADACHES	+ B	Body as a Thole	10	2 (-100)	28AUG00 3 days	Yes	٠	MIL	NO	Yes	PSR	No
	INFECTION	FLU	+ B	Body as a Bhole	10	9 (-93)	04SEP00 5 days	Yes		MIL	NO	Yes	UNR	No
676.203.24814 ie	INFECTION	FLU	+ B	Body as a Whole	10	19 (-51)	28JUN00 12 day	s Yes		MIL	NO	Yes	UNR	No
676.204.24841 i	HEADACHE	HEADACHE	+ B	Body as a Whole	10	1 (-15)	31MAY00 1 day	Yes		MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+ B	Body as a Whole	10	6 (-10)	05JUN00 1 day	Yes	٠	MIL	NO	No	PSR	No
	INFECTION	SEPTIC LEFT BIG TOE NAIL	+ B	Body as a Whole	10	16 (0)	15JUN00 6 days	Yes	٠	MIL	NO	No	UNR	No
	TRAUMA	LACERATION TO LEFT PARIETAL AREA OF HEAD	+ B	Body as a Thole	10	9 (-7)	08JUN00 1 day	Yes		MIL	NO	No	UNR	No
	DYSPEPSIA	HEARTBURN)igestive 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]

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study

Preferred Term Verbatim Text Body System (mg) Med*

Patient / Flag	Preferred Term	Verbatim Text		Body Sy	stem		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.206.24878 ie	HEADACHE	HEADACHE	+	Body as Whole	a	10	26 (-106)	20SEP00	1 day	No	1	MIL	NO	Yes	UNR	No
	HEADACHE	HEADACHE	+	Body as Whole	a	10	50 (-82)	140CT00	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 Whole	a	10	7 (-103)	14JUN00	1 day	Yes		MIL	NO	Yes	UNR	No
	DECREASED APPETITE	LOSS OF APPETITE	+	Digesti System	ve	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	+	Respira System	tory	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 Whole	a	10	2 (-65)	22MAR01	1 day	No	1	MIL	NO	No	PSR	No
	HEADACHE	HEADACHE	+	Body as Whole	a	40	23 (-44)	12APR01	1 day	No	1	MIL	NO	Yes	PSR	No
	FECAL INCONTINENCE	SOILING OF PANTS	+	Digesti System	ve	40	29 (-38)	18APR01	36 days	Yes	•	MIL	NO	No	UNR	No
	COUGH INCREASED	COUGHING	+	Respira System	tory	30	21 (-46)	10APR01	14 days	Yes	•	MIL	NO	Yes	UNR	No
	URINARY INCONTINENCE	NOCTURNAL BED WETTING	+	Urogeni System	tal	40	29 (-38)	18APR01	20 days	Yes	•	MIL	NO	No	UNR	No
	URINARY INCONTINENCE	NOCTURNAL BED WETTING	+	Urogeni System	tal	40	62 (-5)	21MAY01	CON	Yes	•	MOD	NO	No	UNR	No
676.301.25038 ie		HEADACHE	+	Body as Whole	a	10	3 (-109)	09SEP00	1 day	Yes		MIL	NO	No	PSR	No

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 15.1.1

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

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.		Inv. Int.	Action	Corr. Ther.		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)	110CT00	CON	Yes	•	MIL	NO	No	PSR	No
		NOCTURNAL ENURESIS	+ Urogenital System	30	44 (-68)	200CT00	27 days	No	8	MIL	NO	No	PSR	No

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

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

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

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

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

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

Days Rel

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

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Whole

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 15.1.1

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

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

Days Rel Dose To Start (Stop)

Patient / Flag	Preferred Term	Verbatim Text		Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv.	Action	Corr. Ther.		SAE?
676.002.24038 ie	DDVDD	INCREASED		Dada as a	50	47 (66)	2205000	1 4	V		MIL	NO	W	TIMID	No
676.002.24038 Te	FEVER	TEMPERATURE	+	Body as a Whole	50	47 (-66)	23DEC00	1 day	Yes	•	МТГ	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	+	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]

NERVOUSNESS

INCREASED

IRRITABILITY

CONFIDENTIAL

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.003.24075 ie ABDOMINAL PAIN STOMACH ACHE + Body as a 104 (-7) 28AUG01 3 days Yes PSR . MOD NO No No Whole **HEADACHE** HEADACHE + Body as a 108 (-3) 01SEP01 1 day PSR 30 1 MIL NO Yes No Whole RESPIRATORY URI + Respiratory 10 7 (-104) 23MAY01 9 days Yes . MIL NO Yes UNR No DISORDER System 676.004.24085 i ABDOMINAL PAIN STOMACH ACHE + Body as a 25 (-87) 26FEB00 1 day Yes . MIL NO PSR No No Whole + Body as a ASTHENIA FATIGUE 21 (-91) 22FEB00 8 days Yes . MIL NO PSR No No Whole FLU SYNDROME FLU LIKE + Body as a 4 (-108) 05FEB00 2 days Yes . MOD NO PBU No Yes SYMPTOMS Whole TRAUMA HEAD + Body as a 20 53 (-59) 25MAR00 18 days Yes . MOD NO Yes UNR No LACERATION Whole BROKEN RIGHT + Body as a 09APR00 24 days Yes TRAUMA 20 68 (-44) MOD NO Yes UNR No THUMB Whole STOMATITIS MOUTH PAIN + Digestive 22 (-90) 23FEB00 1 day . MIL NO UNR No 20 Yes Yes System 676.005.24114 ie INFECTION FLU SYMPTOMS + Body as a 12 (-102) 27FEB00 2 days Yes . MOD NO UNR No 2.0 No Whole 676.005.24122 ie ASTHENIA FATIGUE + Body as a 33 (-37) 100CT00 23 days Yes . MOD DCR PSR No 50 No Whole INFECTION FLU SYMPTOMS + Body as a 49 (-21) 260CT00 5 days Yes UNR No . MIL No Whole NERVOUSNESS INCREASED + Nervous 40 22 (-48) 29SEP00 9 days Yes MIL NO No PSR No IRRITABILITY System 676.005.24124 ie ABNORMAL INCREASED + Nervous 40 47 (-3) 08JAN01 4 days Yes MIL NO No PSR No DREAMS DREAMING System NERVOUSNESS + Nervous 22DEC00 16 days Yes PSR INCREASED 50 30 (-20) MOD DCR No No System IRRITABILITY

46 (-4)

07JAN01 5 days Yes

. MIL DCR

No

PSR

Nο

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

40

+ Nervous

System

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]

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text		Body System		Of Med	Study	Onset Date	Dura- tion	Cont.		Inv. Int.	Action	Corr. Ther.		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

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]

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. 676.006.24142 ie LIBIDO DECREASED 20 (-93) 12JUN00 112 REL + Nervous Yes MOD NO No No DECREASED LIBIDO System days SWEATING NIGHT SWEATS + Skin and 16JUL00 65 days No MOD NO PSR 54 (-59) 80 No No Appendages 676.006.24143 ie ABDOMINAL PAIN STOMACH CRAMPS + Body as a 111 (-2) 18SEP00 5 days Yes . MIL NO Yes UNR No Whole HEADACHE HEADACHE + Body as a 21 (-92) 20JUN00 1 day 1 MIL NO PSR No 2.0 Nο Yes Whole + Body as a **HEADACHE** HEADACHE 30 23 (-90) 22JUN00 1 day Yes . MIL NO PSR No No Whole **HEADACHE HEADACHE** + Body as a 53 (-60) 22JUL00 1 day Yes . MIL NO PSR No No Whole HEADACHE HEADACHE + Body as a 40 60 (-53) 29JUL00 1 day Yes MOD NO Yes PSR No Whole **HEADACHE HEADACHE** + Body as a 50 79 (-34) 17AUG00 1 day Yes MOD NO Yes PSR No Whole OT INTERVAL PROLONGED OTC + Cardiovascu 50 113 (0) 20SEP00 6 days DCR PSR No Yes . MIL No PROLONGED lar System DECREASED DECREASED + Digestive 15JUL00 28 days Yes PSR No 40 46 (-67) MIT NO No APPETITE APPETITE System DECREASED DECREASE IN + Digestive 11AUG00 61 days Yes MOD NO PSR No 50 73 (-40) No APPETITE APPETITE System DRY MOUTH DRY MOUTH + Digestive 8 (-105) 07JUN00 15 days No NO PSR No MIL No System **PURPURA** BRUISED FOOT + Hemic and 62 (-51) 31JUL00 33 days Yes MOD NO No UNR No Lymphatic System CONTACT POISON OAK + Skin and 40 35 (-78) 04JUL00 15 days Yes SEV NO Yes UNR No DERMATITIS RASH Appendages + Skin and RASH RASH 20 8 (-105) 07JUN00 8 days No 10 MIL NO No PBU No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe, Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,

Appendages

(EXTREMITIES)

STP = Drug Stopped

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676 006 24145 -	III A D A CILIE	IIEADA GUE	. Dada as a	1.0	c / 10c)	20211000	0 4	V		MIT	NO	Ma	Dan	Me
676.006.24145 ie	HEADACHE	HEADACHE	+ Body as a Whole	10	6 (-106)	29AUG00	2 days	res	•	MIL	NO	No	PSR	No
	DECREASED APPETITE	DECREASE IN APPETITE	+ Digestive System	40	22 (-90)		27 days	Yes			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	٠	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

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]

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study Onset

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.007.24170 ie	YAWN	YAWNING	+ Respiratory	10	1 (-112)	30NOV99	43 days	Yes		MIL	NO	No	PSR	No
	CONJUNCTIVITIS	PINKEYE	System + 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	٠	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
	GASTROINTESTIN AL DISORDER	REFLUX	+ Digestive System	50	65 (-43)	29JUL01	35 days	Yes		MIL	NO	No	PSR	No

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]

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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	+ 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	^ Musculoskel etal 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

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 15.1.1

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

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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

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

System

and Nutritional Disorders

+ Nervous

Whole

Whole

System

+ Body as a

+ Body as a

+ Metabolic

WEIGHT GAIN

DROWSINESS

HEADACHE

HEADACHE

WEIGHT GAIN

SOMNOLENCE

HEADACHE

676.014.24368 ie HEADACHE

CONFIDENTIAL

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

Dose

Days Rel To Start

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

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

10

10

Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped

113 (0)

2 (-111)

1 (-109)

13 (-97)

20JUL01 CON

31MAR01 3 days

11FEB00 1 day

23FEB00 1 day

. MIL NO

MIL NO

1 MIL NO

1 MIL NO

Yes

Yes

PSR

PSR

PSR

PSR

No

No

Yes

No

No

No

No

Nο

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

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^{*} 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

DREAMS

THOUGHTS

CONFIDENTIAL

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.014.24368 ie HEADACHE HEADACHE + Body as a 51 (-59) 01APR00 2 days Yes PSR . MOD NO Yes No Whole VOMITING VOMITING + Digestive 1 (-109) 11FEB00 1 day PSR 10 1 MIL NO No No System MYDRIASIS MYDRIASIS + Special 10 6 (-104) 16FEB00 3 days Yes . MIL NO No PSR No Senses 676.014.24371 i RESPIRATORY HEAD COLD Respiratory -5 (-33) 18FEB00 5 days No No . MTT Yes DISORDER System SOMNOLENCE + Nervous DROWSINESS 10 (-18) 04MAR00 21 days Yes . MIL NO No PSR No Svstem SINUSITIS SINUS + Respiratory 16 (-12) 10MAR00 CON . MIL NO PBU No Yes Yes INFECTION System 676.014.24374 ie ABDOMINAL PAIN STOMACH PAIN Body as a 10 2 (-110) 08JUN00 2 days Yes MOD NO Yes UNR No Whole **HEADACHE HEADACHE** + Body as a 15JUN00 1 day 20 9 (-103) 1 MIL NO Yes PSR No Whole NAUSEA NAUSEA + Digestive 20 9 (-103) 15JUN00 1 day No 1 MOD NO PSR No No System NAUSEA NAUSEA + Digestive 25 (-87) 01JUL00 4 days PSR No 2.0 Yes MIT NO No System DIZZINESS MOTION + Nervous 20 25 (-87) 01JUL00 1 day . MIL NO PSR No Yes No SICKNESS System INSOMNIA INSOMNIA + Nervous 01JUL00 5 days NO PSR No 25 (-87) Yes MOD No System NERVOUSNESS IRRITABLE + Nervous 20 67 (-45) 12AUG00 9 days Yes MOD NO No PSR No System SOMNOLENCE DROWSINESS + Nervous 20 9 (-103) 15JUN00 1 day No 1 MIL NO No PSR No System 676.014.24376 i MYALGIA MUSCLE 10SEP00 3 days UNR No + Musculoskel 10 12 (-22) Yes MOD NO Yes DISCOMFORT etal System ABNORMAL MORBID + Nervous 40 30 (-4) 28SEP00 CON Yes SEV STP No PBU Nο

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

System

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]

^{*} 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

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.014.24376 i AGITATION PANIC ATTACK 16 (-18) 14SEP00 1 day 1 MOD INC PBU + Nervous No No No System AGITATION PANIC ATTACK + Nervous 30 (-4) 28SEP00 1 day SEV STP PSR No No No WORSENING System **EMOTIONAL** SUICIDAL + Nervous 40 30 (-4) 28SEP00 CON Yes MOD STP No PBU No LABILITY THOUGHTS System 676.014.24380 ie HEADACHE HEADACHE + Body as a 7 (-76) 30MAY01 1 day No 1 MIL NO UNR No 10 Yes Whole 676.015.24394 ie HEADACHE + Body as a HEADACHE 20 (-100) 20FEB00 2 days No 2 MIL NO Yes UNR No Whole **HEADACHE HEADACHE** + Body as a 46 (-74) 17MAR00 1 day 1 MIL NO Yes UNR No Whole HEADACHE HEADACHE + Body as a 49 (-71) 20MAR00 1 day No 1 MIL NO Yes UNR No Whole **HEADACHE HEADACHE** + Body as a 24MAR00 1 day 40 53 (-67) 1 MIL NO Yes UNR No Whole RHINITIS SEASONAL UNR + Respiratory 20 (-100) 20FEB00 30 days Yes . MIL NO No 20 No RHINITIS System 676.015.24399 ie INFECTION PARENT + Body as a 27JUN00 4 days . MIL NO PBU No 42 (-72) Yes DIAGNOSED FLU Whole MYALGIA LEG CRAMPS + Musculoskel 50 113 (-1) 06SEP00 2 days . MIL NO PBU No Yes Yes FROM EXERCISE etal System SINUSITIS SINUSES/ALLERG + Respiratory 10 8 (-106) 24MAY00 2 days . MIL UNR No Yes System SINUSITIS SINUSES-ALLERG + Respiratory 111 (-3) 04SEP00 2 days Yes MIL NO Yes PBU No IES System 676.015.24406 i VOMITING NAUSEA/VOMITIN + Digestive 10 1 (0) 28AUG00 1 day No 1 MIL STP Yes PSR No System 676.015.24407 ie ABDOMINAL PAIN STOMACH ACHE Body as a 12 (-107) 010CT00 1 day Yes PSR No 20 MIL NO No Whole ABDOMINAL PAIN STOMACH ACHE + Body as a 20 13 (-106) 020CT00 1 day Yes . MIL NO No PSR Nο

