

Appendix D: Patient Data Listings of Adverse Experiences

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PAROXETINE - PROTOCOL 329

Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int ion	Act- Rel	Inv Corr Ther	SAE
Abdominal Pain	"STOMACH ACHE"	329.005.00119	23OCT95	105, 46, -36	5 Days	40	5	MOD NO	PBU No	No	
	ABDOMINAL PAIN(PRESENT PREVIOUSLY)	329.010.00278	22MAR96	43, -14, -197	5 Days	40	CON	SEV NO	PBU Yes	No	
	CRAMPS (ABDOMINAL)	329.007.00294	07APR97	39, ., -3	02:00 Hrs	30	CON	MOD NO	UNR Yes	No	
	DISCOMFORT ACROSS ALL OF ABDOMEN	329.012.00025	06NOV95	14, ., -59	02:00 Hrs	20	1	MOD NO	PBU No	No	
	STOMACH ACHE	329.001.00063	09NOV94 30NOV94	2, ., -46 23, ., -25	8 Days Not Stated	20 20	5 CON	MIL NO MIL NO	PSR No PSR No	No No	
		329.005.00008	10DEC94	25, -31, -117	3 Days	20	CON	MOD NO	UNR No	No	
		329.005.00119	20JUL95	10, -50, -131	4 Days	20	2	MIL NO	PBU No	No	
		329.005.00258	21MAR96 05APR96	10, ., -47 25, ., -32	02:00 Hrs 4 Days	20 20	1 4	MOD NO MOD NO	PBU No PBU No	No No	
		329.005.00299	31JUL96	54, -7, -110	3 Days	20	2	MOD NO	PSR Yes	No	
		329.007.00309	27OCT96	105, 53, -150	3 Days	20	CON	MIL NO	UNR No	No	
		329.009.00130	13SEP95	149, 93, -33	Not Stated	20		MIL NO	PBU Yes	No	
	STOMACH ACHES	329.002.00102	05SEP95	146, 92, -106	36 Days	40	1	MOD NO	REL No	No	
		329.002.00106	03AUG95	8, ., -40	10 Mins	20	10	MIL NO	REL No	No	
	STOMACH ACHES INTERMITTENT AM AND LUNCH	329.004.00015	08DEC94	1, -57, -202	12 Days	20	6	MIL NO	REL No	No	

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Abdominal Pain	STOMACH PAIN	329.002.00319	09JUL96	71, 15, -174	16:00 Hrs	30	1	MIL NO	UNR No	No
		329.004.00017	11NOV95	235, 179, -3	Not Stated	20	CON	MIL NO	UNR No	No
Allergic Reaction	ALLERGIES	329.003.00250	29APR96	47, -11, -28	24:00 Hrs	40		MIL NO	UNR Yes	No
	CONGESTION-NASAL DUE TO ALLERGIES	329.004.00015	09JUN95	184, 127, -19	Not Stated	20	CON	MOD NO	UNR No	No
	ITCHY EYES-DUE TO ALLERGIES	329.004.00015	09JUN95	184, 127, -19	Not Stated	20	CON	MOD NO	UNR No	No
Asthenia	SEASONAL ALLERGIES	329.009.00303	29APR96	28, -29, -237	1 Days	20	CON	MIL NO	UNR No	No
	DECREASED ENERGY/TIRED	329.008.00271	07MAY96	58, -7, -197	Not Stated	40	CON	MIL NO	PSR No	No
	EXTREME SLEEPINESS/FATIGUE	329.005.00008	29DEC94	44, -12, -98	11 Days	40	CON	SEV DCR	REL No	No
	FATIGUE	329.002.00319	01MAY96	2, -55, -243	202 Days	20	CON	MIL NO	REL No	No
		329.004.00015	08DEC94 22DEC94	1, -57, -202 15, -43, -188	15 Days 11 Days	20 20	CON CON	MIL NO MOD NO	REL No REL No	No No
	329.005.00119	11JUL95	1, -59, -140	4 Days	20	CON	MOD NO	PSR No	No	
	329.009.00170	27JUN96	234, 177, -11	11 Days	20	CON	MOD NO	PSR No	Yes	
	329.009.00173	01JAN96	43, -21, -57	Not Stated	30	CON	MOD NO	PSR No	No	
329.012.00025	16NOV95	24, ., -49	Not Stated	20	CON	MOD NO	REL No	No		
FATIGUE NEW	329.004.00015	02FEB95	57, -1, -146	43 Days	20	CON	MOD NO	PBU No	No	

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Intent-to-Treat Population

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Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Asthenia	FATIGUE WITH DIZZINESS AND DROWSINESS [FATIGUE WITH DROWSINESS]	329.005.00011	28JAN95	47, -10, -109	Not Stated	40	CON	MIL NO	PSR No	No
	TIRED	329.003.00075	14JUN95	141, 85, -99	2 Days	20		MIL NO	UNR No	No
		329.003.00089	10MAR95	4, ., -56	Not Stated	20	CON	MIL NO	PSR No	No
	TIREDNESS INCREASED FATIGUE	329.005.00011	19DEC94	7, -50, -149	10 Days	20	4	MIL NO	PSR No	No
	VERY TIRED	329.006.00039	22MAR95	43, -19, -49	7 Days	20	CON	SEV NO	PSR No	No
Back Pain	BACK PAIN	329.005.00151	06SEP95 19OCT95	1, -57, -238 44, -14, -195	1 Days 02:00 Hrs	20 20	1 1	MOD NO MIL NO	UNR Yes UNR Yes	No No
	BACKACHE	329.005.00336	28MAR97 20APR97	25, ., -33 48, ., -10	2 Days 4 Days	20 20	CON CON	MIL NO MIL NO	UNR No UNR Yes	No No
		329.007.00294	21MAR97	22, ., -20	3 Days	20	CON	MOD NO	UNR Yes	No
	NECK PAIN	329.007.00268	26MAY96	56, -4, -206	5 Days	30	CON	MOD NO	UNR Yes	No
Chest Pain	CHEST PAIN	329.002.00319	09JUL96	71, 15, -174	16:00 Hrs	30	1	MIL NO	UNR No	No
		329.005.00002	19JUN94	26, -31, -121	06:30 Hrs	20	CON	MOD NO	PSR No	No
	CHEST PAIN-APPROXIMATELY 3 OCCASIONS-INTENSE JAB THEN REMITS	329.006.00038	27MAR95	41, ., -16	3 Days	20	3	SEV NO	PSR No	No
Chills	SHIVERING AND SHAKING	329.004.00017	28MAR95	7, -50, -231	12 Days	20	CON	MIL NO	PSR No	No

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Fever	FEVER	329.004.00017	29AUG95	161, 105, -77	18:00 Hrs	30		MOD	NO	UNR Yes	No
		329.005.00112	24JAN95	-2, -57, -94	3 Days	0	CON	MOD	NO	UNR Yes	No
		329.007.00309	04DEC96	143, 91, -112	3 Days	20	CON	MIL	NO	UNR Yes	No
Headache	HEADACHE	329.001.00206	10MAR96	19, ., -39	2 Days	20	CON	MIL	NO	PBU No	No
		329.002.00099	03APR95	33, -23, -222	02:00 Hrs	20	CON	MIL	NO	PSR Yes	No
		329.002.00319	18NOV96	203, 147, -42	04:00 Hrs	30	1	MOD	NO	PBU Yes	No
		329.003.00089	14MAR95	8, ., -52	8 Days	20	CON	MIL	NO	PSR Yes	No
		17APR95	42, ., -18	24:00 Hrs	20		MOD	NO	UNR Yes	No	
		329.003.00091	25MAR95	2, -53, -243	15 Mins	20		MIL	NO	PBU No	No
		329.004.00015	20DEC94	13, -45, -190	03:00 Hrs	20	1	MOD	NO	PBU Yes	No
		10JAN95	34, -24, -169	01:00 Hrs	20	1	SEV	NO	PBU Yes	No	
		17JAN95	41, -17, -162	02:00 Hrs	20	1	MOD	NO	PBU Yes	No	
		14FEB95	69, 12, -134	01:00 Hrs	20	1	MOD	NO	PBU Yes	No	
		24FEB95	79, 22, -124	01:00 Hrs	20	1	MOD	NO	PBU Yes	No	
		05JUN95	180, 123, -23	2 Days	20	CON	MOD	NO	UNR No	No	
		329.004.00019	06JUN95	7, ., -8	09:00 Hrs	20	1	MOD	NO	PSR Yes	No
329.004.00214	08NOV96	36, -25, -52	2 Days	30	CON	MIL	DCR	REL Yes	No		
15NOV96	43, -18, -45	1 Days	30	CON	MOD	DCR	PSR Yes	No			
329.005.00002	20MAY94	-5, -61, -151	03:30 Hrs	0	CON	MOD	NO	PSR Yes	No		
17JUL94	54, -3, -93	4 Days	40	3	MOD	NO	PSR Yes	No			
329.005.00004	24OCT94	15, -45, -88	02:30 Hrs	20	CON	MIL	NO	PBU No	No		

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Headache	HEADACHE	329.005.00004	29DEC94	81, 22, -22	2 Days	40	CON	MOD	NO	PBU No	No
		329.005.00008	10DEC94	25, -31, -117	3 Days	20	CON	MOD	NO	UNR No	No
		329.005.00109	20MAR95	81, 28, -57	3 Days	20	4	MOD	NO	UNR Yes	No
		329.005.00112	24JAN95	-2, -57, -94	3 Days	0	CON	MOD	NO	UNR Yes	No
		329.005.00116	12APR95	65, 7, -90	1 Days	20	3	MOD	NO	PBU Yes	No
		329.005.00119	17JUL95 20AUG95	7, -53, -134 41, -19, -100	02:00 Hrs 01:00 Hrs	20 40	2	MOD	NO	PSR Yes PBU No	No No
		329.005.00152	30OCT95	5, ., 0	24:00 Hrs	20	CON	SEV	STP	REL No	No
		329.005.00257	14AUG96	157, 101, -82	8 Days	30	2	MIL	NO	PBU Yes	No
		329.005.00258	21MAR96 05APR96	10, ., -47 25, ., -32	4 Days 4 Days	20 20	2 3	MOD	NO	PBU No PBU No	No No
		329.005.00299	31JUL96 03SEP96 23OCT96 19NOV96	54, -7, -110 88, 28, -76 138, 78, -26 165, 105, 1	5 Days 03:00 Hrs 02:00 Hrs 04:00 Hrs	20 20 30 20	2 4 1 1	MOD	NO	PSR Yes PBU No PBU Yes PBU No	No No No No
		329.005.00300	12NOV96	55, ., -2	02:00 Hrs	20	CON	MOD	NO	UNR No	No
		329.005.00333	24JAN97 26JAN97 13FEB97 24FEB97	2, ., -31 4, ., -29 22, ., -11 33, ., 0	03:20 Hrs 02:30 Hrs 8 Days 03:00 Hrs	20 20 20 20	CON CON 7 CON	MIL	NO	UNR Yes UNR No PSR Yes PBU Yes	No No No No
		329.006.00038	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR No	No

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

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Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther	SAE	
Headache	HEADACHE	329.006.00260	23JUL96	6, -53, -148	45 Mins	20	1	MIL	NO	UNR	Yes	No	
			24JUL96	7, -52, -147	01:00 Hrs	20	1	MOD	NO	UNR	Yes	No	
			27JUL96	10, -49, -144	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No	
			28JUL96	11, -48, -143	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No	
			29JUL96	12, -47, -142	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No	
			30JUL96	13, -46, -141	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No	
			11AUG96	25, -34, -129	45 Mins	20	1	MIL	NO	PBU	Yes	No	
			20AUG96	34, -25, -120	30 Mins	30	1	MIL	NO	PBU	Yes	No	
			26AUG96	40, -19, -114	40 Mins	30	1	MOD	NO	PBU	Yes	No	
			02SEP96	47, -12, -107	30 Mins	30	1	MIL	NO	PBU	Yes	No	
			06SEP96	51, -8, -103	45 Mins	30	1	MOD	NO	PBU	Yes	No	
			08SEP96	53, -6, -101	45 Mins	30	1	SEV	NO	PBU	Yes	No	
			11SEP96	56, -3, -98	30 Mins	30	1	MOD	NO	PBU	Yes	No	
			16SEP96	61, 3, -93	02:00 Hrs	30	1	SEV	NO	PBU	Yes	No	
			08OCT96	83, 25, -71	01:00 Hrs	30	1	MIL	NO	PBU	Yes	No	
			05NOV96	111, 53, -43	01:00 Hrs	30	1	MIL	NO	PBU	No	No	
			329.006.00261	22JAN97	58, -1, -97	01:00 Hrs	30	1	MOD	NO	PBU	Yes	No
			329.007.00145	30APR96	111, 55, -115	16 Days	40	CON	SEV	DCR	PSR	Yes	No
			329.007.00268	26MAY96	56, -4, -206	5 Days	30	CON	MOD	NO	UNR	Yes	No
329.007.00310	17DEC96 14MAR97	83, 23, -188 170, 110, -101	3 Days 10 Days	20 20	CON CON	SEV MOD	NO NO	PBU PBU	No Yes	No No			
329.009.00235	17MAR97	90, 36, -40	29 Days	20	CON	MIL	NO	PSR	No	No			
329.010.00182	28DEC95	10, ., -22	1 Days	20	CON	MIL	NO	PSR	Yes	No			
329.010.00280	25JUN96 27JUN96	40, -16, -34 42, -14, -32	60 Mins 60 Mins	30 40	1 1	MIL MIL	NO NO	PSR PSR	Yes Yes	No No			

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Headache	HEADACHE	329.011.00283	25FEB96	18, -40, -40	01:00 Hrs	20	1	MIL	NO	PBU	No	No	
			11MAR96	33, -25, -25	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No	No
		329.012.00231	18APR97	43, -19, -122	2 Days	20	CON	MOD	NO	PBU	No	No	
			24APR97	49, -13, -116	02:00 Hrs	20	CON	MOD	NO	PBU	Yes	No	No
			28APR97	53, -9, -112	Not Stated	30		MIL	NO	PBU	Yes	No	No
	HEADACHE (CHANGE IN SEVERITY)	329.007.00309	05DEC96	144, 92, -111	04:00 Hrs	20	CON	SEV	NO	PBU	No	No	
	HEADACHE (DAILY)	329.008.00271	07MAY96	58, -7, -197	6 Days	40		MIL	NO	PSR	Yes	No	
	HEADACHE UPON RISING	329.005.00299	14JUN96	7, -54, -157	27 Days	20		MOD	NO	PSR	No	No	
	HEADACHE (WORSENING FROM BASELINE)	329.009.00304	21MAY96	43, -14, -167	8 Days	30	CON	MOD	NO	PSR	No	No	
	HEADACHES	329.001.00072	21MAR95	2, ., -30	3 Days	20	2	MIL	NO	PSR	No	No	
			329.003.00075	08FEB95	15, -42, -225	Not Stated	20	CON	MIL	NO	PBU	No	No
		329.005.00011	20DEC94	8, -49, -148	15 Days	20	14	MOD	NO	PSR	Yes	No	
	HEADACHES (DAILY)	329.007.00268	01OCT96	184, 125, -78	38 Days	30	35	MIL	NO	PSR	Yes	No	
		329.007.00309	14JAN97	184, 132, -71	30 Days	20	24	MOD	NO	PBU	Yes	No	
	HEADACHES (DAILY, 1-2X /DAY)	329.007.00294	04MAR97	5, ., -37	Not Stated	20		MOD	NO	PSR	Yes	No	
	HEADACHES (INCREASED FREQUENCY)	329.007.00309	24SEP96	72, 20, -183	19 Days	20	20	MOD	NO	PBU	Yes	No	

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Headache	HEADACHES 1 DAILY	329.004.00015	11DEC94	4, -54, -199	7 Days	20	3	MIL	NO	PSR	Yes No
	HEADACHES-MORE SEVERE THAN USUAL	329.006.00039	24APR95	76, 15, -16	5 Days	30	3	SEV	NO	PBU	Yes No
	MILD HEADACHE	329.007.00310	17OCT96	22, -39, -249	03:00 Hrs	20	CON	MIL	NO	PSR	No No
	MODERATE HEADACHE	329.012.00231	28APR97	53, -9, -112	Not Stated	30		MOD	NO	PSR	Yes No
Infection	"FLU" HEADACHE, SORE THROAT AND WEAKNESS, FEVER, EARACHE	329.007.00310	05OCT96	10, -51, -261	12 Days	20	CON	MOD	NO	PBU	No No
	COLD AND FLU STUFFY NOSE/NAUSEA/VOMITING DIARRHEA	329.005.00109	09FEB95	42, -12, -96	4 Days	20	CON	MOD	NO	UNR	No No
	FLU	329.003.00248	02APR96	33, ., -30	10 Days	40	CON	MIL	NO	UNR	No No
		329.007.00142	01DEC95	45, ., -3	8 Days	40		1 MOD	NO	UNR	Yes No
	FLU (COUGH, HEAD CONGESTION, LOW-GRADE FEVER)	329.007.00309	12DEC96	151, 99, -104	11 Days	20	CON	MOD	NO	UNR	No No
	FLU SYMPTOMS - FEVER, HEADACHES, MUSCLE ACHES	329.002.00319	06DEC96	221, 165, -24	6 Days	30		1 MOD	NO	UNR	No No
	MONONUCLEOSIS	329.010.00278	01SEP96	206, 150, -34	Not Stated	40	CON	SEV	NO	PBU	Yes No
	NAUSEA VOMITING DIARRHEA (FLU)	329.005.00112	13MAR95	47, -9, -46	2 Days	20	CON	SEV	NO	UNR	No No

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Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Infection	NAUSEA, VOMITING, DIARRHEA (STOMACH FLU)	329.005.00116	06MAR95	28, -31, -127	24:00 Hrs	20	CON	SEV	NO	UNR	No	No
	POSSIBLE STREP THROAT	329.007.00310	17MAR97	173, 113, -98	12 Days	20	CON	MOD	NO	UNR	Yes	No
	REPORT OF SORE THROAT. POSITIVE CULTURE, THROAT. BETA HEMOLYTIC STREP, GROUP A.	329.002.00058	16NOV94	58, -1, -61	3 Days	40	CON	MIL	NO	UNR	Yes	No
	SCABIES ON BOTH ARMS	329.006.00261	18FEB97	85, 27, -70	44 Days	30	CON	MOD	NO	UNR	No	No
	SORE THROAT AND EAR INFECTION DIAGNOSIS: STREP THROAT	329.005.00151	15OCT95	40, -18, -199	12 Days	20	CON	SEV	NO	UNR	Yes	No
	STOMACH FLU WITH NAUSEA, VOMITING AND DIARRHEA	329.005.00008	27NOV94	12, -44, -130	3 Days	20	CON	SEV	NO	UNR	No	No
	STOMACH FLU-NAUSEA, VOMITING AND DIARRHEA	329.005.00008	16DEC94	31, -25, -111	4 Days	30	CON	SEV	NO	UNR	No	No
	TONSILLITIS (STREP PHARYNGITIS)	329.009.00201	01APR96	56, ., -3	Not Stated	30	CON	MIL	NO	UNR	Yes	No
Trauma	FOREIGN OBJECT IN EYE	329.005.00151	06FEB96	154, 97, -85	3 Days	30	CON	MOD	NO	UNR	Yes	No
	HEADACHE DUE TO ACCIDENT	329.007.00268	26MAY96	56, -4, -206	5 Days	30	CON	MOD	NO	UNR	Yes	No
	MOTOR VEHICLE ACCIDENT	329.002.00102	02AUG95	112, 58, -140	1 Days	40	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv 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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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Trauma	NECK PAIN DUE TO ACCIDENT	329.007.00268	26MAY96	56, -4, -206	13 Days	30	CON	MOD NO	UNR Yes	No
	PAIN LEFT WRIST RULE OUT SPRAIN VERSUS TENDONITIS (WORSENERED) [SPRAIN]	329.001.00063	05NOV94	-3, ., -50	12 Days	0	CON	MIL NO	UNR No	No
	PATIENT ACCIDENTALLY THROWN FROM 3 WHEELER STRIKING HEAD AND A NUMBER OF ABRASIONS	329.007.00268	26MAY96	56, -4, -206	5 Mins	30	1	SEV NO	UNR Yes	No
	SUPERFICIAL SCRATCHES	329.006.00039	25FEB95	18, -44, -74	12 Days	20	CON	MIL NO	PBU No	No

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 Number of Episodes [No. Epi]: CON = Continuous
 Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
 Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
 Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
 Corrective Therapy [Corr Ther]
 Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Cardiovascular System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Arrhythmia	IRREGULAR PULSE	329.003.00248	22FEB96	-8, ., -70	Not Stated	0	CON	MIL	NO	UNR	No
	SINUS ARRHYTHMIA (PER EKG)	329.009.00235	17MAR97	90, 36, -40	Not Stated	20	CON	MIL	NO	UNR	No
Av Block	PR PROLONGATION CARDIAC CONDUCTION DELAY	329.012.00226	20DEC96	18, ., 0	4 Days	20	CON	MOD	STP	PSR	No
Hypertension	HYPERTENSION	329.007.00145	14MAY96	125, 69, -101	17 Days	20	CON	MOD	DCR	PSR	No
Migraine	MIGRAINES	329.008.00188	20FEB96	48, ., -7	04:00 Hrs	40	2	MOD	NO	UNR	No
Palpitation	CHEST PALPITATIONS	329.005.00002	19JUN94	26, -31, -121	06:30 Hrs	20	CON	MOD	NO	PSR	No
	HEART PALPITATIONS	329.002.00099	30JUN95	121, 66, -134	63 Days	40	3	MOD	NO	PSR	No
Postural Hypotension	ORTHOSTATIC HYPOTENSION	329.009.00304	21MAY96	43, -14, -167	30 Mins	30	CON	MIL	NO	PSR	No
	POSTURAL HYPOTENSION	329.005.00008	12NOV94	-4, -59, -145	2 Mins	0	2	MIL	NO	PSR	No
Syncope	BLACKNESS IN FRONT OF EYES, LIGHTHEADED, SWEATING {PRE-SYNCOPAL EPISODE/HEAT EXPOSURE}	329.007.00268	01AUG96	123, 64, -139	20 Mins	40	CON	MIL	NO	UNR	No
	FAINTED	329.005.00299	17JUN96	10, -51, -154	1 Mins	20	1	MOD	NO	PSR	No
Tachycardia	ELEVATED PULSE	329.009.00235	06JAN97	20, -35, -110	36 Days	20	CON	MIL	NO	REL	No
	HEART RACING	329.003.00075	06MAY95	102, 46, -138	12 Days	20	CON	MIL	NO	PSR	No
		329.003.00077	20APR95	46, -14, -48	3 Days	30	3	MIL	NO	PSR	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

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----- Treatment Group=PAROXETINE Body System=Cardiovascular System -----

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Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Vasodilatation	FEELING HOT	329.008.00271	06MAR96	-5, -69, -259	61 Days	0		MIL NO	PSR No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE	
Constipation	CONSTIPATION	329.003.00089	21MAR95	15, ., -45	7 Days	20		MIL	NO	PSR	No	
		329.004.00017	13APR95 25APR95	23, -34, -215 35, -22, -203	12 Days 28 Days	20 20	CON CON	MOD MIL	NO NO	REL REL	No No	
		329.006.00038	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR	No	
		329.007.00268	19NOV96	233, 174, -29	02:00 Hrs	30	1	MOD	NO	UNR	Yes	No
		329.009.00131	20MAY95	19, -38, -99	3 Days	20	1	MOD	NO	PSR	Yes	No
		329.009.00170	07JUL96	244, 187, -1	Not Stated	20	CON	MIL	NO	UNR	No	No
		329.009.00196	20DEC95	3, ., -67	Not Stated	20	7	MIL	NO	PBU	No	No
Decreased Appetite	ANOREXIA	329.001.00063	10NOV94	3, ., -45	Not Stated	20	CON	MIL	NO	PSR	No	
		329.001.00072	28MAR95	9, ., -23	Not Stated	20	CON	MIL	NO	PSR	No	
		329.003.00075	05APR95	71, 15, -169	98 Days	20	CON	MIL	NO	PSR	No	
		329.009.00196	19DEC95	2, ., -68	21 Days	20	CON	MIL	NO	PBU	No	
		329.009.00324	16DEC96	50, ., -23	31 Days	20	CON	MIL	NO	PSR	No	
		329.009.00170	09NOV95 21DEC95	3, -55, -242 45, -13, -200	43 Days 14 Days	20 40	CON CON	MIL MOD	NO DCR	PSR PSR	No No	
		329.008.00271	18MAR96	8, -57, -247	24 Days	20	CON	MIL	NO	REL	No	
329.001.00205	09FEB96	3, ., -5	Not Stated	20	CON	MIL	NO	PSR	No			
Diarrhea	DIARRHEA	329.001.00063	09NOV94	2, ., -46	14 Days	20	3	MIL	NO	PSR	No	

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Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act ion	Inv Rel	Corr Ther	SAE	
Diarrhea	DIARRHEA	329.002.00105	03AUG95	8, ., -14	8 Days	20	4	MIL	NO	PSR	No	No	
		329.005.00008	10DEC94	25, -31, -117	3 Days	20	CON	MOD	NO	UNR	No	No	
		329.005.00152	30OCT95	5, ., 0	24:00 Hrs	20	CON	SEV	STP	REL	No	No	
		329.005.00333	21FEB97	30, ., -3	08:00 Hrs	20	CON	SEV	NO	UNR	Yes	No	
		329.007.00268	03APR96	3, -57, -259	8 Days	20	CON	MIL	NO	PSR	No	No	
		LOOSE STOOLS	329.009.00133	29JUN95	17, ., -28	Not Stated	20		MOD	NO	PSR	Yes	No
	Dry Mouth	DRY MOUTH	329.001.00065	21NOV94	5, ., -9	Not Stated	20	CON	MIL	NO	REL	No	No
			329.001.00068	10FEB95	3, ., -69	Not Stated	20	CON	MIL	NO	PSR	No	No
			329.002.00106	03AUG95	8, ., -40	03:00 Hrs	20	CON	MIL	NO	REL	No	No
			329.002.00319	01MAY96	2, -55, -243	202 Days	20	CON	MIL	NO	REL	No	No
329.003.00075			25JAN95	1, -56, -239	4 Days	20	CON	MIL	NO	PSR	No	No	
329.003.00077			16APR95	42, -18, -52	10 Days	30		MIL	NO	PSR	No	No	
329.003.00089			21MAR95	15, ., -45	Not Stated	20	CON	MIL	NO	PSR	No	No	
329.003.00313			18MAY96	2, ., -10	Not Stated	20	CON	MIL	NO	PSR	No	No	
329.005.00008			20NOV94	5, -51, -137	140 Days	20	CON	MIL	NO	PSR	No	No	
329.005.00116			10FEB95	4, -55, -151	152 Days	20	CON	MOD	NO	REL	No	No	
		329.005.00300	24SEP96	6, ., -51	27 Days	20	CON	MOD	NO	REL	No	No	

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE	
Dry Mouth	DRY MOUTH	329.005.00300	21OCT96	33, ., -24	10 Days	20	CON	MIL NO	REL No	No	
		329.005.00336	09MAR97	6, ., -52	39 Days	20	CON	MIL NO	REL No	No	
		329.008.00271	06APR96	27, -38, -228	11 Days	20	CON	MIL NO	PBU No	No	
		329.008.00275	08MAY96	1, -55, -222	Not Stated	20	CON	MIL NO	PSR No	No	
		21JUL96	75, 20, -148	06:00 Hrs	30	1	MIL NO	REL No	No		
		12AUG96	97, 42, -126	9 Days	30	3	MIL NO	REL No	No		
		03SEP96	119, 64, -104	2 Days	30	3	MIL NO	REL No	No		
		04NOV96	181, 126, -42	26:00 Hrs	30	2	MIL NO	REL No	No		
		329.009.00196	03JAN96	17, ., -53	6 Days	20	CON	MIL NO	PSR No	No	
		329.009.00235	30DEC96	13, -42, -117	43 Days	20	CON	MIL NO	PSR No	No	
Dyspepsia	HEARTBURN	329.010.00278	29MAR96	50, -7, -190	6 Days	40	CON	MIL NO	REL No	No	
		329.012.00228	20MAR97	2, ., -2	4 Days	20	CON	MIL NO	PBU No	No	
		329.012.00231	20MAR97	14, -48, -151	41 Days	20	CON	MIL NO	PBU No	No	
		329.009.00196	27JAN96	41, ., -29	Not Stated	30	CON	MIL NO	PBU Yes	No	
		HEARTBURN ON AN EMPTY STOMACH WHEN TAKING MEDS.	329.002.00102	09MAY95	27, -28, -225	7 Days	30	7	MIL NO	REL No	No
		STOMACH UPSET	329.001.00206	10MAR96	19, ., -39	2 Days	20	CON	MIL NO	PBU No	No
		UPSET STOMACH	329.004.00214	09NOV96	37, -24, -51	2 Days	30	CON	MIL DCR	REL Yes	No
			329.005.00116	08FEB95	2, -57, -153	6 Days	20	10	MOD NO	PBU No	No

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Number of Episodes [No. Epi]: CON = Continuous
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Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Dyspepsia	UPSET STOMACH AND HEARTBURN	329.003.00077	12MAR95	7, -53, -87	08:30 Hrs	20	CON	MIL NO	PBU No	No
	UPSET STOMACH {WHEN TAKES MEDICATIONS AT BEDTIME}	329.005.00116	04APR95	57, -2, -98	99 Days	20	CON	MIL NO	PSR No	No
Esophagitis	BURNING ACHE IN UPPER ESOPHAGUS REGION	329.006.00260	05AUG96	19, -40, -135	5 Mins	20	3	MOD NO	PSR No	No
	BURNING ACHE IN UPPER ESOPHAGUS REGION-BRIEF	329.006.00260	07AUG96	21, -38, -133	45 Mins	20	1	MOD NO	PSR No	No
Gastrointestinal Disorder	FOOD POISONING	329.007.00310	16NOV96	52, -9, -219	2 Days	20	CON	MOD NO	UNR Yes	No
	NAUSEA AND REFLUX {ESOPHAGEAL}	329.003.00075	15FEB95	22, -35, -218	24:00 Hrs	20	CON	MIL NO	PSR No	No
Gingivitis	ABSCESSSED TOOTH	329.007.00309	26SEP96	74, 22, -181	1 Days	20	CON	SEV NO	UNR Yes	No
Increased Appetite	INCREASED APPETITE	329.001.00068	01MAR95	22, ., -50	29 Days	20	CON	MIL NO	PSR No	No
		329.003.00081	19DEC95	9, ., -50	16 Days	20	CON	MIL NO	PSR No	No
		329.005.00116	15FEB95	9, -50, -146	162 Days	20	CON	MOD NO	PSR No	No
		329.009.00170	01APR96 30JUN96	147, 90, -98 237, 180, -8	85 Days 9 Days	30 20	CON CON	MIL NO MOD NO	PSR No PSR No	No No
Nausea	NAUSEA	329.001.00063	30NOV94	23, ., -25	Not Stated	20	CON	MIL NO	PSR No	No
		329.001.00065	18NOV94	2, ., -12	Not Stated	20	4	MOD NO	REL No	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Nausea	NAUSEA	329.001.00121	06APR95	3, -54, -151	27 Days	20	CON	MIL	NO	PSR	No	No
		329.002.00099	18APR95	48, -8, -207	7 Days	40	21	MIL	NO	PSR	No	No
		329.003.00075	08MAR95 15SEP95	43, -14, -197 234, 178, -6	128 Days 6 Days	20 20	CON	MIL MOD	INC NO	PSR PBU	No No	No No
		329.003.00077	21APR95 02MAY95	47, -13, -47 58, -2, -36	3 Days 35 Days	30 30	3 2	MIL MIL	NO NO	PSR PSR	No No	No No
		329.003.00089	10MAR95	4, ., -56	Not Stated	20	CON	MIL	NO	PSR	No	No
		329.003.00091	26MAR95	3, -52, -242	10 Mins	20		MIL	NO	PBU	No	No
		329.004.00017	23MAR95 27MAR95 06NOV95	2, -55, -236 6, -51, -232 230, 174, -8	4 Days 5 Days 7 Days	20 0 20	CON CON CON	SEV MIL MOD	DCR NO NO	REL REL UNR	No No Yes	No No No
		329.004.00214	15NOV96 23DEC96	43, -18, -45 81, 21, -7	1 Days 06:00 Hrs	30 20	CON 3	MOD MOD	DCR NO	PSR PSR	Yes No	No No
		329.005.00152	27OCT95	2, ., -3	4 Days	20	CON	SEV	STP	REL	No	No
		329.007.00268	27OCT96	210, 151, -52	10 Days	30	CON	MOD	NO	PBU	Yes	No
		329.007.00309	27OCT96 10MAR97	105, 53, -150 239, 187, -16	3 Days Not Stated	20 30	CON CON	MIL MIL	NO NO	UNR UNR	No No	No No
		329.009.00130	23MAY95	36, -21, -146	3 Days	20	2	MIL	NO	PSR	No	No
		329.009.00133	29JUN95	17, ., -28	Not Stated	20	CON	MOD	NO	PSR	No	No
		329.009.00170	27JUN96	234, 177, -11	12 Days	20	CON	SEV	NO	REL	Yes	Yes