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Whole

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 15.1.1

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

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

Days Rel

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

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = No

System

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]

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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

Days Rel

To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.019.24511 ie HEADACHE **HEADACHE** + Body as a 3 (-105) 26JUN00 2 days PSR 10 Yes . MIL NO Yes No Whole **HEADACHE HEADACHE** + Body as a PSR 20 28 (-80) 21JUL00 1 day Yes . MIL NO Yes No Whole **HEADACHE HEADACHE** + Body as a 30 44 (-64) 06AUG00 1 day Yes . MOD NO Yes PSR No Whole HEADACHE HEADACHE + Body as a 66 (-42) 28AUG00 1 day Yes . MIL NO PSR No 40 Yes Whole MYALGIA MUSCLE + Musculoskel 40 62 (-46) 24AUG00 7 days Yes . MIL DCR Yes PSR No SORENESS etal System 676.019.24518 ie FEVER FEVER + Body as a 78 (-36) 06FEB01 3 days . MIL NO UNR No Yes Whole FEVER LOW GRADE + Body as a 113 (-1) 13MAR01 1 day Yes . MIL NO No UNR No FEVER Whole **HEADACHE** + Body as a **HEADACHE** 10 3 (-111) 23NOV00 1 day Yes . MIL NO No PSR No Whole HEADACHE . MIL NO **HEADACHE** + Body as a 13 (-101) 03DEC00 1 day Yes PSR No 10 Yes Whole HEADACHE HEADACHE + Body as a 01JAN01 1 day . MIL NO PSR 2.0 42 (-72) Yes Yes Nο Whole DIARRHEA INCREASED + Digestive 25 (-89) 15DEC00 4 days Yes . MIL NO PSR No 20 Yes BOWEL MOVEMENT System DIARRHEA DIARRHEA + Digestive 67 (-47) 26JAN01 3 days . MIL UNR No Yes Yes System VOMITING VOMIT + Digestive 30 113 (-1) 13MAR01 1 day Yes MIL NO No UNR No System ARTHRALGIA KNEE PAIN + Musculoskel 30 109 (-5) 09MAR01 1 day Yes MIL NO Yes UNR No etal System RESPIRATORY HEAD COLD 06FEB01 10 days Yes UNR + Respiratory 30 78 (-36) MOD NO Yes No DISORDER System

3 (-111)

23NOV00 1 day

. MIL NO

Yes

UNR

No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = Nor

+ Respiratory 10

System

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 15.1.1

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

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.020.24534 ie ALLERGIC ALLERGIES + Body as a 48 (-99) 01JUN00 2 days No UNR 30 1 MIL NO Yes No REACTION Whole STOMATITIS PAIN FROM + Digestive 68 (-79) 21JUN00 2 days 1 MIL NO UNR No Yes BRACES System PAIN IN ANKLES + Musculoskel ARTHRALGIA 40 94 (-53) 17JUL00 1 day Yes . MIL NO Yes PBU No etal System 676.020.24536 ie BACK PAIN BACK PAIN + Body as a 49 (-71) 300CT00 68 days Yes . MOD NO UNR No No Whole NEUTROPHILS, + Hemic and LEUKOCYTOSIS 120 (0) 09JAN01 CON Yes . MIL NO No PBU No ABSOLUTE 8.90 Lymphatic AND SEGS System 78.1 (ABOVE RANGE) LEUKOPENIA LYMPHOCYTES + Hemic and 120 (0) 09JAN01 CON . MIL NO PBU 30 Yes No No 14.5 (BELOW Lymphatic RANGE) System COLD UNR RESPIRATORY + Respiratory 30 118 (-2) 07JAN01 3 days No 3 MIL NO No Yes DISORDER System RHINITIS NASAL + Respiratory 120 (0) 09JAN01 CON UNR No 30 Yes MIT NO No CONGESTION System 676.021.24565 ie HEADACHE HEADACHE + Body as a 14 (-106) 020CT00 2 days 1 MIL NO PSR No 10 No No Whole **HEADACHE HEADACHE** + Body as a 82 (-38) 09DEC00 1 day 1 MIL NO PSR No No Whole INFECTION FLU + Body as a 30 101 (-19) 28DEC00 11 days No 11 MOD NO Yes PBU No Whole DECREASED DECREASE IN + Digestive 20 23 (-97) 110CT00 CON Yes MIL NO No PSR No APPETITE APPETITE System SOMNOLENCE LETHARGY 200CT00 35 days No PSR No + Nervous 30 32 (-88) MIL NO No System 676.022.17841 ie ASTHENIA FATIGUE + Body as a 20 13 (-20) 06JUN00 2 days No 1 MIL NO No PSR Nο

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Whole

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]

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study

Patient / Flag	Preferred Term	Verbatim Text		Body System		Of Med	Study 1*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.022.17841 ie	INSOMNIA	RESTLESS SLEEP (DECREASE SLEEP TO 5 HOURS/NIGHT)	+	Nervous System	30	26	(-7)	19JUN00	6 days	Yes	٠	MOD	DCR	No	PSR	No
	MANIC REACTION	, ,		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	10	5 (-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

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]

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text		Body System		Of Med		Onset Date	Dura- tion	Cont.		Inv. Int.	Action	Corr. Ther.		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

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe, Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,

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]

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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		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	٠	MOD	NO	Yes	UNR	No
	INFECTION	BACTERIAL INFECTION (FACE ARMS AND TRUNK) CELLULITIS	+ Body as a Whole	50	78 (-36)	13SEP00	71 days	Yes	٠	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

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]

Listing 15.1.1

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

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.100.24703 ie HEADACHE HEADACHE + Body as a 46 (-67) 19NOV00 2 days UNR Yes . MOD NO Yes No Whole DYSPEPSIA HEARTBURN + Digestive 24 (-89) 280CT00 1 day Yes UNR No MOD NO Yes System DYSPEPSIA HEARTBURN + Digestive 81 (-32) 24DEC00 1 day Yes . MIL NO Yes UNR No System 676.100.24705 ie DYSPEPSIA HEARTBURN + Digestive 10 19 (-24) 04NOV00 2 days Yes . MIL NO UNR No Yes System DEPRESSION WORSENING + Nervous 20 43 (0) 28NOV00 CON Yes . MOD STP Yes PSR No DEPRESSION Svstem **EMOTIONAL** SELF + Nervous 38 (-5) 23NOV00 1 day No 1 MIL NO No PBU No LABILITY INFLICTED System SCRATCH ON RT. WRIST LACK OF LACK OF + Nervous 5 (-38) 210CT00 CON PSR 10 Yes . MIL NO No No EMOTION EMOTIONS System 676.100.24708 ie TRAUMA SLIPPED AND + Body as a Yes 49 (-21) 10APR01 1 day . MOD NO UNR No Yes FELL (SLIGHT Whole CUT TO EYEBROW AND EYEGLASSES BROKEN) NEUROSIS SUPERFICIAL + Nervous 66 (-4) 27APR01 1 day . MOD NO PBU No Yes No CUTS TO THE System ARMS (SELF INDUCED SCRATCHES TO GET PARENTS ATTENTION) 676.100.24710 ie ABDOMINAL PAIN STOMACH ACHE + Body as a 33 (-85) 20MAY01 1 day UNR No 30 Yes . MIL NO Yes

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Whole

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]

^{*} 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

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

Days Rel

To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.100.24710 ie ABDOMINAL PAIN STOMACH ACHE + Body as a 84 (-34) 10JUL01 1 day UNR Yes . MIL NO No No Whole ASTHENIA HEAT STROKE + Body as a 08AUG01 1 day UNR 113 (-5) Yes MOD NO Yes No Whole HEADACHE HEADACHE + Body as a 10 7 (-111) 24APR01 1 day Yes . MIL NO Yes UNR No Whole DYSPEPSIA UPSET STOMACH + Digestive 41 (-77) 28MAY01 1 day Yes . MIL NO UNR No 30 Yes System BRUISED ANKLE + Hemic and **PURPURA** 109 (-9) 04AUG01 3 days . MOD NO UNR No Yes Yes AND KNEE Lymphatic System EAR PAIN EARACHE + Special 54 (-64) 10JUN01 4 days Yes MOD NO Yes UNR No Senses 676.101.24623 ie HEADACHE **HEADACHE** + Body as a 01SEP00 81 days No PBU 63 (-47) MIL NO No No Whole MONILIASIS ORAL THRUSH + Body as a 27JUL00 7 days Yes 27 (-83) MOD NO TINR Nο 40 Yes Whole INCREASED INCREASED + Digestive 05AUG00 CON PBU No 40 36 (-74) Yes MIL NO No APPETITE APPETITE System EMOTIONAL MOOD LABILITY + Nervous 40 21 (-89) 21JUL00 20 days No 3 MOD NO No PSR No LABILITY System INSOMNIA INSOMNIA + Nervous 10 (-100) 10JUL00 31 days Yes PBU MOD INC No No System COUGH COUGH + Respiratory 120CT00 11 days Yes UNR 40 104 (-6) MOD NO Yes No INCREASED System PHARYNGITIS SORE THROAT + Respiratory 69 (-41) 07SEP00 1 day MIL NO Yes UNR No System PHARYNGITIS SORE THROAT + Respiratory 40 104 (-6) 120CT00 11 days Yes MOD NO Yes UNR No System + Respiratory 40 RHINITIS RUNNY NOSE 104 (-6) 120CT00 11 days Yes MOD NO Yes UNR No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = No

System

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

EMOTIONAL

LABILITY

INSOMNIA

THREAT OF

FATIGUE/HYPOSO +

SUICIDE

MNIA

UNR

PSR

No

No

1 MIL NO

. MOD NO

No

Nο

CONFIDENTIAL

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

Days Rel

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

99 (-20)

39 (-80)

04JUL01 1 day

05MAY01 41 days Yes

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

40

40

+ Nervous

System

Nervous

System

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]

HEADACHE

DYSPEPSIA

TENSION

SLIGHT

STOMACH

IRRITATION (BURNING)

HEADACHE

CONFIDENTIAL

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

Dose

Days Rel

To Start at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.101.24629 i COUGH COUGH + Respiratory 10 03APR01 11 days Yes UNR 7 (-112) . MOD NO No No INCREASED System **EPISTAXIS** NOSE BLEED + Respiratory 10 03APR01 2 days No 2 MOD NO PBU 7 (-112) No No System RHINITIS SNEEZING + Respiratory 40 50 (-69) 16MAY01 8 days 3 MIL NO No UNR No System 676.102.24589 ie ALLERGIC HAYFEVER + Body as a 14 (-119) 19JUN00 1 day Yes . MIL NO PBU No 2.0 Yes REACTION Whole WEIGHT GAIN 9.5 % WEIGHT + Metabolic 133 (0) 160CT00 CON Yes . MIL NO No PSR No GAIN and Nutritional Disorders **ASTHMA** ASTHMA ATTACK + Respiratory 50 52 (-81) 27JUL00 1 day No 1 MOD NO Yes UNR No System PHARYNGITIS + Respiratory THROAT 52 (-81) 27JUL00 CON No 1 MIL NO Yes UNR No INFECTION System 676.103.24648 i HEADACHE HEADACHE + Body as a 10MAY00 2 days Yes . MOD NO UNR No 30 26 (-84) Yes Whole HEADACHE HEADACHE + Body as a 20MAY00 2 days UNR 30 36 (-74) Yes . MOD NO Yes Nο Whole HEADACHE HEADACHE DUE + Body as a 30 57 (-53) 10JUN00 19 days Yes . MOD NO UNR No Yes TO CAR DOOR Whole CLOSING ON HEAD HEADACHE TENSION + Body as a 84 (-26) 07JUL00 2 days Yes MOD NO Yes UNR No **HEADACHE** Whole

87 (-23)

26 (-84)

10JUL00 CON

10MAY00 5 days No

Yes

MOD

3 MIL NO

NO

No

No

UNR

PSR

No

No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

30

+ Body as a

+ Digestive

System

Whole

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

^{*} 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

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

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

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

INFECTION

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]

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.200.24733 ie RHINITIS VIRAL CORYZA + Respiratory 30 42 (-51) 30MAY00 1 day 1 MIL INC UNR No Yes No System 676.200.24735 ie TOOTH DISORDER TOOTHACHE AND + Digestive 20 14 (-98) 30MAY00 29 days Yes . MOD NO UNR No Yes WISDOM TEETH System EXTRACTION; PATIENT EXPERIENCED CONTINOUS TOOTHACHE FOR A PERIOD TWO WEEKS PRIOR TO EXTRACTION. 676.200.24742 i ASTHENIA FATIGUE / + Body as a 1 (-108) 27SEP00 CON Yes . MIL NO No PSR No TIREDNESS Whole HEADACHE HEADACHE + Body as a 13DEC00 1 day No PSR 78 (-31) 1 MIL NO Yes No Whole INFECTED FOOT UNR INFECTION Body as a 110 (1) 14JAN01 6 days Yes . MOD STP No Yes Whole 676.200.24743 ie HEADACHE **HEADACHES** + Body as a 9 (-109) 200CT00 1 day . MIL NO PSR No Yes Yes Whole NAUSEA NAUSEA + Digestive 10 (-108) 210CT00 2 days . MIL NO PSR No Yes No System SOMNOLENCE DROWSINESS + Nervous 4 (-114) 150CT00 6 days REL No MOD No System 676.200.24748 ie RHINITIS VIRAL CORYZA + Respiratory 20 22 (-91) 24APR01 5 days 1 MIL NO Yes UNR No System 676.201.24762 ie SOMNOLENCE SOMNOLENCE + Nervous 2 (-112) 170CT00 18 days No 18 MIL NO No PSR No System 676.202.24789 ie INFECTION FLU Body as a -4 (-135) 22AUG00 4 days Yes No MIL No Whole ASTHENIA TIREDNESS + Body as a 10 1 (-130) 27AUG00 8 days Yes . MIL NO No PSR Nο

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Whole

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]

^{*} 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

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.202.24798 ie HEADACHE **HEADACHE** + Body as a 29 (-84) 10MAR01 1 day UNR 30 Yes . MIL NO Yes No Whole DECREASED POOR APPETITE + Digestive 26MAR01 15 days Yes PSR 30 45 (-68) . MOD DCR No No APPETITE System 676.202.24799 ie INFECTION FLU WITH + Body as a 20 77 (-38) 01MAY01 11 days Yes . MIL NO Yes UNR No HEADACHE Whole 676.203.24813 ie ABDOMINAL PAIN STOMACHACHE + Body as a 72 (-38) 21MAY00 1 day Yes . MIL NO UNR No 10 Yes Whole + Body as a **HEADACHE** HEADACHE 10 43 (-67) 22APR00 1 day Yes . MIL NO UNR No Yes Whole INFECTION FLU + Body as a 28 (-82) 07APR00 8 days . MIL NO UNR No Yes Whole INFECTION UJT + Body as a 10 65 (-45) 14MAY00 6 days No 1 MIL NO Yes UNR No Whole SOFT TISSUE + Body as a 17APR00 3 days Yes TRAUMA 10 38 (-72) . MIL NO Yes UNR No INJURY (R) HIP Whole INSOMNIA INSOMNIA 11MAR00 10 days Yes + Nervous 1 (-109) . MIL NO PSR No 10 No System INSOMNIA INSOMNIA + Nervous 16 (-94) 26MAR00 14 days Yes . MOD DCR REL No 2.0 No System BRONCHITIS BRONCHITIS + Respiratory 80 (-30) 29MAY00 6 days Yes . MIL NO UNR No 10 Yes System URINARY FREQUENCY OF + Urogenital 16 (-94) 26MAR00 25 days Yes REL No . MOD DCR No FREQUENCY URINE (NIGHT System AND DAYTIME) 676.204.24844 i ABDOMINAL PAIN ABDOMINAL 23JUL00 11 days Yes PBU + Body as a 20 25 (-80) MIL NO Yes No CRAMPS Whole HEADACHE HEADACHE + Body as a 10 1 (-104) 29JUN00 2 days Yes MIL NO No PSR No Whole **HEADACHE** + Body as a **HEADACHE** 10 4 (-101) 02JUL00 1 day Yes . MIL NO Yes PSR No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = Non