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Nausea	NAUSEA	329.009.00196	19DEC95	2, ., -68	21 Days	20	CON	MIL	NO	PSR	No
		329.009.00201	07MAR96	31, ., -28	1 Days	20	CON	MIL	NO	PBU	No
		329.009.00204	26MAR96	8, -49, -203	22 Days	20	CON	MIL	NO	PSR	No
		329.009.00235	27JAN97	41, -14, -89	50 Days	20	CON	MIL	NO	PSR	No
		329.009.00324	29OCT96	2, ., -71	21 Days	20	CON	MIL	NO	PSR	No
		329.012.00025	06NOV95	14, ., -59	02:00 Hrs	20	1	MOD	NO	PBU	No
		329.012.00220	13SEP96	89, 29, -70	04:00 Hrs	30	1	MIL	NO	PBU	No
		329.012.00226	12DEC96	10, ., -8	12 Days	20	CON	MIL	NO	PBU	No
		329.012.00231	25MAY97	80, 19, -85	10 Days	30	4	MIL	NO	PBU	No
			NAUSEA (FOR 10 MINUTES DAILY BEFORE BREAKFAST)	329.002.00099	30JUN95	121, 66, -134	63 Days	40	25	MIL	NO
	NAUSEA DUE TO RIDES AT AMUSEMENT PARK	329.007.00268	29APR96	29, -31, -233	01:00 Hrs	20	1	MOD	NO	UNR	Yes
	NAUSEATED	329.002.00099	04MAR95	3, -53, -252	11 Days	20	CON	MIL	NO	PSR	No
	NAUSEOUS	329.003.00250	15MAR96	2, -56, -73	12 Days	20	CON	MIL	NO	PBU	No
Peptic Ulcer Hemorrhage	BLEEDING ULCER {PEPTIC}	329.005.00109	07MAY95	129, 76, -9	4 Days	20	CON	SEV	NO	UNR	Yes
Tooth Disorder	ORTHODONTIC DISCOMFORT	329.005.00258	01APR96	21, ., -36	03:30 Hrs	20	1	MOD	NO	UNR	Yes
			08APR96	28, ., -29	02:40 Hrs	20	1	MOD	NO	UNR	Yes

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Tooth Disorder	TOOTHACHE	329.005.00112	26FEB95	32, -24, -61	10:30 Hrs	20	CON	MOD	NO	UNR	No	No
		329.006.00260	06AUG96	20, -39, -134	30 Mins	20	1	SEV	NO	UNR	Yes	No
	TOOTHACHE (CUTTING WISDOM TEETH)	329.007.00309	26AUG96	43, -10, -212	17 Days	20	CON	MOD	NO	UNR	Yes	No
	TOOTHACHE PAIN	329.006.00260	25JUL96	8, -51, -146	09:00 Hrs	20	1	MOD	NO	UNR	Yes	No
	WISDOM TOOTH EXTRACTION {TOOTH DISORDER}	329.009.00133	14JUL95	32, ., -13	03:00 Hrs	30	CON	MIL	NO	UNR	Yes	No
Vomiting	NAUSEA AND VOMITING	329.005.00109	10MAY95	132, 79, -6	2 Days	20	CON	SEV	NO	PSR	No	No
		329.005.00119	23OCT95	105, 46, -36	5 Days	40	5	MOD	NO	PBU	No	No
		329.005.00152	27OCT95	2, ., -3	4 Days	20	8	SEV	STP	REL	No	No
	VOMITING	329.001.00065	21NOV94	5, ., -9	1 Mins	20	1	MIL	NO	REL	No	No
		329.004.00017	08NOV95	232, 176, -6	5 Days	20	3	MOD	NO	UNR	No	No
		329.005.00152	30OCT95	5, ., 0	24:00 Hrs	20	CON	SEV	STP	REL	No	No
		329.009.00170	01JUL96	238, 181, -7	6 Days	20	CON	SEV	NO	REL	Yes	No
	329.009.00201	07MAR96	31, ., -28	1 Days	20		MIL	NO	UNR	No	No	

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Hemic and Lymphatic System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Anemia	ANEMIA	329.003.00248	23APR96	54, ., -9	Not Stated	30	CON	MIL NO	PBU No	No
Thrombocythemia	INCREASED PLATELET COUNT	329.009.00131	27JUN95	57, 1, -61	29 Days	20	CON	MIL NO	PBU No	No
Thrombocytopenia	THROMBOCYTOPENIA	329.007.00145	30MAY96	141, 85, -85	29 Days	20	CON	MIL NO	PSR No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Metabolic and Nutritional Disorders -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int ion	Act- ion	Inv Rel	Corr Ther	SAE
Weight Gain	WEIGHT GAIN	329.005.00151	28NOV95	84, 27, -155	156 Days	20	CON	MOD	NO	PSR	No	No
		329.005.00257	03JUN96	85, 29, -154	Not Stated	30	CON	MOD	NO	PSR	No	No
		329.007.00268	30SEP96	183, 124, -79	95 Days	30	CON	MOD	NO	PSR	Yes	No
	WEIGHT GAIN {10 LBS} [WEIGHT GAIN]	329.009.00304	30JUL96	113, 57, -97	Not Stated	30	CON	MIL	NO	PSR	No	No
	WEIGHT GAIN {11LBS} [WEIGHT GAIN]	329.009.00201	02APR96	57, ., -2	Not Stated	20	CON	MOD	NO	PSR	No	No
Weight Loss	WEIGHT LOSS	329.001.00121	11APR95	8, -49, -146	22 Days	20	CON	MIL	NO	PSR	No	No
		329.009.00170	21DEC95	45, -13, -200	14 Days	40	CON	MIL	NO	PBU	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Musculoskeletal System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Arthralgia	LEFT KNEE PAIN	329.007.00310	14NOV96	50, -11, -221	Not Stated	20	CON	MOD NO	UNR Yes	No
Myalgia	CRAMPS IN LEFT LEG	329.005.00116	08MAR95	30, -29, -125	2 Days	20	CON	MOD NO	UNR No	No
	MUSCLE ACHE	329.006.00038	12APR95	57, ., 0	3 Days	20	CON	MOD STP	UNR No	No
	MUSCLE PAIN	329.007.00268	07JUL96	98, 39, -164	124 Days	30	CON	MIL NO	UNR Yes	No
	PAIN IN NECK MUSCLES	329.007.00310	07OCT96	12, -49, -259	9 Days	20	CON	MOD NO	PBU Yes	No
Myasthenia	MUSCLE WEAKNESS	329.006.00038	12APR95	57, ., 0	3 Days	20	CON	MOD STP	UNR No	No
Tendinous Disorder	PAIN LEFT WRIST RULE OUT SPRAIN VERSUS TENDONITIS (WORSENERED) [TENDONITIS]	329.001.00063	05NOV94	-3, ., -50	12 Days	0	CON	MIL NO	UNR No	No

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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
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE	
Abnormal Dreams	INCREASED DREAMING	329.009.00324	25NOV96	29, ., -44	Not Stated	20	CON	MIL	NO	PSR	No	No
	NIGHTMARES	329.009.00324	11NOV96	15, ., -58	15 Days	20	CON	MIL	NO	PSR	No	No
	VIVID DREAMS	329.005.00333	10FEB97	19, ., -14	11 Days	20	10	MOD	NO	PSR	No	No
Agitation	AGITATION	329.009.00170	09JUL96	246, 189, 1	12:00 Hrs	20	CON	MOD	NO	PSR	No	Yes
		329.009.00201	03APR96	58, ., -1	Not Stated	20	CON	SEV	STP	PSR	No	Yes
	FIDGETY/PSYCHOMOTOR AGITATION	329.007.00268	16SEP96	169, 110, -93	17 Days	40	CON	MIL	DCR	PSR	No	No
	["HYPER"{AGITATION}]	329.009.00130	19MAY95	32, -25, -150	26 Days	20	3	MOD	NO	PSR	No	No
Amnesia	"FORGETFUL"	329.002.00099	30JUN95	121, 66, -134	63 Days	40	3	MIL	NO	PBU	No	No
Anxiety	ANXIETY	329.004.00017	23MAR95	2, -55, -236	4 Days	20	CON	SEV	DCR	REL	No	No
	ANXIETY ATTACKS	329.008.00188	24FEB96	52, ., -3	30 Mins	40	1	MIL	NO	PBU	No	No
Concentration Impaired	ATTENTION DEFICIT HYPERACTIVITY DISORDER	329.009.00240	26MAR97	72, ., 21	Not Stated	0	CON	MOD	NO	UNR	Yes	No
	DECREASED CONCENTRATION	329.008.00271	11MAY96	62, -3, -193	4 Days	40	CON	MIL	NO	PSR	No	No
Depression	MORE DEPRESSED	329.006.00039	22MAR95	43, -19, -49	7 Days	20	CON	SEV	NO	PSR	No	No
	WORSENING OF DEPRESSION	329.009.00240	02MAR97	48, ., -3	Not Stated	30	CON	SEV	STP	UNR	Yes	Yes
		329.009.00329	12NOV96	35, ., -35	22 Days	20	CON	MOD	NO	PBU	No	No

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Number of Episodes [No. Epi]: CON = Continuous
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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Depression	WORSENING OF DEPRESSION HOSPITALIZED	329.001.00065	30NOV94	14, ., 0	Not Stated	20	CON	SEV STP	PSR No	Yes
Dizziness	COLD CLAMMY LIGHTHEADEDNESS [LIGHTEADEDNESS]	329.008.00271	05APR96	26, -39, -229	15 Mins	20	1	MIL DCR	PSR No	No
	CONSTANT DIZZINESS (DAILY)	329.002.00099	28JUN95	119, 64, -136	93 Days	40	CON	MOD NO	PSR No	No
	DIZZINESS	329.001.00063	10NOV94	3, ., -45	5 Mins	20	1	MIL NO	PSR No	No
		329.001.00065	18NOV94	2, ., -12	Not Stated	20	4	MIL NO	REL No	No
		329.002.00102	05SEP95	146, 92, -106	36 Days	40	1	MOD NO	REL No	No
		329.003.00075	08MAR95 01JUL95 15SEP95	43, -14, -197 158, 102, -82 234, 178, -6	15 Days 10 Days 6 Days	20 20 20	CON CON	MOD INC MIL NO MOD NO	PSR No PBU No PBU No	No No No
		329.003.00081	28DEC95	18, ., -41	14 Days	20	CON	MIL NO	PBU No	No
		329.003.00248	26MAR96	26, ., -37	17 Days	30	CON	MIL NO	PSR No	No
		329.003.00250	15MAR96	2, -56, -73	5 Mins	20	2	MIL NO	PBU No	No
		329.004.00015	18FEB95 05JUN95	73, 16, -130 180, 123, -23	31 Days 2 Days	20 20	CON CON	MIL NO MOD NO	PBU No UNR No	No No
		329.004.00017	06NOV95	230, 174, -8	5 Days	20	CON	MIL NO	UNR No	No
		329.004.00214	15NOV96 23DEC96	43, -18, -45 81, 21, -7	1 Days 06:00 Hrs	30 20	CON 3	MOD DCR MOD NO	PSR No PSR No	No No

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Number of Episodes [No. Epi]: CON = Continuous
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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Dizziness	DIZZINESS	329.005.00011	02JAN95	21, -36, -135	34 Days	20		MIL	NO	REL No	No
		329.005.00299	05NOV96	151, 91, -13	8 Days	20	CON	MOD	NO	PSR No	No
		329.005.00336	10MAR97	7, ., -51	13 Days	20	2	MIL	NO	REL No	No
		329.006.00038	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR No	No
		329.007.00309	17JUL96	3, -50, -252	2 Days	20	2	MIL	NO	PSR No	No
		329.008.00275	25JUN96	49, -7, -174	9 Days	40	3	MIL	NO	REL No	No
			19JUL96	73, 18, -150	5 Days	30	3	MIL	NO	REL No	No
			10AUG96	95, 40, -128	3 Mins	30	1	MIL	NO	REL No	No
			08SEP96	124, 69, -99	3 Days	30	2	MIL	NO	REL No	No
		329.012.00220	25JUN96	9, -52, -150	3 Days	20	CON	MOD	NO	REL No	No
		329.012.00231	25MAY97	80, 19, -85	10 Days	30	4	MIL	NO	PBU No	No
	DIZZINESS ARISING FROM LAYING SITTING OR SOMETIMES WHEN SITTING	329.002.00099	28MAR95	27, -29, -228	28 Days	20	78	MOD	NO	PSR No	No
	DIZZINESS IN AM	329.009.00329	14OCT96	6, ., -64	10 Days	20	CON	MIL	NO	REL No	No
	DIZZINESS UPON RISING	329.005.00299	14JUN96	7, -54, -157	27 Days	20		MOD	NO	PSR No	No
	DIZZINESS WHEN ARISING SUDDENLY	329.002.00099	14MAR95	13, -43, -242	11 Days	20	33	MOD	NO	PSR No	No
	DIZZINESS WHEN STANDING	329.003.00089	14MAR95	8, ., -52	24:00 Hrs	20	CON	MIL	NO	PSR No	No

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Dizziness	DIZZINESS"FELT LIKE FAINTING"	329.003.00091	01APR95	9, -46,-236	01:30 Hrs	20		MOD NO	PSR Yes	No
	DIZZY	329.001.00121	23MAY95	50, -7,-104	20 Mins	30	1	MIL NO	PBU No	No
		329.002.00099	04MAR95	3, -53,-252	30 Mins	20	CON	MIL NO	PSR No	No
	DIZZY GETTING OUT OF BED OR AFTER LYING DOWN A LONG TIME	329.004.00019	03JUN95	4, ., -11	Not Stated	20		MIL NO	REL No	No
	FATIGUE WITH DIZZINESS AND DROWSINESS [DIZZINESS]	329.005.00011	28JAN95	47, -10,-109	Not Stated	40	CON	MIL NO	PSR No	No
	GIDDINESS	329.005.00336	14MAR97 27MAR97	11, ., -47 24, ., -34	4 Days 3 Days	20 20	4 CON	MIL NO MIL NO	PSR No PSR No	No No
	LIGHT-HEADED (X2 MINUTES)	329.010.00280	10JUL96	55, -1, -19	2 Mins	40	1	MIL NO	PSR No	No
	LIGHTHEADED	329.001.00065	18NOV94	2, ., -12	Not Stated	20	4	MIL NO	REL No	No
		329.008.00271	03APR96	24, -41,-231	15 Mins	20	2	MIL DCR	PSR No	No
	LIGHTHEADED {WHEN STANDING}	329.008.00271	11MAY96	62, -3,-193	Not Stated	40	CON	MIL NO	PSR No	No
	LIGHTHEADEDNESS	329.008.00275	05JUN96	29, -27,-194	3 Days	30	2	MIL NO	REL No	No
Drug Dependence	POSITIVE CANNABIS	329.005.00002	20MAY94	-5, -61,-151	1 Days	0	1	MIL NO	UNR No	No

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Corrective Therapy [Corr Ther]
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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Drug Dependence	POSITIVE URINE DRUG SCREEN CANNABINOIDS	329.005.00109	25MAY95	147, 94,	9 1 Days	20	1	SEV NO	UNR No	No
Emotional Lability	ATTEMPTED SUICIDE {INTENTIONAL}	329.006.00038	12APR95	57, .,	0 1 Days	20	1	SEV STP	UNR No	Yes
	INTENTIONAL OVERDOSE {TYLENOL OVERDOSE TOOK 80 PILLS}	329.002.00058	19JAN95	122, 64,	3 1 Days	40	CON	MOD STP	PBU No	Yes
	OVERDOSE {INTENTIONAL}	329.003.00250	19APR96 27MAY96	37, -21, -38 75, 18, 0	21 Days 01:00 Hrs	40 30	CON	MOD NO 1 SEV STP	UNR No UNR No	Yes Yes
	SELF-MUTILATION	329.004.00015	07JAN95	31, -27, -172	30 Mins	20	1	MIL NO	UNR No	No
	SUICIDAL IDEATION	329.004.00015	18FEB95	73, 16, -130	03:00 Hrs	20	1	MIL NO	UNR No	No
		329.005.00333	28FEB97	37, .,	4 103 Days	20	CON	SEV NO	UNR No	Yes
	SUPERFICIAL CUTS RISK TO SELF	329.003.00313	28MAY96	12, .,	0 6 Days	20	CON	SEV STP	PBU No	Yes
	TYLENOL OVERDOSE {INTENTIONAL}	329.002.00245	10APR96	14, .,	-4 1 Days	20	1	SEV STP	UNR No	Yes
	[OVERDOSE{WITH BAYER EXTRA STRENGTH} [INTENTIONAL]	329.005.00011	17MAY95	156, 100,	0 1 Days	30	1	SEV STP	UNR Yes	Yes
Euphoria	ELATION AND EXPANSIVE MOOD	329.003.00089	04APR95	29, .,	-31 Not Stated	20	CON	SEV STP	PSR No	Yes
Hallucinations	AUDITORY HALLUCINATIONS	329.003.00313	28MAY96	12, .,	0 6 Days	20	CON	SEV STP	PBU No	Yes

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Number of Episodes [No. Epi]: CON = Continuous
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Corrective Therapy [Corr Ther]
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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE	
Hostility	AGGRESSIVE ASSAULTIVE BEHAVIOR	329.009.00201	03APR96	58, ., -1	Not Stated	20	CON	SEV STP	PSR Yes	Yes	
	ALLEGATIONS OF SEXUAL AGGRESSION	329.002.00055	25JUL94	32, -24, -124	1 Days	30		MIL NO	UNR No	No	
	ANGRY (PATIENT NOTICED)	329.006.00038	15MAR95	29, ., -28	8 Days	20	CON	MIL NO	PSR No	No	
	NEEDED 6 STITCHES TO HAND AFTER BREAKING PICTURES (DUE TO ANGER) RESULTED IN HOSPITALIZATION TO PREVENT AGGRESSION AGAINST SELF	329.001.00065	30NOV94	14, ., 0	1 Days	20	CON	MOD STP	PBU No	Yes	
	OPPOSITIONAL BEHAVIOR (PHYSICALLY AND VERBALLY FIGHTING WITH MOTHER)	329.005.00300	18OCT96	30, ., -27	7 Days	20		6 SEV NO	PBU No	No	
				25OCT96	37, ., -20	Not Stated	20		MOD NO	PBU No	No
	OPPOSITIONAL DEFIANT DISORDER	329.002.00106	15SEP95	51, ., 3	16 Days	40	CON	SEV NO	PBU No	Yes	
Hyperkinesia	PHYSICAL FIGHT {AGGRESSION}	329.005.00119	28JUL95	18, -42, -123	10 Mins	20		1 MIL NO	PBU No	No	
	AKATHISIA	329.007.00145	02MAY96	113, 57, -113	29 Days	30	CON	MOD DCR	REL No	No	
	HYPERACTIVE	329.004.00214	08OCT96	5, -56, -83	01:00 Hrs	20		5 MIL NO	PSR No	No	
	HYPERACTIVITY	329.003.00075	13JUL95	170, 114, -70	70 Days	20	CON	MIL NO	PBU No	No	

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Hypertonia	STIFF NECK	329.007.00310	14MAR97	170, 110, -101	10 Days	20	CON	MOD	NO	UNR	Yes	No
		329.008.00271	07APR96	28, -37, -227	30 Mins	20	3	MIL	NO	PBU	No	No
Insomnia	AWAKENING (MIDDLE OF NIGHT)	329.004.00214	12OCT96	9, -52, -79	15 Mins	20	2	MIL	NO	PSR	No	No
	INITIAL AND MIDDLE INSOMNIA	329.012.00025	24OCT95	1, ., -72	Not Stated	20	CON	MOD	NO	PSR	No	No
	INITIAL INSOMNIA	329.009.00201	28FEB96	23, ., -36	Not Stated	20	CON	MOD	NO	PSR	No	No
		329.012.00228	20MAR97	2, ., -2	4 Days	20	CON	MIL	NO	PBU	No	No
	INITIAL INSOMNIA (INCREASE 2 HOURS)	329.002.00099	24MAY95	84, 29, -171	02:00 Hrs	40	39	SEV	NO	PBU	No	No
	INITIAL INSOMNIA MOST NIGHTS INCREASE 2 HOURS	329.002.00099	13JUN95	104, 49, -151	33 Days	40	10	MOD	NO	PSR	No	No
	INSOMNIA	329.003.00077	24MAY95	80, 21, -14	Not Stated	30	CON	SEV	DCR	PSR	No	No
		329.004.00017	27MAR95	6, -51, -232	5 Days	0	CON	MIL	NO	PSR	No	No
		329.009.00173	15JAN96	57, -7, -43	Not Stated	20	CON	MOD	NO	PSR	No	No
		329.009.00324	11NOV96	15, ., -58	8 Days	20	CON	MIL	NO	PSR	No	No
INSOMNIA (INITIAL)		329.009.00196	19DEC95	2, ., -68	21 Days	20	CON	MIL	NO	PBU	No	No
		329.009.00235	03FEB97	48, -7, -82	8 Days	20	CON	MIL	NO	UNR	No	No
	INSOMNIA (NO SLEEP)	329.004.00017	24MAR95	3, -54, -235	3 Days	20	CON	SEV	DCR	REL	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Insomnia	MIDDLE INSOMNIA	329.001.00068	15FEB95	8, ., -64	Not Stated	20	CON	MOD	NO	PSR No	No
		329.009.00170	23NOV95 28NOV95	17, -41, -228 22, -36, -223	6 Days 37 Days	20 20	CON CON	MIL MOD	NO NO	PSR No PSR No	No No
	RESTLESS AT NIGHT	329.002.00099	05MAR95	4, -52, -251	10 Days	20	2	MIL	NO	PSR No	No
	SLEEP PROBLEMS-EXAMPLE WAKES UP TOO EARLY	329.003.00089	14MAR95	8, ., -52	Not Stated	20	CON	MIL	NO	PSR No	No
	TERMINAL INSOMNIA	329.007.00268	09SEP96	162, 103, -100	24 Days	40	12	MOD	DCR	PSR No	No
	TROUBLE SLEEPING	329.003.00075	15SEP95	234, 178, -6	6 Days	20		MOD	NO	PBU No	No
	WORSENING OF SLEEP DISTURBANCE	329.009.00240	05MAR97	51, ., 0	Not Stated	30	CON	SEV	NO	PSR Yes	Yes
Manic Reaction	HOSPITALIZATION RULE-OUT HYPOMANIA	329.004.00017	31AUG95	163, 107, -75	3 Days	30	CON	MIL	NO	UNR No	Yes
	MANIA AND HYPOMANIA SYMPTOMS	329.001.00205	10FEB96	4, ., -4	Not Stated	20	CON	SEV	STP	PSR No	No
	MANIA SYMPTOMS	329.001.00063	11DEC94	34, ., -14	Not Stated	20	CON	MOD	STP	PSR No	No
Myoclonus	GRIMACING FACE WITH BLINKING EYES {TIC}	329.006.00039	22MAR95	43, -19, -49	7 Days	20	CON	MIL	NO	PSR No	No
	LEG TWITCHES	329.005.00336	19APR97	47, ., -11	4 Days	20	4	MIL	NO	PSR No	No
	LEG TWITCHES (NIGHTLY)	329.005.00336	29MAR97 02APR97	26, ., -32 30, ., -28	5 Days 8 Days	20 20	4 7	SEV MIL	NO NO	PSR No PSR No	No No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act ion	Inv Corr Rel Ther	SAE
Nervousness	"JITTERINESS"	329.005.00257	21OCT96	225, 169, -14	Not Stated	30	CON	MOD	NO	PSR No	No
	INCREASED IRRITABILITY	329.008.00271	12MAY96	63, -2, -192	Not Stated	40	CON	MIL	NO	PSR No	No
	IRRITABLE MOOD	329.006.00039	22MAR95	43, -19, -49	7 Days	20	CON	MOD	NO	PSR No	No
	JITTERINESS	329.008.00160	20NOV95	20, -47, -261	8 Days	20	1	MIL	NO	UNR No	No
		329.008.00188	07JAN96	4, ., -51	Not Stated	20	12	MIL	NO	PSR No	No
	NERVOUS JITTERY TREMULOUS	329.003.00075	25JAN95	1, -56, -239	8 Days	20	CON	MIL	NO	PSR No	No
	RESTLESSNESS	329.009.00173	29DEC95	40, -24, -60	18 Days	30	CON	MOD	DCR	PSR No	No
		329.009.00193	01DEC95	4, ., -67	12 Days	20	CON	MIL	NO	PSR No	No
		329.010.00278	03MAR96	24, -33, -216	5 Days	20	CON	MIL	NO	PSR No	No
		TEETH CHATTERING(JITTERINESS)	329.003.00075	16MAR95	51, -6, -189	13 Days	20	CON	MIL	NO	REL No
Paranoid Reaction	PARANOIA	329.009.00201	03APR96	58, ., -1	Not Stated	20	CON	MOD	STP	PSR No	Yes
Paresthesia	TINGLING LEG AND FEET	329.001.00063	10NOV94	3, ., -45	7 Days	20	2	MIL	NO	PSR No	No
Personality Disorder	BEHAVIOR PROBLEMS-->STOLE MOM'S CAR AND WRECKED IT.	329.005.00008	31JAN95	77, 22, -65	02:00 Hrs	30	1	SEV	NO	PSR No	No
	SKIPPING SCHOOL TALKING BACK TO MOM {BEHAVIOR PROBLEMS}	329.005.00008	22DEC94	37, -19, -105	47 Days	40	CON	SEV	NO	PSR No	No

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Number of Episodes [No. Epi]: CON = Continuous
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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Somnolence	DAYTIME SLEEPINESS	329.009.00304	14MAY96	36, -21, -174	15 Days	30	CON	MOD	NO	PSR No	No
	DROWSINESS	329.003.00075	02MAR95	37, -20, -203	5 Days	20	CON	MIL	DCR	PSR No	No
		329.012.00025	16NOV95	24, ., -49	20 Days	20	CON	MOD	NO	REL No	No
	DROWSINESS DURING DAY	329.007.00294	28FEB97	1, ., -41	19 Days	20	CON	MIL	NO	PBU No	No
	DROWSINESS-SLEEPINESS	329.005.00008	16NOV94 02DEC94	1, -55, -141 17, -39, -125	17 Days 160 Days	20 20	7 CON	MIL MOD	NO NO	PSR No REL No	No No
	DROWSY	329.009.00170	27JUN96	234, 177, -11	11 Days	20	CON	MOD	NO	PSR No	Yes
	INCREASED DAYTIME SLEEPINESS SOMNOLENCE	329.009.00173	13DEC95	24, -40, -76	Not Stated	20	CON	MOD	NO	PSR No	No
	MILD SEDATION	329.002.00242	07MAR96	30, -29, -90	8 Days	30	1	MIL	NO	PSR No	No
	SEDATION	329.004.00212	09JUN96 10JUN96 12JUN96	7, ., -16 8, ., -15 10, ., -13	12:00 Hrs 2 Days 14 Days	20 20 20	CON CON CON	MIL MIL SEV	NO NO NO	PSR No PSR No PSR No	No No No
	SLEEPINESS	329.003.00250	19APR96	37, -21, -38	Not Stated	40	CON	MOD	DCR	PSR No	No
		329.005.00333	01FEB97 21FEB97	10, ., -23 30, ., -3	7 Days Not Stated	20 20	CON CON	SEV SEV	NO NO	PSR Yes PSR No	No No
	SLEEPINESS (IN AM)	329.005.00300	01OCT96 12OCT96	13, ., -44 24, ., -33	11 Days Not Stated	20 20	CON CON	MOD SEV	NO NO	REL No REL No	No No
	SLEEPINESS IN AM	329.009.00329	14OCT96	6, ., -64	16 Days	20	CON	MIL	NO	REL No	No

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Number of Episodes [No. Epi]: CON = Continuous
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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Somnolence	SLEEPINESS WHEN TAKING EVENING MEDS	329.009.00170	21DEC95	45, -13, -200	14 Days	40	CON	MOD	NO	PSR No	No
	SLEEPY	329.003.00250	15MAR96	2, -56, -73	12 Days	20	CON	MIL	NO	PBU No	No
	SOMNOLENCE	329.003.00081	19DEC95	9, ., -50	23 Days	20	CON	MIL	NO	PSR No	No
		329.009.00201	26MAR96	50, ., -9	Not Stated	30	CON	MIL	NO	PSR No	No
	SOMNOLENCE DAYTIME	329.008.00271	15MAR96	5, -60, -250	52 Days	20	CON	MIL	NO	PSR No	No
Tremor	"SHAKINESS"	329.011.00283	05MAR96	27, -31, -31	6 Days	20	6	MIL	NO	PSR No	No
	HAND TREMORS	329.005.00109	20JAN95	22, -32, -116	12 Days	20	CON	MIL	NO	REL No	No
		329.005.00116	04MAR95	26, -33, -129	29 Days	20	CON	MIL	NO	REL No	No
		329.005.00336	08MAR97 13MAR97 04APR97	5, ., -53 10, ., -48 32, ., -26	4 Days 7 Days 13 Days	20 20 20	CON CON CON	MOD MIL MIL	NO NO NO	REL REL PSR	No No No
	HANDS TREMBLING INTERMITTENT	329.004.00015	10DEC94	3, -55, -200	14 Days	20	4	MOD	NO	REL No	No
	SHAKINESS OF WHOLE BODY	329.012.00025	24OCT95	1, ., -72	02:00 Hrs	20	CON	MIL	NO	PSR No	No
	SHAKY	329.008.00271	14MAY96	65, 1, -190	Not Stated	40	CON	MIL	NO	PSR No	No
	SHAKY TREMORS	329.009.00170	27JUN96	234, 177, -11	2 Days	20	CON	MOD	NO	PSR No	Yes
	SUBJECTIVE FEELINGS OF SHAKINESS	329.008.00271	03APR96	24, -41, -231	14 Days	20	3	MIL	DCR	PSR No	No

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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
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Tremor	TREMBLING JAW	329.001.00063	10NOV94	3, ., -45	7 Days	20	3	MIL NO	PSR No	No
	TREMOR (HANDS, HEAD, TEETH)	329.007.00309	15JUL96	1, -52, -254	47 Days	20	CON	MIL NO	PSR No	No
	TREMORS	329.001.00063	11DEC94	34, ., -14	Not Stated	20	3	MIL NO	PSR No	No
			329.004.00017	21APR95	31, -26, -207	11 Days	20	CON	MOD NO	REL No
			02MAY95	42, -15, -196	87 Days	30	CON	SEV NO	REL Yes	No
			28JUL95	129, 73, -109	40 Days	30	CON	MOD NO	REL No	No
			06SEP95	169, 113, -69	57 Days	30	CON	MIL NO	REL No	No
Vestibular Disorder	LEFT INNER EAR INFECTION	329.007.00268	01JUL96	92, 33, -170	10 Days	30	CON	MOD NO	UNR Yes	No
Withdrawal Syndrome	MIGRAINE HEADACHE {WITHDRAWAL SYMPTOM}	329.003.00248	29APR96	60, ., -3	6 Days	30	CON	SEV NO	REL Yes	Yes

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Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Respiratory System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Asthma	ASTHMA	329.009.00196	29JAN96	43, ., -27	Not Stated	30	CON	SEV	NO	UNR	Yes	No
	EXERCISE INDUCED ASTHMA	329.005.00257	01SEP96	175, 119, -64	Not Stated	30	CON	MOD	NO	UNR	Yes	No
Bronchitis	BRONCHITIS	329.007.00309	13SEP96	61, 9, -194	7 Days	20	CON	MOD	NO	UNR	Yes	No
		329.012.00220	26SEP96	102, 42, -57	37 Days	30	CON	MOD	NO	PBU	Yes	No
	BRONCHITIS WITH COUGH	329.005.00116	04MAR95	26, -33, -129	25 Days	20	CON	SEV	NO	UNR	Yes	No
Cough Increased	COUGH	329.003.00089	02APR95	27, ., -33	Not Stated	20	CON	MIL	NO	UNR	No	No
		329.004.00015	12DEC94	5, -53, -198	5 Days	20	CON	MIL	NO	UNR	Yes	No
		02FEB95	02FEB95	57, -1, -146	34 Days	20	CON	MOD	NO	UNR	Yes	No
		329.005.00116	22APR95	75, 17, -80	16 Days	20		5 MOD	NO	UNR	Yes	No
		329.005.00258	08MAR96	-4, ., -60	8 Days	0		1 MOD	NO	UNR	Yes	No
		329.005.00336	04APR97	32, ., -26	6 Days	20	CON	MOD	NO	UNR	Yes	No
		10APR97	10APR97	38, ., -20	3 Days	20	CON	MOD	NO	UNR	Yes	No
		329.011.00288	26JUL96	2, ., -41	Not Stated	20	CON	MIL	NO	UNR	Yes	No
Dyspnea	COUGHING	329.004.00017	23MAY95	63, 7, -175	15 Days	30	CON	MOD	NO	UNR	Yes	No
	SHORTNESS OF BREATH	329.005.00333	11FEB97	20, ., -13	3 Days	20		5 MIL	NO	PBU	No	No
		329.008.00160	20NOV95	20, -47, -261	8 Days	20	CON	MIL	NO	UNR	Yes	No
Epistaxis	NOSEBLEED	329.005.00299	12NOV96	158, 98, -6	10 Mins	20		1 MIL	NO	PSR	No	No
Larynx Disorder	LARYNGITIS	329.010.00278	01MAR96	22, -35, -218	4 Days	20		1 MIL	NO	UNR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Respiratory System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Pharyngitis	SORE THROAT	329.001.00063	05DEC94	28, ., -20	9 Days	20	CON	MOD	NO	UNR	Yes	No
		329.001.00068	27MAR95	48, ., -24	2 Days	40	CON	MOD	NO	UNR	Yes	No
		329.003.00091	21SEP95	182, 128, -63	11 Days	40	1	MOD	NO	UNR	Yes	No
		329.004.00015	02FEB95	57, -1, -146	34 Days	20	CON	MOD	NO	UNR	Yes	No
		329.004.00017	09NOV95	233, 177, -5	5 Days	20	CON	MOD	NO	UNR	No	No
		329.005.00004	29DEC94	81, 22, -22	2 Days	40	CON	MOD	NO	UNR	Yes	No
		329.005.00336	04APR97	32, ., -26	6 Days	20	CON	MOD	NO	UNR	Yes	No
		329.007.00310	19DEC96	85, 25, -186	11 Days	20	CON	MOD	NO	UNR	Yes	No
Respiratory Disorder	SORE THROAT SWALLOWING	329.008.00271	06APR96	27, -38, -228	11 Days	20	CON	MIL	NO	PBU	No	No
	THROAT PAIN	329.002.00319	09JUL96	71, 15, -174	16:00 Hrs	30	1	MIL	NO	UNR	No	No
	TONSILLITIS	329.005.00116	24JUN95	138, 80, -17	14 Days	30	CON	SEV	NO	UNR	Yes	No
	COLD SYMPTOMS	329.005.00119	27SEP95	79, 20, -62	4 Days	40	CON	MOD	NO	PBU	Yes	No
	COLD SYMPTOMS (SORE THROAT, COUGH)	329.012.00226	30NOV96	-3, ., -20	24 Days	0	CON	MIL	NO	UNR	No	No
	COLD SYNDROME (URI) {UPPER RESPIRATORY INFECTION}	329.009.00193	10DEC95	13, ., -58	18 Days	20	CON	MOD	NO	UNR	Yes	No
	COLD {SYMPTOMS}	329.003.00091	28APR95 20OCT95	36, -19, -209 211, 157, -34	5 Days 11 Days	40 40	1 CON	MIL MIL	NO NO	UNR UNR	Yes Yes	No No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Respiratory System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Respiratory Disorder	COLD {SYMPTOMS}	329.004.00214	17OCT96	14, -47, -74	4 Days	20	CON	MIL	NO	UNR	No	No
		329.005.00299	10SEP96	95, 35, -69	Not Stated	20	CON	MOD	NO	UNR	Yes	No
		329.006.00260	08OCT96	83, 25, -71	08:00 Hrs	30	1	MIL	NO	PBU	Yes	No
		329.009.00324	09DEC96	43, ., -30	8 Days	20	CON	MIL	NO	UNR	No	No
	FEVER, COLD SYMPTOMS, SORE THROAT	329.007.00145	21AUG96	224, 168, -2	3 Days	20	CON	MIL	NO	UNR	Yes	No
	HEAD COLD	329.002.00099	16MAR95	15, -41, -240	6 Days	20	CON	MIL	NO	UNR	Yes	No
	RHINITIS-COLD	329.004.00017	14SEP95	177, 121, -61	3 Days	30	CON	MIL	NO	UNR	Yes	No
	SORE THROAT (COLD SYMPTOM)	329.005.00257	18MAR96	8, -49, -231	9 Days	20	CON	MOD	NO	PBU	Yes	No
	STUFFY NOSE (COLD SYMPTOMS)	329.005.00257	18MAR96	8, -49, -231	9 Days	20	CON	MOD	NO	PBU	Yes	No
	UPPER RESPIRATORY ILLNESS	329.007.00309	30AUG96	47, -6, -208	9 Days	20	CON	MOD	NO	UNR	Yes	No
	UPPER RESPIRATORY INFECTION	329.005.00151	22OCT95	47, -11, -192	17 Days	20	CON	MOD	NO	UNR	Yes	No
		329.007.00294	02APR97	34, ., -8	6 Days	20	CON	MIL	NO	UNR	Yes	No
	URI (UPPER RESPIRATORY INFECTION)	329.007.00309	26JUL96	12, -41, -243	21 Days	20	CON	MIL	NO	UNR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Respiratory System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Respiratory Disorder	VIRAL UPPER RESPIRATORY INFECTION	329.001.00068	27FEB95	20, ., -52	7 Days	20	CON	MOD	NO	UNR	Yes	No
Rhinitis	"STUFFY" NOSE	329.005.00333	23JAN97	1, ., -32	Not Stated	20	CON	MOD	NO	UNR	No	No
	CONGESTION (NASAL)	329.010.00280	15MAY96	-2, -57, -75	2 Days	0	1	MIL	NO	UNR	Yes	No
	CONGESTION {NOSE}	329.007.00309	04DEC96	143, 91, -112	5 Days	20	CON	MOD	NO	UNR	Yes	No
	NASAL CONGESTION	329.004.00015	11DEC94 02FEB95	4, -54, -199 57, -1, -146	10 Days 34 Days	20 20	CON CON	MIL MOD	NO NO	UNR UNR	Yes Yes	No No
		329.007.00142	30NOV95	44, ., -4	1 Days	40	1	MIL	NO	UNR	Yes	No
		329.007.00145	01FEB96	22, -35, -204	2 Days	20	1	MIL	NO	UNR	Yes	No
		329.007.00310	19DEC96	85, 25, -186	12 Days	20	CON	MOD	NO	UNR	Yes	No
		329.009.00201	07APR96	62, ., 3	3 Days	20	CON	MOD	NO	UNR	Yes	No
	RHINITIS	329.004.00017	09NOV95	233, 177, -5	5 Days	20	CON	MOD	NO	UNR	No	No
	STUFFY NOSE	329.002.00099	29MAR95	28, -28, -227	16:00 Hrs	20	CON	MIL	NO	UNR	Yes	No
		329.005.00336	10APR97	38, ., -20	3 Days	20	CON	MOD	NO	UNR	Yes	No
Sinusitis	COLD-SINUS SYMPTOMS	329.006.00038	22FEB95	8, ., -49	10 Days	20	CON	MIL	NO	UNR	No	No
	SINUS CONGESTION	329.007.00310	05OCT96	10, -51, -261	25 Days	20	CON	MOD	NO	PBU	Yes	No
		329.009.00240	11FEB97	29, ., -22	14 Days	20	CON	MIL	NO	UNR	No	No
	SINUS INFECTION	329.005.00257	24MAR96	14, -43, -225	7 Days	20		MOD	NO	PBU	Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Respiratory System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Sinusitis	SINUS INFECTION	329.005.00257	14APR96	35, -22, -204	37 Days	20	CON	MOD	NO	PBU	Yes	No
		329.009.00130	04SEP95	140, 84, -42	10 Days	20	CON	MOD	NO	PBU	Yes	No
		329.009.00196	29JAN96	43, ., -27	Not Stated	30	CON	MOD	NO	PBU	Yes	No
	SINUSITIS	329.009.00130	25APR95	8, -49, -174	10 Days	20	CON	MOD	NO	PBU	Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Skin and Appendages -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Acne	ACNE	329.010.00280	16JUN96	31, -25, -43	Not Stated	20	CON	MIL	NO	PSR	No
	ACNE WORSE	329.001.00121	12APR95	9, -48, -145	21 Days	20	CON	MIL	NO	PBU	No
	ACNE-FACIAL	329.009.00131	30MAY95	29, -28, -89	Not Stated	20	CON	MOD	NO	PSR	Yes
Contact Dermatitis	POISON IVY	329.005.00116	17JUN95	131, 73, -24	26 Days	30	CON	SEV	STP	UNR	Yes
Fungal Dermatitis	RINGWORM	329.007.00140	13OCT95	29, -27, -40	21 Days	20	CON	MIL	NO	UNR	No
Photosensitivity	SUNBURN	329.007.00310	01MAY97	218, 158, -53	8 Days	20	CON	MOD	NO	UNR	Yes
	SUNBURN, APPROPRIATE TO DEGREE OF EXPOSURE (BEACH)	329.002.00055	13JUL94	20, -36, -136	3 Days	20	1	MIL	NO	UNR	No
Rash	BILATERAL ERYTHEMATOUS EYELIDS	329.009.00240	11FEB97	29, ., -22	8 Days	20	CON	MIL	NO	UNR	No
	BLOTCHES (RED) ON LEGS	329.005.00333	10FEB97	19, ., -14	3 Days	20	CON	MOD	NO	PSR	No
	RASH	329.009.00324	27DEC96	61, ., -12	20 Days	20	CON	MOD	STP	REL	No
	RASH ON ARMS (RED, DRY, ITCHY)	329.004.00214	01DEC96	59, -2, -29	10:00 Hrs	20	CON	MIL	NO	PBU	No
Skin Disorder	COLD, CLAMMY LIGHTHEADEDNESS [COLD, CLAMMY]	329.008.00271	05APR96	26, -39, -229	15 Mins	20	1	MIL	DCR	PSR	No
Sweating	SWEATING INCREASED	329.009.00133	07JUL95	25, ., -20	Not Stated	20	CON	MOD	NO	PSR	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Skin and Appendages -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Urticaria	HIVES - BOTH ARMS BOTH LEGS AND STOMACH AREA (QUESTIONABLE)	329.005.00002	13JUN94	20, -37,-127	2 Days	20	CON	MIL NO	PSR No	No

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Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Special Senses -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Abnormal Vision	BLURRED VISION	329.005.00299	24OCT96	139, 79, -25	6 Days	30	CON	MIL	NO	PBU	No
			05NOV96	151, 91, -13	8 Days	20	CON	MOD	NO	PSR	No
		329.012.00220	25JUN96	9, -52, -150	2 Days	20	CON	MIL	NO	REL	No
Conjunctivitis	CONJUNCTIVITIS BILATERAL	329.004.00015	08DEC94	1, -57, -202	11 Days	20	CON	MOD	NO	UNR	Yes
			03JAN95	27, -31, -176	12 Days	20	CON	MOD	NO	UNR	Yes
	DRY ITCHY EYES	329.008.00271	07APR96	28, -37, -227	2 Days	20	CON	MIL	NO	PSR	No
	ITCHY EYES	329.012.00231	23APR97	48, -14, -117	4 Days	20	CON	MIL	NO	PBU	No
Ear Pain	EARACHE	329.007.00309	06JAN97	176, 124, -79	8 Days	20	CON	MIL	NO	UNR	Yes
			05DEC94	28, ., -20	9 Days	20	CON	MOD	NO	UNR	Yes
Otitis Externa	SWIMMER'S EAR	329.005.00257	31JUL96	143, 87, -96	3 Days	30	CON	MOD	NO	PBU	Yes
Otitis Media	EAR INFECTION	329.007.00268	10APR96	10, -50, -252	5 Days	20	CON	MOD	NO	UNR	Yes
			04MAR95	26, -33, -129	25 Days	20	CON	SEV	NO	UNR	Yes
			21JUN96	82, 23, -180	9 Days	30	CON	MOD	NO	UNR	Yes

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Urogenital System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Albuminuria	PROTEIN IN URINE	329.005.00151	31JAN96	148, 91, -91	92 Days	30	CON	MOD	NO	PBU No	No
Amenorrhea	AMENORRHEA	329.003.00075	01FEB95	8, -49, -232	161 Days	20	CON	MOD	NO	PSR No	No
Breast Enlargement	INCREASE IN BREAST SIZE {FEMALE}	329.008.00160	27NOV95	27, -40, -254	Not Stated	20	CON	MIL	NO	PSR No	No
Cystitis	BLADDER INFECTION	329.012.00222	18JUL96	21, -43, -65	4 Days	20	CON	MIL	NO	UNR Yes	No
Dysmenorrhea	DYSMENORRHEA	329.009.00170	07JUL96	244, 187, -1	Not Stated	20	CON	MIL	NO	UNR Yes	No
	MENSTRUAL CRAMPS	329.004.00015	17APR95	131, 74, -72	30 Mins	20	CON	1 MOD	NO	UNR Yes	No
		329.005.00116	28MAY95	111, 53, -44	3 Days	20	CON	SEV	NO	UNR Yes	No
		329.007.00309	16AUG96	33, -20, -222	4 Days	20	CON	MOD	NO	UNR Yes	No
		PREMENSTRUAL CRAMPS	329.004.00015	29JAN95	53, -5, -150	02:00 Hrs	20	CON	1 MOD	NO	UNR Yes
Female Genital Disorders	ANORGASMIA {FEMALE}	329.003.00075	25JAN95	1, -56, -239	57 Days	20	CON	SEV	DCR	REL No	No
			23MAR95	58, 2, -182	56 Days	20	CON	MIL	NO	REL No	No
Haematuria	RBC IN URINE (PT MENSTRUATING WHEN SAMPLE TAKEN)	329.005.00257	21OCT96	225, 169, -14	Not Stated	30	CON	MOD	NO	UNR No	No
Urinary Casts	COURSE GRANULAR CASTS HYALINE CAST IN URINE	329.005.00151	31JAN96	148, 91, -91	92 Days	30	CON	MOD	NO	PBU No	No
Urinary Tract Infection	YEAST INFECTION (SQUAMOUS EPITHELIAL CELLS IN URINE)	329.005.00257	15OCT96	219, 163, -20	Not Stated	30	CON	MOD	NO	PBU No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PAROXETINE Body System=Urogenital System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Urinary Tract Infection	[URINARY INFECTION QUESTIONABLE]	329.012.00025	19DEC95	57, ., -16	9 Days	40	CON	MIL NO	UNR No	No
Urine Abnormality	ABNORMAL URINALYSIS	329.010.00280	21AUG96	97, 42, 23	Not Stated	0	CON	MIL NO	UNR No	No
	ABNORMAL URINE ROUTINE & MICROSCOPIC (URINALYSIS)	329.005.00258	07MAY96	57, ., 0	Not Stated	30	CON	MOD NO	PBU No	No
	CLOUDY URINE ON URINALYSIS	329.001.00068	05APR95	57, ., -15	Not Stated	40	CON	MIL NO	UNR No	No

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Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Abdominal Pain	STOMACH ACHE	329.002.00103	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR No	No
		329.002.00322	21JAN97	13, ., -33	02:00 Hrs	100	1	MOD	NO	PBU No	No
	329.003.00092	22DEC95	234, 176, -27	02:00 Hrs	200	1	MIL	NO	PBU No	No	
	329.005.00255	05MAR96	2, ., -69	04:00 Hrs	50	1	MOD	NO	PBU No	No	
	329.009.00194	19DEC95	15, -42, -169	181 Days	150	CON	MOD	NO	REL Yes	No	
	329.010.00281	18DEC96	146, 85, -32	2 Days	300	CON	MIL	NO	PBU No	No	
	329.011.00208	16SEP96	11, -49, -68	03:00 Hrs	100	1	MIL	NO	UNR No	No	
	20SEP96	15, -45, -64	3 Days	150	6	MIL	NO	PBU No	No		
	STOMACH ACHE FOLLOWING INGESTION OF MEDS	329.002.00103	21APR95	2, -55, -126	21 Days	50	14	MIL	NO	PSR No	No
	STOMACH ACHE FOLLOWING INGESTION OF STUDY MEDS	329.002.00103	20JUN95	62, 6, -66	52 Days	250	2	MIL	NO	PSR No	No
	STOMACH ACHE, RE-OCCURRING	329.002.00322	06FEB97	29, ., -17	Not Stated	200		MIL	NO	PSR No	No
	STOMACH ACHES	329.002.00243	21MAR96	8, ., -15	Not Stated	100	CON	MIL	NO	REL No	No
	STOMACH CRAMPS	329.003.00092	21MAY95	19, -40, -242	30 Mins	150	2	MIL	NO	PBU No	No
	10JUN95	39, -20, -222	1 Days	200	1	MOD	NO	PBU Yes	No		
STOMACH PAIN	329.010.00279	02OCT96	195, 139, -51	6 Days	300	5	MOD	DCR	PBU No	No	
STOMACH PAINS	329.010.00279	30SEP96	193, 137, -53	02:00 Hrs	300	CON	MIL	NO	PSR Yes	No	

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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
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Abnormal Laboratory Value	TOXIC IMIPRAMINE LEVEL	329.011.00208	07NOV96	63, 4, -16	Not Stated	300		MIL STP	REL No	No
Accidental Overdose	TRICYCLIC TOXICITY	329.008.00273	09SEP96	116, 53, 0	8 Days	300		SEV STP	REL No	Yes
Allergic Reaction	ALLERGY	329.003.00317	14JAN97	27, ., -43	24:00 Hrs	200	CON	MIL NO	PBU Yes	No
Asthenia	FATIGUE	329.006.00040	22FEB95	7, ., -7	8 Days	50	CON	SEV STP	REL No	No
		329.008.00272	04APR96	2, -55, -167	Not Stated	50	CON	MIL NO	PSR No	No
		329.009.00134	10JUL95	5, ., -61	65 Days	50	CON	MIL NO	PSR No	No
		329.009.00137	14NOV95	36, ., -32	22 Days	200	CON	MOD NO	PSR No	No
		329.010.00281	05DEC96	133, 72, -45	20 Days	300	CON	MOD NO	PSR No	No
		24DEC96	152, 91, -26	30 Days	300	CON	SEV STP	PSR No	No	
		329.002.00244	22MAR96	2, -56, -82	14 Days	50	CON	MIL NO	PSR No	No
	FEELS MORE TIRED AFTER TAKING MEDS	329.002.00244	22MAR96	2, -56, -82	14 Days	50	CON	MIL NO	PSR No	No
	TIRED	329.003.00247	30APR96	90, 36, -21	1 Days	200	1	MIL NO	UNR No	No
	TIREDNESS AND DROWSINESS	329.002.00243	14MAR96	1, ., -22	Not Stated	50	CON	MOD NO	PSR No	No
	WEAKNESS	329.004.00215	30APR97	42, ., 2	Not Stated	200	CON	MOD STP	REL No	No
Back Pain	BACK PAIN	329.005.00153	23JAN96	-2, -58, -237	04:00 Hrs	0	1	MIL NO	UNR Yes	No
		329.003.00317	07JAN97	20, ., -50	27 Days	150	3	MIL NO	PSR No	No
		329.005.00256	17MAR96	13, -44, -122	4 Days	100	CON	MOD NO	UNR Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Chest Pain	CHEST PAIN	329.005.00295	15APR96	19, ., -50	2 Days	150	2	MOD NO	PSR No	No
		329.007.00139	17MAY95	10, ., -8	8 Days	50	4	MOD STP	PSR No	No
		329.009.00195	04JAN96	21, ., -15	19 Days	200	2	MOD NO	PSR No	No
	CHEST PAIN WHEN TAKING MEDS	329.009.00127	17APR95	8, ., -39	45 Days	100	CON	MIL NO	PBU No	No
	CHEST PAIN, CHEST TIGHTNESS	329.007.00270	19JUN96	42, ., -1	03:00 Hrs	200	1	SEV STP	PSR No	Yes
			20JUN96	43, ., 0	05:00 Hrs	200	CON	MIL STP	PSR No	No
Chills	CHILLS	329.009.00325	10OCT96	45, -11, -79	40 Days	200	CON	MOD NO	UNR Yes	No
	CHILLS / GOOSE BUMPS WHILE EXERCISING (1X)	329.002.00103	08MAY95	19, -38, -109	2 Mins	150	CON	MIL NO	PSR No	No
	CHILLS-INCREASED AND DECREASED BACK AND ARMS-NO FEVER	329.005.00117	18MAR95	1, ., -69	31 Days	50	11	MOD NO	PSR No	No
	FEELING HOT/COLD	329.002.00103	23MAY95	34, -23, -94	8 Days	200	CON	MOD NO	PSR No	No
Fever	FEVER	329.002.00050	23MAR95	1, ., -34	6 Days	50	CON	MOD NO	PBU Yes	No
		329.005.00256	05MAR96	1, -56, -134	2 Days	50	1	MOD NO	PBU No	No
Headache	HEAD PAIN	329.009.00195	02JAN96	19, ., -17	21 Days	200	20	MOD NO	PSR No	No
	HEADACHE	329.001.00066	23NOV94	2, ., -20	5 Days	50	2	MIL NO	PSR No	No
		329.002.00050	23MAR95	1, ., -34	5 Days	50	CON	MIL NO	PBU Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Headache	HEADACHE	329.003.00082	02JAN96	23, ., -15	04:00 Hrs	100	1	MOD	NO	PSR	No
			17JAN96	38, ., 0	Not Stated	250	CON	MIL	NO	PSR	No
		329.003.00090	16MAR95	3, ., -66	13 Days	50	CON	SEV	DCR	PSR	Yes
		329.003.00249	07MAR96	1, ., -61	3 Days	50	2	MIL	NO	PSR	Yes
		329.004.00211	23FEB96	22, ., -27	Not Stated	200	CON	MOD	NO	PBU	Yes
		329.004.00215	25MAR97	6, ., -34	2 Days	50	1	MIL	NO	UNR	No
			01APR97	13, ., -27	30 Days	100	CON	MIL	NO	PSR	No
		329.005.00003	23SEP94	4, ., -11	03:00 Hrs	50	1	MOD	NO	PSR	No
		329.005.00007	07MAY95	180, 117, -12	03:30 Hrs	250	CON	MOD	NO	UNR	Yes
		329.005.00009	16DEC94	5, ., -68	4 Days	50	3	MOD	NO	PSR	Yes
			01JAN95	21, ., -52	04:00 Hrs	150	1	SEV	NO	PSR	Yes
		329.005.00113	31JAN95	2, ., -30	03:45 Hrs	50	1	SEV	NO	UNR	Yes
		329.005.00117	25APR95	39, ., -31	Not Stated	200	CON	SEV	NO	PBU	No
		329.005.00118	09JUN95	24, ., -26	02:00 Hrs	200	2	MOD	NO	PBU	No
		329.005.00153	10FEB96	17, -40, -219	05:00 Hrs	150	CON	MIL	NO	PBU	Yes
			21FEB96	28, -29, -208	03:00 Hrs	200	CON	MIL	NO	PBU	Yes
			02MAR96	38, -19, -198	03:30 Hrs	250	CON	MIL	NO	UNR	Yes
			21MAR96	57, 1, -179	28 Days	250	3	MOD	NO	UNR	Yes
			17APR96	84, 28, -152	57 Days	300	9	MIL	NO	UNR	Yes
		329.005.00255	12JUN96	140, 84, -96	55 Days	300	3	MIL	NO	UNR	Yes
		329.005.00255	04MAR96	1, ., -70	22 Days	50	16	MOD	NO	PSR	Yes

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Headache	HEADACHE	329.005.00256	05MAR96	1, -56, -134	3 Days	50	1	MOD	NO	PBU	Yes	No
			17MAR96	13, -44, -122	4 Days	100	CON	MOD	NO	UNR	Yes	No
		329.005.00295	18APR96	22, ., -47	03:30 Hrs	200	CON	MIL	NO	PBU	No	No
			05MAY96	39, ., -30	04:30 Hrs	200	CON	MOD	NO	PSR	No	No
		329.005.00297	10MAY96	22, ., -4	02:00 Hrs	150	2	MOD	NO	PSR	Yes	No
		329.005.00335	27FEB97	-1, ., -68	03:30 Hrs	0	CON	MOD	NO	PBU	Yes	No
			10MAR97	11, ., -57	03:30 Hrs	100	CON	MIL	NO	UNR	No	No
			17MAR97	18, ., -50	4 Days	150	6	MOD	NO	UNR	No	No
			21MAR97	22, ., -46	6 Days	200	5	MOD	NO	UNR	No	No
			30MAR97	31, ., -37	4 Days	250	3	MOD	NO	UNR	No	No
			11APR97	43, ., -25	04:00 Hrs	200	CON	SEV	NO	PBU	Yes	No
		22APR97	54, ., -14	03:30 Hrs	200	CON	MOD	NO	PBU	Yes	No	
		329.006.00041	23AUG95	141, 77, -104	1 Days	300	1	SEV	NO	PBU	Yes	No
		329.007.00270	24JUN96	47, ., 4	2 Days	200	CON	MOD	NO	UNR	No	No
		329.009.00132	18JUN95	27, -31, -140	3 Days	200	CON	MIL	NO	UNR	No	No
		329.009.00137	17NOV95	39, ., -29	4 Days	200		MIL	NO	PSR	No	No
		329.009.00239	18FEB97	92, 35, -55	Not Stated	200	CON	MIL	NO	PSR	No	No
329.010.00279	01APR96	11, -46, -235	03:00 Hrs	100	1	MOD	NO	PBU	Yes	No		
329.010.00281	03SEP96	40, -22, -138	16:00 Hrs	250	1	MOD	NO	PSR	Yes	No		
	18DEC96	146, 85, -32	2 Days	300	CON	MIL	NO	PBU	Yes	No		
329.011.00163	23NOV95	-2, ., -29	04:00 Hrs	0	1	MIL	NO	UNR	Yes	No		
	28NOV95	4, ., -24	18:00 Hrs	50	1	MOD	NO	PBU	Yes	No		

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Headache	HEADACHE	329.011.00284	21APR96	31, -26, -107	01:00 Hrs	200	1	MOD	NO	PBU Yes	No
			07JUN96	78, 22, -60	01:00 Hrs	250	CON	MIL NO	PBU Yes	No	
		329.012.00230	31MAR97	32, -38, -56	1 Days	200	CON	MIL NO	PBU Yes	No	
		329.005.00332	16DEC96	5, ., -67	30 Mins	50	CON	MIL NO	PSR No	No	
		329.009.00134	12AUG95	38, ., -28	Not Stated	200		MIL NO	PSR Yes	No	
		329.002.00098	21FEB95	50, ., -23	9 Days	250	CON	MOD DCR	PSR No	No	
		329.003.00090	11APR95	29, ., -40	15 Days	200	CON	MIL NO	PSR Yes	No	
			26APR95	44, ., -25	9 Days	250	CON	MOD DCR	PSR Yes	No	
			05MAY95	53, ., -16	1 Days	200	3	MIL NO	PSR Yes	No	
			329.003.00289	28FEB96	1, -56, -237	85 Days	50		MIL NO	PBU No	No
			329.003.00317	19DEC96	1, ., -69	48 Days	50	7	MIL NO	PSR Yes	No
			329.004.00013	20JUL94	2, -58, -246	5 Days	50	CON	SEV NO	REL No	No
			329.004.00215	01MAY97	43, ., 3	Not Stated	200	CON	SEV STP	REL Yes	No
			329.005.00009	22DEC94	11, ., -62	6 Days	100	3	SEV NO	PSR Yes	No
			329.005.00255	24MAR96	21, ., -50	9 Days	150	4	MOD NO	PBU No	No
		329.005.00295	21MAR96	-7, ., -75	1 Days	0	1	MOD NO	UNR Yes	No	
		329.007.00307	04JUL96	50, ., 14	Not Stated	0	20	MOD NO	UNR No	No	
		329.009.00199	13MAR96	58, ., -13	Not Stated	200	5	MIL NO	PBU No	No	

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int ion	Act- ion	Inv Corr Rel Ther	SAE
Headache	HEADACHES	329.009.00325	10OCT96	45, -11, -79	40 Days	200	CON	MOD	NO	PBU Yes	No
	HEADACHES (SEVERE)	329.012.00221	10SEP96	78, 15, -54	06:00 Hrs	200	1	SEV	NO	PBU Yes	No
	MODERATE HEADACHE	329.012.00227	05JAN97	19, -51, -241	52 Days	100	5	MOD	NO	PSR No	No
	OCCASIONAL HEADACHE	329.009.00127	12APR95	3, ., -44	Not Stated	50		MIL	NO	PSR No	No
	SEVERE HEADACHES	329.012.00227	24DEC96	7, -63, -253	07:00 Hrs	50	2	SEV	NO	PSR No	No
	SOMATIC COMPLAINT HEADACHE	329.005.00255	29APR96	57, ., -14	Not Stated	200		MOD	NO	PSR No	No
Infection	FLU	329.003.00314	15NOV96	25, ., -52	3 Days	200	1	MIL	NO	UNR Yes	No
		329.010.00279	01MAY96	41, -16, -205	3 Days	300	CON	MIL	NO	PBU No	No
	GI VIRUS-NAUSEA, VOMITING AND DIARRHEA	329.005.00007	10DEC94	32, -32, -160	4 Days	200	CON	SEV	NO	UNR No	No
	INCREASED SWEATING (VIRAL SYNDROME)	329.009.00301	09APR96	22, -35, -75	20 Mins	150	CON	MIL	NO	PBU No	No
	NAUSEA (VIRAL SYNDROME)	329.009.00301	09APR96	22, -35, -75	1 Days	150	CON	MIL	NO	PBU No	No
	NAUSEA, VOMITING, DIARRHEA, FLU	329.005.00007	30DEC94	52, -12, -140	2 Days	250	CON	SEV	NO	UNR No	No
	STREP THROAT	329.002.00104	21DEC95	232, 176, -27	11 Days	300	1	MOD	NO	UNR Yes	No
	STREP THROAT/FEVER/SORE THROAT	329.005.00006	26NOV94	23, -38, -152	5 Days	150	CON	SEV	NO	UNR Yes	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Infection	VOMITING(VIRAL SYNDOME)	329.009.00301	09APR96	22, -35, -75	1 Days	150	CON	MIL NO	PBU No	No
Trauma	DIZZINESS - (HIT HEAD DURING FALL)	329.002.00243	17MAR96	4, ., -19	Not Stated	50	CON	MOD STP	PSR No	No
	FOOT PAIN{INJURY}	329.007.00269	21APR96	11, ., -4	2 Days	100	CON	MIL NO	UNR Yes	No
	MOUTH CUTS	329.004.00211	20MAR96	48, ., -1	Not Stated	200	CON	SEV STP	REL Yes	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Cardiovascular System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Arrhythmia	ORTHOSTATIC CHANGES [IRREGULAR PULSE]	329.002.00322	13FEB97	36, ., -10	Not Stated	200	CON	MOD STP	PSR No	No
Av Block	1ST DEGREE AV BLOCK	329.009.00203	26MAR96	23, ., -10	Not Stated	150	CON	MOD STP	REL No	No
	INCREASED PR INTERVAL (PER EKG)	329.009.00262	07MAR97	19, ., -50	11 Days	200	CON	MIL NO	PSR No	No
Bradycardia	SINUS BRADYCARDIA PER EKG	329.009.00239	12MAY97	175, 118, 28	Not Stated	0	CON	MIL NO	PBU No	No
Bundle Branch Block	PROLONGED QRS DURATION	329.010.00281	18SEP96	55, -7, -123	15 Days	300	CON	MIL NO	REL No	No
Electrocardiogram Abnormal	EKG CHANGE	329.005.00335	03APR97	35, ., -33	1 Days	200	CON	MOD DCR	REL No	No
	LOW OR NEGATIVE T WAVES	329.007.00269	18APR96	8, ., -7	15 Days	100	CON	MIL STP	REL No	No
	NONSPECIFIC T-WAVE ABNORMALITY (PER EKG) BASELINE ARTIFACT	329.009.00264	23DEC96	53, ., -12	Not Stated	200	CON	MIL NO	PSR No	No
	POSITIVE/NEGATIVE RIGHT AXIS DEVIATION (EKG)	329.009.00305	10JAN97	249, 192, -12	19 Days	200	CON	MIL NO	PBU No	No
Extrasystoles	CARIDAC ARRHYTHMIA [PREMATURE VENTRICULAR CONTRACTIONS]	329.009.00195	08JAN96	25, ., -11	15 Days	150	CON	MOD STP	REL No	No
	PVC'S ON EKG [PREMATURE VENTRICULAR CONTRACTIONS]	329.001.00122	27JUN95	8, -50, -174	9 Days	100	CON	MIL NO	PBU No	No