Whole

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]

676.204.24845 ie INFECTION

NAUSEA

FLU

NAUSEA

CONFIDENTIAL

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

Days Rel

To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.204.24844 i HEADACHE **HEADACHE** + Body as a 19 (-86) 17JUL00 1 day PBU Yes . MIL NO Yes No Whole **HEADACHE HEADACHE** + Body as a 18JUL00 1 day Yes PBU No 20 20 (-85) . MIL NO No Whole **HEADACHE** HEADACHE + Body as a 30 42 (-63) 09AUG00 3 days Yes . MIL NO Yes UNR No Whole HEADACHE HEADACHE + Body as a 54 (-51) 21AUG00 1 day Yes . MIL NO PSR No 40 Yes Whole HEADACHE + Body as a HEADACHE 40 59 (-46) 26AUG00 1 day Yes . MIL NO Yes PSR No Whole **HEADACHE HEADACHE** + Body as a 63 (-42) 30AUG00 1 day Yes . MIL NO PSR No Yes Whole INFECTION UJT + Body as a 50 103 (-2) 090CT00 7 days Yes . MIL NO Yes UNR No Whole PAINFUL LEFT + Body as a 06SEP00 3 days PAIN 40 70 (-35) Yes . MIL NO Yes UNR No Whole ARM DIARRHEA DIARRHEA + Digestive . MIL NO PBU 25 (-80) 23JUL00 8 days No 20 Yes Yes System DIARRHEA DIARRHOEA + Digestive 47 (-58) 14AUG00 2 days 2 MIL NO PSR No 30 Yes System RECTAL PRURITUS ANI + Digestive 20 32 (-73) 30JUL00 6 days . MIL NO UNR No Yes Yes DISORDER System DIZZINESS DIZZINESS + Nervous 2 (-103) 30JUN00 1 day Yes . MIL NO PSR No No System + Body as a

34 (-81)

115 (0)

03AUG00 2 days

230CT00 1 day

Yes

Yes

MIL NO

. MIL NO

Yes

No

UNR

PBU

No

No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe, Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,

50

Whole

+ Digestive

System

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]

^{*} 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

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. 676.204.24845 ie DIZZINESS LIGHTHEADED 79 (-36) 17SEP00 2 days Yes UNR + Nervous . MIL NO No No ASSOCIATED System WITH MENSTRUAL CYCLE DIZZINESS DIZZY + Nervous 80 (-35) 18SEP00 3 days Yes . MIL NO PSR No No System DIZZINESS DIZZY + Nervous 115 (0) 230CT00 1 day Yes . MIL NO No PBU No System 676.204.24849 ie ABDOMINAL PAIN ABDOMINAL + Body as a 20 (-93) 30JAN01 1 day PSR Yes . MIL NO Yes No CRAMPS Whole ABDOMINAL PAIN ABDOMINAL + Body as a 70 (-43) 21MAR01 2 days Yes . MIL NO No PSR No CRAMPS Whole NAUSEA NAUSEA + Digestive 21MAR01 2 days PSR 50 70 (-43) Yes . MIL NO No No System 676.204.24851 ie HEADACHE HEADACHE + Body as a 1 (-111) 15FEB01 1 day REL Yes . MIL NO Nο 10 No Whole HEADACHE **HEADACHE** + Body as a 16FEB01 1 day REL 10 2 (-110) Yes . MIL NO Yes No Whole **HEADACHE HEADACHE** + Body as a 20 14 (-98) 28FEB01 1 day Yes . MIL NO Yes PBU No Whole INFECTION FLU SYMPTOMS + Body as a 30MAR01 2 davs 44 (-68) Yes MIL NO Yes PBU No Whole RESPIRATORY UPPER + Respiratory 50 UNR 108 (-4) 02JUN01 CON Yes . MIL NO Yes No DISORDER RESPIRATORY System TRACT INFECTION YAWN YAWNING + Respiratory 10 2 (-110) 16FEB01 7 days Yes . MIL NO No REL No System HERPES SIMPLEX HERPES + Skin and UNR 50 108 (-4) 02JUN01 10 days Yes . MIL NO No No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Appendages

STOMATITIS

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

+ Body as a

Whole

TRAUMA

SORE FOOT

AFTER FALL

CONFIDENTIAL

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

Days Rel

To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.205.24982 ie HEADACHE HEADACHE + Body as a 56 (-56) 25MAY00 57 days Yes PSR . MOD DCR No No Whole INFECTION FLU + Body as a 68 (-44) 06JUN00 5 days Yes UNR No . MIL NO Yes Whole 09JUN00 4 days No NAUSEA NAUSEA + Digestive 40 71 (-41) 4 MOD DCR No PSR No System 676.205.24985 i INFECTION FLU + Body as a 10 18 (-8) 25FEB01 5 days Yes . MIL NO UNR No Yes Whole ANEMIA + Hemic and ANAEMIA 20 25 (-1) 04MAR01 3 days No 2 SEV STP Yes UNR Yes Lymphatic System 676.205.24988 ie INFECTION FLU + Body as a 97 (-16) 06JUN01 4 days Yes . MIL NO Yes UNR No Whole DECREASED LOSS OF + Digestive 24MAR01 32 days Yes PSR 20 23 (-90) . MIL NO No No EVENING System APPETITE APPETITE 676.206.24870 ie INFECTION FLU + Body as a UNR 15 (-95) 01APR00 3 days Yes . MIL NO No No Whole 676.206.24871 ie ASTHENIA FATIGUE + Body as a 10 (-106) 10APR00 8 days Yes . MOD NO PSR 2.0 Yes Nο Whole

30

84 (-32) 23JUN00 38 days Yes

. MIL NO

UNR

No

No

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

Timbium 15 1

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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	+ Cardiovascu lar System	30	83 (-33)	22JUN00	1 day	No	1	MOD	NO	Yes	РВИ	No
	NAUSEA	HYPOTENSION. 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)	150CT00	5 days	Yes		MIL	NO	No	UNR	No

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]

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

Days Rel

To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.206.24875 ie RHINITIS RUNNY NOSE + Respiratory 10 20AUG00 1 day UNR 28 (-82) No 1 MIL NO Yes No System 676.206.24877 ie HEADACHE **HEADACHE** + Body as a 29AUG00 2 days PSR 10 4 (-127) No 2 MIL NO No No Whole 676.206.24882 ie HEADACHE ELECTIVE + Body as a 10 3 (-111) 10FEB01 1 day Yes . MIL NO Yes UNR No SURGERY L EFT Whole AND RIGHT TM JOINT INFECTION FLU + Body as a 68 (-46) 16APR01 5 days Yes . MIL NO Yes UNR No Whole INFECTION FLU + Body as a 114 (0) 01JUN01 8 days . MIL NO UNR No Yes Whole INSOMNIA INSOMNIA + Nervous 13 (-101) 20FEB01 CON Yes . MOD INC No PSR No System 676.207.24900 ie ASTHENIA + Body as a PSR TIREDNESS 30 16 (-97) 19JUL00 1 day Yes MOD DCR No No Whole HEADACHE HEADACHE PBU + Body as a 112 (-1) 230CT00 1 day No NO No 20 1 MIL Yes Whole DEPERSONALIZAT DEJA VU + Nervous 16 (-97) 19JUL00 1 day . MOD DCR PSR 30 Yes No Nο ION System NERVOUSNESS EDGY FEELING + Nervous 16 (-97) 19JUL00 1 day . MOD DCR PSR No 30 Yes No System 676.207.24901 ie HEADACHE **HEADACHE** + Body as a 190CT00 1 day NO PSR No 1 (-111) MOD No Whole KETOSIS KETONES(+) IN + Metabolic 20 15 (-97) 02NOV00 14 days Yes MIL NO No UNR No URINE and Nutritional Disorders ALBUMINURIA PROTEIN IN + Urogenital 15 (-97) 02NOV00 98 days Yes . MIL NO UNR No 20 No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe, Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,

System

URINE (+)

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 15.1.1

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

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study Onset

Patient / Flag	Preferred Term	Verbatim Text		Body System		Of Med	Study l*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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	٠	MIL	NO	No	PSR	No

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

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]

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.207.24907 i DEPRESSION DEPRESSED MOOD + Nervous 17 (-15) 05MAR01 5 days Yes PSR . MIL NO No No System DIZZINESS DIZZINESS + Nervous 1 (-31) 17FEB01 1 day Yes PSR 10 . MIL NO No No System INSOMNIA INITIAL + Nervous 10 5 (-27) 21FEB01 10 days Yes . MIL NO No PSR No INSOMNIA System NERVOUSNESS IRRITABILITY + Nervous 17 (-15) 05MAR01 7 days Yes . MIL NO PSR No No System + Respiratory YAWN INCREASED 10 1 (-31) 17FEB01 CON Yes . MIL NO PSR No No YAWNING System RASH SKIN RASH + Skin and 15 (-17) 03MAR01 11 days Yes . MIL NO PSR No No Appendages 676.207.24911 ie ABDOMINAL PAIN STOMACH CRAMPS + Body as a 111 (-2) 21AUG01 2 days Yes . MIL NO Yes PBU No Whole ASTHENIA DAYTIME + Body as a 10 (-103) 12MAY01 7 days 20 Yes . MIL NO No PSR No TIREDNESS Whole ASTHENIA DAYTIME 26MAY01 8 days + Body as a 24 (-89) Yes . MIL NO PSR No 30 No Whole TIREDNESS HEADACHE HEADACHE + Body as a 21MAY01 1 day 1 SEV NO PSR No 2.0 19 (-94) Nο Yes Whole INCREASED INCREASE IN + Digestive 30 24 (-89) 26MAY01 CON . MIL NO PSR No Yes No APPETITE APPETITE System VOMITING VOMITING + Digestive 111 (-2) 21AUG01 2 days . MIL PBU No Yes No System PHARYNGITIS SORE THROAT + Respiratory 10 7 (-106) 09MAY01 3 days Yes MIL NO Yes PBU No System RHINITIS RHINITIS + Respiratory 10 8 (-105) 10MAY01 8 days Yes MIL NO Yes PBU No System ACNE ACNE (FACE) + Skin and 02JUN01 CON PSR 30 31 (-82) Yes . MIL NO Yes No Appendages 676.209.24954 ie ABDOMINAL PAIN STOMACH CRAMPS Body as a UNR 10 112 (-2) 15AUG00 1 day Yes . MIL NO Yes Nο

Whole

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

+ Digestive

+ Respiratory

System

System

Whole

Whole

Whole

+ Body as a

+ Body as a

+ Body as a

DIARRHEA

676.209.24959 ie ABDOMINAL PAIN ABDOMINAL

ASTHENIA

BRONCHITIS

DIARRHEA

CRAMPS

TIREDNESS

(FATIGUE)

PAIN

ABDOMINAL PAIN EPIGASTRIC

BRONCHITIS

CONFIDENTIAL

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

Dose

Days Rel To Start

at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. 676.209.24954 ie HEADACHE HEADACHE (DUE + Body as a 83 (-31) 17JUL00 1 day 10 Yes . MIL NO No UNR No TO SMOKE Whole INHALATION) TRAUMA HEADACHE (DUE + Body as a 83 (-31) 17JUL00 1 day UNR 10 Yes . MIL NO No Nο TO SMOKE Whole INHALATION) COUGH COUGHING + Respiratory 10 46 (-68) 10JUN00 14 days Yes . MIL NO UNR No Yes INCREASED System PHARYNGITIS PHARYNGITIS + Respiratory 20 10 (-104) 05MAY00 2 days No 1 MIL NO Yes UNR No System PHARYNGITIS SORE THROAT + Respiratory 10 28 (-86) 23MAY00 4 days . MIL NO UNR No Yes RESPIRATORY UPPER + Respiratory 10 18 (-96) 13MAY00 4 days Yes . MIL NO No UNR No DISORDER RESPIRATORY System TRACT INFECTION RHINITIS RHINITIS 20MAY00 7 days Yes UNR + Respiratory 10 25 (-89) . MIL NO No Yes System 676.209.24956 ie ASTHENIA TIREDNESS + Body as a 14MAY00 8 davs . MIL NO PSR 10 3 (-108) No Nο Whole INFECTION FLU + Body as a 30 (-81) 10JUN00 2 days . MIL NO UNR No 30 Yes Yes Whole

30

10

10

20

13 (-98)

78 (-33)

1 (-111)

1 (-111)

21 (-91)

24MAY00 3 days

01AUG00 1 day

01AUG00 1 day

28JUL00 10 days Yes

21AUG00 32 days Yes

Yes

Yes

. MIL

MOD NO

MIL NO

. MIL NO

. SEV NO

PBU

UNR

PSR

PBU

PBU

No

Yes

Yes

Yes

No

No

No

No

No

Nο

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 15.1.1

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

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

Days Rel

To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.209.24959 ie ASTHENIA TIREDNESS + Body as a 73 (-39) 120CT00 CON . SEV NO PBU Yes No No (FATIGUE) Whole **HEADACHE** HEADACHE + Body as a 14 (-98) 14AUG00 1 day UNR 10 Yes . MIL NO Yes No Whole **HEADACHE HEADACHE** + Body as a 30 28 (-84) 28AUG00 2 days No 2 MIL NO Yes PSR No Whole HEADACHE HEADACHE + Body as a 50 (-62) 19SEP00 1 day . MOD NO UNR No 40 Yes Yes Whole NAUSEA NAUSEA + Digestive 10 1 (-111) 01AUG00 50 days Yes . MIL NO PSR No Yes System MYALGIA BACKACHE (MUSCL + Musculoskel 30 29 (-83) 29AUG00 1 day . MIL NO UNR No Yes E PAIN) etal System 676.209.24961 i ALLERGIC BEE STING-+ Body as a 20 (-63) 300CT00 3 days Yes MOD NO Yes UNR No REACTION SWOLLEN (L) Whole FOOT ASTHENIA FATIGUE + Body as a 110CT00 16 days Yes REL 10 1 (-82) . MIL NO Nο No DURING DAY Whole HEADACHE **HEADACHE** + Body as a 3 (-80) 130CT00 5 days Yes REL No 10 . MIL NO Yes Whole **HEADACHE HEADACHE** + Body as a 40 51 (-32) 30NOV00 1 day Yes . MIL NO Yes UNR No Whole DYSPEPSIA HEARTBURN + Digestive 28NOV00 33 davs Yes REL 49 (-34) SEV NO Yes No System 676.209.24964 ie AGITATION PANIC ATTACK + Nervous 210CT00 1 day PSR 4 (-123) Yes . MIL NO No No System AGITATION PANIC ATTACK + Nervous 10 7 (-120) 240CT00 1 day No 1 MIL NO No PSR No System DIZZINESS DIZZINESS + Nervous 40 41 (-86) 27NOV00 7 days Yes MIL NO Yes UNR No System 676.209.24966 ie RHINITIS Respiratory ALLERGIC -1 (-121) 05FEB01 1 day Yes . MIL Yes No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