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Cardiovascular System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int ion	Act- ion	Inv Rel	Corr Ther	SAE
Heart Malformation	POSSIBLE RIGHT ATRIAL ENLARGEMENT (PER EKG)	329.009.00262	17MAR97	29, ., -40	15 Days	200	CON	MIL	NO	PSR	No	No
Hypertension	HIGH BLOOD PRESSURE	329.003.00290	20MAR96	10, ., -2	15 Days	100	CON	MIL	STP	PSR	No	No
	HYPERTENSION	329.012.00223	30SEP96	32, ., -12	Not Stated	200	CON	MOD	NO	UNR	No	Yes
		329.012.00227	25APR97	129, 60, -131	117 Days	300		MOD	NO	PBU	No	No
Migraine	MIGRAINE HEADACHE	329.005.00118	20MAY95	4, ., -46	04:00 Hrs	50	CON	SEV	NO	UNR	No	No
Palpitation	HEART WAS POUNDING	329.005.00113	19FEB95	21, ., -11	30 Mins	150		1 MOD	NO	REL	No	No
	PALPITATIONS	329.005.00153	02FEB96	9, -48, -227	9 Days	100		MIL	NO	PSR	No	No
		329.009.00203	24MAR96	21, ., -12	Not Stated	150	CON	MOD	NO	PSR	No	No
Postural Hypotension	POSTURAL HYPOTENSION	329.009.00134	11AUG95	37, ., -29	33 Days	200		3 MOD	NO	PSR	No	No
	DIZZINESS WHEN STANDING UP ORTHOSTATIC HYPOTENSION	329.003.00247	09FEB96	9, -46, -102	33 Days	100	CON	MIL	NO	PSR	No	No
	DIZZINESS WITH ORTHOSTATIC HYPOTENSION	329.002.00050	30MAR95	8, ., -27	6 Days	100	CON	MIL	STP	PSR	No	No
	DIZZINESS-POSTURAL HYPOTENSION (ONLY IN GYM CLASSES)	329.005.00007	01DEC94	23, -41, -169	14 Days	150		1 MOD	NO	REL	No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Cardiovascular System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Postural Hypotension	MILD OTHOSTATIC STATE (1X) (DUE TO BLOOD DRAW) {ORTHOSTATIC HYPOTENSION}	329.009.00262	14APR97	57, ., -12	5 Mins	200	CON	MIL NO	PSR No	No
	ORTHOSTATIC HYPOTENSION	329.002.00243	28MAR96	15, ., -8	Not Stated	150	CON	MIL NO	PSR No	No
		329.003.00088	12MAR95	13, ., -28	1 Days	100	1	MIL NO	PSR No	No
		329.004.00211	12FEB96	11, ., -38	7 Days	100	CON	MIL NO	PSR No	No
		19FEB96	18, ., -31	15 Days	150	CON	MOD NO	REL No	No	
		05MAR96	33, ., -16	Not Stated	200	CON	MIL NO	REL No	No	
		329.004.00215	01APR97	13, ., -27	21 Days	100	CON	MOD NO	REL No	No
		22APR97	34, ., -6	11 Days	200	CON	MIL NO	REL No	No	
		329.007.00270	01JUN96	24, ., -19	4 Days	200	5	MIL NO	PSR No	No
		329.012.00230	18APR97	50, -20, -38	19 Days	200		MIL NO	PBU No	No
	ORTHOSTATIC SYMPTOMS {ORTHOSTATIC HYPOTENSION}	329.003.00073	03FEB95	16, ., -29	Not Stated	150	CON	MOD NO	PSR No	No
	POSTURAL HYPOTENSION	329.001.00067	30NOV94	9, ., -13	Not Stated	100	CON	MOD STP	PSR No	No
Qt Interval Prolonged	INCREASED QT/{CORRECTED}QTC RATIO	329.009.00134	29AUG95	55, ., -11	15 Days	150	CON	MOD STP	REL No	No
	PROLONGED QT-QUANTITATIVE TIP CULTURES	329.009.00203	26MAR96	23, ., -10	Not Stated	150	CON	MOD STP	REL No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Cardiovascular System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Qt Interval Prolonged	WIDENED CORRECTED QT {INTERVAL} QRS	329.001.00061	01SEP94	35, ., -13	Not Stated	200	CON	MIL STP	REL No	No
Syncope	BLACKOUTS	329.009.00134	11AUG95	37, ., -29	33 Days	200	3	MOD NO	PSR No	No
	DIZZINESS WITH SYNCOPE	329.009.00325	01SEP96	6, -50, -118	1 Days	50	CON	MIL NO	PSR No	No
	FAINTNESS UPON STANDING	329.001.00070	10MAR95	17, ., -14	Not Stated	150	3	MIL NO	PSR No	No
	LIGHTHEADED FAINT SYNCOPE	329.006.00041	22APR95	18, -47, -227	1 Mins	150	1	MIL NO	PSR No	No
Tachycardia	SYNCOPE	329.012.00227	23MAR97	96, 27, -164	161 Days	300		MIL NO	PBU No	No
	"RACING HEART"	329.005.00003	23SEP94	4, ., -11	12 Days	50	4	MOD NO	PBU No	No
	ELEVATED HEART RATE	329.006.00040	01MAR95	14, ., 0	14 Days	50	CON	MOD STP	REL No	No
	ELEVATED PULSE	329.009.00239	25NOV96	7, -51, -140	141 Days	100	CON	MIL NO	REL No	No
	HEART RACING (BEATS HARD)	329.001.00122	12SEP95	85, 28, -97	30 Days	200	2	MIL NO	REL No	No
	HEART RATE INCREASE	329.002.00050	23MAR95	1, ., -34	22 Days	50	CON	MOD STP	PSR No	No
	INCREASE IN PULSE (SECONDARY TO ALUPENT)	329.009.00301	23APR96	36, -21, -61	15 Mins	200	CON	MOD NO	PBU No	No
	INCREASED HEART RATE	329.001.00066	05DEC94	14, ., -8	Not Stated	100	CON	MOD STP	REL No	No
		329.002.00056	02AUG94	15, ., -21	22 Days	150	CON	MIL STP	PSR No	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Cardiovascular System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Tachycardia	INCREASED HEART RATE	329.005.00117	10APR95	24, ., -46	22 Days	200	CON	MOD	NO	PSR No	No
		329.009.00264	11NOV96	11, ., -54	Not Stated	150	CON	MIL	NO	PSR No	No
	INCREASED PULSE ON EXERTION	329.005.00153	26FEB96	33, -24, -203	4 Days	250	4	MIL	NO	PSR No	No
	PULSE {INCREASED} 2 CONSECUTIVE WEEKS	329.001.00070	08MAR95	15, ., -16	Not Stated	150	CON	SEV	STP	REL No	No
	QUESTIONABLE INCREASED HEART RATE QUESTIONABLE TACHYCARDIA	329.005.00113	19FEB95	21, ., -11	30 Mins	150	1	MOD	NO	REL No	No
	RACING HEARTBEAT	329.005.00003	30SEP94	11, ., -4	5 Days	100	2	MOD	STP	REL No	No
	SINUS TACHYCARDIA	329.009.00264	23DEC96	53, ., -12	Not Stated	200	CON	MIL	NO	PSR No	No
	TACHYCARDIA	329.003.00290	20MAR96	10, ., -2	Not Stated	100	CON	MIL	STP	PSR No	No
		329.007.00269	18APR96	8, ., -7	15 Days	100	CON	MIL	STP	REL No	No
		329.009.00134	11AUG95	37, ., -29	33 Days	200		MOD	NO	PSR No	No
		329.009.00172	14NOV95	2, -56, -249	14 Days	50	2	MIL	NO	PBU No	No
		329.009.00325	23OCT96	58, 3, -66	27 Days	200		MOD	NO	PSR No	No
		329.009.00326	30SEP96	26, -28, -89	Not Stated	200	CON	MIL	NO	PSR No	No
	TACHYCARDIA INCREASED PULSE	329.005.00153	03FEB96	10, -47, -226	8 Days	100		MIL	NO	PSR No	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Cardiovascular System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Vasodilatation	FACIAL FLUSHING	329.009.00195	25DEC95	11, ., -25	29 Days	100	CON	MOD NO	PSR No	No
	FLUSHED FACE	329.005.00255	11MAR96	8, ., -63	04:00 Hrs	100	1	MOD NO	PSR No	No
	FLUSHED FACE-NO HIVES	329.005.00117	18MAR95	1, ., -69	4 Days	50	3	MIL NO	PSR No	No
	HOT FLASHES	329.001.00070	01MAR95	8, ., -23	Not Stated	100	2	MIL NO	PBU No	No
		329.005.00256	23MAR96	19, -38, -116	3 Days	150	2	MOD NO	PSR No	No
	HOT FLASHES (FACIAL FLUSHING)	329.009.00203	24MAR96	21, ., -12	Not Stated	150	CON	MOD NO	PSR No	No

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Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Constipation	CONSTIPATED	329.004.00014	02DEC94	4, ., -11	Not Stated	50	CON	MOD NO	REL No	No
	CONSTIPATION	329.001.00122	05JUL95	16, -42, -166	4 Days	150	CON	MIL NO	PSR No	No
			14JUL95	25, -33, -157	19 Days	200	CON	MIL NO	PSR No	No
	329.002.00098	02MAR95	59, ., -14	Not Stated	250	CON	MIL DCR	PSR No	No	
	329.002.00243	04APR96	22, ., -1	Not Stated	150	CON	SEV NO	PSR No	No	
	329.003.00088	14MAR95	15, ., -26	Not Stated	100	CON	MIL NO	PSR No	No	
	329.003.00090	26APR95	44, ., -25	6 Days	250	CON	SEV DCR	PSR Yes	No	
		02MAY95	50, ., -19	Not Stated	200	CON	MOD NO	PSR Yes	No	
	329.006.00040	22FEB95	7, ., -7	8 Days	50	CON	MOD STP	REL No	No	
	329.011.00208	12OCT96	37, -23, -42	13 Days	300	CON	MIL NO	PSR No	No	
329.011.00284	22APR96	32, -25, -106	11 Days	200	CON	MIL NO	PSR No	No		
329.012.00221	14OCT96	112, 49, -20	19 Days	200	CON	MOD NO	UNR Yes	No		
Decreased Appetite	DECREASE APPETITE	329.001.00066	23NOV94	2, ., -20	Not Stated	50	CON	MIL NO	PSR No	No
	DECREASED APPETITE	329.005.00153	25JAN96	1, -56, -235	42 Days	50	CON	MOD NO	PSR No	No
Diarrhea	DIARRHEA	329.005.00117	19MAR95	2, ., -68	3 Days	50	1	MOD NO	PSR No	No
		329.007.00146	04JUL96	162, 109, -79	02:00 Hrs	200	CON	MOD NO	UNR Yes	No
		329.007.00270	19JUN96	42, ., -1	30 Mins	200	CON	MIL NO	UNR No	No
24JUN96	47, ., 4		2 Days	200	CON	MIL NO	UNR No	No		

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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Diarrhea	DIARRHEA	329.009.00172	18JUL96	249, 192, -2	2 Days	50	CON	MIL	NO	PBU	No	No
		329.011.00284	08JUN96	79, 23, -59	03:00 Hrs	250	3	MIL	NO	PBU	No	No
	UPSET STOMACH WITH DIARRHEA	329.005.00335	10MAR97	11, ., -57	2 Days	100	CON	SEV	NO	UNR	No	No
Dry Mouth	DRY MOUTH	329.001.00061	11AUG94	14, ., -34	Not Stated	150	CON	MIL	NO	REL	No	No
		329.001.00070	08MAR95	15, ., -16	Not Stated	150	CON	MIL	NO	REL	No	No
		329.002.00098	10JAN95	8, ., -65	Not Stated	100	CON	MOD	DCR	PSR	No	No
		329.002.00100	14APR95	39, -20, -46	10 Mins	250	12	MIL	NO	PSR	No	No
		329.002.00103	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No	No
		329.002.00104	11MAY95	8, -49, -251	76 Days	100	CON	MOD	NO	REL	No	No
		329.003.00076	01FEB95	2, -54, -238	48 Days	50	CON	MIL	NO	PSR	No	No
		329.003.00082	17JAN96	38, ., 0	Not Stated	250	CON	MIL	NO	PSR	No	No
		329.003.00088	21MAR95	22, ., -19	Not Stated	200	CON	MIL	NO	PSR	No	No
		329.003.00090	28MAR95	15, ., -54	15 Days	100	CON	MIL	NO	PSR	No	No
		329.003.00092	04MAY95	2, -57, -259	146 Days	50	CON	MIL	NO	PSR	No	No
		329.003.00093	20JUN95	-1, -64, -80	106 Days	0	CON	MIL	NO	PSR	No	No
329.003.00247	10FEB96 07MAR96	10, -45, -101 36, -19, -75	23 Days 15 Days	100 200	CON CON	MIL MIL	NO NO	PSR PSR	No No	No No		

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Dry Mouth	DRY MOUTH	329.003.00289	11MAR96	13, -44, -225	31 Days	100		MIL NO	PSR No	No
		329.003.00290	12MAR96	2, ., -10	24:00 Hrs	50	1	MIL NO	PBU No	No
		329.003.00314	14NOV96	24, ., -53	Not Stated	200	1	MIL NO	PSR No	No
		329.004.00013	30JUL94	12, -48, -236	Not Stated	100	CON	MOD NO	REL No	No
		329.004.00211	05FEB96	4, ., -45	14 Days	50	CON	MIL NO	PSR No	No
			19FEB96	18, ., -31	15 Days	150	CON	SEV NO	REL No	No
			05MAR96	33, ., -16	14 Days	200	CON	MOD NO	REL No	No
			19MAR96	47, ., -2	Not Stated	200	CON	SEV STP	REL No	No
		329.004.00215	28MAR97	9, ., -31	Not Stated	100	CON	MOD NO	REL No	No
		329.005.00006	09NOV94	6, -55, -169	Not Stated	50	CON	MOD NO	REL No	No
		329.005.00007	20DEC94	42, -22, -150	151 Days	250	CON	MOD NO	REL No	No
		329.005.00009	16DEC94	5, ., -68	Not Stated	50	CON	MOD NO	REL No	No
			09JAN95	29, ., -44	Not Stated	200	CON	MOD NO	REL No	No
		329.005.00113	05FEB95	7, ., -25	Not Stated	50	CON	MOD NO	REL No	No
		329.005.00256	30MAR96	26, -31, -109	33 Days	200	CON	MOD NO	PSR No	No
		329.005.00295	07APR96	11, ., -58	55 Days	100	CON	MOD NO	REL No	No
		329.005.00332	03JAN97	23, ., -49	4 Days	200	CON	MIL NO	REL No	No
		329.005.00335	08MAR97	9, ., -59	Not Stated	100	CON	MOD NO	REL No	No
		329.007.00270	23MAY96	15, ., -28	15 Days	150	CON	MIL NO	PSR No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Dry Mouth	DRY MOUTH	329.007.00307	18MAY96	3, ., -33	39 Days	50	CON	MIL	NO	REL	No	No
		329.008.00159	04OCT95	22, -41, -112	29 Days	200	CON	MIL	NO	PSR	No	No
		329.008.00161	16NOV95	1, -55, -55	4 Days	50	CON	MIL	NO	REL	No	No
		329.008.00187	30NOV95	2, ., -71	Not Stated	50	CON	MIL	NO	PSR	No	No
		329.008.00192	26MAR96	22, ., -16	Not Stated	200	CON	MIL	DCR	PBU	No	No
		329.009.00134	27JUL95	22, ., -44	48 Days	200	CON	MIL	NO	PSR	No	No
		329.009.00172	05DEC95	23, -35, -228	231 Days	200	CON	MOD	NO	PSR	No	No
		329.009.00199	24JAN96	9, ., -62	15 Days	100	CON	MIL	NO	PSR	No	No
		329.009.00239	09DEC96 06JAN97	21, -37, -126 49, -9, -98	8 Days 10 Days	200 200	CON CON	MIL MIL	NO NO	PSR PSR	No No	No No
		329.009.00262	24FEB97	8, ., -61	64 Days	100	CON	MIL	NO	REL	No	No
		329.009.00305	14MAY96 03JUL96 09SEP96	8, -50, -253 58, 1, -203 126, 69, -135	22 Days 35 Days 142 Days	100 200 200	CON CON CON	MOD MIL MIL	NO NO NO	PSR PSR PSR	No No No	No No No
		329.009.00325	23SEP96	28, -28, -96	8 Days	200	CON	MIL	NO	PSR	No	No
		329.012.00221	30AUG96	67, 4, -65	52 Days	200	CON	MOD	NO	PSR	No	No
		329.012.00227	17JAN97	31, -39, -229	Not Stated	200	CON	MIL	NO	PBU	No	No
		329.012.00230	11MAR97	12, -58, -76	77 Days	100	CON	MOD	NO	PSR	No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther	SAE	
Dry Mouth	DRY THROAT, MOUTH	329.002.00244	29MAR96	9, -49, -75	61 Days	100	CON	MOD	NO	PSR	No	No	
	SEVERE DRY MOUTH	329.012.00227	25APR97	129, 60, -131	128 Days	300	CON	SEV	NO	PSR	No	No	
Dyspepsia	GI UPSET	329.005.00256	11JUL96	129, 73, -6	Not Stated	50	CON	MOD	NO	UNR	Yes	No	
	HEARTBURN	329.003.00090	02MAY95	50, ., -19	Not Stated	200	CON	MIL	NO	PSR	Yes	No	
		329.003.00314	04DEC96	44, ., -33	48:00 Hrs	200		1 MIL	NO	UNR	No	No	
		329.005.00009	09JAN95	29, ., -44	03:00 Hrs	200		1 MOD	NO	PBU	No	No	
		329.005.00297	24APR96	6, ., -20	04:00 Hrs	50	CON	MOD	NO	UNR	No	No	
		329.008.00192	30MAR96	26, ., -12	Not Stated	200	CON	MIL	DCR	PSR	No	No	
		329.012.00230	14MAR97	15, -55, -73	74 Days	150		MIL	NO	PBU	Yes	No	
		INDIGESTION	329.003.00090	26APR95 02MAY95	44, ., -25 50, ., -19	6 Days Not Stated	250 200	CON CON	MOD MIL	DCR NO	PSR PSR	No Yes	No No
			329.006.00040	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	PSR	No	No
		UPSET STOMACH	329.005.00006	26NOV94	23, -38, -152	64 Days	150	CON	MOD	NO	UNR	Yes	No
		329.007.00146	22MAR96	58, 5, -183	04:00 Hrs	200	CON	MOD	NO	PBU	Yes	No	
	UPSET STOMACH/INDIGESTION	329.005.00009	17DEC94	6, ., -67	Not Stated	50		6 MIL	NO	PSR	No	No	
Dysphagia	DIFFICULTY SWALLOWING 1 HOUR DURATION AFTER AWAKENING	329.001.00061	28AUG94	31, ., -17	Not Stated	200		3 MIL	NO	PSR	No	No	

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Dysphagia	DIFFICULTY SWALLOWING PILL	329.009.00239	16DEC96	28, -30, -119	8 Days	200	CON	MIL	NO	REL	No No
	LUMP IN THE THROAT	329.004.00014	29NOV94	1, ., -14	11 Days	50	7	MOD	NO	REL	No No
Esophagitis	ESOPHAGEAL IRRITATION	329.004.00215	09APR97	21, ., -19	3 Days	150	CON	MIL	NO	PSR	No No
Gastritis	GASTRITIS	329.005.00117	27APR95	41, ., -29	Not Stated	200	CON	MOD	NO	PBU	Yes No
Gastroenteritis	BACTERIAL GASTROENTERITIS	329.004.00211	21MAR96	49, ., 0	3 Days	200	CON	SEV	STP	UNR	Yes No
Gastrointestinal Disorder	NAUSEA, VOMITING HEADACHES, DIARRHEA (GASTROINTESTINAL ILLNESS)	329.003.00073	23FEB95	36, ., -9	Not Stated	250	CON	MOD	NO	UNR	No No
	STOMACH PROBLEMS	329.003.00092	22OCT95	173, 115, -88	2 Days	0		MOD	DCR	PBU	Yes No
Increased Appetite	CRAVINGS: CEREALS, PASTAS, CARBOHYDRATES	329.005.00006	24NOV94	21, -40, -154	41 Days	150	CON	MOD	NO	PSR	No No
	INCREASED APPETITE	329.001.00122	11OCT95	114, 57, -68	Not Stated	200	CON	MOD	NO	REL	No No
Nausea	INFREQUENTLY NAUSEA	329.008.00187	10DEC95	12, ., -61	Not Stated	100	CON	MIL	NO	PSR	No No
	NAUSEA	329.001.00066	23NOV94	2, ., -20	13 Days	50	CON	MIL	NO	PSR	No No
		329.001.00070	23FEB95	2, ., -29	Not Stated	50	CON	MIL	NO	PSR	No No
		329.002.00103	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No No
		329.002.00243	21MAR96	8, ., -15	Not Stated	100	CON	MIL	NO	REL	No No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Nausea	NAUSEA	329.004.00014	05DEC94	7, ., -8	3 Days	100	1	MOD	NO	PSR No	No
			07DEC94	9, ., -6	Not Stated	100	18	SEV	NO	PSR No	No
		329.004.00215	30APR97	42, ., 2	Not Stated	200	CON	SEV	STP	REL Yes	No
		329.005.00006	26NOV94	23, -38, -152	64 Days	150	CON	MOD	NO	UNR Yes	No
		329.005.00256	05MAR96	1, -56, -134	3 Days	50	1	MOD	NO	PBU No	No
		329.005.00295	05MAY96	39, ., -30	02:00 Hrs	200	CON	MIL	NO	PSR No	No
		329.007.00269	16APR96	6, ., -9	1 Days	50	CON	MIL	NO	PSR No	No
		329.007.00308	30JUN96	-2, ., -11	01:00 Hrs	0	CON	MIL	NO	PSR Yes	No
		329.009.00127	24APR95	15, ., -32	38 Days	150		MOD	STP	REL No	No
		329.009.00132	18JUN95	27, -31, -140	3 Days	200		MIL	NO	UNR No	No
		329.009.00172	24AUG95	94, 37, -73	62 Days	200		MIL	NO	PSR No	No
		329.009.00172	18JUL96	249, 192, -2	2 Days	50	CON	MIL	NO	PBU No	No
		329.009.00194	16JAN96	43, -14, -141	153 Days	200	CON	MOD	STP	PSR No	No
		329.009.00199	17JAN96	2, ., -69	42 Days	50	CON	MOD	NO	PSR No	No
		329.009.00239	28FEB96	44, ., -27	15 Days	250	CON	MIL	NO	PSR No	No
329.009.00239	26DEC96	38, -20, -109	5 Days	200	CON	MOD	NO	PBU No	No		
329.009.00305	14MAY96	8, -50, -253	15 Days	100	CON	MOD	NO	PSR No	No		
	28MAY96	22, -36, -239	23 Days	200	CON	MIL	NO	PSR No	No		
	02JUL96	57, -1, -204	1 Days	200	CON	MOD	NO	UNR Yes	No		

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Nausea	NAUSEA	329.009.00325	06SEP96	11, -45, -113	11 Days	100	CON	MIL	NO	PSR No	No
			23SEP96	28, -28, -96	8 Days	200	CON	MIL	NO	PSR No	No
	329.009.00326	14OCT96	40, -14, -75	4 Days	200	CON	MIL	NO	PSR No	No	
			329.010.00279	01OCT96	194, 138, -52	03:00 Hrs	300	CON	MIL	NO	PSR No
	329.011.00163	28NOV95	17DEC95	23, ., -5	5 Days	150	CON	MIL	NO	PBU No	No
			22DEC95	28, ., 0	Not Stated	200	CON	MOD	STP	PSR No	No
			23DEC95	29, ., 1	Not Stated	200	CON	MOD	STP	PSR No	No
			329.011.00284	21MAR96	-1, -57, -138	13 Days	0	4	MIL	NO	PSR No
	329.012.00230	18APR97	07MAY97	50, -20, -38	7 Days	200		MOD	NO	UNR No	No
			69, -1, -19	14:00 Hrs	250	CON	MIL	NO	UNR Yes	No	
	NAUSEA WHEN TAKING PM MEDS	329.009.00203	05MAR96	2, ., -31	Not Stated	50	CON	MIL	NO	PSR No	No
	RETCHING	329.004.00014	05DEC94	7, ., -8	Not Stated	100	21	MOD	STP	PSR No	No
	SOMATIC COMPLAINT NAUSEA	329.005.00255	29APR96	57, ., -14	Not Stated	200		MOD	NO	PSR No	No
Tooth Disorder	MOLAR ERUPTING	329.010.00279	07AUG96	139, 83, -107	02:00 Hrs	300	CON	MOD	NO	UNR Yes	No
	PAIN DUE TO WISDOM TOOTH EXTRACTION	329.005.00117	08MAY95	52, ., -18	8 Days	200	CON	MOD	NO	UNR Yes	No
	PAIN RE: 4 IMPACTED WISDOM TEETH EXTRACTED UNDER GENERAL ANESTHETIC	329.012.00230	18APR97	50, -20, -38	1 Days	200	CON	MOD	NO	UNR Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

PAROXETINE - PROTOCOL 329

Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Ulcerative Stomatitis	MOUTH SORES	329.004.00211	20MAR96	48, ., -1	Not Stated	200	CON	SEV STP	REL Yes	No
		329.010.00279	03OCT96	196, 140, -50	Not Stated	300	CON	MOD NO	PBU No	No
Vomiting	EMESIS NAUSEA AND VOMITING DURING DOWN TITRATION NAUSEA, VOMITING NAUSEATED AND VOMITING VOMITING VOMITING WHEN FORGOT DOSE	329.006.00041	22AUG95	140, 76, -105	1 Days	300	2	MIL NO	UNR No	No
		329.002.00104	10JAN96	252, 196, -7	6 Days	100	1	MOD NO	PSR No	No
		329.002.00057	06OCT94	29, -29, -100	20 Mins	250	CON	MIL NO	UNR No	No
		329.005.00117	07APR95	21, ., -49	Not Stated	150	CON	SEV NO	PBU No	No
		329.003.00073	04MAR95	45, ., 0	Not Stated	250	CON	SEV STP	PSR Yes	No
		329.004.00215	30APR97	42, ., 2	Not Stated	200	CON	SEV STP	REL Yes	No
		329.005.00295	15MAY96	49, ., -20	30 Mins	250	CON	MOD NO	PBU No	No
		329.007.00308	30JUN96	-2, ., -11	01:00 Hrs	0	CON	MIL NO	PSR No	No
		329.009.00132	19JUN95	28, -30, -139	06:00 Hrs	200		MIL NO	UNR No	No
		329.009.00239	26DEC96	38, -20, -109	5 Days	200	CON	MOD NO	PBU Yes	No
329.011.00163	22DEC95	28, ., 0	4 Days	200		4 MOD STP	PSR No	No		
329.002.00104	25JUL95	83, 27, -176	1 Days	300		1 MOD NO	REL No	No		

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Hemic and Lymphatic System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther	SAE
Anemia	ANEMIA	329.003.00289	11OCT96	227, 171, -11	Not Stated	150	CON	MIL	NO	UNR	No	No
Eosinophilia	EOSINOPHILS ELEVATED	329.005.00255	29APR96	57, ., -14	Not Stated	200	CON	MOD	NO	PBU	No	No
Leukocytosis	NEUTROPHILS, SEGS {INCREASED}	329.005.00009	07DEC94	-5, ., -77	1 Days	0	1	MIL	NO	UNR	No	No
Leukopenia	LOW NEUTROPHILS	329.011.00284	16MAY96	56, -1, -82	Not Stated	250	CON	MOD	NO	PBU	No	No
	LOW WHITE CELL COUNT	329.011.00284	16MAY96	56, -1, -82	Not Stated	250	CON	MOD	NO	PBU	No	No
	LYMPHOCYTES {DECREASED}	329.005.00009	07DEC94	-5, ., -77	1 Days	0	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Metabolic and Nutritional Disorders -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int ion	Act- ion	Inv Corr Rel Ther	SAE
Dehydration	DEHYDRATION	329.005.00007	18MAY95	191, 128, -1	8 Days	250	CON	SEV	STP	PBU Yes	No
Hyperglycemia	GLUCOSE ELEVATED	329.005.00009	08FEB95	59, ., -14	1 Days	250	1	SEV	NO	UNR No	No
Thirst	INCREASED THIRST	329.002.00244	29MAR96	9, -49, -75	61 Days	100	CON	MOD	NO	PBU No	No
		329.009.00203	24MAR96	21, ., -12	Not Stated	150	CON	MIL	NO	PSR No	No
Weight Gain	WEIGHT GAIN	329.001.00122	11OCT95	114, 57, -68	Not Stated	200	CON	MOD	NO	REL No	No
Weight Loss	WEIGHT LOSS	329.009.00195	27DEC95	13, ., -23	13 Days	150	CON	MIL	NO	PSR No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Musculoskeletal System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Arthralgia	JOINT PAINS	329.004.00215	30APR97	42, ., 2	Not Stated	200	CON	MIL STP	REL Yes	No
Myalgia	LEFT KNEE MUSCLE SPASMS	329.007.00146	18SEP96	238, 185, -3	06:00 Hrs	50	CON	MIL NO	UNR Yes	No
	LEG CRAMPS AND ACHES	329.005.00007	28JAN95	81, 18, -111	Not Stated	250	CON	MOD NO	PSR Yes	No
	MUSCLE SPASMS IN RIBS	329.012.00227	09MAY97	143, 74, -117	11:00 Hrs	300	CON	MOD NO	PBU No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Abnormal Dreams	INCREASED DREAMING	329.009.00194	07DEC95	3, -54, -181	34 Days	50		MOD	NO	PSR	No
		329.009.00325	30SEP96	35, -21, -89	11 Days	200	CON	MIL	NO	PSR	No
	NIGHTMARES	329.004.00215	25APR97	37, ., -3	7 Days	200	CON	MOD	STP	REL	No Yes
	329.005.00007	02APR95	145, 82, -47	15 Days	250	10	SEV	NO	UNR	No	No
	329.009.00172	18DEC95	36, -22, -215	52 Days	200		MOD	NO	PSR	No	No
Agitation	AGITATION	329.009.00194	07DEC95	3, -54, -181	13 Days	50	1	MOD	NO	PSR	No
		329.009.00264	11NOV96	11, ., -54	8 Days	150	CON	MOD	NO	PSR	No
	INCREASE AGITATION	329.001.00070	28FEB95	7, ., -24	Not Stated	100	CON	MIL	NO	PBU	No
Amnesia	MORE FORGETFUL	329.001.00122	11JUL95	22, -36, -160	15 Days	200	CON	MIL	NO	PSR	No
Anxiety	ANXIETY	329.007.00146	14JUL96	172, 119, -69	04:00 Hrs	200	CON	MIL	NO	UNR	Yes
Concentration Impaired	DECREASE CONCENTRATION	329.001.00061	30JUL94	2, ., -46	27 Days	50	CON	MOD	NO	REL	No
			01SEP94	35, ., -13	Not Stated	200	CON	MIL	NO	PBU	No
Convulsion	SEIZURE	329.005.00007	24MAY95	197, 134, 5	5 Mins	250	CON	SEV	STP	UNR	Yes
Depersonalization	"SPACEY" 1X	329.002.00244	23MAR96	3, -55, -81	02:00 Hrs	50	7	MIL	NO	PSR	No
Depression	MAJOR DEPRESSION	329.012.00223	29SEP96	31, ., -13	Not Stated	200	CON	MOD	NO	UNR	No
Dizziness	DIZZINESS	329.002.00103	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No
		329.002.00104	24MAY95	21, -36, -238	133 Days	150	CON	MIL	NO	REL	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Dizziness	DIZZINESS	329.002.00322	11JAN97	3, ., -43	Not Stated	50	CON	MOD STP	PBU No	No
		329.003.00076	06AUG95	188, 133, -52	66 Days	200	CON	MIL NO	PBU No	No
		329.003.00088	14MAR95	15, ., -26	764 Days	100	CON	MIL NO	PBU No	No
		329.003.00090	28MAR95 09MAY95	15, ., -54 57, ., -12	29 Days Not Stated	100 200	CON CON	MIL NO MIL NO	PSR No PSR No	No No
		329.003.00093	08AUG95	49, -15, -31	20 Mins	300	1	MIL NO	PBU No	No
		329.003.00249	15APR96	40, ., -22	1 Mins	300	1	MIL NO	PSR No	No
		329.003.00314	17DEC96	57, ., -20	Not Stated	200	CON	MIL NO	PSR No	No
		329.004.00013	20JUL94	2, -58, -246	5 Days	50	CON	MOD NO	REL No	No
		329.004.00211	19FEB96	18, ., -31	18 Days	150	CON	MIL NO	REL No	No
		329.004.00215	04APR97 25APR97	16, ., -24 37, ., -3	2 Days Not Stated	150 200	CON CON	MIL NO MOD STP	REL No REL No	No Yes
		329.005.00003	27SEP94	8, ., -7	10 Days	100	CON	MOD NO	PSR No	No
		329.005.00110	15JAN95	5, ., -4	5 Mins	50	CON	MIL NO	PSR No	No
		329.005.00113	06FEB95	8, ., -24	Not Stated	50	9	MIL NO	REL No	No
		329.005.00295	04MAY96	38, ., -31	2 Days	200	4	MIL NO	PSR No	No
		329.005.00335	01MAR97 05MAR97	2, ., -66 6, ., -62	4 Days 01:00 Hrs	50 50	CON CON	MIL NO SEV NO	REL No REL No	No No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Dizziness	DIZZINESS	329.006.00040	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	REL	No	No
		329.008.00159	24OCT95	42, -21, -92	9 Days	250		MIL	NO	REL	No	No
		329.009.00127	24APR95	15, ., -32	38 Days	150		MOD	NO	REL	No	No
		329.009.00134	11AUG95	37, ., -29	33 Days	200	CON	MOD	STP	REL	No	No
		329.009.00172	03DEC95	21, -37, -230	233 Days	150	CON	MOD	NO	PSR	No	No
		329.009.00195	04JAN96	21, ., -15	19 Days	200	CON	MOD	NO	PSR	No	No
		329.009.00199	17JAN96	2, ., -69	Not Stated	50	CON	MOD	NO	PSR	No	No
		329.009.00236	20JAN97	22, ., -19	Not Stated	200	CON	MOD	STP	REL	No	No
		329.009.00301	09APR96	22, -35, -75	1 Days	150	CON	MIL	NO	PBU	No	No
		329.009.00305	14MAY96	8, -50, -253	15 Days	100	CON	MOD	NO	PSR	No	No
			28MAY96	22, -36, -239	71 Days	200	CON	MIL	NO	PSR	No	No
			09SEP96	126, 69, -135	142 Days	200	CON	MIL	NO	PSR	No	No
		329.009.00325	01SEP96	6, -50, -118	16 Days	50	CON	MOD	NO	PSR	No	No
			17SEP96	22, -34, -102	Not Stated	200	CON	MIL	NO	PSR	No	No
		329.009.00326	14OCT96	40, -14, -75	4 Days	200	CON	MIL	NO	PSR	No	No
		329.011.00163	28NOV95	4, ., -24	18:00 Hrs	50	1	MIL	NO	PBU	No	No
		329.012.00221	02AUG96	39, -25, -93	8 Days	200	5	MOD	NO	PBU	No	No
		329.012.00230	12MAR97	13, -57, -75	3 Days	100	2	MIL	NO	PBU	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Dizziness	DIZZINESS (ORTHOSTATIC)	329.003.00249	16APR96	41, ., -21	2 Mins	300		MIL	NO	PSR	No
	DIZZINESS (WHEN GOING FROM SIT TO STAND)	329.002.00103	10AUG95	113, 57, -15	16 Days	250		MIL	NO	PSR	No
	DIZZINESS IN GYM CLASS X1	329.005.00332	20DEC96	9, ., -63	5 Mins	100	CON	MIL	NO	PSR	No
	DIZZINESS ORTHOSTATIC	329.003.00317	07JAN97	20, ., -50	29 Days	150	4	MIL	NO	PSR	No
	DIZZINESS UPON GETTING UP SUDDENLY	329.001.00061	06AUG94	9, ., -39	20 Days	100	CON	MIL	NO	REL	No
	DIZZINESS UPON STANDING	329.005.00256	04APR96	31, -26, -104	13 Days	250	4	MIL	NO	REL	No
	DIZZINESS UPON STANDING {1-2X/DAILY}	329.002.00244	29MAR96	9, -49, -75	24 Days	100	48	MOD	NO	PSR	No
	DIZZINESS WHEN GETTING OUT OF BED IN AM	329.005.00006	11NOV94	8, -53, -167	25 Days	50	CON	MIL	NO	REL	No
	DIZZINESS WHEN WAKING UP IN AM	329.003.00247	10FEB96	10, -45, -101	32 Days	100		MIL	NO	PSR	No
	DIZZINESS"OFF AND ON"	329.002.00100	14APR95	39, -20, -46	15 Mins	250	15	MIL	NO	PSR	No
	DIZZY	329.001.00066	02DEC94	11, ., -11	5 Mins	100	1	MIL	NO	PSR	No
		329.003.00082	03JAN96	24, ., -14	Not Stated	150	CON	MIL	NO	PSR	No
	FAINTNESS	329.001.00067	30NOV94	9, ., -13	Not Stated	100	CON	MOD	STP	PSR	No
	LIGHT HEADED	329.003.00314	24OCT96	3, ., -74	13 Days	50	CON	MIL	NO	PSR	No