System

RHINITIS

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

TREMOR

RESPIRATORY

DISORDER

TREMOR IN

COUGHING

(URTI)

BOTH HANDS

CONFIDENTIAL

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

Days Rel

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

1 (-114)

27FEB01 4 days

19 (-96) 17MAR01 2 days

Yes

Yes

MOD NO

. MIL NO

No

Yes

PSR

UNR

No

Nο

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

10

+ Nervous

System

System

+ Respiratory 10

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]

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text		Body System			Study !*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.209.24969 ie	GINGIVITIS	GINGIVITIS DUE TO ORTHODONTIC	+	Digestive System	20	78	(-36)	19JUN01	CON	Yes		MIL	NO	Yes	UNR	No
	PHARYNGITIS	PROCEDURE 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	GASTROINTESTIN AL 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		(-77)		14 days			MIL		Yes	PBU	No
	INCREASED APPETITE	INCREASED APPETITE		Digestive System	20				15 days			MIL		No	PSR	No
	INCREASED APPETITE	INCREASED APPETITE		Digestive System	30		(-85)		18 days			MIL		No	PBU	No
	BRONCHITIS	BRONCHITIS		Respiratory System			(-66)		6 days			MOD	NO	Yes	UNR	No
	PHARYNGITIS	SORE THROAT	+	Respiratory System					6 days			MOD	NO	No	PBU	No
	RESPIRATORY DISORDER	COLD		Respiratory System			(-38)		13 days			MIL		Yes	PBU	No
	RHINITIS	RHINITIS		Respiratory System			(-74)		4 days			MIL		No	UNR	No
	SWEATING	DYSHYDROSIS	+	Skin and Appendages	30	26	(-93)	290CT00	17 days	Yes	•	MIL	NO	No	PSR	No

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 15.1.1

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

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

Days Rel
Dose To Start
at (Stop)

	_
676.301.25041 ie SYNCOPE WEAK + Cardiovascu 40 118 (-2) 18SEP01 4 days Yes . MOD NO lar System RHINITIS RHINITIS + Respiratory 20 11 (-109) 03JUN01 7 days Yes . MIL NO System	

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 15.1.1

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

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

Days Rel
Dose To Start
at (Stop)

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

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

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

System

CRAMPS

CONFIDENTIAL

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

Days Rel

To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.002.24045 i DYSMENORRHEA MENSTRUAL + Urogenital 19 (-63) 11JUN01 2 days UNR 20 Yes . MOD NO Yes No CRAMPS System 676.005.24118 ie DYSMENORRHEA MENSTRUAL + Urogenital 50 75 (-44) 16JUL00 1 day Yes UNR No MOD NO Yes CRAMPS System 676.006.24145 ie DYSMENORRHEA MENSTRUAL + Urogenital 30 20 (-92) 12SEP00 1 day Yes SEV NO Yes UNR No CRAMPS System DYSMENORRHEA MENSTRUAL + Urogenital 40 55 (-57) 170CT00 1 day Yes SEV NO UNR No Yes CRAMPS System MENSTRUAL DYSMENORRHEA + Urogenital 40 96 (-16) 27NOV00 2 days Yes . MIL NO Yes UNR No CRAMPS System 676.015.24399 ie DYSMENORRHEA MENSTRUAL + Urogenital 8 (-106) 24MAY00 3 days MIL NO UNR No Yes CRAMPING System 676.022.17845 ie AMENORRHEA POSSIBLE + Urogenital 10 1 (-110) 01SEP00 124 Yes MIL NO No PBU No **AMENORRHEA** System days 676.023.17879 i DYSMENORRHEA MENSTRUAL + Urogenital 26 (-109) 09DEC00 1 day No MOD NO Yes UNR No CRAMPS System DYSMENORRHEA MENSTRUAL + Urogenital 20 51 (-84) 03JAN01 1 day MIL NO UNR No Yes Yes CRAMPS System DYSMENORRHEA MENSTRUAL + Urogenital 20 61 (-74) 13JAN01 1 day Yes UNR MIT NO Yes Nο

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

No

Nο

No

No

Nο

CONFIDENTIAL

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

Days Rel Dose To Start

at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.001.24012 i DIARRHEA + Digestive 21 (-97) 28DEC00 2 days No PBU NAUSEA, 1 MOD NO No VOMITING, System DIARRHEA NAUSEA NAUSEA, + Digestive 21 (-97) 28DEC00 2 days No 1 MOD NO PBU No VOMITING, System DIARRHEA VOMITING NAUSEA, + Digestive 21 (-97) 28DEC00 2 days No 1 MOD NO PBU No VOMITING, System DIARRHEA RESPIRATORY UPPER + Respiratory 6 (-112) 13DEC00 2 days Yes . MOD NO PBU Yes DISORDER RESPIRATORY System ILLNESS (COUGH) 676.003.24067 ie INFECTION FLU + Body as a 2 (-119) 29SEP00 2 days Yes NO UNR MOD Yes Whole INFECTION + Body as a 50 (-71) 16NOV00 1 day UJT Yes . MOD NO UNR Yes

				Whole												
	DYSPEPSIA	UPSET STOMACH	+	Digestive	0	110	(-11)	15JAN01	CON	Yes		MIL	NO	Yes	UNR	No
				System												
676.003.24069 i	TRAUMA	BUMP ON LEFT	+	Body as a	0	26	(-87)	21JAN01	CON	Yes		MIL	NO	No	UNR	No
		KNEE		Whole												
676.005.24113 ie	CONSTIPATION	CONSTIPATION	+	Digestive	0	39	(-93)	20MAR00	CON	Yes		MIL	NO	No	PSR	No
				System												
676.005.24123 ie	INFECTION	FLU SYMPTOMS	+	Body as a	0	5 (-107)	27NOV00	4 davs	Yes		MOD	NO	Yes	UNR	No
				Whole												
	NERVOUSNESS	INCREASED	+	Nervous	0	49	(-63)	10JAN01	16 days	Yes		MOD	DCR	No	PSR	No
		IRRITABILITY		System					-							
676.007.24175 i	PHARYNGITIS	THROAT	+	Respiratory	0	12	(-14)	16FEB00	2 davs	Yes	_	MIL	NO	Yes	UNR	No
		INFECTION		System	-		(,									
676.007.24178 ie	PP1/PD	FEVER	_	Body as a	0	37	(-47)	15MAR00	2 dave	Yes		MIL	NO	Yes	UNR	No
070.007.24170 16	LEVEK	PEVER	т	Whole	U	51	(-4/)	TOMAKOO	z days	165	•	141711	INO	165	OIVIC	IVO
				MITOTE												

^{*} 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]

PHARYNGITIS

SORE THROAT

CONFIDENTIAL

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

Days Rel

To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.007.24178 ie FEVER FEVER + Body as a 82 (-2) 29APR00 4 days UNR No . MIL NO No No Whole **HEADACHE HEADACHE** + Body as a 1 (-83) 08FEB00 1 day PSR Yes . MIL NO Yes No Whole **HEADACHE HEADACHE** + Body as a 13 (-71) 20FEB00 1 day Yes . MIL NO Yes PSR No Whole INFECTION INFLUENZA + Body as a 22 (-62) 29FEB00 5 days Yes . MIL NO UNR No Yes Whole + Body as a INFECTION HEAD LICE 32 (-52) 10MAR00 6 days Yes . MIL NO UNR No Yes Whole 676.007.24182 ie DIARRHEA DIARRHEA + Digestive 85 (-33) 24MAY00 1 day . MIL NO PSR No Yes System SINUSITIS SINUS + Respiratory 62 (-56) 01MAY00 42 days Yes . MIL NO Yes UNR No CONGESTION System SINUSITIS SINUSITIS + Respiratory 104 (-14) 12JUN00 CON Yes MOD NO Yes UNR No System 676.010.24259 ie HEADACHE HEADACHE + Body as a 4 (-106) 15AUG00 9 days No MIL NO PSR No 6 Yes Whole HEADACHE HEADACHE + Body as a 28AUG00 1 day 1 MIL NO PSR No 17 (-93) No Yes Whole HEADACHE HEADACHE + Body as a 18 (-92) 29AUG00 1 day No 1 MIL NO PSR No No Whole No **HEADACHE HEADACHE** + Body as a 04SEP00 1 day 1 MIL NO PBU No 24 (-86) Yes Whole HEADACHE HEADACHE + Body as a 45 (-65) 25SEP00 4 days Yes MOD NO Yes UNR No Whole **HEADACHE HEADACHE** + Body as a 67 (-43) 170CT00 1 day Yes MIL NO Yes PBU No Whole TRAUMA SKINNED KNEES Body as a Yes UNR 33 (-77) 13SEP00 1 day MIL NO Yes No Whole

45 (-65)

25SEP00 4 days

Yes

. MOD NO

Yes

UNR

Nο

0

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

+ Respiratory

System

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 15.1.1

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

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text		Body System		Of Study Med*	Onset Date	Dura- tion	Cont.		Inv. Int.	Action	Corr. Ther.		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
	GASTROENTERITI S	VIRAL GASTROENTERITI S		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

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]

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

Days Rel

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

10 (-102) 27APR01 1 day

Yes

. MIL NO

Yes

PSR

No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = N

0

+ Body as a

Whole

HEADACHE

HEADACHE

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]

CONCENTRATION

PHARYNGITIS

IMPAIRED

RHINITIS

CONCENTRATION

SORE THROAT

CONGESTION

PROBLEMS

NASAL

Nervous

System

System + Respiratory

System

Respiratory

CONFIDENTIAL

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

Dose

Days Rel

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

25 (-93)

8 (-110)

28AUG00 2 days

11AUG00 1 day

16 (-102) 19AUG00 1 day

Yes

Yes

Yes

MIL NO

MIL NO

MIL NO

No

Yes

Yes

PSR

UNR

UNR

No

No

No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

0

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]

^{*} 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

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.019.24514 ie RHINITIS + Respiratory 20SEP00 8 days PBU NASAL 0 48 (-70) Yes . MIL NO Yes No CONGESTION System 676.020.24533 ie ABDOMINAL PAIN STOMACH HURTS + Body as a 77 (-37) 10JUL00 1 day PBU 1 MIL NO No No WHEN PATIENT Whole TAKES MEDICATION ON AN EMPTY STOMACH DECREASED EATING LESS + Digestive 34 (-80) 28MAY00 CON Yes . MIL NO No PBU No APPETITE System **EPISTAXIS** NOSEBLEED + Respiratory 01MAY00 6 days MIL NO No PBU No System RASH ALLERGIC + Skin and 18 (-96) 12MAY00 CON Yes MIL NO Yes UNR No REACTION Appendages (RASH) TO PLANT 676.023.17878 i FLU SYNDROME ^ Body as a FLU-LIKE -7 (-47) 05SEP00 2 days Yes . MIL No No ILLNESS Whole PAIN FOOT PAIN Body as a -13 (-53) 30AUG00 CON 42 MOD No No No Whole CONJUNCTIVITIS CONJUNCTIVITIS Special -3 (-43) 09SEP00 4 days Yes No Yes . MIL Senses DECREASED DECREASED + Digestive 11 (-29) 23SEP00 8 days . MIL NO PSR No Yes No APPETITE APPETITE System AGITATION AGITATION + Nervous 28 (-12) 100CT00 15 days Yes MOD STP No REL No System SOMNOLENCE DROWSINESS + Nervous 0 23 (-17) 050CT00 1 day MOD NO No PSR No (FELL ASLEEP System AT SCHOOL) COUGH UNR COUGH + Respiratory 0 4 (-36) 16SEP00 CON Yes MOD NO No No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

System

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

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INCREASED

^{*} 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

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study
Fext Body System (mg) Med*

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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)	160CT00	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)	300CT00	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	4	0	3 (-93)	29AUG00	1 day	Yes		MIL	NO	Yes	PSR	No
676.204.24852 ie	ABDOMINAL PAIN	ABDOMINAL PAIN		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

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

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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		+ Body as a Whole	0	5 (-103)	30AUG00	1 day	Yes	•	MIL	NO	Yes	UNR	No

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 15.1.1

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

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text		Body System		Of Med	Study l*	Onset Date	Dura- tion	Cont.		Inv. Int.	Action	Corr. Ther.		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)	020CT00	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	0	29	(-82)	14JUL00	18 days	Yes		MOD	NO	Yes	UNR	No
	CONCENTRATION IMPAIRED	IMPAIRED CONCENTRATION	+	System Nervous System	0	1	(-110)	16JUN00	7 days	Yes		MIL	NO	No	PSR	No

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]

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body	y System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.207.24899 ie	SOMNOLENCE	LETHARGY	+ Nerv	7011S	0	1 (-110)	16JUN00	8 davs	Yes		MIL	NO	No	PSR	No
0,0120,121033 10	501110221102		Syst		ŭ	_ (10001100	0 4475	100	•		2.0	1.0	1011	1.0
	PHARYNGITIS	SORE THROAT	+ Resp	piratory tem	0	65 (-46)	19AUG00	7 days	Yes		MIL	NO	No	PSR	No
	PHARYNGITIS	SORE THROAT	+ Resp	piratory tem	0	83 (-28)	06SEP00	5 days	Yes	•	MIL	NO	No	PBU	No
	PHOTOSENSITIVI TY	PHOTOSENSITIVI TY		n and endages	0	99 (-12)	22SEP00	CON	Yes	•	MIL	NO	No	PBU	No
	HAEMATURIA	TRACE OF BLOOD IN URINE	Svst	genital cem		112 (1)	05OCT00	CON	Yes	•	MIL	NO	No	UNR	No
676.208.24926 ie	EOSINOPHILIA	RAISED EOSINOPHILS	^ Hemi Lymp Syst	phatic	•	-7 (-122)	04APR00	CON			MIL		No		No
	RHINITIS	RUNNY NOSE AND EYES (ALLERGIC RHINITIS)	^ Resp Syst	piratory tem		-4 (-119)	07APR00	13 days	Yes		MOD		Yes		No
676.209.24953 ie	INFECTION	INFLUENZA	^ Body Whol			-6 (-120)	19APR00	4 days	Yes		MIL		No		No
	HEADACHE	HEADACHE	+ Body Whol		0	42 (-72)	06JUN00	1 day	Yes	•	MIL	NO	No	UNR	No
	COUGH INCREASED	COUGHING	+ Resp	piratory tem	0	52 (-62)	16JUN00	13 days	Yes	•	MIL	NO	Yes	UNR	No
	RHINITIS	RHINITIS	+ Resp	piratory tem	0	52 (-62)	16JUN00	13 days	Yes	•	MIL	NO	Yes	UNR	No
	RHINITIS	RHINITIS	+ Resp	piratory tem	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 Whol		0	42 (-70)	11SEP00	11 days	Yes	•	MIL	NO	No	REL	Yes

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe, Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,

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]

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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	+ Cardiovascu lar 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	٠	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	٠	MIL	NO	Yes	UNR	No
	OTITIS MEDIA	OTITIS MEDIA (L) EAR.	+ Special Senses	0	62 (-51)	100CT00	6 days	Yes	•	MOD	NO	Yes	UNR	No

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

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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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. (mg) Med* Date tion Cont. F

No. Inv. Corr. Inv.

tion Cont. Epi. Int. Action Ther. Rel. SAE?