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Number of Episodes [No. Epi]: CON = Continuous
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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Dizziness	LIGHT HEADEDNESS	329.003.00249	20MAR96	14, ., -48	14 Days	150	CON	MIL	NO	PSR No	No
	LIGHT-HEADEDNESS	329.005.00118	23MAY95	7, ., -43	23 Days	50	5	MIL	NO	PSR No	No
	LIGHTHEADED	329.005.00153	25JAN96	1, -56, -235	29 Days	50	7	MIL	NO	PSR No	No
	LIGHTHEADEDNESS	329.008.00192	26MAR96	22, ., -16	Not Stated	200	CON	MIL	DCR	PBU No	No
	ORTHOSTATIC CHANGES [DIZZINESS]	329.002.00322	13FEB97	36, ., -10	Not Stated	200	CON	MOD	STP	PSR No	No
Drug Dependence	CANNABIS USE	329.012.00227	18JAN97	32, -38, -228	1 Days	200	1	MIL	NO	UNR No	No
Emotional Lability	OVERDOSE {INTENTIONAL}	329.012.00221	03NOV96	132, 69, 0	19:30 Hrs	200	CON	SEV	STP	UNR No	Yes
	SELF MUTILATION	329.012.00223	29SEP96	31, ., -13	Not Stated	200	CON	MOD	NO	UNR No	Yes
	SUICIDAL IDEATION	329.005.00113	02MAR95	32, ., 0	1 Days	200	CON	MOD	STP	UNR No	No
		329.012.00223	24SEP96	26, ., -18	10 Days	200	1	MOD	NO	UNR No	No
	SUICIDAL THREAT WITH SCISSORS	329.005.00295	19APR96	23, ., -46	1 Days	200	1	MOD	NO	PBU No	No
Euphoria	MILD ELATION AND DISINHIBITION	329.012.00221	24JUL96	30, -34, -102	13 Days	250	CON	MIL	DCR	PSR No	No
Hallucinations	VISUAL HALLUCINATIONS	329.004.00215	25APR97	37, ., -3	7 Days	200	CON	SEV	STP	REL No	Yes
Hostility	HOMICIDAL TENDENCIES TOWARDS PARENTS	329.005.00295	18MAY96	52, ., -17	04:30 Hrs	250	CON	SEV	STP	PSR No	No
	INTENSE ANGER	329.008.00161	24DEC95	39, -17, -17	30 Mins	200	2	MOD	NO	PSR No	No

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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
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE	
Hostility	PSYCHIATRIC HOSPITALIZATION FOLLOWING ASSAULTIVE BEHAVIOR	329.002.00321	02JUN96	11, ., -1	Not Stated	50	1	SEV STP	UNR No	Yes	
Hyperkinesia	AKATHISIA	329.009.00326	30SEP96	26, -28, -89	18 Days	200	CON	MIL NO	PSR No	No	
	SENSATION OF RESTLESSNESS IN LEGS NO OBSERVABLE TREMORS	329.002.00057	27SEP94	20, -38, -109	45 Mins	150	CON	MIL NO	PBU No	No	
Hypertonia	STIFF NECK	329.004.00211	23FEB96	22, ., -27	18 Days	200	CON	MIL NO	PBU No	No	
Hypesthesia	NUMBNESS IN HANDS AND ARMS WHEN AWAKES	329.001.00122	18JUL95	29, -29, -153	30 Days	200	CON	MIL NO	PBU No	No	
Insomnia	DECREASED SLEEP (INITIAL, MIDDLE)	329.009.00264	11DEC96	41, ., -24	6 Days	200	CON	MIL NO	PSR No	No	
	INITIAL INSOMNIA	329.009.00127	17APR95	8, ., -39	45 Days	100	CON	MOD NO	PSR No	No	
		329.009.00172	10JUN96	211, 154, -40	29 Days	200	CON	MIL NO	PBU No	No	
		329.009.00194	27FEB96	85, 29, -99	64 Days	200	CON	MIL NO	PSR No	No	
		INSOMNIA	329.003.00289	13MAR96	15, -42, -223	129 Days	150		MIL NO	PBU No	No
			329.003.00314	23OCT96	2, ., -75	3 Days	50	3	MOD NO	PSR No	No
			329.006.00041	16AUG95	134, 70, -111	8 Days	300	6	MOD NO	UNR No	No
		329.012.00221	15AUG96	52, -12, -80	39 Days	200		MOD NO	UNR Yes	No	

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Insomnia	INSOMNIA (FREQUENT AWAKENING)	329.003.00079	11MAY95	9, ., -8	Not Stated	100	CON	MOD NO	PSR No	No
	INSOMNIA MIDDLE	329.001.00061	18AUG94	21, ., -27	Not Stated	200	7 MIL	NO	REL No	No
	MIDDLE INSOMNIA	329.001.00070	22FEB95	1, ., -30	16 Days	50	CON	MIL NO	PBU No	No
		329.009.00236	15JAN97	17, ., -24	6 Days	150	CON	MIL NO	PSR No	No
		329.009.00239	30DEC96	42, -16, -105	8 Days	200	CON	MIL NO	PSR Yes	No
	POOR SLEEP	329.008.00161	16NOV95	1, -55, -55	4 Days	50	CON	MIL NO	REL No	No
	TERMINAL INSOMNIA	329.001.00070	11MAR95	18, ., -13	Not Stated	150	CON	MIL NO	PBU No	No
		329.012.00227	07FEB97	52, -18, -208	Not Stated	200		MIL INC	PBU No	No
	TROUBLE GETTING TO SLEEP AND EARLY AWAKENING	329.008.00159	29OCT95	47, -16, -87	8 Days	250	CON	MIL NO	PSR No	No
Myoclonus	MUSCLE TWITCH RIGHT EYE	329.001.00122	14JUL95	25, -33, -157	19 Days	200	CON	MIL NO	PSR No	No
	RIGHT KNEE TWITCH	329.001.00122	14JUL95	25, -33, -157	62 Days	200	CON	MIL NO	REL No	No
Nervousness	INCREASED IRRITABILITY	329.005.00117	15APR95	29, ., -41	Not Stated	200	CON	MOD NO	PBU No	No
	IRRITABILITY	329.004.00215	25APR97	37, ., -3	7 Days	200	CON	SEV STP	REL No	Yes
	IRRITABLE EDGY BURNT SELF WITH CIGARETTE	329.003.00247	16MAR96	45, -10, -66	11 Days	200	1 MIL	DCR	PSR No	No
	IRRITABLE MOOD	329.006.00040	22FEB95	7, ., -7	8 Days	50	CON	MOD STP	REL No	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Nervousness	IRRITABLE MOOD	329.006.00041	16APR95	12, -53, -233	3 Days	100	1	MOD	NO	UNR	No
	RESTLESSNESS	329.008.00161	16NOV95	1, -55, -55	4 Days	50	CON	MIL	NO	REL	No
Neurosis	OBSESSIVE THOUGHTS	329.005.00006	27FEB95	116, 56, -59	Not Stated	300	CON	MOD	STP	PBU	No
Somnolence	DAYTIME DROWSINESS	329.009.00127	12APR95	3, ., -44	Not Stated	50	CON	MIL	NO	PSR	No
	DAYTIME SEDATION	329.009.00236	20JAN97	22, ., -19	Not Stated	200	CON	MOD	STP	REL	No
	DAYTIME SOMNOLENCE	329.009.00239	09DEC96	21, -37, -126	22 Days	200	CON	MIL	NO	PSR	No
		329.009.00262	24FEB97	8, ., -61	8 Days	100	CON	MIL	NO	PSR	No
		329.009.00264	08NOV96 16DEC96	8, ., -57 46, ., -19	25 Days Not Stated	100 200	CON CON	MOD MOD	NO NO	PSR PSR	No No
	DROWSINESS	329.003.00092	17MAY95	15, -44, -246	16 Days	150	CON	MIL	NO	PSR	No
		329.008.00192	26MAR96	22, ., -16	Not Stated	200	CON	MIL	DCR	PBU	No
		329.008.00272	24JUL96	113, 57, -56	Not Stated	200	CON	MIL	NO	REL	No
	HYPERSOMNIA	329.001.00067	30NOV94	9, ., -13	Not Stated	100	5	MIL	NO	PSR	No
	HYPERSOMNOLENCE	329.009.00134	10JUL95	5, ., -61	65 Days	50	CON	MOD	NO	PSR	No
	SEDATION	329.008.00187	22DEC95	24, ., -49	Not Stated	200	CON	MOD	NO	REL	No
	SLEEPINESS	329.004.00013	20JUL94	2, -58, -246	3 Days	50	2	MIL	NO	REL	No
	SOMNOLENCE	329.009.00137	25OCT95	16, ., -52	42 Days	150	CON	MOD	NO	PSR	No

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Number of Episodes [No. Epi]: CON = Continuous
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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Somnolence	SOMNOLENCE	329.009.00172	29NOV95	17, -41, -234	6 Days	150	CON	MOD	NO	PSR No	No
Thinking Abnormal	"STRANGE THOUGHTS"	329.010.00279	23APR96	33, -24, -213	2 Days	250	1	MIL	NO	PBU No	No
	RACING THOUGHTS	329.009.00172	22DEC95	40, -18, -211	13 Days	200		MIL	NO	PBU No	No
Tremor	"SHAKINESS"	329.005.00255	05MAR96	2, ., -69	4 Days	50	CON	MOD	NO	PSR No	No
	(WORSENING) ENTIRE BODY SHAKES AND SHAKY HAND	329.002.00243	22MAR96	9, ., -14	Not Stated	100	CON	MOD	NO	PSR No	No
	HAND TREMORS	329.001.00061	25AUG94	28, ., -20	Not Stated	200	4	MIL	NO	REL No	No
		329.001.00070	23FEB95	2, ., -29	Not Stated	50	CON	MIL	NO	PSR No	No
		329.001.00122	08AUG95	50, -8, -132	120 Days	200	CON	MOD	NO	REL No	No
		329.005.00007	20DEC94	42, -22, -150	6 Days	250	CON	MIL	NO	REL No	No
			26DEC94	48, -16, -144	3 Days	300	CON	MOD	DCR	REL No	No
			29DEC94	51, -13, -141	142 Days	250	CON	MIL	NO	REL No	No
		329.005.00009	12JAN95	32, ., -41	Not Stated	250	CON	MIL	NO	REL No	No
			15JAN95	35, ., -38	10 Days	250	CON	MIL	NO	REL No	No
			24JAN95	44, ., -29	8 Days	300	CON	SEV	DCR	REL No	No
		329.005.00113	06FEB95	8, ., -24	Not Stated	50	CON	MIL	NO	REL No	No
		329.005.00255	05APR96	33, ., -38	19 Days	250	CON	MOD	DCR	REL No	No
		329.005.00335	01MAR97	2, ., -66	4 Days	50	CON	MIL	NO	REL No	No
			05MAR97	6, ., -62	12:00 Hrs	50	CON	SEV	NO	REL No	No
			06MAR97	7, ., -61	14 Days	50	CON	MOD	NO	REL No	No
			01APR97	33, ., -35	5 Days	250	CON	MOD	NO	REL No	No

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Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Tremor	HAND TREMORS	329.005.00335	06APR97	38, ., -30	4 Days	200	CON	MIL NO	REL No	No
	RIGHT KNEE TREMOR	329.001.00122	14JUL95	25, -33, -157	62 Days	200	CON	MIL NO	REL No	No
	SHAKINESS	329.005.00003	27SEP94	8, ., -7	10 Days	100	CON	MOD NO	PSR No	No
	SHAKING	329.002.00098	14FEB95	43, ., -30	Not Stated	250	CON	MOD DCR	PSR No	No
	TREMBLING OF HANDS	329.004.00013	07AUG94	20, -40, -228	4 Days	150	2	MIL NO	REL No	No
	TREMORS	329.004.00211	19FEB96	18, ., -31	22 Days	150	CON	MIL NO	PSR No	No
		329.007.00307	30MAY96	15, ., -21	25 Days	150	CON	MIL NO	REL No	No

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Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Respiratory System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE	
Cough Increased	COUGH	329.009.00262	15MAR97	27, ., -42	2 Days	200	CON	MIL	NO	PBU	Yes No	
		329.009.00325	10OCT96	45, -11, -79	40 Days	200	CON	MOD	NO	UNR	Yes No	
	COUGHING	329.002.00050	23MAR95	1, ., -34	12 Days	50	CON	MIL	NO	PBU	Yes No	
Dyspnea	SHORTNESS OF BREATH	329.007.00139	17MAY95	10, ., -8	8 Days	50	CON	MIL	STP	PSR	No No	
		329.007.00270	19JUN96	42, ., -1	03:00 Hrs	200	1	SEV	STP	PSR	No Yes	
		329.009.00325	01SEP96	6, -50, -118	16 Days	50	CON	MIL	NO	PSR	No No	
	SHORTNESS OF BREATH (WITH EXERCISE)	329.008.00187	07JAN96	40, ., -33	Not Stated	200	CON	MIL	NO	PSR	No No	
Epistaxis	NOSEBLEEDS	329.005.00117	14APR95	28, ., -42	15 Mins	200	2	MIL	NO	PBU	No No	
Pharyngitis	PHARYNGITIS	329.012.00227	06JAN97	20, -50, -240	36 Days	150	CON	MOD	NO	PBU	Yes No	
		SORE THROAT	329.002.00050	23MAR95	1, ., -34	6 Days	50	CON	MOD	NO	PBU	Yes No
		329.003.00079	17MAY95	15, ., -2	Not Stated	100	CON	MIL	NO	PBU	Yes No	
		329.003.00092	01MAY95	-2, -60, -262	16 Days	0	CON	MIL	NO	UNR	No No	
		329.004.00215	25MAR97	6, ., -34	5 Days	50	CON	MIL	NO	UNR	Yes No	
		329.005.00118	20MAY95	4, ., -46	4 Days	50	CON	MOD	NO	UNR	Yes No	
		329.005.00255	14APR96	42, ., -29	4 Days	300	CON	MIL	NO	PBU	No No	
329.005.00256	28MAR96	24, -33, -111	5 Days	200	CON	MOD	NO	UNR	Yes No			

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Respiratory System -----													
Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE	
Pharyngitis	SORE THROAT	329.006.00041	16APR95	12, -53, -233	3 Days	100	1	MOD	NO	PBU	Yes	No	
		329.009.00171	14NOV95	8, ., 0	Not Stated	50	CON	MIL	NO	PBU	No	No	
		329.011.00163	30NOV95	6, ., -22	20:00 Hrs	50	CON	MIL	NO	UNR	Yes	No	
		329.011.00284	30MAR96	9, -48, -129	4 Days	100	CON	MIL	NO	UNR	Yes	No	
		329.012.00227	10FEB97	55, -15, -205	11 Days	200	CON	MIL	NO	PBU	No	No	
	SORE THROAT 1 HOUR DURATION AFTER AWAKENING	329.001.00061	28AUG94	31, ., -17	Not Stated	200	3	MIL	NO	PSR	No	No	
Respiratory Disorder	CHEST CONGESTION AND COUGH	329.005.00118	19MAY95	3, ., -47	6 Days	50	CON	MOD	NO	UNR	Yes	No	
		329.010.00279	08MAY96	48, -9, -198	4 Days	300	CON	MIL	NO	PBU	No	No	
		329.006.00041	22AUG95	140, 76, -105	3 Days	300	CON	MOD	NO	UNR	Yes	No	
		329.007.00146	20JUL96	178, 125, -63	3 Days	200	CON	MIL	NO	UNR	Yes	No	
		329.009.00194	02JAN96	29, -28, -155	15 Days	200	CON	MIL	NO	UNR	Yes	No	
		329.003.00317	14JAN97	27, ., -43	24:00 Hrs	200	CON	MIL	NO	PBU	Yes	No	
		329.003.00247	05MAR96	34, -21, -77	3 Days	200	CON	MOD	NO	UNR	Yes	No	
		329.003.00249	23APR96	48, ., -14	8 Days	300		MIL	NO	UNR	Yes	No	

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Respiratory System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Respiratory Disorder	COMMON COLD	329.004.00014	24NOV94	-5, ., -19	6 Days	0	1	MIL NO	UNR Yes	No
		329.012.00227	05MAY97	139, 70, -121	18 Days	300	CON	MIL NO	UNR Yes	No
	HEAD COLD	329.009.00239	06JAN97	49, -9, -98	10 Days	200	CON	MIL NO	UNR No	No
	HEADCOLD AND NASAL CONGESTION	329.005.00297	14APR96	-5, ., -30	3 Days	0	CON	MOD NO	UNR Yes	No
Rhinitis	CONGESTION BACK OF THROAT	329.001.00122	07OCT95	110, 53, -72	8 Days	200	CON	MIL NO	UNR No	No
	NASAL CONGESTION	329.009.00325	10OCT96	45, -11, -79	40 Days	200	CON	MOD NO	UNR Yes	No
	RHINITIS	329.004.00215	26MAR97	7, ., -33	4 Days	50	CON	MIL NO	UNR Yes	No
	RUNNY NOSE	329.011.00209	30SEP96	20, -43, -80	4 Days	150	CON	MIL NO	UNR Yes	No
Sinusitis	SINUS CONGESTION	329.009.00171	14NOV95	8, ., 0	Not Stated	50	CON	MIL NO	PBU No	No
		329.009.00239	18FEB97	92, 35, -55	28 Days	200	CON	MIL NO	UNR Yes	No
	SINUSITIS	329.007.00307	02JUN96 23JUL96	18, ., -18 69, ., 33	6 Days Not Stated	150 0	CON CON	MIL NO MOD NO	UNR Yes UNR Yes	No No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Skin and Appendages -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act-Int ion	Inv Corr Rel Ther	SAE
Acne	ACNE	329.007.00143	15NOV95	7, ., -16	Not Stated	50	CON	MOD STP	PSR No	No
		329.010.00279	15JUN96	86, 30, -160	Not Stated	300	CON	MOD NO	PBU Yes	No
	INCREASED ACNE (FACE, CHEST, BACK)	329.008.00187	30NOV95	2, ., -71	Not Stated	50	CON	MIL NO	PSR No	No
Contact Dermatitis	POISON IVY	329.007.00270	17MAY96	9, ., -34	3 Days	100	CON	MOD NO	UNR Yes	No
		329.010.00279	09JUL96 23AUG96	110, 54, -136 155, 99, -91	11 Days 51 Days	300 300	CON CON	MIL NO MOD NO	UNR Yes UNR Yes	No No
Dry Skin	DRY FINGERTIPS	329.009.00239	17MAR97	119, 62, -28	Not Stated	200	CON	MIL NO	PSR Yes	No
Fungal Dermatitis	RINGWORM	329.007.00270	30MAY96	22, ., -21	17 Days	200	CON	MIL NO	UNR Yes	No
Maculopapular Rash	MORBILLIFORM "MEASLES LIKE" ERUPTION, GENERALIZED SIMILAR TO TRICYCLIC RASH, ON TRUNK, BACK, EXTREMITIES, CHEST, BUTTOCKS, TORSO/FRONT AND BACK, AND LOWER NECK	329.007.00307	16JUN96	32, ., -4	10 Days	200	CON	MOD STP	REL Yes	Yes
		329.009.00171	10NOV95	4, ., -4	Not Stated	50	CON	SEV STP	PBU No	No
Pruritus	ITCHING-WITHOUT HIVES	329.005.00117	19MAR95	2, ., -68	3 Days	50	1	MIL NO	PSR No	No
Rash	ITCHING AND RASH TO RIGHT FOREARM AND BOTH CALVES	329.002.00243	17MAR96	4, ., -19	6 Days	50	CON	MOD NO	UNR Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Skin and Appendages -----													
Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE	
Rash	RASH	329.011.00163	21NOV95	-4, ., -31	Not Stated	0	CON	MIL	NO	UNR	Yes	No	
	RASH-BILATERAL FOREARMS	329.005.00007	10NOV94	2, -62, -190	5 Days	50	CON	MOD	STP	PBU	Yes	No	
	RED SPOTS / BLOTCHES ON SKIN ARMS, THROAT, CHEST	329.002.00103	11MAY95	22, -35, -106	35 Days	200		MIL	NO	PSR	No	No	
Sweating	EPISODIC CALOR AND PERSPIRATION	329.008.00187	10DEC95	12, ., -61	Not Stated	100	CON	MIL	NO	PSR	No	No	
	INCREASED SWEATING	329.009.00134	27JUL95	22, ., -44	48 Days	200	CON	MIL	NO	PSR	No	No	
	NIGHT SWEATS	329.009.00194	02APR96	120, 64, -64	76 Days	200	CON	MIL	NO	PSR	No	No	
	SWEATINESS	329.005.00003	22SEP94	3, ., -12	6 Days	50	CON	MOD	NO	PSR	No	No	
	SWEATING	329.004.00013	20JUL94	2, -58, -246	3 Days	50	CON	MIL	NO	REL	No	No	
		329.005.00153	16FEB96	23, -34, -213	13 Days	200		5 MIL	NO	PSR	No	No	
		329.009.00195	25DEC95	11, ., -25	29 Days	100	CON	MOD	NO	PSR	No	No	
Urticaria	HIVES-BILATERAL FOREARMS	329.005.00007	10NOV94	2, -62, -190	5 Days	50	CON	MOD	NO	PBU	Yes	No	

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
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Corrective Therapy [Corr Ther]
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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Special Senses -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act ion	Inv Rel	Corr Ther	SAE
Abnormal Vision	BLURRED VISION	329.003.00088	14MAR95	15, ., -26	Not Stated	100	CON	MIL	NO	PSR	No	No
		329.005.00113	06FEB95	8, ., -24	Not Stated	50	10	MIL	NO	REL	No	No
		329.005.00255	15APR96	43, ., -28	8 Days	250	15	SEV	DCR	REL	No	No
		329.009.00305	03JUL96	58, 1, -203	35 Days	200	CON	MIL	NO	PSR	No	No
	BLURRED VISION WHEN READING LONG TIME	329.001.00066	02DEC94	11, ., -11	Not Stated	100	3	MIL	NO	PSR	No	No
	BLURRED VISION WHEN STANDS QUICKLY	329.002.00103	08JUN95	50, -7, -78	36 Days	250	10	MIL	NO	PSR	No	No
Ear Pain	EARACHE	329.004.00013	20JUL94	2, -58, -246	5 Days	50	8	MIL	NO	REL	No	No
		329.003.00314	20DEC96	60, ., -17	24:00 Hrs	250	1	MIL	NO	UNR	Yes	No
Eye Disorder	EYE INFECTION (LEFT AND RIGHT EYE)	329.009.00262	03MAR97	15, ., -54	5 Days	150	CON	MIL	NO	PBU	No	No
		329.009.00262	10FEB97	-7, ., -75	57 Days	0	CON	MOD	NO	UNR	Yes	No
Keratoconjunctivitis	IRRITATION IN EYES (DRY EYES)	329.009.00325	09SEP96	14, -42, -110	8 Days	150	CON	MIL	NO	PSR	No	No
Mydriasis	EYE DILATION	329.006.00040	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	REL	No	No
Photophobia	LIGHT SENSITIVITY	329.008.00187	18DEC95	20, ., -53	Not Stated	150	CON	MIL	NO	REL	No	No
Taste Perversion	BAD TASTE	329.003.00088	10MAR95	11, ., -30	21 Days	100	CON	MIL	NO	PSR	No	No
		329.003.00090	16MAR95	3, ., -66	5 Days	50	CON	MIL	DCR	PSR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Special Senses -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Taste Perversion	BITTER TASTE IN MOUTH	329.008.00187	30NOV95	2, ., -71	Not Stated	50	CON	MIL NO	PSR No	No
Tinnitus	RINGING IN EARS	329.009.00172	03DEC95	21, -37, -230	30 Days	150		MIL NO	PSR No	No
	RINGING IN EARS-5-10 MINUTES IN A.M.	329.004.00013	03AUG94	16, -44, -232	8 Days	150	7	MIL NO	REL No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Urogenital System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Cystitis	FEELING BLADDER FULL AFTER URINATING	329.012.00230	01MAY97	63, -7, -25	28 Days	200	CON	MIL NO	PBU Yes	No
Dysmenorrhea	MENSTRUAL CRAMPS	329.003.00249	13APR96	38, ., -24	3 Days	300		MIL NO	UNR Yes	No
		329.003.00289	24APR96	57, 1, -181	Not Stated	200	6	MIL NO	UNR No	No
		329.005.00009	20JAN95	40, ., -33	5 Days	300	CON	SEV NO	UNR No	No
		329.005.00153	31JAN96	7, -50, -229	12:00 Hrs	50	CON	MOD NO	UNR Yes	No
		329.005.00256	20MAR96	16, -41, -119	2 Days	100	CON	MOD NO	UNR Yes	No
Dysuria	DYSURIA	329.011.00284	09JUN96	80, 24, -58	2 Days	250	3	MOD NO	PBU No	No
Haematuria	[URINE OCCULT BLOOD]	329.005.00009	07DEC94	-5, ., -77	1 Days	0	1	MIL NO	UNR No	No
Nocturia	NOCTURIA	329.006.00041	24MAY95	50, -15, -195	8 Days	250	CON	MIL NO	PSR No	No
Polyuria	POLYURIA	329.004.00014	05DEC94	7, ., -8	1 Days	100		MIL NO	PSR No	No
Pyuria	URINALYSIS - WBC'S {INCREASED}	329.005.00006	28APR95	176, 116, 1	Not Stated	50		MIL NO	UNR No	No
Unintended Pregnancy	POSITIVE PREGNANCY TEST RESULT	329.005.00110	21JAN95	11, ., 2	1 Days	100	CON	SEV STP	UNR No	No
	PREGNANCY NAUSEA VOMITING	329.002.00057	10DEC94	94, 37, -35	Not Stated	300	CON	MOD STP	UNR No	No
Urinary Frequency	INCREASED URINATION	329.009.00137	17OCT95	8, ., -60	8 Days	100	CON	MIL NO	PBU No	No
Urinary Retention	URINARY RETENTION	329.003.00088	14MAR95	15, ., -26	Not Stated	100	CON	SEV STP	REL No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE Body System=Urogenital System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Urinary Retention	URINARY RETENTION	329.006.00040	22FEB95	7, ., -7	8 Days	50	CON	MOD STP	REL No	No
		329.009.00172	09JAN96	58, 1, -193	8 Days	200	CON	MOD NO	PBU No	No
Urination Impaired	DIFFICULTY INITIATING URINATION	329.002.00104	04MAY95	1, -56, -258	8 Days	50	2	MIL NO	REL No	No
	HARD TO INITIATE URINATION	329.009.00172	09JAN96	58, 1, -193	8 Days	200	CON	MOD NO	PBU No	No
	URINARY HESITANCY	329.002.00050	30MAR95	8, ., -27	6 Days	100	CON	MIL STP	PSR No	No
Vaginal Moniliasis	YEAST INFECTION (VAGINAL)	329.005.00255	19APR96	47, ., -24	5 Days	250	CON	MOD NO	PBU Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Abdominal Pain	ABDOMINAL PAIN	329.007.00311	09OCT96	7, -54,-197	01:00 Hrs	0	CON	MIL NO	UNR Yes	No
	STOMACH ACHE	329.001.00064	23NOV94 01DEC94	14, -41,-138 22, -33,-130	03:00 Hrs 8 Days	0 0	1 2	MIL NO MIL NO	PSR No PSR No	No No
		329.002.00097	23MAR95	80, 22,-181	20 Mins	0	3	MIL NO	PSR No	No
		329.005.00254	28FEB96	14, -42,-244	03:00 Hrs	0	CON	MOD NO	UNR No	No
	STOMACH ACHE HEADACHE {SIMULTANEOUS} [STOMACH ACHE]	329.010.00263	08SEP96	31, ., -41	10 Mins	0	1	MIL NO	PSR No	No
	STOMACH ACHE,NO VOMITING	329.007.00267	16MAY96	71, ., 15	04:00 Hrs	0	CON	MOD NO	PBU No	No
	STOMACH ACHES	329.004.00213	03AUG96 11AUG96	2, -53,-239 10, -45,-231	8 Days 192 Days	0 0	CON CON	MIL NO MOD NO	PSR No UNR Yes	No No
	STOMACH ACHES (IF TAKES MEDS WITHOUT FOOD)	329.002.00246	20MAY96	33, ., -39	Not Stated	0		MIL NO	PSR No	No
	STOMACH ACHES IN AM	329.009.00202	08MAR96	18, ., -18	12 Days	0	CON	MOD NO	PSR No	No
	STOMACH CRAMPS	329.001.00207	03MAR96	5, ., -53	23:00 Hrs	0	CON	MIL NO	UNR No	No
		329.004.00016	28MAR95	16, ., -22	3 Days	0	CON	MOD NO	UNR Yes	No
	STOMACH CRAMPS (SINCE STARTING BIAIXIN)	329.001.00207	24APR96	57, ., -1	3 Days	0	CON	MIL NO	UNR No	No
	STOMACH CRAMPS(VIRAL)	329.009.00202	22FEB96	3, ., -33	3 Days	0	CON	MIL NO	PBU No	No
	STOMACH PAINS	329.003.00291	09JUL96	7, -59,-113	01:00 Hrs	0	2	MIL NO	PSR No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Allergic Reaction	"PUFFY", ITCHY, WATERY EYES {ALLERGIES}	329.005.00111	04MAR95	53, -4, -57	9 Days	0	CON	SEV NO	PBU No	No
	COUGHING DUE TO ALLERGIES	329.004.00016	30MAR95	18, ., -20	Not Stated	0	CON	MIL NO	UNR Yes	No
	HEADACHES DUE TO ALLERGIES	329.004.00016	24MAR95	12, ., -26	Not Stated	0	CON	MOD NO	UNR Yes	No
	RHINITIS, SNEEZING, ITCHY EYES (POLLEN ALLERGY)	329.004.00018	12MAY95	10, ., -63	7 Days	0	CON	MOD NO	UNR Yes	No
	SNEEZING DUE TO ALLERGIES	329.004.00016	24MAR95	12, ., -26	Not Stated	0	CON	MOD NO	UNR Yes	No
	STUFFED SINUSES DUE TO ALLERGIES	329.004.00016	24MAR95	12, ., -26	Not Stated	0	CON	MOD NO	UNR Yes	No
Asthenia	DROP IN ENERGY	329.008.00162	20DEC95	50, -16, -210	8 Days	0	1	MIL INC	PSR No	No
	FATIGUE	329.002.00246	25APR96	8, ., -64	Not Stated	0	CON	MIL NO	PSR No	No
		329.002.00323	04MAR97	113, 55, -114	Not Stated	0	CON	MIL NO	PSR No	No
		329.003.00080	04JAN96	39, ., -36	Not Stated	0	CON	SEV NO	PBU No	No
		329.003.00252	25APR96	16, ., -54	20 Days	0	CON	MIL NO	PSR No	No
		329.005.00111	31JAN95	21, -36, -89	8 Days	0	CON	MIL NO	PSR No	No
		329.009.00198	03JAN96	2, ., -66	Not Stated	0	CON	MOD NO	PSR No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int ion	Act- ion	Inv Corr Rel Ther	SAE
Asthenia	FATIGUE	329.011.00210	24OCT96	27, -40, -40	12 Days	0	CON	MIL	NO	PSR	No
	SLIGHTLY TIRED	329.005.00005	03NOV94	3, ., -6	14 Days	0	5	MIL	NO	PSR	No
	TIRED	329.005.00254	16MAR96	31, -25, -227	Not Stated	0	CON	MIL	NO	PSR	No
	WEAKNESS	329.003.00094	11DEC95 12DEC95	49, ., -24 50, ., -23	02:00 Hrs Not Stated	0	1	MOD	NO	PSR	No
Back Pain	BACK ACHE	329.005.00298	12SEP96	114, 58, -134	3 Days	0	CON	MOD	NO	UNR	No
		329.005.00334	19MAR97	48, ., -8	24:00 Hrs	0	CON	MOD	NO	UNR	Yes
		329.010.00263	07SEP96	30, ., -42	06:00 Hrs	0	1	MIL	NO	UNR	No
	BACK AND NECK ACHES	329.001.00062	31OCT94	12, ., -15	19 Days	0		MOD	NO	PSR	No
	BACK PAIN	329.002.00320	17SEP96	125, 64, -21	Not Stated	0	CON	MOD	NO	UNR	No
	BACK PAIN (OLD SOCCER INJURY)	329.005.00298	23JUN96	33, -24, -215	03:00 Hrs	0	CON	MOD	NO	UNR	Yes
	BACKACHE	329.004.00213	02AUG96	1, -54, -240	8 Days	0	CON	MIL	NO	UNR	No
		329.005.00111	07JAN95	-4, -60, -113	39 Days	0	12	MOD	NO	PBU	Yes
		329.005.00331	20DEC96 07JAN97	30, ., -27 48, ., -9	6 Days 2 Days	0	CON	MIL	NO	UNR	No
		329.005.00334	20FEB97	21, ., -35	04:00 Hrs	0	CON	MOD	NO	UNR	No
	329.010.00282	15AUG96	21, ., -58	12 Days	0	CON	MIL	NO	UNR	Yes	

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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

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Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Back Pain	BACKACHE	329.011.00164	11JAN96	21, ., -15	01:00 Hrs	0	1	MIL NO	UNR Yes	No
	BACKACHES	329.009.00312	06JAN97	64, ., -14	15 Days	0	CON	MIL NO	PBU No	No
	NECK SPASM	329.012.00027	21DEC95	16, ., -21	Not Stated	0	CON	MOD NO	PBU Yes	No
Chest Pain	CHEST PAIN	329.005.00254	28FEB96	14, -42, -244	03:00 Hrs	0	CON	MIL NO	UNR No	No
		329.011.00210	03OCT96	6, -61, -61	20 Mins	0	1	MIL NO	PBU No	No
Fever	FEVER	329.003.00086	02JAN95	36, -22, -243	02:00 Hrs	0		MIL NO	UNR Yes	No
		329.005.00111	15FEB95	36, -21, -74	6 Days	0	CON	MOD NO	UNR Yes	No
		329.009.00276	13MAR97	52, ., -19	6 Days	0	CON	MIL NO	PBU Yes	No
		FEVER - 102 DEGREES [FEVER]	329.005.00334	19MAR97	48, ., -8	24:00 Hrs	0	CON	MOD NO	UNR Yes
Headache	HEADACHE	329.001.00064	26JAN95	78, 24, -74	6 Days	0	2	MIL NO	PBU No	No
		329.001.00123	21FEB96	49, ., 0	Not Stated	0	CON	MOD NO	PSR Yes	No
		329.001.00207	18APR96	51, ., -7	8 Days	0	CON	MOD NO	PBU Yes	No
		329.002.00049	25MAR95	17, ., -57	3 Days	0	3	MIL NO	PSR Yes	No
		329.002.00323	01FEB97	82, 24, -145	4 Days	0	1	MIL NO	PSR No	No
		329.003.00094	11DEC95 12DEC95	49, ., -24 50, ., -23	02:00 Hrs Not Stated	0 0	1 CON	MOD NO MIL NO	PSR No PSR No	No No
	329.003.00252	30APR96	21, ., -49	30 Mins	0	5	MIL NO	PSR No	No	

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Headache	HEADACHE	329.003.00252	18MAY96	39, ., -31	02:00 Hrs	0	1	MOD	DCR	PSR	Yes	No
		329.003.00291	14JUL96	12, -54, -108	01:00 Hrs	0	1	MOD	NO	PSR	No	No
		329.004.00018	24MAY95	22, ., -51	02:00 Hrs	0	1	SEV	NO	UNR	Yes	No
		329.005.00012	24JAN95	37, -23, -128	04:30 Hrs	0	CON	MOD	NO	PSR	Yes	No
		329.005.00111	07JAN95	-4, -60, -113	39 Days	0	12	MOD	NO	PBU	Yes	No
			14APR95	94, 38, -16	2 Days	0	CON	SEV	NO	UNR	Yes	No
			16APR95	96, 40, -14	2 Days	0	CON	SEV	NO	UNR	Yes	No
		329.005.00115	12FEB95	7, -65, -68	02:30 Hrs	0	CON	MIL	NO	PSR	No	No
		329.005.00120	14SEP95	16, ., -42	30 Mins	0	1	MIL	NO	UNR	No	No
		329.005.00253	02FEB96	-6, ., -61	04:00 Hrs	0	2	MIL	NO	UNR	Yes	No
			26FEB96	19, ., -37	05:00 Hrs	0	CON	MIL	NO	UNR	Yes	No
			27FEB96	20, ., -36	03:30 Hrs	0	CON	MIL	NO	UNR	Yes	No
			23MAR96	45, ., -11	04:30 Hrs	0	CON	MIL	NO	UNR	Yes	No
		329.005.00254	11FEB96	-4, -59, -261	03:00 Hrs	0	CON	MIL	NO	UNR	Yes	No
			16FEB96	2, -54, -256	5 Days	0	3	MIL	NO	PSR	No	No
			24FEB96	10, -46, -248	1 Days	0	2	MIL	NO	PBU	No	No
			08MAR96	23, -33, -235	02:00 Hrs	0	CON	SEV	NO	UNR	Yes	No
			07APR96	53, -3, -205	02:30 Hrs	0	CON	MOD	NO	PBU	Yes	No
			02SEP96	201, 146, -57	02:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
			03SEP96	202, 147, -56	04:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
		329.005.00293	06APR97	26, ., -31	03:30 Hrs	0	1	MOD	NO	PBU	Yes	No
			19APR97	39, ., -18	01:00 Hrs	0	1	MOD	NO	PBU	Yes	No
			06MAY97	56, ., -1	45 Mins	0	1	MOD	NO	PBU	No	No

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Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Headache	HEADACHE	329.005.00298	06NOV96	169, 113, -79	02:30 Hrs	0	CON	MOD	NO	UNR No	No
		329.005.00331	21NOV96	1, ., -56	4 Days	0	4	MOD	NO	REL Yes	No
			23NOV96	3, ., -54	1 Days	0	2	MIL	NO	PSR No	No
			24NOV96	4, ., -53	1 Days	0	CON	MIL	NO	PSR No	No
			30NOV96	10, ., -47	2 Days	0	2	MOD	NO	REL Yes	No
			26DEC96	36, ., -21	02:30 Hrs	0	CON	MOD	NO	UNR Yes	No
			09JAN97	50, ., -7	02:30 Hrs	0	CON	MIL	NO	PBU No	No
		329.005.00334	03MAR97	32, ., -24	02:30 Hrs	0	CON	MIL	NO	PBU Yes	No
			12MAR97	41, ., -15	05:00 Hrs	0	CON	SEV	NO	PBU Yes	No
		329.006.00037	06FEB95	10, ., -15	Not Stated	0	CON	MOD	NO	REL No	No
		329.006.00042	23MAR96	108, 51, -130	30 Mins	0	1	MOD	NO	PBU Yes	No
			24APR96	140, 83, -98	01:30 Hrs	0	1	MOD	NO	PBU Yes	No
			09JUL96	216, 159, -22	01:00 Hrs	0	1	MOD	NO	UNR Yes	No
			11JUL96	218, 161, -20	06:00 Hrs	0	1	SEV	NO	UNR Yes	No
			13JUL96	220, 163, -18	01:00 Hrs	0	1	MIL	NO	UNR Yes	No
		329.007.00144	14JAN96	39, -18, -18	2 Days	0	1	MIL	NO	PSR Yes	No
		329.007.00266	08MAR96	2, ., -69	04:00 Hrs	0	1	SEV	NO	PSR No	No
		329.007.00267	06MAR96	-1, ., -56	01:00 Hrs	0	1	MOD	NO	PSR No	No
		329.009.00136	04NOV95	33, ., -37	11 Days	0	3	MIL	NO	PBU Yes	No
		329.009.00174	03DEC95	13, -45, -72	Not Stated	0		MOD	NO	PSR Yes	No
		329.010.00263	14AUG96	6, ., -66	03:00 Hrs	0	1	MIL	NO	PBU Yes	No
			17AUG96	9, ., -63	02:00 Hrs	0	1	MIL	NO	PBU Yes	No
			04SEP96	27, ., -45	15 Mins	0	1	MIL	NO	PBU No	No

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----- Treatment Group=PLACEBO Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Headache	HEADACHE	329.010.00277	06AUG96	159, 103, 46	02:00 Hrs	0	1	MIL	NO	UNR	Yes	No
		329.010.00282	02SEP96	39, ., -40	30 Mins	0	1	MOD	NO	PBU	Yes	No
		329.011.00164	11JAN96	21, ., -15	01:00 Hrs	0	1	MIL	NO	PBU	Yes	No
		329.011.00210	03OCT96	6, -61, -61	20 Mins	0	1	MIL	NO	PBU	No	No
	HEADACHE (MODERATE)	329.012.00218	08JUN96	-8, -66, -115	02:00 Hrs	0	1	MOD	NO	UNR	Yes	No
			11JUL96	26, -33, -82	01:00 Hrs	0	1	MOD	NO	UNR	Yes	No
	HEADACHES	329.001.00123	21JAN96	18, ., -31	8 Days	0	CON	MIL	NO	UNR	No	No
		329.002.00323	30DEC96	49, -10, -178	11 Days	0	CON	MIL	NO	PSR	Yes	No
		329.003.00074	09FEB95	16, -41, -258	01:30 Hrs	0	2	MIL	NO	PSR	No	No
		329.003.00080	03JAN96	38, ., -37	Not Stated	0	CON	MIL	NO	PSR	No	No
		329.004.00018	22JUN95	51, ., -22	Not Stated	0	CON	MOD	NO	PSR	Yes	No
		329.004.00213	04AUG96	3, -52, -238	227 Days	0	CON	MIL	NO	UNR	Yes	No
		329.005.00115	14MAR95	37, -35, -38	02:00 Hrs	0	7	MIL	NO	PSR	No	No
		329.006.00042	28DEC95	22, -36, -216	6 Days	0	7	MIL	NO	UNR	No	No
		329.009.00276	04FEB97	15, ., -56	15 Days	0	CON	MIL	NO	PSR	No	No
	HEADACHES (WORSENING)	329.002.00246	10MAY96	23, ., -49	Not Stated	0		MIL	NO	PSR	Yes	No
	INCREASE HEADACHE	329.009.00238	03DEC96	22, ., -47	Not Stated	0	CON	MOD	NO	PSR	Yes	No

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Appendix D.1

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Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Headache	INCREASE IN HEADACHES	329.009.00312	27DEC96	54, ., -24	Not Stated	0		MOD NO	PSR Yes	No
	STOMACH ACHE HEADACHE {SIMULTANEOUS} [HEADACHE]	329.010.00263	08SEP96	31, ., -41	10 Mins	0	1	MIL NO	PSR No	No
Infection	CHLAMYDIA	329.005.00253	04MAR96	26, ., -30	9 Days	0	CON	MIL NO	UNR Yes	No
	FLU	329.012.00217	13JUN96	24, ., -1	7 Days	0	CON	MOD STP	UNR Yes	No
	FLU SYMPTOMS	329.002.00097	16JAN95	14, -45, -247	3 Days	0	CON	MIL NO	UNR Yes	No
		329.007.00311	23JAN97	113, 53, -91	2 Days	0	CON	MOD NO	UNR Yes	No
	FLU (STOMACH ACHE)	329.009.00174	03DEC95	13, -45, -72	5 Days	0	CON	MIL NO	UNR Yes	No
	FLU-NAUSEA, CRAMPS DIARRHEA, STOMACH ACHE	329.005.00010	18JAN95	37, -21, -218	3 Days	0	CON	SEV NO	UNR No	No
	SCABIES	329.009.00169	03DEC95	34, -32, -63	13 Days	0	CON	MOD NO	UNR Yes	No
	STOMACH FLU- (HEADACHE, NAUSEA/VOMITING AND DIARRHEA)	329.005.00012	31DEC94	13, -47, -152	4 Days	0	CON	SEV NO	UNR No	No
	STOMACH VIRUS	329.009.00276	31MAR97	70, ., -1	2 Days	0	CON	MIL NO	PSR Yes	No
	STREP THROAT	329.002.00107	16SEP96	236, 180, -22	46 Days	0	CON	MOD NO	UNR Yes	No
329.012.00224		08DEC96	84, 18, -83	11 Days	0	CON	MIL NO	UNR Yes	No	
STREP THROAT SORE THROAT AND FEVER	329.005.00114	04FEB95	5, -53, -93	11 Days	0	CON	SEV NO	UNR Yes	No	

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Intent-to-Treat Population

 ----- Treatment Group=PLACEBO Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Infection	TOXOPLASMOSIS	329.005.00012	01JUN95	165, 106, 0	Not Stated	0	CON	MOD STP	UNR Yes	No
Pain	BODY ACHES	329.001.00123	22JAN96	19, ., -30	7 Days	0	CON	MIL NO	UNR No	No
		329.001.00207	18APR96	51, ., -7	7 Days	0	CON	MIL NO	UNR No	No
	FACE PAIN	329.005.00111	14APR95	94, 38, -16	2 Days	0	CON	SEV NO	UNR Yes	No
Trauma	SIDE ACHE LEFT SIDE	329.010.00263	10SEP96	33, ., -39	01:30 Hrs	0	1	MIL NO	UNR Yes	No
	CAR ACCIDENT (NO INJURIES)	329.002.00246	15MAY96	28, ., -44	1 Days	0	CON	MIL NO	UNR No	No
	CHARLEY HORSE LEFT LEG-THIGH	329.005.00298	01OCT96	133, 77, -115	4 Days	0	CON	MOD NO	UNR Yes	No
	FACIAL CUTS {LEFT CHEEK}	329.009.00198	18FEB96	48, ., -20	1 Days	0	CON	MOD NO	UNR Yes	No
	FALL FROM ROPE RESULTING IN DIZZINESS, HEADACHES, AND FATIGUE	329.002.00246	26MAY96	39, ., -33	5 Days	0		MOD NO	UNR No	No
	FOOT/ANKLE (RUN OVER BY CAR INJURY-PAIN)	329.005.00010	13APR96	488, 431, 233	3 Days	0	CON	MOD NO	UNR Yes	No
FRACTURED LEFT INDEX FINGER	329.001.00064	25JAN95	77, 23, -75	35 Days	0	CON	MOD NO	UNR No	No	

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 Number of Episodes [No. Epi]: CON = Continuous
 Investigator Intensity [Inv 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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Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Body as a Whole -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther SAE
Trauma	HEAD INJURY WITH LACERATION TO SCALP (4 STITCHES) NO LOSS OF CONSCIOUSNESS (PUSHED ONTO SUBWAY TRACK)	329.004.00213	05OCT96	65, 11, -176	5 Mins	0	1	MOD	NO	UNR	No No
	KNEE INJURY (SOCCER RELATED)	329.005.00298	15JUL96	55, -2, -193	3 Days	0	CON	MOD	NO	UNR	Yes No
	PAIN IN RIGHT LEG (FOLLOWING AUTOMOBILE ACCIDENT)	329.005.00298	16JUN96	26, -31, -222	04:30 Hrs	0	CON	MOD	NO	UNR	Yes No
	PULLED MUSCLE - LEFT SHIN (SOCCER INJURY)	329.005.00298	17OCT96	149, 93, -99	06:00 Hrs	0	CON	MOD	NO	UNR	Yes No
	SCALP LACERATIONS (TOP OF HEAD)	329.009.00197	17JUN96	172, 118, -76	2 Days	0	CON	MOD	NO	UNR	Yes No
	SHOULDER TRAUMA	329.002.00320	16JUN96	32, -30, -114	1 Days	0	CON	MOD	NO	UNR	Yes No
	SPRAINED ANKLE	329.001.00064	04JAN95	56, 2, -96	18 Days	0	CON	MOD	NO	UNR	No No
	SPRAINED WRIST LEFT	329.012.00225	15JUL97	232, 168, -26	Not Stated	0	CON	MIL	NO	UNR	Yes No

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Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Cardiovascular System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Angina Pectoris	ANGINA ON EXERTION	329.007.00141	13SEP95	-8, ., -29	30 Days	0	2	MOD	STP	PBU No	No
Arrhythmia	SINUS ARRHYTHMIA	329.011.00210	24OCT96	27, -40, -40	40 Days	0	2	MIL	NO	PBU No	No
	SINUS-ARRHYTHMIA	329.003.00291	02OCT96	92, 27, -28	29 Days	0	1	MIL	NO	PBU No	No
Av Block	SERIAL INCREASE PR INTERVAL	329.009.00238	26NOV96	15, ., -54	15 Days	0	CON	MIL	NO	PSR No	No
	SINUS ARRHYTHMIA(MOBITZ I)	329.009.00200	06FEB96	15, ., -42	43 Days	0	2	MIL	NO	PBU No	No
Bradycardia	SINUS BRADYCARDIA	329.009.00330	28OCT96	8, ., -7	8 Days	0	CON	MIL	NO	PSR No	No
Bundle Branch Block	RIGHT BUNDLE BRANCH BLOCK	329.009.00128	18APR95	8, ., -14	Not Stated	0	CON	MIL	STP	PSR No	No
Heart Malformation	POSSIBLE LEFT VENTRICULAR HYPERTROPHY	329.009.00330	28OCT96	8, ., -7	8 Days	0	CON	MIL	NO	PSR No	No
Nodal Arrhythmia	JUNCTIONAL ESCAPE PATTERN (EKG)	329.009.00302	03APR96	8, ., -7	Not Stated	0	CON	MIL	NO	PSR No	No
Palpitation	HEART PALPITATION {ONE TIME ONLY}	329.006.00042	18MAY96	164, 107, -74	1 Mins	0	1	MIL	NO	PBU No	No
Postural Hypotension	ORTHOSTATIC HYPOTENSION	329.009.00135	30OCT95	29, ., -20	21 Days	0	CON	MIL	NO	PSR No	No
Supraventricular Extrasystoles	OCCASIONAL PREMATURE ATRIAL COMPLEXES	329.009.00330	28OCT96	8, ., -7	8 Days	0	CON	MIL	NO	PSR No	No
Syncope	FAINT UPON STANDING	329.001.00069	17MAR95	30, ., -32	22 Days	0	CON	MIL	NO	PSR No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

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----- Treatment Group=PLACEBO Body System=Cardiovascular System -----

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Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Tachycardia	ELEVATED HEART RATE	329.005.00005	08NOV94	8, ., -1	2 Days	0	2	MOD STP	PSR No	No
Vasodilatation	HOT FLASHES	329.002.00097	25JAN95	23, -36, -238	5 Mins	0	4	MIL NO	PSR No	No
		329.009.00306	02JUL96	22, ., -48	50 Days	0	CON	MIL NO	PSR No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
Constipation	CONSTIPATION	329.003.00074	18FEB95	25, -32, -249	12 Days	0	CON	MIL	NO	PSR No	No
		329.003.00291	21AUG96	50, -16, -70	Not Stated	0	1	MIL	NO	PBU No	No
		329.004.00213	08AUG96 10AUG96	7, -48, -234 9, -46, -232	5 Days 13 Days	0 0	2 CON	MIL MIL	NO NO	PSR No UNR No	No No
		329.009.00174	10DEC95	20, -38, -65	Not Stated	0		MIL	NO	PSR No	No
Decreased Appetite	ANOREXIA APPETITE DOWN DECREASED APPETITE	329.001.00069	18MAR95	31, ., -31	21 Days	0	CON	MIL	NO	PSR No	No
		329.008.00191	03FEB96	3, -59, -131	Not Stated	0	CON	MIL	NO	PSR No	No
		329.001.00207	21MAR96	23, ., -35	15 Days	0	CON	MIL	NO	PBU No	No
		329.009.00276	18MAR97	57, ., -14	Not Stated	0	CON	MIL	NO	PSR No	No
Diarrhea	DIARRHEA	329.001.00064	23NOV94 31JAN95	14, -41, -138 83, 29, -69	03:00 Hrs 2 Days	0 0	2 CON	MIL MIL	NO NO	PSR No UNR No	No No
		329.001.00207	03MAR96 06APR96 24APR96	5, ., -53 39, ., -19 57, ., -1	15:00 Hrs 13:00 Hrs 3 Days	0 0 0	3 4 CON	MOD MIL MIL	NO NO NO	UNR No PBU No UNR No	No No No
		329.004.00213	07AUG96 09FEB97	6, -49, -235 192, 138, -49	4 Days 31 Days	0 0	4 CON	MIL MIL	NO NO	PSR No UNR No	No No
		329.007.00311	18OCT96 23JAN97	16, -45, -188 113, 53, -91	02:00 Hrs 2 Days	0 0	1 12	MIL MOD	NO NO	UNR No UNR Yes	No No
		329.009.00135	21OCT95	20, ., -29	1 Days	0	CON	MIL	NO	UNR No	No
		329.010.00282	19SEP96	56, ., -23	6 Days	0	20	MOD	NO	PSR No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Diarrhea	DIARRHEA(VIRAL)	329.009.00202	22FEB96	3, ., -33	3 Days	0	CON	MIL NO	PBU No	No
	STOMACH ACHE WITH DIARRHEA	329.005.00298	18MAY96	-4, -60, -251	4 Days	0	CON	SEV NO	UNR No	No
Dry Mouth	DRY MOUTH	329.001.00062	04NOV94	16, ., -11	Not Stated	0	CON	MIL NO	PSR No	No
		329.002.00246	25APR96	8, ., -64	Not Stated	0	CON	MIL NO	REL No	No
		329.002.00320	14JUN96	30, -32, -116	11 Days	0	CON	MIL NO	PSR No	No
		329.003.00080	04JAN96	39, ., -36	Not Stated	0	CON	MIL NO	PSR No	No
		329.003.00085	22DEC94	45, ., -26	4 Days	0	1	MIL NO	PSR No	No
		329.003.00086	01DEC94	4, -54, -275	Not Stated	0	CON	MIL NO	PSR No	No
		329.003.00291	28AUG96	57, -9, -63	8 Days	0	CON	MIL NO	UNR No	No
		329.004.00018	20JUN95	49, ., -24	21 Days	0	CON	SEV NO	PSR No	No
		329.004.00213	14SEP96	44, -11, -197	Not Stated	0	CON	MIL NO	PSR No	No
		329.005.00115	08FEB95	3, -69, -72	6 Days	0	CON	MIL NO	REL No	No
Dyspepsia	DRY MOUTH (1/2 HOUR AFTER TAKING MEDICATION)	329.005.00331	23NOV96	3, ., -54	5 Days	0	CON	MIL NO	REL No	No
		329.005.00012	22DEC94	4, -56, -161	13 Days	0	CON	MIL NO	REL No	No
Dyspepsia	INDIGESTION(MEXICAN SPICY FOOD)	329.006.00042	31DEC95	25, -33, -213	3 Days	0	3	MOD NO	UNR No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Dyspepsia	STOMACH ACIDITY	329.003.00094	24NOV95	32, ., -41	Not Stated	0	CON	MIL NO	PSR Yes	No
	STOMACH UPSET	329.001.00069	22MAR95	35, ., -27	17 Days	0	2	MIL NO	PSR No	No
	UPSET STOMACH	329.006.00042	07JAN96	32, -26, -206	22:00 Hrs	0	1	MOD NO	UNR Yes	No
	UPSET STOMACH (1/2 HOUR AFTER TAKING MEDICATION)	329.005.00012	22DEC94	4, -56, -161	13 Days	0	CON	MIL NO	REL No	No
Gastrointestinal Disorder	FOOD POISONING	329.005.00334	18MAR97	47, ., -9	3 Days	0	CON	SEV NO	UNR No	No
Increased Appetite	INCREASED APPETITE	329.001.00062	23OCT94	4, ., -23	Not Stated	0	CON	MOD NO	PSR No	No
Nausea	NAUSEA	329.001.00064	31JAN95	83, 29, -69	2 Days	0	CON	MIL NO	UNR No	No
		329.001.00069	21FEB95	6, ., -56	02:30 Hrs	0	1	MIL NO	PSR No	No
		329.001.00071	04APR95	41, ., -30	23 Days	0	CON	MIL NO	PSR No	No
		329.001.00123	22JAN96 21FEB96	19, ., -30 49, ., 0	7 Days Not Stated	0 0	CON CON	MIL NO MIL NO	UNR No PSR No	No No
		329.003.00252	30APR96	21, ., -49	30 Mins	0	5	MIL NO	PSR No	No
		329.004.00018	09MAY95	7, ., -66	5 Days	0	CON	MOD NO	REL No	No
		329.004.00020	12NOV95	4, ., -12	3 Days	0	CON	MOD NO	UNR No	No
		329.005.00111	15FEB95 16MAR95	36, -21, -74 65, 9, -45	4 Days 2 Days	0 0	CON CON	MIL NO MIL NO	PSR No PBU No	No No
329.006.00037	15FEB95	19, ., -6	Not Stated	0	CON	MIL NO	REL No	No		

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Number of Episodes [No. Epi]: CON = Continuous
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Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int ion	Act- ion	Inv Rel Ther	Corr Ther	SAE		
Nausea	NAUSEA	329.006.00042	07JAN96	32, -26, -206	22:00 Hrs	0	1	MOD	NO	UNR	Yes	No		
		329.007.00266	08MAR96	2, ., -69	04:00 Hrs	0	1	MIL	NO	PSR	No	No		
		329.007.00311	18OCT96	16, -45, -188	02:00 Hrs	0	1	MIL	NO	UNR	No	No		
		329.009.00135	21OCT95	20, ., -29	2 Days	0	CON	MIL	NO	UNR	No	No		
		329.009.00197	20AUG96	236, 182, -12	4 Days	0		MOD	NO	UNR	No	No		
		329.009.00198	08JAN96	7, ., -61	13 Days	0	CON	MIL	NO	PSR	No	No		
		329.009.00200	20FEB96	29, ., -28	9 Days	0	CON	MIL	NO	PSR	No	No		
		329.009.00238	03DEC96	22, ., -47	Not Stated	0	CON	MIL	NO	PSR	No	No		
		329.009.00276	04FEB97	15, ., -56	29 Days	0	CON	MIL	NO	PSR	No	No		
		329.009.00330	21OCT96	1, ., -14	Not Stated	0	CON	MOD	STP	REL	No	No		
			NAUSEA (POST TAKING MEDS)	329.001.00123	05JAN96	2, ., -47	04:30 Hrs	0	2	MIL	NO	PSR	No	No
					29JAN96	26, ., -23	5 Days	0	CON	MIL	NO	PSR	No	No
			NAUSEA AM	329.001.00069	22MAR95	35, ., -27	17 Days	0	2	MIL	NO	PSR	No	No
Tooth Disorder	ORTHODONTIC PAIN	329.006.00042	02JUL96	209, 152, -29	5 Days	0	CON	SEV	NO	UNR	Yes	No		
		329.005.00111	14APR95	94, 38, -16	2 Days	0	CON	SEV	NO	UNR	Yes	No		
		329.011.00285	04JUN96	18, ., -57	Not Stated	0	CON	MOD	NO	UNR	Yes	No		
		329.012.00224	01OCT96	16, -51, -151	1 Days	0	CON	MIL	NO	UNR	Yes	No		

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Digestive System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Tooth Disorder	{TOOTH DISORDER}	329.005.00334	29JAN97	-2, ., -57	01:00 Hrs	0	CON	SEV NO	UNR No	No
Ulcerative Stomatitis	MOUTH SORES	329.010.00263	06OCT96	59, ., -13	8 Days	0	CON	MIL NO	UNR No	No
Vomiting	EMESIS	329.006.00042	07JAN96	32, -26, -206	1 Mins	0	1	MOD NO	UNR No	No
	NAUSEA AND VOMITING	329.002.00241	03MAR96	27, -30, -81	3 Days	0	2	MIL NO	PBU No	No
	NAUSEA-VOMITING	329.004.00018	01JUN95	30, ., -43	38 Days	0	CON	MIL NO	PSR No	No
	VOMITING	329.002.00246	02MAY96	15, ., -57	2 Days	0	2	MIL NO	PBU No	No
		329.007.00311	23JAN97	113, 53, -91	2 Days	0	12	MOD NO	UNR Yes	No
		329.009.00135	21OCT95	20, ., -29	2 Days	0	CON	MIL NO	UNR No	No
		329.009.00197	20AUG96	236, 182, -12	4 Days	0	3	MIL NO	UNR No	No
		329.009.00330	01NOV96	12, ., -3	2 Days	0	2	MIL STP	PSR No	No
	VOMITING DRY HEAVES	329.005.00111	17APR95	97, 41, -13	20:00 Hrs	0	CON	SEV NO	UNR No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Hemic and Lymphatic System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Anemia	ANEMIA	329.009.00306	03JUN96	-8, ., -77	Not Stated	0	CON	MIL NO	UNR Yes	No
Eosinophilia	INCREASED EOSINOPHILS	329.005.00120	22AUG95 26OCT95	-8, ., -65 58, ., 0	Not Stated Not Stated	0 0	CON CON	MIL NO MIL NO	UNR No UNR No	No No
Lymphadenopathy	SLIGHTLY ENLARGED NON-TENDER LEFT JUGULO-DIGASTRIC NODE	329.012.00225	04APR97	130, 66, -128	59 Days	0	1	MIL NO	UNR No	No
	SWOLLEN LYMPH NODES IN NECK	329.001.00071	13MAR95	19, ., -52	4 Days	0	CON	MIL NO	UNR No	No
Thrombocythemia	ELEVATED PLATELETS	329.003.00316	11FEB97	57, ., -7	Not Stated	0	CON	MIL NO	PBU No	No
Wbc Abnormality	ATYPICAL LYMPHS	329.005.00115	18APR95	72, 1, -3	1 Days	0	1	MIL NO	PBU No	No
	ELEVATED ATYPICAL LYMPHS	329.002.00107	16SEP96	236, 180, -22	46 Days	0	CON	MOD NO	UNR Yes	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Metabolic and Nutritional Disorders -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE	
Hyperglycemia	INCREASED GLUCOSE	329.005.00120	22AUG95	-8, ., -65	Not Stated	0	CON	MIL	NO	UNR	No	No	
			26OCT95	58, ., 0	Not Stated	0	CON	MIL	NO	UNR	No	No	
Thirst	INCREASE IN THIRST	329.009.00136	10OCT95	8, ., -62	15 Days	0	CON	MIL	NO	PSR	No	No	
			329.009.00200	12FEB96	21, ., -36	3 Days	0	CON	MIL	NO	PSR	No	No
			329.002.00323	26NOV96	15, -44, -212	10 Days	0	CON	MIL	NO	REL	No	No
Weight Loss	WEIGHT LOSS	329.009.00276	13MAR97	52, ., -19	20 Days	0	CON	MIL	NO	PSR	No	No	
			329.005.00115	10APR95	64, -8, -11	9 Days	0	CON	SEV	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Musculoskeletal System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int ion	Act- ion	Inv Rel	Corr Ther	SAE
Arthralgia	KNEE PAIN (RIGHT KNEE)	329.007.00311	18NOV96	47, -14, -157	5 Days	0	CON	MOD	NO	UNR	Yes	No
	LEFT KNEE PAIN	329.012.00224	03OCT96	18, -49, -149	18:00 Hrs	0	CON	MIL	NO	UNR	No	No
	SHOULDER PAIN IN AM	329.005.00254	18MAR96	33, -23, -225	3 Days	0	3	MOD	NO	UNR	No	No
	SHOULDER PAIN RIGHT SHOULDER	329.010.00263	11SEP96	34, ., -38	12:00 Hrs	0	1	MIL	NO	UNR	No	No
Myalgia	ARM AND LEG MUSCLE ACHES	329.001.00071	21MAR95	27, ., -44	5 Days	0	CON	MIL	NO	PBU	No	No
	MUSCLE ACHE	329.006.00042	07JAN96	32, -26, -206	34:00 Hrs	0	1	MIL	NO	UNR	No	No

* days relative to start of acute phase, days relative to start of continuation phase, days relative to stop of study medication
Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Abnormal Dreams	NIGHTMARE	329.009.00198	03JAN96	2, ., -66	7 Days	0	6	MOD NO	PSR No	No
	VIVID DREAMING	329.009.00238	26NOV96	15, ., -54	8 Days	0	CON	MIL NO	PSR No	No
Anxiety	ANXIETY	329.012.00027	21DEC95	16, ., -21	Not Stated	0	CON	MOD NO	PBU Yes	No
	TENSION {ANXIOUS FEELING POST CONFRONTATION NON-MEDICATION RELATED}	329.004.00018	28MAY95	26, ., -47	1 Days	0	1	SEV NO	UNR Yes	No
Depersonalization	"SPACED OUT" FEELING	329.005.00331	08DEC96	18, ., -39	5 Days	0	CON	MIL DCR	PSR No	No
Depression	DEPRESSION (WORSENING)	329.012.00217	19JUN96	30, ., 5	8 Days	0	CON	SEV NO	UNR Yes	Yes
	WORSENING OF DEPRESSION	329.001.00123	18FEB96	46, ., -3	Not Stated	0	CON	SEV STP	REL No	Yes
Dizziness	DIZZINESS	329.002.00246	23MAY96	36, ., -36	7 Days	0	CON	MIL NO	PSR No	No
		329.003.00080	04JAN96	39, ., -36	Not Stated	0	CON	MIL NO	PSR No	No
		329.003.00086	12DEC94	15, -43, -264	Not Stated	0	CON	MIL NO	PBU No	No
		329.003.00094	11DEC95	49, ., -24	02:00 Hrs	0	1	MOD NO	PSR No	No
		329.003.00252	29APR96	20, ., -50	1 Mins	0	1	MIL NO	PSR No	No
		329.003.00291	07AUG96	36, -30, -84	8 Days	0	1	MIL NO	PBU No	No
	329.005.00010	22DEC94 20JAN95	10, -48, -245 39, -19, -216	6 Days 24:00 Hrs	0 0	4 CON	MIL NO MIL NO	PSR No PSR No	No No	
	329.005.00331	19DEC96	29, ., -28	5 Mins	0	CON	MIL NO	PBU No	No	