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med*

Conc. Epi. inc. Accion inel. Rel.

NO DATA PRESENT

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BRL-029060-676individual-data

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* 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

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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

Days Rel Dose To Start (Stop)

at

Onset Of Study Onset Dura-Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date

No. Inv.

tion Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

BRL-029060-676-individual-data

CONFIDENTIAL

* 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]

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.001.24004 ie ALLERGIC SEASONAL + Body as a 72 (-39) 260CT00 10 days Yes PBU . MIL NO Yes No REACTION ALLERGIES Whole SOMNOLENCE DROWSINESS + Nervous 38 (-73) 22SEP00 11 days No 10 MOD NO PSR No No AROUND 2 PM System RESPIRATORY UPPER + Respiratory 0 52 (-59) 060CT00 20 days Yes . MOD NO Yes UNR No DISORDER RESPIRATORY System ILLNESS 676.002.24030 ie ASTHENIA INCREASED + Body as a 25 (-91) 06MAR00 25 days Yes . MIL NO No PSR No TIREDNESS Whole DYSPEPSIA UPSET STOMACH Digestive 16FEB00 1 dav 6 (-110) Yes . MIL NO No PBU No System WEIGHT LOSS WEIGHT LOSS + Metabolic 97 (-19) 17MAY00 CON Yes . MOD NO No PBU No and Nutritional Disorders ^ Respiratory 676.002.24033 ie RESPIRATORY TOT -1 (-112) 02MAY00 2 days Yes . MTT. No Yes DISORDER System + Body as a ASTHENIA INCREASED 8 (-103) 11MAY00 17 days Yes . MIL NO PSR No No TIREDNESS Whole ASTHENIA INCREASED + Body as a 40 (-71) 12JUN00 3 days Yes . MIL NO No PBU No TIREDNESS Whole 676.002.24037 ie WEIGHT GAIN WEIGHT GAIN + Metabolic 35 (-76) 23NOV00 117 Yes . MIL NO No PBU No and days Nutritional Disorders DIZZINESS DIZZINESS 200CT00 2 days + Nervous 1 (-110) Yes . MIL NO No PSR No System EMOTIONAL INCREASED + Nervous 18 (-93) 06NOV00 7 days Yes . MIL NO No UNR No LABILITY MOODINESS System NERVOUSNESS INCREASED + Nervous 0 18 (-93) 06NOV00 7 days Yes . MIL NO No UNR No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe, ction Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = No

IRRITABILITY

System

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]

System

System

System

System

System

+ Body as a

Whole

+ Respiratory

+ Respiratory

+ Nervous

+ Nervous

INSOMNIA

INITIAL

URI

UPPER

INSOMNIA

INCREASED

IRRITABILITY

RESPIRATORY

INFECTION

HEADACHE

INSOMNIA

DISORDER

DISORDER

676.002.24044 ie RESPIRATORY

676.002.24046 ie HEADACHE

NERVOUSNESS

RESPIRATORY

CONFIDENTIAL

Listing 15.1.1

Dose

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

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

Days Rel To Start

52 (-66)

48 (-70)

6 (-106)

5 (-110)

30MAR01 13 days Yes

26MAR01 31 days Yes

27FEB01 10 days Yes

Yes

108 (-10) 25MAY01 3 days Yes

06JUN01 1 day

. MOD

. MOD

MIL NO

MOD NO

. MIL NO

NO

PBU

PBU

UNR

UNR

PBU

Yes

No

Yes

Yes

No

No

No

No

No

No

at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.002.24037 ie URINARY TRACT URINARY TRACT + Uroqenital 10 (-101) 290CT00 7 days Yes UNR . MOD NO Yes No INFECTION INFECTION System 676.002.24040 ie BACK PAIN NECK PAIN + Body as a 28APR01 8 days Yes UNR 81 (-37) MOD NO No No Whole BACK PAIN BACK PAIN + Body as a 81 (-37) 28APR01 54 days Yes . MOD NO Yes UNR No Whole BACK PAIN NECK PAIN + Body as a 111 (-7) 28MAY01 14 days Yes . MIL NO UNR No No Whole FLU SYNDROME FLU-LIKE + Body as a 1 (-117) 07FEB01 15 days Yes . SEV NO UNR No Yes SYMPTOMS Whole INFECTION YEAST + Body as a 11 (-107) 17FEB01 6 days Yes . MIL NO UNR No Yes INFECTION Whole PAIN ARM PAIN + Body as a 81 (-37) 28APR01 6 days Yes . MIL NO No UNR No Whole NECK AND BACK + Musculoskel 29APR01 6 days Yes ARTHROSIS 82 (-36) MOD NO Yes UNR No STIFFNESS etal System CHEST PAIN UNR MYALGIA + Musculoskel 0 81 (-37) 28APR01 4 days Yes . MIL NO No No MUSCULAR etal System INSOMNIA MIDDLE + Nervous 41 (-77) 19MAR01 38 days Yes . MOD NO PBU No 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,

0

0

Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped

HEADACHE

HEADACHE

CONFIDENTIAL

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

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

46 (-24)

29APR00 1 day

Yes

. MIL NO

Yes

PSR

No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe, Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,

0

+ Body as a

Whole

Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,

STP = Drug Stopped

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

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

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = No

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]

SWIMMING)

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

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

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Whole

SYMPTOMS

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

676.009.24228 ie TRAUMA

WHIPLASH

UNR

Nο

No

. MOD NO

CONFIDENTIAL

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

Days Rel

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

33 (-31)

06JUN00 6 days Yes

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

+ Body as a

Whole

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]

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.009.24230 i	RESPIRATORY	UPPER	+ Respiratory	0	45 (-72)	03FEB01	11 days	Yes		MOD	NO	Yes	UNR	No
	DISORDER	RESPIRATORY INFECTION	System .											
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	+ Musculoskel etal System	0	48 (-61)	24MAR01	7 days	Yes		MIL	NO	Yes	UNR	No
	ARTHRALGIA	LEFT HIP PAIN	+ Musculoskel etal 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	^ 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

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]

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

Days Rel

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

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Whole

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]

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study

Patient / Flag	Preferred Term	Verbatim Text	Body	System		Of Med	Study l*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.013.24342 ie	DECREASED APPETITE	DECREASED APPETITE	+ Diges Syste		0	13	(-110)	11MAY00	21 days	Yes		MIL	NO	No	PSR	No
	DIARRHEA	DIARRHEA	+ Diges	tive	0	11	(-112)	09MAY00	1 day	Yes		MIL	NO	No	UNR	No
	TOOTH DISORDER	IMPACTED WISDOM TEETH	+ Diges	tive	0	70	(-53)	07JUL00	1 day	Yes		MOD	NO	Yes	UNR	No
	SOMNOLENCE	DROWSINESS	+ Nervo	us	0	14	(-109)	12MAY00	15 days	Yes		MIL	NO	No	PSR	No
676.013.24346 ie	WEIGHT GAIN	WEIGHT GAIN	+ Metab and	olic tional	0	42	(-12)	04AUG00	CON	Yes	٠	MIL	NO	No	PSR	No
676.013.24349 ie	RESPIRATORY DISORDER	COMMON COLD SYMPTOMS	^ Respi	ratory	•	-8	(-50)	02NOV00	3 days	Yes	ė	MIL		No		No
	ASTHENIA	FATIGUE	+ Body Whole	as a	0	6 ((-36)	16NOV00	2 days	Yes		MOD	NO	No	UNR	No
	FEVER	ELEVATED TEMPERATURE	+ Body Whole		0	6 ((-36)	16NOV00	2 days	Yes	•	MOD	NO	No	UNR	No
	INFECTION	FLU SYMPTOMS	+ Body Whole		0	6 ((-36)	16NOV00	2 days	Yes		MOD	NO	No	UNR	No
	DYSPEPSIA	INCREASED SEVERITY OF HEARTBURN	+ Diges Syste		0	16	(-26)	26NOV00	1 day	Yes	•	MOD	NO	Yes	UNR	No
	NAUSEA	NAUSEA	+ Diges		0	6 ((-36)	16NOV00	2 days	Yes	•	MOD	NO	No	UNR	No
	NAUSEA	NAUSEA	+ Diges	tive	0	14	(-28)	24NOV00	2 days	Yes	•	MIL	NO	No	UNR	No
	NAUSEA	NAUSEA	+ Diges	tive	0	19	(-23)	29NOV00	1 day	Yes	•	MIL	NO	No	REL	No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe, Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,

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 15.1.1

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

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study
lag Preferred Term Verbatim Text Body System (mg) Med*

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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	٠	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

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]

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

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

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

System

ANGER

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]

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

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

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
ion Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = Nor

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]

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

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

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = N

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]

UNR

No

No

1 MOD NO

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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

Days Rel

To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.020.24535 ie RASH SPOTS ON FACE + Skin and 10 (-35) 11MAY00 CON Yes . MIL No No Appendages ALBUMINURIA PROTEIN IN + Urogenital 45 (0) 15JUN00 CON MIL NO UNR No No URINE System 676.020.24537 i POLYCYTHEMIA RED BLOOD + Hemic and 126 (0) 16MAR01 CON Yes . MIL NO No PBU No CELL COUNT Lymphatic OUT OF RANGE. System 676.021.24564 ie ALLERGIC ALLERGIES Body as a 0 (-113) 10AUG00 CON Yes . MIL Yes No REACTION Whole DRY MOUTH DRY MOUTH + Digestive 28 (-85) 07SEP00 103 MIL NO PSR No No System days DIZZINESS DIZZINESS + Nervous 21 (-92) 31AUG00 23 days No MIL NO No PSR No System INSOMNIA DECREASED + Nervous 05SEP00 82 days No PSR 26 (-87) MIL NO No No SLEEP System SOMNOLENCE LETHARGY + Nervous 04SEP00 CON PSR 25 (-88) . MIL NO Nο Yes No System RHINITIS NASAL + Respiratory 29 (-84) 08SEP00 CON PBU No Yes . MIL NO Yes CONGESTION System RHINITIS NASAL + Respiratory 78 (-35) 270CT00 2 days No 1 MIL NO Yes PBU No CONGESTION System SWEATING INCREASED + Skin and 17AUG00 CON 7 (-106) Yes MOD NO No PSR No SWEATING Appendages 676.022.17843 ie TRAUMA BACK STRAIN + Body as a 07SEP00 2 days Yes UNR 23 (-90) . MIL NO Yes No Whole UNR BRONCHITIS BRONCHIAL + Respiratory 41 (-72) 25SEP00 14 days No 1 MIL NO No No INFECTION System OTITIS MEDIA OTITIS MEDIA Special 41 (-72) 25SEP00 14 days Yes MIL NO Yes UNR No

30 (-96)

19APR01 1 day

Investigator Intensity [Inv Int]: Mil = Mild, Mod-Moderate, Sev-Severe,

Senses

Whole

Body as a

676.022.17862 ie ABDOMINAL PAIN STOMACH ACHE

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 15.1.1

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

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.022.17862 ie HEADACHE **HEADACHE** + Body as a 1 (-125) 21MAR01 1 day PSR Yes . MOD NO No No Whole **HEADACHE HEADACHE** + Body as a 29MAR01 1 day UNR 9 (-117) Yes . MIL NO No No Whole RESPIRATORY COMMON COLD + Respiratory 0 35 (-91) 24APR01 4 days No 1 MIL NO Yes UNR No DISORDER System RESPIRATORY COMMON COLD + Respiratory 44 (-82) 03MAY01 3 days No 1 MIL NO UNR No Yes DISORDER System + Skin and ACNE ACNE 126 (0) 24JUL01 CON Yes . MIL NO No UNR No Appendages 676.100.24702 i HEADACHE **HEADACHE** Body as a 0 (-99) 09AUG00 1 day Yes MOD NO UNR No Yes Whole HEADACHE HEADACHE Body as a 52 (-47) 30SEP00 1 day Yes MOD NO Yes UNR No Whole **HEADACHE HEADACHE** Body as a 78 (-21) 260CT00 1 day Yes MOD NO Yes UNR No Whole HEADACHE HEADACHE Body as a 79 (-20) 270CT00 2 days Yes MOD NO UNR No Yes Whole WEIGHT GAIN WEIGHT GAIN + Metabolic 6 (-93) 15AUG00 CON PBU Yes . MTT, NO No Nο and Nutritional Disorders INSOMNIA INSOMNIA + Nervous 55 (-44) 03OCT00 CON Yes . MIL NO UNR No No System RESPIRATORY COMMON COLD + Respiratory 7 (-92) 16AUG00 7 days Yes MOD NO Yes UNR No DISORDER System 676.100.24704 ie HEADACHE **HEADACHE** + Body as a 46 (-67) 18NOV00 8 days Yes MIL NO No UNR No Whole ARTHRALGIA JOINT PAIN 18NOV00 8 days UNR No + Musculoskel 0 46 (-67) Yes MIL NO No etal System 676.100.24706 ie HEADACHE HEADACHE + Body as a UNR 0 84 (-28) 16JAN01 1 day Yes . MOD NO Yes Nο

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Whole

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]

DIZZINESS

EMOTIONAL

LABILITY

DIZZINESS

BAD MOOD

+ Nervous

+ Nervous

System

System

CONFIDENTIAL

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

Dose

Days Rel

To Start at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.100.24706 ie HEADACHE HEADACHE + Body as a 109 (-3) 10FEB01 1 day UNR Yes . MOD NO Yes No Whole DIZZINESS DIZZINESS + Nervous 4 (-108) 280CT00 4 days UNR Yes . MIL NO No No System 676.100.24707 ie INFECTION INFLUENZA Body as a -2 (-114) 17DEC00 6 days Yes . MIL NO Yes UNR No Whole ASTHENIA INCREASED + Body as a 1 (-111) 20DEC00 56 days Yes . MIL NO PSR No No TIREDNESS Whole **HEADACHES** + Body as a Yes **HEADACHE** 1 (-111) 20DEC00 1 day . MIL NO PSR No No Whole **HEADACHE HEADACHE** + Body as a 13 (-99) 01JAN01 1 day Yes . MIL NO UNR No No Whole HEADACHE HEADACHE + Body as a 14 (-98) 02JAN01 1 day Yes . MIL NO No UNR No Whole **HEADACHE HEADACHE** + Body as a 03JAN01 1 day 15 (-97) Yes . MIL NO No PSR No Whole HEADACHE UNR **HEADACHE** + Body as a 109 (-3) 07APR01 1 day Yes . MIL NO No Yes Whole 09MAR01 4 days INFECTION FLU Body as a UNR 0 80 (-32) Yes . MTT, NO No Nο Whole TRAUMA RIB SPACE + Body as a 103 (-9) 01APR01 CON . MOD NO UNR No Yes No TENDERNESS (CAR Whole TILAGE TYPE) INCREASED INCREASED + Digestive 1 (-111) 20DEC00 56 days Yes PSR No . MIL NO No APPETITE HUNGER System MYALGIA 10 (-102) 29DEC00 47 days Yes MUSCLE CRAMPS + Musculoskel MIL NO No PSR No TO MID BACK etal System