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action]: DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Dizziness	DIZZINESS	329.009.00330	21OCT96	1, ., -14	Not Stated	0	CON	MOD STP	REL No	No
		329.011.00164	24JAN96	34, ., -2	06:00 Hrs	0	7	MIL NO	PSR No	No
	DIZZINESS (ESPECIALLY DURING AEROBICS AND HEAVY LIFTING)	329.002.00323	19NOV96	8, -51, -219	37 Days	0	CON	MOD NO	PSR No	No
	DIZZINESS (WHEN STANDING)	329.002.00107	25AUG96	214, 158, -44	Not Stated	0	CON	MIL NO	PSR No	No
	DIZZINESS (WHEN STANDS QUICKLY)	329.002.00097	23MAR95	80, 22, -181	1 Mins	0	3	MIL NO	PSR No	No
	DIZZINESS IN AM	329.005.00331	09DEC96	19, ., -38	4 Days	0	3	MIL NO	PBU No	No
	DIZZINESS WHEN RIDING IN ELEVATOR OR ESCALATOR	329.001.00062	10NOV94	22, ., -5	9 Days	0		MIL NO	UNR No	No
	DIZZINESS WHEN STANDING UP	329.005.00298	09DEC96	202, 146, -46	3 Days	0	3	MIL NO	PBU No	No
	DIZZY	329.009.00197	18JAN96	21, -34, -227	1 Days	0	CON	MIL NO	PBU No	No
	DIZZY UPON POSITION CHANGE	329.001.00064	12NOV94	3, -52, -149	6 Days	0	5	MIL NO	PSR No	No
	FAINTING	329.002.00320	03SEP96	111, 50, -35	Not Stated	0	CON	MOD NO	UNR No	No
	SLIGHT DIZZINESS WHEN TAKING MEDS	329.009.00169	19DEC95	50, -16, -47	Not Stated	0	CON	MOD NO	PSR No	No
	SLIGHTLY DIZZY	329.005.00005	03NOV94	3, ., -6	14 Days	0	4	MIL NO	PSR No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Drug Dependence	POSITIVE MARIJUANA URINE SCREEN (PROTOCOL DEVIATION)	329.002.00101	22JUN95	87, 29, -19	1 Days	0	CON	MOD NO	UNR No	No
Emotional Lability	PT. HOSPITALIZED FOR SUICIDAL IDEATION	329.002.00241	23MAY96	108, 52, 0	Not Stated	0	CON	SEV STP	PBU Yes	Yes
	SUICIDAL THOUGHTS	329.001.00123	18FEB96	46, ., -3	Not Stated	0	CON	SEV STP	REL No	Yes
Euphoria	LAUGHING A LOT {EUPHORIA}	329.005.00120	19SEP95	21, ., -37	17 Days	0	3	MOD NO	UNR No	No
Hostility	PT. HOSPITALIZED FOR HOMICIDAL IDEATION	329.002.00241	23MAY96	108, 52, 0	Not Stated	0	CON	SEV STP	PBU No	Yes
Hyperkinesia	AKATHISIA	329.007.00266	11MAR96	5, ., -66	46 Days	0	CON	MIL NO	REL No	No
Hypertonia	STIFF NECK	329.005.00298	29JUN96	39, -18, -209	04:00 Hrs	0	CON	MOD NO	UNR Yes	No
Hypesthesia	NUMB LEFT UPPER LEG	329.012.00225	20MAR97	115, 51, -143	1 Days	0	1	MIL NO	PBU No	No
Insomnia	DIFFICULTY FALLING TO SLEEP	329.012.00224	01JAN97	108, 42, -59	1 Days	0	1	MIL NO	PBU Yes	No
	DROP IN SLEEP	329.008.00162	20DEC95	50, -16, -210	8 Days	0	1	MIL INC	PSR No	No
	INSOMNIA	329.006.00037	06FEB95	10, ., -15	Not Stated	0	CON	MOD NO	REL No	No
	INSOMNIA (WORSENING)	329.004.00018	07MAY95	5, ., -68	20 Days	0	CON	SEV NO	REL No	No
	MILD INITIAL INSOMNIA	329.009.00169	12DEC95	43, -23, -54	Not Stated	0	CON	MIL NO	PSR No	No
Manic Reaction	HYPOMANIA	329.009.00169	02JAN96	64, -2, -33	Not Stated	0	CON	SEV STP	REL No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Nervous System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int ion	Act- ion	Inv Corr Rel Ther	SAE	
Nervousness	FIDGETINESS	329.005.00331	23NOV96	3, ., -54	10:00 Hrs	0	CON	MIL	NO	PSR	No	
	IRRITABILITY	329.003.00252	16MAY96	37, ., -33	13 Days	0	CON	MOD	DCR	PSR	No	
	NERVOUS	329.005.00120	19SEP95	21, ., -37	2 Days	0		MIL	NO	UNR	No	
			21SEP95	23, ., -35	8 Days	0	CON	MIL	NO	UNR	No	
	RESTLESS AND JUMPY	329.008.00191	28FEB96	28, -34, -106	Not Stated	0	CON	MIL	NO	PSR	No	
RESTLESSNESS	329.009.00198	16JAN96	15, ., -53	8 Days	0	CON	MIL	NO	PSR	No		
Somnolence	DAYTIME SLEEPINESS	329.009.00169	22NOV95	23, -43, -74	17 Days	0		MIL	NO	PSR	No	
	FALLING ASLEEP IN THE AFTERNOON	329.002.00323	15NOV96	4, -55, -223	42 Days	0	CON	MOD	NO	PSR	No	
	SLEEPINESS	329.008.00191	03FEB96	3, -59, -131	Not Stated	0	CON	MOD	NO	PSR	No	
Tremor	HAND TREMORS	329.001.00123	04FEB96	32, ., -17	Not Stated	0		3	MIL	NO	PSR	No
		329.005.00114	01MAR95	30, -28, -68	22 Days	0	CON	MIL	NO	REL	No	

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Number of Episodes [No. Epi]: CON = Continuous
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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Respiratory System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Asthma	BRONCHOSPASM	329.012.00225	29MAR97	124, 60, -134	11 Days	0	CON	MOD NO	UNR Yes	No
	RECURRENT ASTHMA	329.012.00217	15JUN96	26, ., 1	5 Days	0	CON	MOD NO	UNR Yes	No
Bronchitis	BRONCHITIS	329.006.00037	06FEB95	10, ., -15	8 Days	0	CON	MOD NO	UNR Yes	No
		329.007.00311	17MAR97	166, 106, -38	15 Days	0	CON	MOD NO	UNR Yes	No
		329.008.00162	29NOV95	29, -37, -231	11 Days	0	1	MIL NO	UNR No	No
	BRONCHITIS SYMPTOMS: CONGESTION, COUGH	329.007.00311	22OCT96	20, -41, -184	12 Days	0	CON	MOD NO	UNR Yes	No
	BRONCHITIS WITH BRONCHOSPASMS	329.001.00123	13JAN96	10, ., -39	13 Days	0	CON	MOD NO	UNR Yes	No
Cough Increased	CONGESTED COUGH	329.001.00064	24DEC94	45, -10, -107	18 Days	0	CON	MIL NO	UNR No	No
	COUGH	329.001.00207	05APR96	38, ., -20	7 Days	0	CON	MIL NO	UNR No	No
		329.002.00241	09APR96	64, 8, -44	22 Days	0	CON	MOD NO	UNR Yes	No
		329.005.00120	12SEP95	14, ., -44	8 Days	0	CON	MOD NO	UNR Yes	No
		329.009.00238	23DEC96	42, ., -27	9 Days	0	CON	MIL NO	UNR Yes	No
	COUGHING	329.005.00120	23OCT95	55, ., -3	Not Stated	0	CON	MIL NO	UNR Yes	No
	DRY COUGH	329.001.00123	07JAN96	4, ., -45	19 Days	0	CON	MOD NO	UNR No	No
Dyspnea	SHORTNESS OF BREATH	329.003.00252	21MAY96	42, ., -28	30 Mins	0	1	MIL DCR	PSR No	No
Epistaxis	NOSEBLEEDS	329.005.00298	06JAN97	230, 174, -18	7 Days	0	8	SEV NO	PSR No	No

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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Respiratory System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Pharyngitis	PHARYNGITIS	329.002.00323	11APR97	151, 93, -76	8 Days	0	1	MIL	NO	UNR	Yes	No
	SORE THROAT	329.001.00069	09MAR95	22, ., -40	8 Days	0	CON	MIL	NO	UNR	No	No
		329.001.00071	13MAR95	19, ., -52	15 Days	0	CON	MOD	NO	UNR	No	No
		329.001.00207	10APR96	43, ., -15	2 Days	0	CON	MIL	NO	UNR	No	No
	329.005.00111	15FEB95		36, -21, -74	6 Days	0	CON	MOD	NO	UNR	Yes	No
		16MAR95		65, 9, -45	2 Days	0	CON	SEV	NO	UNR	Yes	No
		16APR95		96, 40, -14	2 Days	0	CON	SEV	NO	UNR	Yes	No
	329.005.00334	03FEB97	4, ., -52	8 Days	0	CON	MOD	NO	UNR	Yes	No	
	329.007.00266	27APR96	52, ., -19	13 Days	0	CON	MOD	NO	UNR	Yes	No	
	329.009.00238	23DEC96	42, ., -27	9 Days	0	CON	MIL	NO	UNR	Yes	No	
329.009.00276	20FEB97		31, ., -40	12:00 Hrs	0	CON	MIL	NO	PBU	No	No	
	13MAR97		52, ., -19	6 Days	0	CON	MIL	NO	PBU	Yes	No	
	TONSILLITIS	329.002.00107	16SEP96	236, 180, -22	46 Days	0	CON	MOD	NO	UNR	Yes	No
Respiratory Disorder	COLD AND CONGESTION	329.010.00263	22SEP96	45, ., -27	8 Days	0	CON	MIL	NO	UNR	Yes	No
	COLD SYMPTOMS	329.003.00080	23DEC95	27, ., -48	12 Days	0	1	MIL	NO	UNR	No	No
		329.012.00224	22SEP96	7, -60, -160	11 Days	0	CON	MIL	NO	UNR	No	No
	COLD SYMPTOMS:STUFFY NOSE, SORE THROAT, FEVER	329.005.00298	08DEC96	201, 145, -47	12 Days	0	CON	MOD	NO	UNR	Yes	No
	COLD {SYMPTOMS}	329.003.00086	12DEC94	15, -43, -264	3 Days	0	CON	MIL	NO	UNR	Yes	No

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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Respiratory System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Respiratory Disorder	COLD {SYMPTOMS}	329.003.00086	15MAY95	169, 112, -110	5 Days	0	CON	MIL	NO	UNR	Yes	No
		329.003.00315	18NOV96	7, ., -53	3 Days	0	1	MIL	NO	UNR	Yes	No
	COMMON COLD	329.012.00027	15DEC95	10, ., -27	13 Days	0	CON	SEV	NO	UNR	Yes	No
		329.012.00217	03JUN96	14, ., -11	10 Days	0	CON	MIL	NO	UNR	Yes	No
	RESPIRATORY CONGESTION	329.005.00293	18MAR97	7, ., -50	8 Days	0	CON	MOD	NO	PBU	Yes	No
	UPPER RESPIRATORY CONGESTION	329.001.00069	09MAR95	22, ., -40	12 Days	0	CON	MIL	NO	UNR	No	No
	UPPER RESPIRATORY INFECTION	329.001.00071	13MAR95	19, ., -52	15 Days	0	CON	MOD	NO	UNR	No	No
UPPER RESPIRATORY INFECTION (COLD)	329.004.00213	12AUG96	11, -44, -230	19 Days	0	CON	MIL	NO	UNR	Yes	No	
Rhinitis	CONGESTION {NOSE}	329.009.00238	23DEC96	42, ., -27	9 Days	0	CON	MIL	NO	UNR	Yes	No
	NASAL CONGESTION	329.001.00064	24DEC94	45, -10, -107	18 Days	0	CON	MIL	NO	UNR	No	No
	NASAL STUFFINESS	329.005.00111	16FEB95	37, -20, -73	49 Days	0	CON	SEV	NO	PBU	Yes	No
	NOSE PAIN	329.005.00111	14APR95	94, 38, -16	2 Days	0	CON	SEV	NO	UNR	Yes	No
	RUNNY NOSE	329.005.00120	12SEP95	14, ., -44	7 Days	0	CON	MIL	NO	UNR	Yes	No
Sinusitis	HEAD CONGESTION	329.001.00207	05APR96	38, ., -20	7 Days	0	CON	MIL	NO	UNR	No	No
		329.001.00207	22MAR96	24, ., -34	4 Days	0	CON	MIL	NO	UNR	No	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Respiratory System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
Sinusitis	SINUS CONGESTION	329.005.00298	30JUN96	40, -17, -208	2 Days	0	CON	MOD	NO	UNR	Yes	No
			28AUG96	99, 43, -149	8 Days	0	CON	MOD	NO	UNR	No	No
		329.007.00311	26DEC96	85, 25, -119	2 Days	0	CON	MIL	NO	UNR	Yes	No
	SINUS HEADACHE	329.006.00042	07JAN96	32, -26, -206	5 Days	0	CON	MOD	NO	UNR	No	No
	SINUS HEADACHE AND CONGESTION	329.005.00298	02JUN96	12, -45, -236	4 Days	0	CON	MOD	NO	UNR	Yes	No
	SINUS INFECTION	329.001.00207	18APR96	51, ., -7	15 Days	0	CON	MOD	NO	UNR	Yes	No
		329.005.00111	17APR95	97, 41, -13	Not Stated	0	CON	SEV	STP	UNR	Yes	No
		329.005.00331	17DEC96	27, ., -30	11 Days	0	CON	SEV	NO	UNR	Yes	No
	SINUS STUFFINESS	329.005.00111	16FEB95	37, -20, -73	49 Days	0	CON	SEV	NO	PBU	Yes	No
	SINUSITIS	329.007.00311	23OCT96	21, -40, -183	31 Days	0	CON	MIL	NO	UNR	Yes	No
TOOTHACHE/QUESTIONABLE SINUS INFECTION	329.005.00115	23FEB95	18, -54, -57	26 Days	0	CON	SEV	NO	UNR	Yes	No	

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int] : MIL = Mild, MOD = Moderate, SEV = Severe
Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Skin and Appendages -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Acne	ACNE	329.005.00293	26MAR97	15, ., -42	Not Stated	0	CON	MIL NO	UNR No	No
Contact Dermatitis	CONTACT DERMATITIS LOWER AND UPPER HIP	329.009.00136	10OCT95	8, ., -62	15 Days	0	CON	MIL NO	PBU No	No
Herpes Zoster	VARICELLA	329.002.00246	12JUN96	56, ., -16	5 Days	0		MOD NO	UNR No	No
Maculopapular Rash	RASH ON WRIST ELBOWS, ANKLE, (MACULOPAPU LAR)	329.009.00302	03APR96	8, ., -7	Not Stated	0	CON	MOD STP	PSR No	No
Rash	NON PAPULAR RASH (UPPER TORSO AND BACK)	329.009.00200	19MAR96	57, ., 0	Not Stated	0	CON	MIL NO	PBU No	No
	RASH	329.004.00213	20DEC96	141, 87, -100	8 Days	0	CON	MIL NO	PBU No	No
	RASH ON BACK	329.003.00086	13FEB95	78, 21, -201	72 Days	0	CON	MOD NO	PSR Yes	No
	RASH ON BOTH FOREARMS	329.005.00111	30JAN95	20, -37, -90	6 Days	0	CON	MOD NO	PBU No	No
	RASH {MINOR OF UNKNOWN CAUSES}	329.003.00094	28OCT95	5, ., -68	24:00 Hrs	0		1 MIL NO	PBU No	No
Sweating	SWEATY HANDS	329.002.00097	17JAN95	15, -44, -246	127 Days	0		MIL NO	PBU No	No
Urticaria	HIVES	329.005.00010	02MAR95	80, 23, -175	6 Days	0	CON	MOD NO	UNR Yes	No

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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
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Special Senses -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Abnormal Vision	BLURRING VISION	329.002.00097	18JAN95	16, -43, -245	126 Days	0	99	MOD NO	PSR No	No
	BLURRY VISION	329.004.00018	20JUN95	49, ., -24	21 Days	0	CON	MOD NO	PSR No	No
Eye Disorder	EYE INFECTION	329.008.00162	07DEC95	37, -29, -223	11 Days	0	1	MIL NO	UNR No	No
Otitis Media	EAR INFECTION	329.002.00320	09SEP96	117, 56, -29	11 Days	0	1	MOD NO	UNR Yes	No
	EAR INFECTION LEFT	329.012.00225	29MAR97	124, 60, -134	11 Days	0	CON	MOD NO	UNR Yes	No
	OTITIS MEDIA(EAR INFECTION)	329.012.00027	26NOV95	-10, ., -46	12 Days	0	CON	MOD NO	UNR Yes	No

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Number of Episodes [No. Epi]: CON = Continuous
Investigator Intensity [Inv Int]: MIL = Mild, MOD = Moderate, SEV = Severe
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Corrective Therapy [Corr Ther]
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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Urogenital System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Albuminuria	ABNORMAL URINALYSIS POSITIVE PROTEIN MODERATE BACTERIA [ABNORMAL URINALYSIS POSITIVE PROTEIN]	329.005.00334	27MAR97	56, ., 0	1 Days	0	CON	MOD NO	UNR No	No
	URINE 1+PROTEIN	329.001.00064	28MAR95	139, 85, -13	Not Stated	0	CON	MIL NO	PBU No	No
		329.001.00069	13APR95	57, ., -5	Not Stated	0	CON	MIL NO	PBU No	No
Breast Pain	BREAST SORENESS {FEMALE}	329.008.00158	12SEP95	-1, -63, -106	16 Days	0		MIL NO	UNR No	No
Dysmenorrhea	CRAMPS (MENSTRUAL)	329.010.00282	19SEP96	56, ., -23	12:00 Hrs	0	CON	MIL NO	PBU Yes	No
	MENSTRUAL CRAMPS	329.005.00254	09MAR96	24, -32, -234	12:00 Hrs	0	CON	SEV NO	UNR Yes	No
			28MAY96	104, 49, -154	06:30 Hrs	0	CON	SEV NO	UNR Yes	No
			06JUL96	46, -11, -202	2 Days	0	CON	MOD NO	UNR Yes	No
			04NOV96	167, 111, -81	24:00 Hrs	0	CON	SEV NO	UNR Yes	No
		07DEC96	200, 144, -48	3 Days	0	CON	MOD NO	UNR Yes	No	
		07JAN97	231, 175, -17	3 Days	0	CON	MOD NO	UNR Yes	No	
		329.012.00224	09OCT96	24, -43, -143	Not Stated	0		MOD NO	UNR Yes	No
Kidney Function Abnormal	DECREASED UREA NITROGEN	329.005.00120	22AUG95	-8, ., -65	66 Days	0	CON	MIL NO	UNR No	No
Menstrual Disorder	2 MENSTRUAL CYCLES IN JULY-2 WEEKS APART	329.005.00010	03JUL95	203, 146, -52	6 Days	0	CON	MOD NO	PBU No	No
			18JUL95	218, 161, -37	7 Days	0	CON	MOD NO	PBU No	No

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Appendix D.1

Listing of Adverse Experiences by Treatment Group, ADECS Body System and Preferred Term
Intent-to-Treat Population

----- Treatment Group=PLACEBO Body System=Urogenital System -----

Preferred Term	Verbatim Term	Patient ID	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
Pyuria	ABNORMAL URINALYSIS POSITIVE PROTEIN MODERATE BACTERIA [ABNORMAL URINALYSIS MODERATE BACTERIA]	329.005.00334	27MAR97	56, ., 0	1 Days	0	CON	MOD NO	UNR No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int ion	Act- Rel	Inv Corr Ther	SAE
329.001.00063	Abdominal Pain	STOMACH ACHE	09NOV94	2, ..	-46 8 Days	20	5	MIL NO	PSR No	No	
			30NOV94	23, ..	-25 Not Stated	20	CON	MIL NO	PSR No	No	
	Decreased Appetite	ANOREXIA	10NOV94	3, ..	-45 Not Stated	20	CON	MIL NO	PSR No	No	
	Diarrhea	DIARRHEA	09NOV94	2, ..	-46 14 Days	20	3	MIL NO	PSR No	No	
	Dizziness	DIZZINESS	10NOV94	3, ..	-45 5 Mins	20	1	MIL NO	PSR No	No	
	Ear Pain	RIGHT EARACHE	05DEC94	28, ..	-20 9 Days	20	CON	MOD NO	UNR Yes	No	
	Manic Reaction	MANIA SYMPTOMS	11DEC94	34, ..	-14 Not Stated	20	CON	MOD STP	PSR No	No	
	Nausea	NAUSEA	30NOV94	23, ..	-25 Not Stated	20	CON	MIL NO	PSR No	No	
	Paresthesia	TINGLING LEG AND FEET	10NOV94	3, ..	-45 7 Days	20	2	MIL NO	PSR No	No	
	Pharyngitis	SORE THROAT	05DEC94	28, ..	-20 9 Days	20	CON	MOD NO	UNR Yes	No	
	Tendinous Disorder	PAIN LEFT WRIST RULE OUT SPRAIN VERSUS TENDONITIS (WORSENER) [TENDONITIS]	05NOV94	-3, ..	-50 12 Days	0	CON	MIL NO	UNR No	No	
	Trauma	PAIN LEFT WRIST RULE OUT SPRAIN VERSUS TENDONITIS (WORSENER) [SPRAIN]	05NOV94	-3, ..	-50 12 Days	0	CON	MIL NO	UNR No	No	
	Tremor	TREMBLING JAW TREMORS	10NOV94	3, ..	-45 7 Days	20	3	MIL NO	PSR No	No	
			11DEC94	34, ..	-14 Not Stated	20	3	MIL NO	PSR No	No	

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
329.001.00065	Depression	WORSENING OF DEPRESSION HOSPITALIZED	30NOV94	14, ..	0 Not Stated	20	CON	SEV STP	PSR No	Yes
	Dizziness	DIZZINESS LIGHTHEADED	18NOV94 18NOV94	2, .. 2, ..	-12 Not Stated -12 Not Stated	20	4 MIL NO 4 MIL NO	REL No REL No	No No	
	Dry Mouth	DRY MOUTH	21NOV94	5, ..	-9 Not Stated	20	CON	MIL NO	REL No	No
	Hostility	NEEDED 6 STITCHES TO HAND AFTER BREAKING PICTURES (DUE TO ANGER) RESULTED IN HOSPITALIZATION TO PREVENT AGGRESSION AGAINST SELF	30NOV94	14, ..	0 1 Days	20	CON	MOD STP	PBU No	Yes
	Nausea	NAUSEA	18NOV94	2, ..	-12 Not Stated	20	4 MOD NO	REL No	No	
	Vomiting	VOMITING	21NOV94	5, ..	-9 1 Mins	20	1 MIL NO	REL No	No	
329.001.00068	Dry Mouth	DRY MOUTH	10FEB95	3, ..	-69 Not Stated	20	CON	MIL NO	PSR No	No
	Increased Appetite	INCREASED APPETITE	01MAR95	22, ..	-50 29 Days	20	CON	MIL NO	PSR No	No
	Insomnia	MIDDLE INSOMNIA	15FEB95	8, ..	-64 Not Stated	20	CON	MOD NO	PSR No	No
	Pharyngitis	SORE THROAT	27MAR95	48, ..	-24 2 Days	40	CON	MOD NO	UNR Yes	No
	Respiratory Disorder	VIRAL UPPER RESPIRATORY INFECTION	27FEB95	20, ..	-52 7 Days	20	CON	MOD NO	UNR Yes	No
	Urine Abnormality	CLOUDY URINE ON URINALYSIS	05APR95	57, ..	-15 Not Stated	40	CON	MIL NO	UNR No	No

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Corrective Therapy [Corr Ther]
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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.001.00072	Decreased Appetite	APPETITE DECREASED	28MAR95	9, ., -23	Not Stated	20	CON	MIL	NO	PSR	No
	Headache	HEADACHES	21MAR95	2, ., -30	3 Days	20	2	MIL	NO	PSR	No
329.001.00121	Acne	ACNE WORSE	12APR95	9, -48,-145	21 Days	20	CON	MIL	NO	PBU	No
	Dizziness	DIZZY	23MAY95	50, -7,-104	20 Mins	30	1	MIL	NO	PBU	No
	Nausea	NAUSEA	06APR95	3, -54,-151	27 Days	20	CON	MIL	NO	PSR	No
	Weight Loss	WEIGHT LOSS	11APR95	8, -49,-146	22 Days	20	CON	MIL	NO	PSR	No
329.001.00205	Decreased Appetite	SLIGHT DECREASE APPETITE	09FEB96	3, ., -5	Not Stated	20	CON	MIL	NO	PSR	No
	Manic Reaction	MANIA AND HYPOMANIA SYMPTOMS	10FEB96	4, ., -4	Not Stated	20	CON	SEV	STP	PSR	No
329.001.00206	Dyspepsia	STOMACH UPSET	10MAR96	19, ., -39	2 Days	20	CON	MIL	NO	PBU	No
	Headache	HEADACHE	10MAR96	19, ., -39	2 Days	20	CON	MIL	NO	PBU	No
329.002.00055	Hostility	ALLEGATIONS OF SEXUAL AGGRESSION	25JUL94	32, -24,-124	1 Days	30		MIL	NO	UNR	No
	Photosensitivity	SUNBURN, APPROPRIATE TO DEGREE OF EXPOSURE (BEACH)	13JUL94	20, -36,-136	3 Days	20	1	MIL	NO	UNR	No
329.002.00058	Emotional Lability	INTENTIONAL OVERDOSE {TYLENOL OVERDOSE TOOK 80 PILLS}	19JAN95	122, 64, 3	1 Days	40	CON	MOD	STP	PBU	Yes

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Corrective Therapy [Corr Ther]
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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----											
Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.002.00058	Infection	REPORT OF SORE THROAT.POSITIVE CULTURE,THROAT.BETA HEMOLYTIC STREP,GROUP A.	16NOV94	58, -1, -61	3 Days	40	CON	MIL	NO	UNR	Yes No
329.002.00099	Amnesia	"FORGETFUL"	30JUN95	121, 66, -134	63 Days	40	3	MIL	NO	PBU	No No
	Dizziness	CONSTANT DIZZINESS (DAILY)	28JUN95	119, 64, -136	93 Days	40	CON	MOD	NO	PSR	No No
		DIZZINESS ARISING FROM LAYING SITTING OR SOMETIMES WHEN SITTING	28MAR95	27, -29, -228	28 Days	20	78	MOD	NO	PSR	No No
		DIZZINESS WHEN ARISING SUDDENLY	14MAR95	13, -43, -242	11 Days	20	33	MOD	NO	PSR	No No
		DIZZY	04MAR95	3, -53, -252	30 Mins	20	CON	MIL	NO	PSR	No No
	Headache	HEADACHE	03APR95	33, -23, -222	02:00 Hrs	20	CON	MIL	NO	PSR	Yes No
	Insomnia	INITIAL INSOMNIA (INCREASE 2 HOURS)	24MAY95	84, 29, -171	02:00 Hrs	40	39	SEV	NO	PBU	No No
		INITIAL INSOMNIA MOST NIGHTS INCREASE 2 HOURS	13JUN95	104, 49, -151	33 Days	40	10	MOD	NO	PSR	No No
		RESTLESS AT NIGHT	05MAR95	4, -52, -251	10 Days	20	2	MIL	NO	PSR	No No
	Nausea	NAUSEA	18APR95	48, -8, -207	7 Days	40	21	MIL	NO	PSR	No No
		NAUSEA (FOR 10 MINUTES DAILY BEFORE BREAKFAST)	30JUN95	121, 66, -134	63 Days	40	25	MIL	NO	PSR	No No
		NAUSEATED	04MAR95	3, -53, -252	11 Days	20	CON	MIL	NO	PSR	No No
	Palpitation	HEART PALPITATIONS	30JUN95	121, 66, -134	63 Days	40	3	MOD	NO	PSR	No No
	Respiratory Disorder	HEAD COLD	16MAR95	15, -41, -240	6 Days	20	CON	MIL	NO	UNR	Yes No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.002.00099	Rhinitis	STUFFY NOSE	29MAR95	28, -28, -227	16:00 Hrs	20	CON	MIL	NO	UNR	Yes No
329.002.00102	Abdominal Pain	STOMACH ACHES	05SEP95	146, 92, -106	36 Days	40	1	MOD	NO	REL	No No
	Dizziness	DIZZINESS	05SEP95	146, 92, -106	36 Days	40	1	MOD	NO	REL	No No
	Dyspepsia	HEARTBURN ON AN EMPTY STOMACH WHEN TAKING MEDS.	09MAY95	27, -28, -225	7 Days	30	7	MIL	NO	REL	No No
	Trauma	MOTOR VEHICLE ACCIDENT	02AUG95	112, 58, -140	1 Days	40	1	MIL	NO	UNR	No No
329.002.00105	Diarrhea	DIARRHEA	03AUG95	8, ., -14	8 Days	20	4	MIL	NO	PSR	No No
329.002.00106	Abdominal Pain	STOMACH ACHES	03AUG95	8, ., -40	10 Mins	20	10	MIL	NO	REL	No No
	Dry Mouth	DRY MOUTH	03AUG95	8, ., -40	03:00 Hrs	20	CON	MIL	NO	REL	No No
	Hostility	OPPOSITIONAL DEFIANT DISORDER	15SEP95	51, ., 3	16 Days	40	CON	SEV	NO	PBU	No Yes
329.002.00242	Somnolence	MILD SEDATION	07MAR96	30, -29, -90	8 Days	30	1	MIL	NO	PSR	No No
329.002.00245	Emotional Lability	TYLENOL OVERDOSE {INTENTIONAL}	10APR96	14, ., -4	1 Days	20	1	SEV	STP	UNR	No Yes
329.002.00319	Abdominal Pain	STOMACH PAIN	09JUL96	71, 15, -174	16:00 Hrs	30	1	MIL	NO	UNR	No No
	Asthenia	FATIGUE	01MAY96	2, -55, -243	202 Days	20	CON	MIL	NO	REL	No No
	Chest Pain	CHEST PAIN	09JUL96	71, 15, -174	16:00 Hrs	30	1	MIL	NO	UNR	No No
	Dry Mouth	DRY MOUTH	01MAY96	2, -55, -243	202 Days	20	CON	MIL	NO	REL	No No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE	
329.002.00319	Headache	HEADACHE	18NOV96	203, 147, -42	04:00 Hrs	30	1	MOD	NO	PBU Yes	No	
	Infection	FLU SYMPTOMS - FEVER, HEADACHES, MUSCLE ACHES	06DEC96	221, 165, -24	6 Days	30	1	MOD	NO	UNR No	No	
	Pharyngitis	THROAT PAIN	09JUL96	71, 15, -174	16:00 Hrs	30	1	MIL	NO	UNR No	No	
329.003.00075	Amenorrhea	AMENORRHEA	01FEB95	8, -49, -232	161 Days	20	CON	MOD	NO	PSR No	No	
	Asthenia	TIRED	14JUN95	141, 85, -99	2 Days	20		MIL	NO	UNR No	No	
	Decreased Appetite	APPETITE SUPPRESSION	05APR95	71, 15, -169	98 Days	20	CON	MIL	NO	PSR No	No	
	Dizziness		DIZZINESS	08MAR95	43, -14, -197	15 Days	20	CON	MOD	INC	PSR No	No
				01JUL95	158, 102, -82	10 Days	20	CON	MIL	NO	PBU No	No
				15SEP95	234, 178, -6	6 Days	20		MOD	NO	PBU No	No
	Dry Mouth	DRY MOUTH	25JAN95	1, -56, -239	4 Days	20	CON	MIL	NO	PSR No	No	
	Female Genital Disorders	ANORGASMIA {FEMALE}	25JAN95	1, -56, -239	57 Days	20	CON	SEV	DCR	REL No	No	
			23MAR95	58, 2, -182	56 Days	20	CON	MIL	NO	REL No	No	
	Gastrointestinal Disorder	NAUSEA AND REFLUX {ESOPHAGEAL}	15FEB95	22, -35, -218	24:00 Hrs	20	CON	MIL	NO	PSR No	No	
	Headache	HEADACHES	08FEB95	15, -42, -225	Not Stated	20	CON	MIL	NO	PBU No	No	
	Hyperkinesia	HYPERACTIVITY	13JUL95	170, 114, -70	70 Days	20	CON	MIL	NO	PBU No	No	
	Insomnia	TROUBLE SLEEPING	15SEP95	234, 178, -6	6 Days	20		MOD	NO	PBU No	No	
Nausea	NAUSEA	08MAR95	43, -14, -197	128 Days	20	CON	MIL	INC	PSR No	No		