1 (-111)

15 (-97)

20DEC00 56 days Yes

03JAN01 7 days No

MIL NO

10 MIL NO

No

No

PSR

PSR

No

No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe, Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,

0

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]

^{*} 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

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

Days Rel

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

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe, Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,

Appendages

BOTH ARMS

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]

S

S AND VOMITING

System

CONFIDENTIAL

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

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

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

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

0

108 (0)

108 (0)

Days Rel Dose To Start at (Stop) Patient / Flag Preferred Term Verbatim Text Body System (mg) Med*

EOSINOPHILS

Onset Of Study Onset Dura-No. Inv. Corr. Inv. Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

No

No

1 MIL NO

1 MIL NO

No

No

UNR

UNR

No

No

22SEP00 CON

22SEP00 CON

FUNCTION ABSOLUTE0.63 System TESTS ABNORMAL 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 EOSINOPHILIA EOSINOPHILS ABSOLUTE0.63

+ Hemic and Lymphatic System

+ Digestive

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

676.200.24736 ie LIVER

* 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,

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

STP = Drug Stopped

Serious AE as Judged by SB Criteria (Investigator) [SAE]

Tinking 15 1 1

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	: 	Body System			Study	Onset Date	Dura- tion	Cont.		Inv. Int.	Action	Corr. Ther.		SAE?
676.200.24736 ie	LEUKOPENIA	EOSINOPHILS ABSOLUTEO.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;BILIRUBIN 26 HIGHER THAN RANGE		Hemic and Lymphatic System	0	108	(0)	22SEP00	CON	No	1	MIL	NO	No	UNR	No
	BILIRUBINEMIA	EOSINOPHILS ABSOLUTEO.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

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]

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

Days Rel

Dose To Start at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.200.24736 ie BRONCHITIS + Respiratory 17 (-91) 23JUN00 9 days Yes UNR VIRAL 0 . MIL NO Yes No CORYZA/BRONCHI System TIS + Respiratory RHINITIS VIRAL 0 17 (-91) 23JUN00 9 days Yes . MIL NO UNR Yes Nο CORYZA/BRONCHI System TIS 676.200.24737 ie ABDOMINAL PAIN ABDOMINAL + Body as a 7 (-104) 01AUG00 CON . MIL NO PSR No Yes No DISCOMFORT Whole AFTER EATING RHINITIS ALLERGIC + Respiratory 92 (-19) 250CT00 CON . MIL NO PBU Yes Yes No RHINITIS System ACNE ACNE VULGARIS Skin and 88 (-23) 210CT00 CON Yes . MIL NO Yes PBU No Appendages 676.200.24744 ie HEADACHE **HEADACHES** + Body as a 30NOV00 37 days No MOD NO PSR 23 (-90) 5 Yes No Whole SOMNOLENCE DROWSINESS + Nervous 26NOV00 19 days No PSR 19 (-94) 10 MOD NO Nο No System + Digestive No 676.200.24746 ie NAUSEA NAUSEA 28FEB01 6 days Yes REL 1 (-111) . MIL NO No System DIZZINESS DIZZINESS + Nervous 1 (-111) 28FEB01 4 days 1 MIL NO No PSR No System SOMNOLENCE DROWSINESS + Nervous 28FEB01 6 davs 1 (-111) Yes MOD NO No PSR No System 676.200.24747 i RHINITIS VIRAL CORYZA + Respiratory 50 (-62) 09MAY01 2 days UNR Yes . MIL NO Yes No System 676.201.24761 ie INFECTION + Body as a INFLUENZA 7 (-64) 160CT00 4 days 1 MIL NO No UNR No Whole 676.203.24816 i HEADACHE HEADACHE Body as a -3(-62)29MAR00 2 days Yes MIL Yes No Whole **HEADACHE HEADACHE** + Body as a UNR 0 2 (-57) 03APR00 1 day Yes MOD NO Yes No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Whole

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]

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.203.24816 i HEADACHE **HEADACHE** + Body as a 7 (-52) 08APR00 1 day UNR Yes . MOD NO Yes No Whole **HEADACHE HEADACHE** Body as a 15 (-44) 16APR00 1 day UNR Yes . MIL NO Yes No Whole **HEADACHE** HEADACHE Body as a 22 (-37) 23APR00 1 day Yes . MIL NO Yes UNR No Whole HEADACHE HEADACHE Body as a 35 (-24) 06MAY00 1 day Yes . MIL NO UNR No Yes Whole HEADACHE Body as a HEADACHE 44 (-15) 15MAY00 1 day Yes . MIL NO UNR No Yes Whole **HEADACHE HEADACHE** Body as a 55 (-4) 26MAY00 1 day Yes . MIL NO UNR No Yes Whole INFECTION UJT + Body as a 30 (-29) 01MAY00 3 days Yes . MIL NO Yes UNR No Whole 676.203.24819 ie HEADACHE **HEADACHE** + Body as a 050CT00 2 days 69 (-35) Yes . MIL NO Yes UNR No Whole UNR INFECTION TLIT + Body as a 17 (-87) 14AUG00 9 days Yes . MIL NO No No Whole SINUSITIS SINUSITIS + Respiratory 0 25 (-79) 22AUG00 CON . MOD NO UNR Yes Yes Nο System 676.204.24842 ie COUGH NOCTURNAL + Respiratory 28JUN00 15 days Yes . MIL NO UNR No 21 (-21) No INCREASED COUGH System RESPIRATORY UPPER + Respiratory 5 (-37) 12JUN00 5 days Yes UNR No . MIL NO Yes DISORDER RESPIRATORY System TRACT INFECTION RHINITIS BLOCKED NOSE + Respiratory 21 (-21) 28JUN00 15 days Yes . MIL NO No UNR No System 676.204.24843 i INCREASED INCREASED + Digestive 01JUL00 47 days Yes 17 (-95) . MIL NO No PSR No APPETITE APPETITE System DIZZINESS DIZZINESS + Nervous 0 53 (-59) 06AUG00 1 day Yes . MIL NO No PBU Nο

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

System

Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,

STP = Drug Stopped tigator Relationship [Inv Rel]: PBU = Probab

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]

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

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

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Whole

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 15.1.1

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

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

Days Rel To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.204.24847 i INFECTION FLU + Body as a 83 (-28) 21NOV00 CON UNR Yes . MIL NO No No Whole TRAUMA INJURY TO + Body as a 104 (-7) 12DEC00 2 days Yes UNR MOD NO Yes No LEFT HAND Whole DIARRHEA DIARRHOEA + Digestive 52 (-59) 210CT00 1 day Yes . MIL NO Yes PBU No System NAUSEA NAUSEA + Digestive 36 (-75) 050CT00 6 days Yes . MIL DCR REL No No System ULCERATIVE + Digestive MOUTH ULCERS 25 (-86) 24SEP00 14 days Yes . MIL NO Yes UNR No STOMATITIS System EXTRAPYRAMIDAL EXTRAPYRAMIDAL + Nervous 36 (-75) 050CT00 7 days No 3 MOD DCR Yes REL No SYNDROME SIDE EFFECTS System (THICK TONGUE & OUIVERING JAW) INSOMNIA MIDDLE + Nervous 16 (-95) 15SEP00 48 days Yes PSR . MIL NO Nο Nο INSOMNIA System UPPER + Respiratory RESPIRATORY 240CT00 6 days Yes UNR No 55 (-56) . MIL NO Yes DISORDER RESPIRATORY System TRACT INFECTION YAWN YAWNING + Respiratory 050CT00 6 days REL 36 (-75) 3 MIL DCR No No System 676.204.24850 i ABDOMINAL PAIN PAINFUL Body as a No 0 (-51) 25JAN01 1 day Yes . MIL No ABDOMEN Whole PHARYNGITIS PAINFUL THROAT Respiratory 0 (-51) 25JAN01 1 day Yes MIL No No System NAUSEA NAUSEA Digestive 12 (-39) 06FEB01 1 day Yes MIL NO No PSR No System 676.205.24987 ie HEADACHE **HEADACHE** + Body as a PBU 0 3 (-109) 25FEB01 1 day 1 MIL NO Yes No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Whole

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 15.1.1

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

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

Days Rel

To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.205.24987 ie AGITATION AGITATION 14 (-98) 08MAR01 CON PBU + Nervous Yes . MOD NO No No System 676.206.24874 ie HEADACHE **HEADACHE** + Body as a 2 (-108) 10JUL00 5 days No 5 MIL NO PSR No No Whole COUGH COUGH + Respiratory 0 21 (-89) 29JUL00 14 days Yes . MOD NO Yes UNR No INCREASED System RESPIRATORY COLD (COMMON) + Respiratory 0 12 (-98) 20JUL00 6 days Yes . MOD NO UNR No Yes DISORDER System 676.206.24876 ie INFECTION + Body as a FLU 21 (-109) 15SEP00 12 days Yes . MOD NO Yes UNR No Whole 676.206.24880 ie INFECTION + Body as a 50 (-64) 10MAR01 6 days Yes MOD NO UNR No Yes Whole HYPOTENSION DIZZINESS-DUE + Cardiovascu 7 (-107) 26JAN01 CON Yes MIL NO No PBU No TO LOW BLOOD lar System PRESSURE 676.207.24897 ie RESPIRATORY COMMON COLD + Respiratory 23APR00 9 days Yes UNR 52 (-33) . MIL NO Nο No DISORDER System RHINITIS RHINITIS DUE + Respiratory 12 (-73) 14MAR00 13 days Yes . MOD NO UNR No Yes TO ALLERGY System 676.207.24902 ie DIZZINESS DIZZINESS + Nervous 1 (-111) 200CT00 6 days Yes . MIL NO No PSR No System 676.207.24904 ie ASTHENIA TIREDNESS + Body as a 11 (-101) 13FEB01 32 days Yes . MIL NO No PSR No Whole ASTHENIA TIREDNESS + Body as a 27APR01 37 days Yes PSR 84 (-28) . MOD NO No No Whole 08MAY01 2 days Yes BACK PAIN BACKACHE + Body as a 95 (-17) SEV NO Yes PBU No Whole DIARRHEA DIARRHOEA + Digestive 0 87 (-25) 30APR01 6 days Yes MOD NO Yes PBU No

90 (-22)

03MAY01 2 days Yes

MIL NO

Yes

PBU

No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,
Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = No

0

System + Respiratory

System

SORE THROAT

PHARYNGITIS

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]

HEADACHE

676.209.24963 ie ABDOMINAL PAIN ABDOMINAL

HEADACHE

HEADACHE

DISCOMFORT

HEADACHE

CONFIDENTIAL

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

Dose

Days Rel To Start

at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.207.24904 ie PHARYNGITIS SORE THROAT + Respiratory 100 (-12) 13MAY01 2 days Yes PBU 0 . MIL NO Yes No System 676.207.24910 ie ABDOMINAL PAIN ABDOMINAL PAIN + Body as a 20 (-92) 25APR01 1 day 1 MIL NO PBU No Yes Whole **HEADACHE HEADACHE** + Body as a 5 (-107) 10APR01 1 day No 1 MIL NO No PSR No Whole HEADACHE HEADACHE + Body as a 23 (-89) 28APR01 1 day No 1 MIL NO PSR No No Whole VASODILATATION HOT FLUSHES + Cardiovascu 0 28 (-84) 03MAY01 15 days Yes . MIL NO PSR No No lar System ANXIETY INCREASED + Nervous 77 (-35) 21JUN01 36 days Yes . MIL NO PSR No No ANXIETY System DIZZINESS DIZZINESS + Nervous 40 (-72) 15MAY01 1 day 1 MIL NO No PBU No System SOMNOLENCE DROWSINESS + Nervous 07APR01 2 days 2 (-110) Yes . MIL NO No PSR No System 676.209.24957 i RASH RIGHT Skin and RASH -6 (-117) 05MAY00 CON . MIL No Yes No ARM DUE TO Appendages MICROPORE INFECTION INFLUENZA + Body as a 4 (-107) 15MAY00 1 day Yes . MIL NO Yes UNR No Whole NAUSEA NAUSEA + Digestive 12MAY00 1 day 1 (-110) Yes . MIL NO No PSR No System 676.209.24962 ie ASTHENIA + Body as a 1 (-61) 110CT00 27 days Yes REL FATIGUE . MIL NO No No DURING DAYTIME Whole

0

32 (-30)

7 (-120)

31 (-96)

11NOV00 1 day

240CT00 1 day

17NOV00 1 day

Yes

No

Yes

MIL NO

MIL NO

1 MIL NO

Yes

No

Yes

UNR

UNR

UNR

No

No

No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

+ Body as a

+ Body as a

+ Body as a

Whole

Whole

Whole

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]

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study Onset
ent / Flag Preferred Term Verbatim Text Body System (mg) Med* Date

Patient / Flag	Preferred Term	Verbatim Text	 Body System	Onset (mg)	Of S Med*		Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.209.24963 ie	MYALGIA	MUSCLE PAIN IN RIGHT SHOULDER	Musculoskel etal System	0	28 ((-99)	14NOV00	2 days	Yes		MIL	NO	Yes	UNR	No
676.209.24965 ie	GASTROENTERITI S		Digestive System	0	14 ((-103)	01NOV00	2 days	Yes	•	MIL	NO	Yes	UNR	No
	GASTROENTERITI S	NAUSEA/VOMITIN G/DIARRHOEA.	Digestive System	0	69 ((-48)	26DEC00	5 days	Yes	•	MOD	NO	Yes	UNR	No
	COUGH INCREASED	COUGHING	Respiratory System	0	1 (-	-116)	190CT00	13 days	Yes	•	MIL	NO	Yes	UNR	No
	PHOTOPHOBIA	LIGHT SENSITIVITY	Special Senses	0	3 (-	-114)	210CT00	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	Cardiovascu lar 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	Cardiovascu lar System	0	3 (-	-95)	19MAY00	1 day	Yes	•	MOD	NO	Yes	PBU	No

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,

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

Days Rel

Dose To Start at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.300.25011 i SYNCOPE LIPOTHYMIA + Cardiovascu 15 (-83) 31MAY00 CON 1 MOD NO UNR 0 No No No lar System PHARYNGITIS RHINOPHARYNGIT + Respiratory 0 13 (-85) 29MAY00 8 days Yes . MOD NO UNR No Yes IS System 676.301.25037 ie ABDOMINAL PAIN STOMACHACHE + Body as a 45 (-68) 200CT00 20 days Yes . MIL NO No PSR No Whole HEADACHE HEADACHE + Body as a 41 (-72) 160CT00 24 days Yes . MIL NO PBU No Yes Whole RHINITIS RHINITIS + Respiratory 42 (-71) 170CT00 7 days Yes . MIL NO Yes PBU No Svstem 676.301.25040 i COUGH COUGH + Respiratory 11 (-93) 29APR01 8 days Yes . MIL NO No PBU No INCREASED System

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

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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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

360

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* 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

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study
(mg) Med*

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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

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

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.001.24008 ie	RESPIRATORY DISORDER	UPPER RESPIRATORY INFECTION (URI)	+ Respiratory System	٠	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		Yes	•		NO	Yes	UNR	No
676.007.24193 ie	HEADACHE	HEADACHE	+ Body as a Whole	40	138 (28)	170CT01	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)	280CT00	10 days	Yes	•	MIL	NO	No	PSR	No
	FLU SYNDROME	FLU LIKE SYMPTOMS	+ Body as a Whole	30	129 (10)	210CT00	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 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

Corr. Inv.

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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

Dura-

No. Inv.

Days Rel Dose To Start (Stop) at Onset Of Study Onset

Patient / Flag	Preferred Term	Verbatim Text	Body System	(mg)	Med*	Date	tion	Cont.	Epi.	Int.	Action	Ther.	Rel.	SAE?
							_							
676.013.24345 ie	HEADACHE	INTERMITTENT HEADACHES	+ Body as a Whole	30	124 (5)	160CT00	22 days	Yes	•	MOD	NO	Yes	PSR	No
	DIZZINESS	INTERMITTENT DIZZINESS	+ Nervous System	30	136 (17)	280CT00	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

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

Days Rel Dose To Start (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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)	100CT00	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

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

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^{*} 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,

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Listing 15.1.2

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

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- N Body System (mg) Med* Date tion Cont. E

No. Inv. Corr. Inv.

tion Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT .

Patient / Flag Preferred Term Verbatim Text

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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 15.1.2

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

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

Days Rel
Dose To Start
at (Stop)

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

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.

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

^{*} 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 Continuous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Agtion Taken On Study Medigation [Action] Description of No. 2 No.

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study Onset

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.		Inv. Int.	Action	Corr. Ther.		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	٠	140 (21)	03JAN01	CON	Yes		MOD	NO	No	PSR	No
	LACK OF EMOTION	SADNESS, IRRITABILITY, AND LACK OF MOTIVATION	+ Nervous System	٠	140 (21)	03JAN01	CON	Yes		MOD	NO	No	PSR	No
	NERVOUSNESS	SADNESS, IRRITABILITY, AND LACK OF MOTIVATION	+ Nervous System	٠	140 (21)	03JAN01	CON	Yes	٠	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)		13 days	Yes	•		NO	Yes	UNR	No
	ASTHENIA	INCREASED TIREDNESS	+ Body as a Whole	•	144 (31)	17JUL00	1	Yes	•	MOD		No	PSR	No
	HEADACHE	HEADACHE	+ Body as a Whole	•	144 (31)		-	Yes	•	MOD		Yes	PSR	No
	DIARRHEA	DIARRHEA	+ Digestive System	•	144 (31)	17JUL00	-	Yes	•	MIL		No	PBU	No
	NAUSEA	NAUSEA	+ Digestive System	•	144 (31)	17JUL00	-	Yes	•		NO	No	PSR	No
	MYALGIA	MUSCLE ACHES	+ Musculoskel etal System	•	144 (31)			Yes	•	MIL		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 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

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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
	LYMPHADENOPATH Y	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			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 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]

Corr. Inv.

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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

Days Rel

No. Inv.

Dose To Start at (Stop) Onset Of Study Onset Dura-Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

676.004.24085 i HYPERKINESIA	ATTENTION + Nervo		126 (14)	06JUN00 CON	Yes .	MOD	NO :	Yes	UNR	No
676.005.24122 ie ANXIETY	HYPERACTIVITY DISORDER. HOSPITALIZATIO + Nervo N DUE TO HIS Syste FEARS AND DEP		84 (14)	30NOV00 5 days	Yes .	MOD	NO :	Yes	UNR	Yes
DEPRESSION	DISEASE UNDER STUDY HOSPITALIZATIO + Nervo N DUE TO HIS Systo FEARS AND DEP DISEASE UNDER		84 (14)	30NOV00 5 days	Yes .	MOD	NO :	Yes	UNR	Yes
676.006.24143 ie RESPIRATORY DISORDER	STUDY UPPER + Resp. RESPIRATORY Syste	ratory 40 em	124 (11)	010CT00 5 days	Yes .	MOD	NO 3	Yes	UNR	No
HEADACHE	HEADACHE + Body Whole		141 (28)	180CT00 CON	No 5	MOD	NO 3	Yes	PSR	No
676.006.24145 ie DIZZINESS	DIZZINESS + Nervo	ous 30	119 (7)	20DEC00 14 days	Yes .	SEV	NO 3	Yes	REL	No
MYOCLONUS	MYOCLONIC + Nervo	ous 30	119 (7)	20DEC00 19 days	No 25	MOD	NO I	No	REL	No
DIZZINESS	DIZZINESS + Nervo	ous .	133 (21)	03JAN01 5 days	Yes .	MIL	NO I	No	REL	No
MYOCLONUS	MYOCLONIC + Nervo	ous .	138 (26)	08JAN01 2 days	No 5	MIL	NO I	No	REL	No
676.007.24172 ie ABDOMINAL PA	2	as a .	124 (9)	09APR00 8 days	No .	MOD	NO I	No	PSR	No
ASTHENIA	FATIGUE + Body Whole	as a .	125 (10)	10APR00 7 days	Yes .	MIL	NO 3	Yes	PSR	No
HEADACHE	HEADACHES + Body Whole	as a .	123 (8)	08APR00 4 days	No .	MOD	NO I	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]

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study Onset

Patient / Flag Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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		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		+ Body as a Whole	30	114 (2)	03JUN01	2 days	Yes	•	MIL	NO	Yes	UNR	No
DIZZINESS	LIGHTHEADEDNES S	+ 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)	010CT00	CON	Yes	•	MOD	NO	No	PSR	No
676.014.24376 i INSOMNIA	SLEEP DISTURBANCE	+ Nervous System	•	42 (8)	100CT00	CON	Yes	•	SEV	NO	No	PBU	No
676.015.24394 ie ANXIETY	SOCIAL ANXIETY		•	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 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 Flaq: i = Intention-To-Treat Population, e = Per-Protocol Population

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study Onset

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.015.24407 ie	TRAUMA	PAIN FROM	+ Body as a		152 (33)	18FEB01	1 day	Yes		MIL	NO	Yes	UNR	No
676.015.24414 i	ANXIETY	BROKEN ARM EXACERBATION OF SOCIAL	Whole + Nervous System	•	154 (37)	21AUG01	CON	Yes	•	MIL	NO	Yes	REL	No
	DIZZINESS	ANXIETY 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		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 1	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	+ Body as a Whole	•	56 (13)	11DEC00	1 day	Yes	•	MOD	NO	Yes	UNR	No
676.100.24710 ie		HEADACHE	+ Body as a Whole	40	130 (12)	25AUG01	1		•	MOD	NO	Yes	PSR	No
	NAUSEA	NAUSEA	+ Digestive System	40	130 (12)		29 days		•	MOD	NO	Yes	PSR	No
	DIZZINESS	DIZZINESS	+ Nervous System	40	130 (12)		29 days		•		NO	No	PSR	No
676.101.24623 ie		WRIST INJURY	Body as a Whole	•	167 (57)	14DEC00	-	Yes			NO	Yes	UNR	No
676.101.24629 i	DYSPEPSIA	UPSET STOMACH (ANXIETY)	Digestive System	•	183 (64)	26SEP01	1	No	1		NO	No	UNR	No
	ANXIETY	UPSET STOMACH (ANXIETY)	Nervous System	•	183 (64)	26SEP01	-	No	1		NO	No	UNR	No
676.103.24649 ie	RESPIRATORY DISORDER	COLD	+ Respiratory System	•	147 (30)	130CT00	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 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

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

Days Rel

To Start Dose at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE? 676.103.24654 i HEADACHE **HEADACHE** + Body as a 21JUL01 6 days No 6 MOD NO REL 120 (8) Yes No Whole DIZZINESS LIGHTHEADEDNES Nervous 120 (8) 21JUL01 6 days No REL MOD NO No No S System 676.202.24789 ie HEADACHE **HEADACHES** + Body as a 139 (8) 12JAN01 2 days Yes SEV NO No PSR No Whole 676.202.24798 ie ANXIETY TEARFULL AND + Nervous 129 (16) 18JUN01 12 days Yes . MIL NO PSR No Yes IRRITABLE DUE System TO SOCIAL ANXIETY DISORDER 676.202.24799 ie WITHDRAWAL NAUSEA WITH + Nervous 125 (10) 18JUN01 4 days Yes . MOD NO PSR No SYNDROME HEADACHE (System WITHDRAWAL SYMPTOMS) 676.203.24813 ie HEADACHE HEADACHE + Body as a REL 113 (3) 01JUL00 5 days Yes . MOD NΩ Nο Yes Whole + Digestive NAUSEA NAUSEA 113 (3) . MOD NO REL 01JUL00 5 days Yes Yes No System 676.204.24844 i ABNORMAL MYOPIA + Special 119 (14) 250CT00 CON Yes . MIL NO No UNR No VISION Senses NAUSEA NAUSEA + Digestive 09NOV00 3 days 134 (29) Yes . MIL NO No PSR No System DIZZINESS DIZZINESS + Nervous 09NOV00 3 days PSR 134 (29) Yes . MIL NO No No System 676.204.24845 ie ACNE FACIAL PIMPLES Skin and 168 (53) 15DEC00 CON Yes MIL NO No UNR No Appendages 676.204.24851 ie SOMNOLENCE AFTERNOON + Nervous 40 125 (13) 19JUN01 11 days Yes MIL NO No PSR No SLEEPINESS System RESPIRATORY UPPER + Respiratory UNR 137 (25) 01JUL01 CON Yes . MIL NO Yes No RESPIRATORY DISORDER System

TRACT INFECTION

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

^{*} 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,

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.		Inv. Int.	Action	Corr. Ther.		SAE?
676.205.24983 ie	e ASTHENIA	MOOD IRRITABLE, TIRED, TEARFUL DUE TO STOPPING	+ Body as a Whole		149 (28)	23NOV00	CON	Yes		MOD	NO	No	PSR	No
	EMOTIONAL LABILITY	TREATMENT. MOOD IRRITABLE, TIRED, TEARFUL DUE TO STOPPING	+ Nervous System		149 (28)	23NOV00	CON	Yes		MOD	NO	No	PSR	No
	NERVOUSNESS	TREATMENT. MOOD IRRITABLE, TIRED, TEARFUL DUE TO STOPPING TREATMENT.	+ Nervous System	٠	149 (28)	23NOV00	CON	Yes	٠	MOD	NO	No	PSR	No
676.205.24985 i	HYPOCHROMIC ANEMIA	IRON DEFICIENCY ANAEMIA-ADMITT ED FOR PARENTERAL IRON THERAPY	+ Hemic and Lymphatic System	٠	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	+ Digestive System	•	121 (11)	16JUL00	5 days	No	1	MIL	NO	No	PSR	No
676.206.24871 ie	HYPOTENSION	APPETITE DIZZINESS RELATED TO HYPOTENSION	+ Cardiovascu lar 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 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]

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text		Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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)	290CT00	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	+	Cardiovascu lar 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 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 Flaq: i = Intention-To-Treat Population, e = Per-Protocol Population

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study

Patient / Flag	Preferred Term	Verbatim Text	Body	y System	Onset (mg)	Of S *Med	tudy	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.300.25012 ie	ABDOMINAL PAIN	STOMACH CRAMPS	+ Body	as a	20	125	(9)	20SEP00	CON	Yes		MOD	NO	Yes	PSR	No
	NAUSEA	NAUSEA	+ Dige	estive	20	125	(9)	20SEP00	CON	Yes	•	MOD	NO	Yes	PSR	No
	VERTIGO	VERTIGO	+ Nerv	rous	20	125	(9)	20SEP00	CON	No		MOD	NO	No	PSR	No
676.301.25039 ie	DIZZINESS	DIZZINESS	+ Nerv	ous	30	143	(24)	23FEB01	16 days	Yes	•	MIL	NO	No	PSR	No
	EMOTIONAL LABILITY	TEARFUL	+ Nerv	rous	30	143	(24)	23FEB01	14 days	Yes	•	MIL	NO	No	PSR	No
	NERVOUSNESS	IRRITABLE	+ Nerv	ous	30	143	(24)	23FEB01	CON	Yes	•	MIL	NO	No	PSR	No
	ABDOMINAL PAIN	STOMACH ACHE	+ Body Who	as a	•	144	(25)	24FEB01	5 days	Yes	•	MIL	NO	Yes	PSR	No
676.301.25041 ie	SYNCOPE	WEAK (SLEPT A LOT) (LIPOTHYMIA)		liovascu System	•	142	(22)	120CT01	7 days	Yes	٠	MOD	NO	No	PBU	No

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 15.1.2

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

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

Days Rel Dose To Start at (Stop)

Onset Of Study Onset Dura-

No. Inv. Corr. Inv.

tion Cont. Epi. Int. Action Ther. Rel. SAE?

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med*

Date

NO DATA PRESENT

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

^{*} 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 Continuus, 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

Listing 15.1.2

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

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

Days Rel Dose To Start (Stop)

at

Onset Of Study Onset Dura-Body System (mg) Med* Date

No. Inv. Corr. Inv.

tion Cont. Epi. Int. Action Ther. Rel. SAE?

Patient / Flag Preferred Term Verbatim Text

NO DATA PRESENT

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

^{*} 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 Continuus, 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

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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 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]

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

Days Rel
Dose To Start
at (Stop)

Patient / Fl	.ag Preferred Term	n Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.205.2498	99 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
676.207.2489	9 ie PYURIA	LEUCOCYTES IN URINE (+)	+ Urogenital System	0	140 (29)	02NOV00	15 days	Yes		MIL	NO	No	UNR	No
	URINARY TRACT INFECTION	URINARY TRACT	+ Urogenital System	•	141 (30)	03NOV00	5 days	Yes		MIL	NO	Yes	UNR	No

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]

Listing 15.1.2

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

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

Days Rel Dose To Start at (Stop)

Onset Of Study Onset Date

No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text

Body System (mg) Med*

Dura-

tion Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

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

^{*} 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 Continuus, 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

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Listing 15.1.2

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

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

Days Rel Dose To Start at (Stop)

Onset Of Study Onset Dura-Body System (mg) Med* Date

No. Inv. Corr. Inv.

tion Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

Patient / Flag Preferred Term Verbatim Text

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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

Days Rel
Dose To Start
at (Stop)
Onset Of Study

Patient / Flag	Preferred Term	Verbatim Text		Body System	Onset (mg)	Of S Med*		Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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	+	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 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]

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

Days Rel
Dose To Start
at (Stop)
Onset Of Study

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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		+ 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 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]

REL

PSR

PSR

REL

UNR

UNR

PSR

UNR

PSR

UNR

UNR

UNR

UNR

PSR

PSR

Yes

No

Yes

Yes

Yes

No

No

No

. MOD

MIT NO

1 MIL NO

MOD

SEV NO

MOD NO

MIL NO

MOD NO

Yes

Yes

No

Yes

Yes

Yes

Yes

Yes

NO

676.100.24706 ie HEADACHE

676.101.24617 ie ASTHENIA

676.103.24650 ie INFECTION

676.202.24797 ie GINGIVITIS

676.203.24819 ie HEADACHE

676.103.24652 ie MYALGIA

RESPIRATORY

DISORDER

INSOMNIA

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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

Dose

Days Rel To Start

137 (25)

106 (7)

104 (5)

125 (8)

146 (26)

130 (18)

116 (12)

115 (11)

10MAR01 1 day

05SEP00 2 days

120CT00 8 days

25MAR01 6 days

21NOV00 4 days

30MAY01 CON

20NOV00 CON

07SEP00 CON

at (Stop) Onset Of Study Onset Dura-No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. 676.015.24408 ie ANXIETY SOCIAL 10JAN01 CON + Nervous 96 (30) Yes MOD NO Yes ANXIETY System WORSENING 676.015.24412 i DRY MOUTH DRY MOUTH + Digestive 96 (33) 04JUN01 5 days Yes . MIL NO No System NAUSEA NAUSEA + Digestive 96 (33) 04JUN01 5 days Yes . MIL NO No System 676.015.24413 ie ANXIETY EXACERBATION + Nervous 140 (23) 25JUL01 CON Yes . MIL NO Yes OF SOCIAL System ANXIETY 676.017.24451 ie RESPIRATORY URI + Respiratory 155 (36) 30AUG00 1 day Yes . MIL NO Yes DISORDER System 676.019.24516 i PHARYNGITIS ENLARGED + Respiratory 37 (14) 06DEC00 CON Yes MIL NO No TONSILS System 676.021.24562 i AGITATION INCREASED + Nervous 9 (7) 16FEB00 7 days No 1 MOD STP No

0

0

0

System

Whole

Whole

System

Whole

+ Body as a

+ Body as a

+ Body as a

+ Respiratory

Musculoskel

etal System

Digestive

Body as a

System

Whole

+ Nervous

System

AGITATION

HEADACHE

FATIGUED

HEAD COLD

HEADACHE

INSOMNIA

STREP THROAT

SORE FOREARMS

DENTAL ABSCESS

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

^{*} 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,

676.209.24967 i HEADACHE

HEADACHE

UNR

No

Yes

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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

Days Rel

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

111 (21) 12JUN01 1 day

Yes

. MIL NO

Body as a

Whole

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]

^{*} 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 Continuous, if No then No. Epi = Number Of Episodes,

Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System	at Onset (mg)	(Stop Of St Med*		Onset Date	Dura- tion	Cont.		Inv. Int.	Action	Corr. Ther.		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	٠	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

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 15.1.2

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

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

Days Rel Dose To Start at (Stop)

Onset Of Study Onset

Dura-No. Inv. Corr. Inv.

tion Cont. Epi. Int. Action Ther. Rel. SAE?

Patient / Flag Preferred Term Verbatim Text

Body System (mg) Med*

Date

NO DATA PRESENT

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

^{*} 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 Continuus, 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,

Listing 15.1.2

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

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

Days Rel
Dose To Start
at (Stop)

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

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

1

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel.

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* 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 Continuing,

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

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. 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 Continuing,

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

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. 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 Continuing,

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

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel.

* 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 Continuing,

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

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. 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 Continuing,

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

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. 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 Continuing,

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

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

	Days Rel
Dose	To Start
at	(Stop)

Patient / Flag Preferred Te	erm Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.		Inv. Int.	Action	Corr. Ther.	
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	٠	-4 (-116)	07MAR00	37 days	Yes	٠	MOD		Yes	

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

^{*} 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 Continuing,

if No then No. Epi = Number Of Episodes,

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel.

* 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 Continuing,

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

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. 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 Continuing,

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

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Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel.

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^{*} 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 Continuing,

if No then No. Epi = Number Of Episodes,

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Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel.

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* 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 Continuing,

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

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. 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 Continuing,

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

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel.

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

^{*} 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 Continuing,

if No then No. Epi = Number Of Episodes,

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel.

NO DATA PRESENT . . .

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

^{*} 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 Continuing,

if No then No. Epi = Number Of Episodes,

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel.

* 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 Continuing,

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

Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. 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 Continuing,

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

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Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel.

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* 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 Continuing,

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

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Listing 15.1.3.1

Serious Adverse Experiences (Pre Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv. Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel.

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* 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 Continuing,

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

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura-Body System (mg) Med* Date tion No. Inv. Corr. Inv.

Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT . . .

Patient / Flag Preferred Term Verbatim Text

Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped

^{*} 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 Continuous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

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

Days Rel Dose To Start at (Stop)

Onset Of Study Onset

No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med*

Date

Dura-

tion Cont. Epi. Int. Action Ther. 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 Continuus, 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

Body System (mg) Med*

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Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

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

Days Rel Dose To Start at (Stop)

Onset Of Study Onset Dura-Date

tion

No. Inv. Corr. Inv.

Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

Patient / Flag Preferred Term Verbatim Text

* 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 Continuus, 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

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Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

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

Days Rel Dose To Start at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System			Onset Date	Dura- tion	Cont.			Action	Corr. Ther.		SAE?
676.205.24985 i	ANEMIA	ANAEMIA	+ Hemic and Lymphatic System	20	25 (-1)	04MAR01	3 days	No	2	SEV	STP	Yes	UNR	Yes

Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped

^{*} 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 Continuous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

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

Days Rel Dose To Start at (Stop)

Onset Of Study Onset Dura-No. Inv. Corr. Inv. Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

. MIL NO

No

REL

Yes

0 42 (-70) 11SEP00 11 days Yes

676.209.24958 i ABNORMAL UNINTENTIONAL + Body as a LABORATORY OVERDOSE OF Whole

> VALUE STUDY

MEDICATION

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

Patient / Flag

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Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

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

Days Rel Dose To Start at (Stop)

Onset Of Study Onset Dura-Date tion No. Inv. Corr. Inv.

Cont. Epi. Int. Action Ther. Rel. SAE?

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med*

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 Continuus, 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,

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Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT . . .

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

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

Days Rel Dose To Start at (Stop)

Onset Of Study Onset

Dura-Date

No. Inv. Corr. Inv.

tion Cont. Epi. Int. Action Ther. Rel. SAE?

Patient / Flag Preferred Term Verbatim Text

Body System (mg) Med*

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 Continuus, 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

Listing 15.1.3.2

Serious Adverse Experiences (Treatment Phase)

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. 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 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

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped

^{*} 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 Continuous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

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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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

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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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body Syst		4	Onset Date	Dura- tion	Cont.	No. Epi.		Action	Corr. Ther.		SAE?
676.005.24122 ie	ANXIETY	HOSPITALIZATIO 4 N DUE TO HIS FEARS AND DEP DISEASE UNDER	Nervous System		84 (14)	30NOV00	5 days	Yes		MOD	NO	Yes	UNR	Yes
	DEPRESSION	STUDY HOSPITALIZATIO N DUE TO HIS FEARS AND DEP DISEASE UNDER	- Nervous System		84 (14)	30NOV00	5 days	Yes		MOD	NO	Yes	UNR	Yes
676.015.24407 ie	TRAUMA	STUDY FRACTURED ARM +	- Body as a Whole	30	139 (20)	05FEB01	CON	Yes		SEV	NO	Yes	UNR	Yes

Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped

^{*} 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 Continuous, if No then No. Epi = Number Of Episodes,
Investigator Intensity [Inv Int]: Mil = Mild, Mod=Moderate, Sev=Severe,

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

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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

Days Rel Dose To Start at (Stop)

Onset Of Study Onset Dura-Body System (mg) Med* Date tion

No. Inv. Corr. Inv.

Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

Patient / Flag Preferred Term Verbatim Text

^{*} 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 Continuus, 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

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

Days Rel Dose To Start (Stop)

at

Onset Of Study Onset Dura-Body System (mg) Med* Date tion

No. Inv. Corr. Inv. Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

Patient / Flag Preferred Term Verbatim Text

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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

Days Rel Dose To Start at (Stop)

Onset Of Study Onset Dura-Body System (mg) Med* Date tion

No. Inv. Corr. Inv.

Cont. Epi. Int. Action Ther. Rel. SAE?

Patient / Flag Preferred Term Verbatim Text

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 Continuus, 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

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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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

Corr. Inv.

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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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv.

Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

Patient / Flag Preferred Term Verbatim Text

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

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura-

Date

tion

No. Inv. Corr. Inv.

Cont. Epi. Int. Action Ther. Rel. SAE?

Body System (mg) Med*

Patient / Flag Preferred Term Verbatim Text

NO DATA PRESENT

Action Taken On Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None,

STP = Drug Stopped

Converting Theorem [Conv. Theor.] Investigation [Conv. Theor.] Theorem [Conv. Theor.] Investigation [Conv. Theor.] Investigation

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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 Continuing,

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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

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

^{*} 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 Continuing,

if No then No. Epi = Number Of Episodes,

3

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

Body System (mg) Med*

Days Rel Dose To Start at (Stop)

Onset Of Study Onset

Dura-Date

No. Inv. Corr. Inv.

tion Cont. Epi. Int. Action Ther. Rel. SAE?

Patient / Flag Preferred Term Verbatim Text

NO DATA PRESENT

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^{*} 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,

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

Days Rel
Dose To Start
at (Stop)

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

* 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 Continuing,

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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		+ 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	+ Musculoskel etal 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	٠	42 (8)	100CT00	CON	Yes		SEV	NO	No	PBU	No
676.015.24406 i	VOMITING	NAUSEA/VOMITIN	4	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

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

^{*} 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 Continuing,

if No then No. Epi = Number Of Episodes,

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body Syster		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		SAE?
676.022.17841 ie	INSOMNIA	RESTLESS SLEEP (DECREASE SLEEP TO 5	+ Nervous System	30	26 (-7)	19JUN00	6 days	Yes		MOD	DCR	No	PSR	No
	MANIC REACTION	HOURS/NIGHT) BEHAVIORAL ACTIVATION/HYP OMANIA	+ 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)	210CT00	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 Continuing,

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 IRON THERAPY

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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

Days Rel

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

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

^{*} 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 Continuing,

if No then No. Epi = Number Of Episodes,

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

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* 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 Continuing,

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

Days Rel
Dose To Start
at (Stop)

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

439

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* 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 Continuing,

if No then No. Epi = Number Of Episodes,

IT 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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Term	Verbatim Text	Body System		Of Study Med*	Onset Date	Dura- tion	Cont.	No. Epi.	Inv. Int.	Action	Corr. Ther.		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		•	-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)	100CT00	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		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 Continuing,

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, Male Specific Adverse Experiences

Body System (mg) Med*

Days Rel Dose To Start at (Stop)

Onset Of Study Onset Dura-

Date

No. Inv.

tion Cont. Epi. Int. Action Ther. Rel. SAE?

Patient / Flag Preferred Term Verbatim Text

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

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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

Days Rel Dose To Start at (Stop)

Onset Of Study Onset Dura-

No. Inv.

tion Cont. Epi. Int. Action Ther. Rel. SAE?

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date

NO DATA PRESENT

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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

^{*} 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,

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

Days Rel
Dose To Start
at (Stop)

Patient / Flag	Preferred Terr	m Verbatim Text	Body System	Of Study Med*	Onset Date	Dura- tion		No. Epi.		Action	Corr. Ther.		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 Continuing,

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: Adolescents, Male Specific Adverse Experiences

Days Rel Dose To Start at (Stop)

Onset Of Study Onset Dura-

No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text

Body System (mg) Med*

Date

tion Cont. Epi. Int. Action Ther. Rel. SAE?

NO DATA PRESENT

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

^{*} 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,

-5

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

Days Rel
Dose To Start
at (Stop)

at (Stop)
Onset Of Study O

Onset Of Study Onset Dura- No. Inv. Corr. Inv.

Patient / Flag Preferred Term Verbatim Text Body System (mg) Med* Date tion Cont. Epi. Int. Action Ther. Rel. SAE?

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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

^{*} 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 Continuing,

if No then No. Epi = Number Of Episodes,

Listing 15.1.5

Summary of Deaths

NO DATA AVAILABLE FOR THIS REPORT

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Listing 15.4.1

Medical Procedures

Treatment Group: No Therapy Dispensed Age Group: Children

Patient/Flag Procedure text Indication Procedure Start Date End Date

NO MEDICAL PROCEDURES FOR THIS TREATMENT AND AGE GROUP

CONFIDENTIAL

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Medical Procedures

Treatment Group: No Therapy Dispensed Age Group: Adolescents

Patient/Flag Procedure text Indication Procedure End Date

NO MEDICAL PROCEDURES FOR THIS TREATMENT AND AGE GROUP

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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

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Listing 15.4.1

Medical Procedures

Treatment Group: Paroxetine Age Group: Adolescents

			Procedure	Procedure
Patient/Flag	Procedure text	Indication	Start Date	End Date
676.004.24085 i	RIGHT HAND X-RAY BRACES TIGHTENED {ORTHODONTIA}	BROKEN RIGHT THUMB	02MAY2000	02MAY2000
	BRACES TIGHTENED {ORTHODONTIA}	ROUTINE	23FEB2000	23FEB2000
		ROUTINE	08MAR2000	08MAR2000
		ROUTINE	22MAR2000	22MAR2000
	DERMATOLOGICAL EXAMINATION	FACIAL ANCE ROUTINE	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
	INSERTION OF DENTAL SEPARATORS 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	IMPACTED WISDOM TEETH	20JUN2000	20JUN2000
	ANAESTHETIC.			
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
	THE THE PROPERTY OF THE OTHER		03111112001	03111112001
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 TO RECTIFY TEETH APPLY ELASTIC BANDS FOR BRACES	26JUN2001 19JUN2001	26JUN2001 19JUN2001
676.301.25039 ie	CLINICAL EXAMINATION BY GENERAL PRACTITIONER	BRONCHITIS	27NOV2000	27NOV2000
	PHYSICAL EXAMINATION BY GENERAL PRACTITIONER	MYCOSIS (HAND/FEET) COLD	14NOV2000 01OCT2000	14NOV2000 01OCT2000
		SORE THROAT STOMACHACHE	22JAN2001 24FEB2001	22JAN2001 24FEB2001

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 X-RAY LEFT ARM	FRACTURE L ARM FRACTURE L ARM	20JUL2000 20JUL2000	20JUL2000 20JUL2000
676.017.24456 ie	X-RAY OF RIGHT ELBOW	PAIN ON EXTENSION	29MAY2001	29MAY2001
676.023.17878 i	AUDIOLOGY EXAMINATION FOOT X-RAY	TALKING LOUD FOOT PAIN	110CT2000 30AUG2000	110CT2000 30AUG2000
676.100.24709 ie	CHEST EXAM BY FAMILY DOCTOR	COMMON COLD	08JUN2001	08JUN2001
676.207.24899 ie	DENTAL EXTRACTION	DENTAL CARIES	01AUG2000	01AUG2000

Listing 15.4.1

Medical Procedures

Age Group: Adolescents Treatment Group: Placebo

Patient/Flag	Procedure text	Indication	Procedure Start Date	Procedure End Date
676.002.24040 ie	BACK X-RAY NECK X-RAY PHYSICAL THERAPY	BACK PAIN NECK PAIN BACK AND NECK PAIN	04MAY2001 01MAY2001 31MAY2001	04MAY2001 01MAY2001 02JUN2001
676.003.24074 ie	EYE EXAM	BLURRED VISION	13JUN2001	13JUN2001
676.004.24087 ie	ORTHODONTIA BRACES TIGHTENED ORTHODONTIC BRACES TIGHTENED	ROUTINE ROUTINE	08APR2000 02JUN2000	08APR2000 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 PHYSIOTHERAPY	PVCS STRAINED ELBOW	24MAY2000 15MAY2000	24MAY2000 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