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther SAE
329.003.00075	Nausea	NAUSEA	15SEP95	234, 178, -6	6 Days	20		MOD	NO	PBU	No
	Nervousness	NERVOUS JITTERY	25JAN95	1, -56, -239	8 Days	20	CON	MIL	NO	PSR	No
		TREMULOUS TEETH CHATTERING (JITTERINESS)	16MAR95	51, -6, -189	13 Days	20	CON	MIL	NO	REL	No
	Somnolence	DROWSINESS	02MAR95	37, -20, -203	5 Days	20	CON	MIL	DCR	PSR	No
	Tachycardia	HEART RACING	06MAY95	102, 46, -138	12 Days	20	CON	MIL	NO	PSR	No
329.003.00077	Dry Mouth	DRY MOUTH	16APR95	42, -18, -52	10 Days	30		MIL	NO	PSR	No
	Dyspepsia	UPSET STOMACH AND HEARTBURN	12MAR95	7, -53, -87	08:30 Hrs	20	CON	MIL	NO	PBU	No
	Insomnia	INSOMNIA	24MAY95	80, 21, -14	Not Stated	30	CON	SEV	DCR	PSR	No
	Nausea	NAUSEA	21APR95	47, -13, -47	3 Days	30	3	MIL	NO	PSR	No
			NAUSEA	02MAY95	58, -2, -36	35 Days	30	2	MIL	NO	PSR
	Tachycardia	HEART RACING	20APR95	46, -14, -48	3 Days	30	3	MIL	NO	PSR	No
329.003.00081	Dizziness	DIZZINESS	28DEC95	18, ., -41	14 Days	20	CON	MIL	NO	PBU	No
	Increased Appetite	INCREASED APPETITE	19DEC95	9, ., -50	16 Days	20	CON	MIL	NO	PSR	No
	Somnolence	SOMNOLENCE	19DEC95	9, ., -50	23 Days	20	CON	MIL	NO	PSR	No
329.003.00089	Asthenia	TIRED	10MAR95	4, ., -56	Not Stated	20	CON	MIL	NO	PSR	No
	Constipation	CONSTIPATION	21MAR95	15, ., -45	7 Days	20		MIL	NO	PSR	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE	
329.003.00089	Cough Increased	COUGH	02APR95	27, .. -33	Not Stated	20	CON	MIL	NO	UNR	No	
	Dizziness	DIZZINESS WHEN STANDING	14MAR95	8, .. -52	24:00 Hrs	20	CON	MIL	NO	PSR	No	
	Dry Mouth	DRY MOUTH	21MAR95	15, .. -45	Not Stated	20	CON	MIL	NO	PSR	No	
	Euphoria	ELATION AND EXPANSIVE MOOD	04APR95	29, .. -31	Not Stated	20	CON	SEV	STP	PSR	Yes	
	Headache	HEADACHE	14MAR95 17APR95	8, .. -52 42, .. -18	8 Days 24:00 Hrs	20 20	CON	MIL MOD	NO NO	PSR UNR	Yes Yes	No No
	Insomnia	SLEEP PROBLEMS-EXAMPLE WAKES UP TOO EARLY	14MAR95	8, .. -52	Not Stated	20	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	10MAR95	4, .. -56	Not Stated	20	CON	MIL	NO	PSR	No	No
329.003.00091	Dizziness	DIZZINESS"FELT LIKE FAINTING"	01APR95	9, -46,-236	01:30 Hrs	20		MOD	NO	PSR	Yes	No
	Headache	HEADACHE	25MAR95	2, -53,-243	15 Mins	20		MIL	NO	PBU	No	No
	Nausea	NAUSEA	26MAR95	3, -52,-242	10 Mins	20		MIL	NO	PBU	No	No
	Pharyngitis	SORE THROAT	21SEP95	182, 128, -63	11 Days	40	1	MOD	NO	UNR	Yes	No
	Respiratory Disorder	COLD {SYMPTOMS}	28APR95 20OCT95	36, -19,-209 211, 157, -34	5 Days 11 Days	40 40	1 CON	MIL MIL	NO NO	UNR UNR	Yes Yes	No No
329.003.00248	Anemia	ANEMIA	23APR96	54, .. -9	Not Stated	30	CON	MIL	NO	PBU	No	No
	Arrhythmia	IRREGULAR PULSE	22FEB96	-8, .. -70	Not Stated	0	CON	MIL	NO	UNR	No	No

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Intent-to-Treat Population

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329.003.00248	Dizziness	DIZZINESS	26MAR96	26, ., -37	17 Days	30	CON	MIL NO	PSR No	No
	Infection	FLU	02APR96	33, ., -30	10 Days	40	CON	MIL NO	UNR No	No
	Withdrawal Syndrome	MIGRAINE HEADACHE {WITHDRAWAL SYMPTOM}	29APR96	60, ., -3	6 Days	30	CON	SEV NO	REL Yes	Yes
329.003.00250	Allergic Reaction	ALLERGIES	29APR96	47, -11, -28	24:00 Hrs	40		MIL NO	UNR Yes	No
	Dizziness	DIZZINESS	15MAR96	2, -56, -73	5 Mins	20	2	MIL NO	PBU No	No
	Emotional Lability	OVERDOSE {INTENTIONAL}	19APR96 27MAY96	37, -21, -38 75, 18, 0	21 Days 01:00 Hrs	40 30	CON 1	MOD NO SEV STP	UNR No UNR No	Yes Yes
	Nausea	NAUSEOUS	15MAR96	2, -56, -73	12 Days	20	CON	MIL NO	PBU No	No
	Somnolence	SLEEPINESS SLEEPY	19APR96 15MAR96	37, -21, -38 2, -56, -73	Not Stated 12 Days	40 20	CON CON	MOD DCR MIL NO	PSR No PBU No	No No
329.003.00313	Dry Mouth	DRY MOUTH	18MAY96	2, ., -10	Not Stated	20	CON	MIL NO	PSR No	No
	Emotional Lability	SUPERFICIAL CUTS RISK TO SELF	28MAY96	12, ., 0	6 Days	20	CON	SEV STP	PBU No	Yes
	Hallucinations	AUDITORY HALLUCINATIONS	28MAY96	12, ., 0	6 Days	20	CON	SEV STP	PBU No	Yes
329.004.00015	Abdominal Pain	STOMACH ACHES INTERMITTENT AM AND LUNCH	08DEC94	1, -57, -202	12 Days	20	6	MIL NO	REL No	No
	Allergic Reaction	CONGESTION-NASAL DUE TO ALLERGIES	09JUN95	184, 127, -19	Not Stated	20	CON	MOD NO	UNR No	No

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329.004.00015	Allergic Reaction	ITCHY EYES-DUE TO ALLERGIES	09JUN95	184, 127, -19	Not Stated	20	CON	MOD	NO	UNR No	No
	Asthenia	FATIGUE	08DEC94	1, -57, -202	15 Days	20	CON	MIL	NO	REL No	No
		FATIGUE NEW	22DEC94	15, -43, -188	11 Days	20	CON	MOD	NO	REL No	No
			02FEB95	57, -1, -146	43 Days	20	CON	MOD	NO	PBU No	No
	Conjunctivitis	CONJUNCTIVITIS BILATERAL	08DEC94	1, -57, -202	11 Days	20	CON	MOD	NO	UNR Yes	No
			03JAN95	27, -31, -176	12 Days	20	CON	MOD	NO	UNR Yes	No
	Cough Increased	COUGH	12DEC94	5, -53, -198	5 Days	20	CON	MIL	NO	UNR Yes	No
			02FEB95	57, -1, -146	34 Days	20	CON	MOD	NO	UNR Yes	No
	Dizziness	DIZZINESS	18FEB95	73, 16, -130	31 Days	20	CON	MIL	NO	PBU No	No
			05JUN95	180, 123, -23	2 Days	20	CON	MOD	NO	UNR No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	17APR95	131, 74, -72	30 Mins	20		1 MOD	NO	UNR Yes	No
		PREMENSTRUAL CRAMPS	29JAN95	53, -5, -150	02:00 Hrs	20		1 MOD	NO	UNR Yes	No
	Emotional Lability	SELF-MUTILATION	07JAN95	31, -27, -172	30 Mins	20		1 MIL	NO	UNR No	No
		SUICIDAL IDEATION	18FEB95	73, 16, -130	03:00 Hrs	20		1 MIL	NO	UNR No	No
	Headache	HEADACHE	20DEC94	13, -45, -190	03:00 Hrs	20		1 MOD	NO	PBU Yes	No
			10JAN95	34, -24, -169	01:00 Hrs	20		1 SEV	NO	PBU Yes	No
			17JAN95	41, -17, -162	02:00 Hrs	20		1 MOD	NO	PBU Yes	No
			14FEB95	69, 12, -134	01:00 Hrs	20		1 MOD	NO	PBU Yes	No
			24FEB95	79, 22, -124	01:00 Hrs	20		1 MOD	NO	PBU Yes	No
			05JUN95	180, 123, -23	2 Days	20	CON	MOD	NO	UNR No	No
		HEADACHES 1 DAILY	11DEC94	4, -54, -199	7 Days	20		3 MIL	NO	PSR Yes	No
	Pharyngitis	SORE THROAT	02FEB95	57, -1, -146	34 Days	20	CON	MOD	NO	UNR Yes	No
	Rhinitis	NASAL CONGESTION	11DEC94	4, -54, -199	10 Days	20	CON	MIL	NO	UNR Yes	No

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329.004.00015	Rhinitis	NASAL CONGESTION	02FEB95	57, -1,-146	34 Days	20	CON	MOD	NO	UNR Yes	No
	Tremor	HANDS TREMBLING INTERMITTENT	10DEC94	3, -55,-200	14 Days	20	4	MOD	NO	REL No	No
329.004.00017	Abdominal Pain	STOMACH PAIN	11NOV95	235, 179, -3	Not Stated	20	CON	MIL	NO	UNR No	No
	Anxiety	ANXIETY	23MAR95	2, -55,-236	4 Days	20	CON	SEV	DCR	REL No	No
	Chills	SHIVERING AND SHAKING	28MAR95	7, -50,-231	12 Days	20	CON	MIL	NO	PSR No	No
	Constipation	CONSTIPATION	13APR95	23, -34,-215	12 Days	20	CON	MOD	NO	REL No	No
			25APR95	35, -22,-203	28 Days	20	CON	MIL	NO	REL No	No
	Cough Increased	COUGHING	23MAY95	63, 7,-175	15 Days	30	CON	MOD	NO	UNR Yes	No
	Dizziness	DIZZINESS	06NOV95	230, 174, -8	5 Days	20	CON	MIL	NO	UNR No	No
	Fever	FEVER	29AUG95	161, 105, -77	18:00 Hrs	30		MOD	NO	UNR Yes	No
	Insomnia	INSOMNIA INSOMNIA(NO SLEEP)	27MAR95	6, -51,-232	5 Days	0	CON	MIL	NO	PSR No	No
			24MAR95	3, -54,-235	3 Days	20	CON	SEV	DCR	REL No	No
	Manic Reaction	HOSPITALIZATION RULE-OUT HYPOMANIA	31AUG95	163, 107, -75	3 Days	30	CON	MIL	NO	UNR No	Yes
	Nausea	NAUSEA	23MAR95	2, -55,-236	4 Days	20	CON	SEV	DCR	REL No	No
			27MAR95	6, -51,-232	5 Days	0	CON	MIL	NO	REL No	No
			06NOV95	230, 174, -8	7 Days	20	CON	MOD	NO	UNR Yes	No
Pharyngitis	SORE THROAT	09NOV95	233, 177, -5	5 Days	20	CON	MOD	NO	UNR No	No	
Respiratory Disorder	RHINITIS-COLD	14SEP95	177, 121, -61	3 Days	30	CON	MIL	NO	UNR Yes	No	

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE	
329.004.00017	Rhinitis	RHINITIS	09NOV95	233, 177, -5	5 Days	20	CON	MOD	NO	UNR	No	
	Tremor	TREMORS	21APR95	31, -26, -207	11 Days	20	CON	MOD	NO	REL	No	
			02MAY95	42, -15, -196	87 Days	30	CON	SEV	NO	REL	Yes	No
			28JUL95	129, 73, -109	40 Days	30	CON	MOD	NO	REL	No	No
			06SEP95	169, 113, -69	57 Days	30	CON	MIL	NO	REL	No	No
Vomiting	VOMITING	08NOV95	232, 176, -6	5 Days	20	3	MOD	NO	UNR	No	No	
329.004.00019	Dizziness	DIZZY GETTING OUT OF BED OR AFTER LYING DOWN A LONG TIME	03JUN95	4, ., -11	Not Stated	20		MIL	NO	REL	No	No
	Headache	HEADACHE	06JUN95	7, ., -8	09:00 Hrs	20	1	MOD	NO	PSR	Yes	No
329.004.00212	Somnolence	SEDATION	09JUN96	7, ., -16	12:00 Hrs	20	1	SEV	NO	PSR	No	No
			10JUN96	8, ., -15	2 Days	20	CON	MIL	NO	PSR	No	No
			12JUN96	10, ., -13	14 Days	20	CON	SEV	NO	PSR	No	No
329.004.00214	Dizziness	DIZZINESS	15NOV96	43, -18, -45	1 Days	30	CON	MOD	DCR	PSR	No	No
			23DEC96	81, 21, -7	06:00 Hrs	20	3	MOD	NO	PSR	No	No
	Dyspepsia	UPSET STOMACH	09NOV96	37, -24, -51	2 Days	30	CON	MIL	DCR	REL	Yes	No
	Headache	HEADACHE	08NOV96	36, -25, -52	2 Days	30	CON	MIL	DCR	REL	Yes	No
15NOV96			43, -18, -45	1 Days	30	CON	MOD	DCR	PSR	Yes	No	
	Hyperkinesia	HYPERACTIVE	08OCT96	5, -56, -83	01:00 Hrs	20	5	MIL	NO	PSR	No	No
	Insomnia	AWAKENING (MIDDLE OF NIGHT)	12OCT96	9, -52, -79	15 Mins	20	2	MIL	NO	PSR	No	No
	Nausea	NAUSEA	15NOV96	43, -18, -45	1 Days	30	CON	MOD	DCR	PSR	Yes	No

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329.004.00214	Nausea	NAUSEA	23DEC96	81, 21, -7	06:00 Hrs	20	3	MOD	NO	PSR	No	No	
	Rash	RASH ON ARMS (RED, DRY, ITCHY)	01DEC96	59, -2, -29	10:00 Hrs	20	CON	MIL	NO	PBU	No	No	
	Respiratory Disorder	COLD {SYMPTOMS}	17OCT96	14, -47, -74	4 Days	20	CON	MIL	NO	UNR	No	No	
329.005.00002	Chest Pain	CHEST PAIN	19JUN94	26, -31, -121	06:30 Hrs	20	CON	MOD	NO	PSR	No	No	
	Drug Dependence	POSITIVE CANNABIS	20MAY94	-5, -61, -151	1 Days	0	1	MIL	NO	UNR	No	No	
	Headache	HEADACHE	20MAY94 17JUL94	-5, -61, -151 54, -3, -93	03:30 Hrs 4 Days	0 40	CON	MOD	NO	PSR	Yes	No	No
	Palpitation	CHEST PALPITATIONS	19JUN94	26, -31, -121	06:30 Hrs	20	CON	MOD	NO	PSR	No	No	
329.005.00004	Headache	HEADACHE	13JUN94	20, -37, -127	2 Days	20	CON	MIL	NO	PSR	No	No	
			24OCT94 29DEC94	15, -45, -88 81, 22, -22	02:30 Hrs 2 Days	20 40	CON CON	MIL MOD	NO NO	PBU PBU	No No	No No	
329.005.00008	Pharyngitis	SORE THROAT	29DEC94	81, 22, -22	2 Days	40	CON	MOD	NO	UNR	Yes	No	
	Abdominal Pain	STOMACH ACHE	10DEC94	25, -31, -117	3 Days	20	CON	MOD	NO	UNR	No	No	
	Asthenia	EXTREME SLEEPINESS/FATIGUE	29DEC94	44, -12, -98	11 Days	40	CON	SEV	DCR	REL	No	No	
	Diarrhea	DIARRHEA	10DEC94	25, -31, -117	3 Days	20	CON	MOD	NO	UNR	No	No	
	Dry Mouth	DRY MOUTH	20NOV94	5, -51, -137	140 Days	20	CON	MIL	NO	PSR	No	No	

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329.005.00008	Headache	HEADACHE	10DEC94	25, -31,-117	3 Days	20	CON	MOD	NO	UNR No	No
	Infection	STOMACH FLU WITH NAUSEA, VOMITING AND DIARRHEA	27NOV94	12, -44,-130	3 Days	20	CON	SEV	NO	UNR No	No
		STOMACH FLU-NAUSEA, VOMITING AND DIARRHEA	16DEC94	31, -25,-111	4 Days	30	CON	SEV	NO	UNR No	No
	Personality Disorder	BEHAVIOR PROBLEMS-->STOLE MOM'S CAR AND WRECKED IT. SKIPPING SCHOOL TALKING BACK TO MOM {BEHAVIOR PROBLEMS}	31JAN95	77, 22, -65	02:00 Hrs	30	1	SEV	NO	PSR No	No
			22DEC94	37, -19,-105	47 Days	40	CON	SEV	NO	PSR No	No
	Postural Hypotension	POSTURAL HYPOTENSION	12NOV94	-4, -59,-145	2 Mins	0	2	MIL	NO	PSR No	No
Somnolence	DROWSINESS-SLEEPINESS	16NOV94	1, -55,-141	17 Days	20	7	MIL	NO	PSR No	No	
		02DEC94	17, -39,-125	160 Days	20	CON	MOD	NO	REL No	No	
329.005.00011	Asthenia	FATIGUE WITH DIZZINESS AND DROWSINESS [FATIGUE WITH DROWSINESS]	28JAN95	47, -10,-109	Not Stated	40	CON	MIL	NO	PSR No	No
		TIREDDNESS INCREASED FATIGUE	19DEC94	7, -50,-149	10 Days	20	4	MIL	NO	PSR No	No
	Dizziness	DIZZINESS	02JAN95	21, -36,-135	34 Days	20		MIL	NO	REL No	No
	FATIGUE WITH DIZZINESS AND DROWSINESS [DIZZINESS]	28JAN95	47, -10,-109	Not Stated	40	CON	MIL	NO	PSR No	No	

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329.005.00011	Emotional Lability	[OVERDOSE{WITH BAYER EXTRA STRENGTH} [INTENTIONAL]	17MAY95	156, 100, 0	1 Days	30	1	SEV	STP	UNR Yes	Yes
	Headache	HEADACHES	20DEC94	8, -49, -148	15 Days	20	14	MOD	NO	PSR Yes	No
329.005.00109	Drug Dependence	POSITIVE URINE DRUG SCREEN CANNABINOIDS	25MAY95	147, 94, 9	1 Days	20	1	SEV	NO	UNR No	No
	Headache	HEADACHE	20MAR95	81, 28, -57	3 Days	20	4	MOD	NO	UNR Yes	No
	Infection	COLD AND FLU STUFFY NOSE/NAUSEA/VOMITING DIARRHEA	09FEB95	42, -12, -96	4 Days	20	CON	MOD	NO	UNR No	No
	Peptic Ulcer Hemorrhage	BLEEDING ULCER {PEPTIC}	07MAY95	129, 76, -9	4 Days	20	CON	SEV	NO	UNR Yes	Yes
	Tremor	HAND TREMORS	20JAN95	22, -32, -116	12 Days	20	CON	MIL	NO	REL No	No
	Vomiting	NAUSEA AND VOMITING	10MAY95	132, 79, -6	2 Days	20	CON	SEV	NO	PSR No	No
329.005.00112	Fever	FEVER	24JAN95	-2, -57, -94	3 Days	0	CON	MOD	NO	UNR Yes	No
	Headache	HEADACHE	24JAN95	-2, -57, -94	3 Days	0	CON	MOD	NO	UNR Yes	No
	Infection	NAUSEA VOMITING DIARRHEA (FLU)	13MAR95	47, -9, -46	2 Days	20	CON	SEV	NO	UNR No	No
	Tooth Disorder	TOOTHACHE	26FEB95	32, -24, -61	10:30 Hrs	20	CON	MOD	NO	UNR No	No
329.005.00116	Bronchitis	BRONCHITIS WITH COUGH	04MAR95	26, -33, -129	25 Days	20	CON	SEV	NO	UNR Yes	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int ion	Act- ion	Inv Corr Rel Ther	SAE
329.005.00116	Contact Dermatitis	POISON IVY	17JUN95	131, 73, -24	26 Days	30	CON	SEV	STP	UNR Yes	No
	Cough Increased	COUGH	22APR95	75, 17, -80	16 Days	20	5	MOD	NO	UNR Yes	No
	Dry Mouth	DRY MOUTH	10FEB95	4, -55, -151	152 Days	20	CON	MOD	NO	REL No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	28MAY95	111, 53, -44	3 Days	20	CON	SEV	NO	UNR Yes	No
	Dyspepsia	UPSET STOMACH UPSET STOMACH {WHEN TAKES MEDICATIONS AT BEDTIME}	08FEB95	2, -57, -153	6 Days	20	10	MOD	NO	PBU No	No
			04APR95	57, -2, -98	99 Days	20	CON	MIL	NO	PSR No	No
	Headache	HEADACHE	12APR95	65, 7, -90	1 Days	20	3	MOD	NO	PBU Yes	No
	Increased Appetite	INCREASED APPETITE	15FEB95	9, -50, -146	162 Days	20	CON	MOD	NO	PSR No	No
	Infection	NAUSEA, VOMITING, DIARRHEA (STOMACH FLU)	06MAR95	28, -31, -127	24:00 Hrs	20	CON	SEV	NO	UNR No	No
	Myalgia	CRAMPS IN LEFT LEG	08MAR95	30, -29, -125	2 Days	20	CON	MOD	NO	UNR No	No
	Otitis Media	EAR INFECTION/ACHE	04MAR95	26, -33, -129	25 Days	20	CON	SEV	NO	UNR Yes	No
	Pharyngitis	TONSILLITIS	24JUN95	138, 80, -17	14 Days	30	CON	SEV	NO	UNR Yes	No
	Tremor	HAND TREMORS	04MAR95	26, -33, -129	29 Days	20	CON	MIL	NO	REL No	No
329.005.00119	Abdominal Pain	"STOMACH ACHE"	23OCT95	105, 46, -36	5 Days	40	5	MOD	NO	PBU No	No
		STOMACH ACHE	20JUL95	10, -50, -131	4 Days	20	2	MIL	NO	PBU No	No
Asthenia	FATIGUE	11JUL95	1, -59, -140	4 Days	20	CON	MOD	NO	PSR No	No	

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329.005.00119	Headache	HEADACHE	17JUL95	7, -53, -134	02:00 Hrs	20		MOD	NO	PSR	Yes No
			20AUG95	41, -19, -100	01:00 Hrs	40	2	MOD	NO	PBU	No No
	Hostility	PHYSICAL FIGHT {AGGRESSION}	28JUL95	18, -42, -123	10 Mins	20	1	MIL	NO	PBU	No No
	Respiratory Disorder	COLD SYMPTOMS	27SEP95	79, 20, -62	4 Days	40	CON	MOD	NO	PBU	Yes No
	Vomiting	NAUSEA AND VOMITING	23OCT95	105, 46, -36	5 Days	40	5	MOD	NO	PBU	No No
329.005.00151	Albuminuria	PROTEIN IN URINE	31JAN96	148, 91, -91	92 Days	30	CON	MOD	NO	PBU	No No
	Back Pain	BACK PAIN	06SEP95	1, -57, -238	1 Days	20	1	MOD	NO	UNR	Yes No
			19OCT95	44, -14, -195	02:00 Hrs	20	1	MIL	NO	UNR	Yes No
	Infection	SORE THROAT AND EAR INFECTION DIAGNOSIS:STREP THROAT	15OCT95	40, -18, -199	12 Days	20	CON	SEV	NO	UNR	Yes No
	Respiratory Disorder	UPPER RESPIRATORY INFECTION	22OCT95	47, -11, -192	17 Days	20	CON	MOD	NO	UNR	Yes No
	Trauma	FOREIGN OBJECT IN EYE	06FEB96	154, 97, -85	3 Days	30	CON	MOD	NO	UNR	Yes No
	Urinary Casts	COURSE GRANULAR CASTS HYALINE CAST IN URINE	31JAN96	148, 91, -91	92 Days	30	CON	MOD	NO	PBU	No No
	Weight Gain	WEIGHT GAIN	28NOV95	84, 27, -155	156 Days	20	CON	MOD	NO	PSR	No No
329.005.00152	Diarrhea	DIARRHEA	30OCT95	5, ., 0	24:00 Hrs	20	CON	SEV	STP	REL	No No
	Headache	HEADACHE	30OCT95	5, ., 0	24:00 Hrs	20	CON	SEV	STP	REL	No No

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329.005.00152	Nausea	NAUSEA	27OCT95	2, ., -3	4 Days	20	CON	SEV	STP	REL No	No
	Vomiting	NAUSEA AND VOMITING VOMITING	27OCT95 30OCT95	2, ., -3 5, ., 0	4 Days 24:00 Hrs	20 20	8 CON	SEV SEV	STP STP	REL No REL No	No No
329.005.00257	Asthma	EXERCISE INDUCED ASTHMA	01SEP96	175, 119, -64	Not Stated	30	CON	MOD	NO	UNR Yes	No
	Haematuria	RBC IN URINE (PT MENSTRUATING WHEN SAMPLE TAKEN)	21OCT96	225, 169, -14	Not Stated	30	CON	MOD	NO	UNR No	No
	Headache	HEADACHE	14AUG96	157, 101, -82	8 Days	30	2	MIL	NO	PBU Yes	No
	Nervousness	"JITTERINESS"	21OCT96	225, 169, -14	Not Stated	30	CON	MOD	NO	PSR No	No
	Otitis Externa	SWIMMER'S EAR	31JUL96	143, 87, -96	3 Days	30	CON	MOD	NO	PBU Yes	No
	Respiratory Disorder	SORE THROAT (COLD SYMPTOM) STUFFY NOSE (COLD SYMPTOMS)	18MAR96	8, -49, -231	9 Days	20	CON	MOD	NO	PBU Yes	No
			18MAR96	8, -49, -231	9 Days	20	CON	MOD	NO	PBU Yes	No
	Sinusitis	SINUS INFECTION	24MAR96	14, -43, -225	7 Days	20	MOD	NO	PBU Yes	No	
14APR96			35, -22, -204	37 Days	20	CON	MOD	NO	PBU Yes	No	
Urinary Tract Infection	YEAST INFECTION (SQUAMOUS EPITHELIAL CELLS IN URINE)	15OCT96	219, 163, -20	Not Stated	30	CON	MOD	NO	PBU No	No	
Weight Gain	WEIGHT GAIN	03JUN96	85, 29, -154	Not Stated	30	CON	MOD	NO	PSR No	No	
329.005.00258	Abdominal Pain	STOMACH ACHE	21MAR96	10, ., -47	02:00 Hrs	20	1	MOD	NO	PBU No	No
			05APR96	25, ., -32	4 Days	20	4	MOD	NO	PBU No	No

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----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.005.00258	Cough Increased	COUGH	08MAR96	-4, .. -60	8 Days	0	1	MOD	NO	UNR Yes	No
	Headache	HEADACHE	21MAR96	10, .. -47	4 Days	20	2	MOD	NO	PBU No	No
			05APR96	25, .. -32	4 Days	20	3	MOD	NO	PBU No	No
	Tooth Disorder	ORTHODONTIC DISCOMFORT	01APR96	21, .. -36	03:30 Hrs	20	1	MOD	NO	UNR Yes	No
08APR96			28, .. -29	02:40 Hrs	20	1	MOD	NO	UNR Yes	No	
	Urine Abnormality	ABNORMAL URINE ROUTINE & MICROSCOPIC (URINALYSIS)	07MAY96	57, .. 0	Not Stated	30	CON	MOD	NO	PBU No	No
329.005.00299	Abdominal Pain	STOMACH ACHE	31JUL96	54, -7, -110	3 Days	20	2	MOD	NO	PSR Yes	No
	Abnormal Vision	BLURRED VISION	24OCT96	139, 79, -25	6 Days	30	CON	MIL	NO	PBU No	No
			05NOV96	151, 91, -13	8 Days	20	CON	MOD	NO	PSR No	No
	Dizziness	DIZZINESS DIZZINESS UPON RISING	05NOV96	151, 91, -13	8 Days	20	CON	MOD	NO	PSR No	No
			14JUN96	7, -54, -157	27 Days	20		MOD	NO	PSR No	No
	Epistaxis	NOSEBLEED	12NOV96	158, 98, -6	10 Mins	20	1	MIL	NO	PSR No	No
	Headache	HEADACHE	31JUL96	54, -7, -110	5 Days	20	2	MOD	NO	PSR Yes	No
			03SEP96	88, 28, -76	03:00 Hrs	20	4	MOD	NO	PBU No	No
			23OCT96	138, 78, -26	02:00 Hrs	30	1	MOD	NO	PBU Yes	No
			19NOV96	165, 105, 1	04:00 Hrs	20	1	MOD	NO	PBU No	No
	HEADACHE UPON RISING	14JUN96	7, -54, -157	27 Days	20		MOD	NO	PSR No	No	
Respiratory Disorder	COLD {SYMPTOMS}	10SEP96	95, 35, -69	Not Stated	20	CON	MOD	NO	UNR Yes	No	
Syncope	FAINTED	17JUN96	10, -51, -154	1 Mins	20	1	MOD	NO	PSR No	No	
329.005.00300	Dry Mouth	DRY MOUTH	24SEP96	6, .. -51	27 Days	20	CON	MOD	NO	REL No	No
			21OCT96	33, .. -24	10 Days	20	CON	MIL	NO	REL No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.005.00300	Headache	HEADACHE	12NOV96	55, .. -2	02:00 Hrs	20	CON	MOD	NO	UNR No	No
	Hostility	OPPOSITIONAL BEHAVIOR (PHYSICALLY AND VERBALLY FIGHTING WITH MOTHER)	18OCT96	30, .. -27	7 Days	20	6	SEV	NO	PBU No	No
			25OCT96	37, .. -20	Not Stated	20	MOD	NO	PBU No	No	
	Somnolence	SLEEPINESS (IN AM)	01OCT96	13, .. -44	11 Days	20	CON	MOD	NO	REL No	No
12OCT96			24, .. -33	Not Stated	20	CON	SEV	NO	REL No	No	
329.005.00333	Abnormal Dreams	VIVID DREAMS	10FEB97	19, .. -14	11 Days	20	10	MOD	NO	PSR No	No
	Diarrhea	DIARRHEA	21FEB97	30, .. -3	08:00 Hrs	20	CON	SEV	NO	UNR Yes	No
	Dyspnea	SHORTNESS OF BREATH	11FEB97	20, .. -13	3 Days	20	5	MIL	NO	PBU No	No
	Emotional Lability	SUICIDAL IDEATION	28FEB97	37, .. 4	103 Days	20	CON	SEV	NO	UNR No	Yes
	Headache	HEADACHE	24JAN97	2, .. -31	03:20 Hrs	20	CON	MIL	NO	UNR Yes	No
			26JAN97	4, .. -29	02:30 Hrs	20	CON	MIL	NO	UNR No	No
			13FEB97	22, .. -11	8 Days	20	7	MOD	NO	PSR Yes	No
			24FEB97	33, .. 0	03:00 Hrs	20	CON	MOD	NO	PBU Yes	No
	Rash	BLOTCHES (RED) ON LEGS	10FEB97	19, .. -14	3 Days	20	CON	MOD	NO	PSR No	No
	Rhinitis	"STUFFY" NOSE	23JAN97	1, .. -32	Not Stated	20	CON	MOD	NO	UNR No	No
Somnolence	SLEEPINESS	01FEB97	10, .. -23	7 Days	20	CON	SEV	NO	PSR Yes	No	
		21FEB97	30, .. -3	Not Stated	20	CON	SEV	NO	PSR No	No	
329.005.00336	Back Pain	BACKACHE	28MAR97	25, .. -33	2 Days	20	CON	MIL	NO	UNR No	No
			20APR97	48, .. -10	4 Days	20	CON	MIL	NO	UNR Yes	No

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----- Treatment Group=PAROXETINE -----

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329.005.00336	Cough Increased	COUGH	04APR97	32, ..	-26 6 Days	20	CON	MOD	NO	UNR Yes	No	
			10APR97	38, ..	-20 3 Days	20	CON	MOD	NO	UNR Yes	No	
	Dizziness	DIZZINESS GIDDINESS	10MAR97	7, ..	-51 13 Days	20	2	MIL	NO	REL	No	No
			14MAR97	11, ..	-47 4 Days	20	4	MIL	NO	PSR	No	No
			27MAR97	24, ..	-34 3 Days	20	CON	MIL	NO	PSR	No	No
			09MAR97	6, ..	-52 39 Days	20	CON	MIL	NO	REL	No	No
	Myoclonus	LEG TWITCHES LEG TWITCHES (NIGHTLY)	19APR97	47, ..	-11 4 Days	20	4	MIL	NO	PSR	No	No
			29MAR97	26, ..	-32 5 Days	20	4	SEV	NO	PSR	No	No
			02APR97	30, ..	-28 8 Days	20	7	MIL	NO	PSR	No	No
	Pharyngitis	SORE THROAT	04APR97	32, ..	-26 6 Days	20	CON	MOD	NO	UNR	Yes	No
			10APR97	38, ..	-20 3 Days	20	CON	MOD	NO	UNR	Yes	No
	Tremor	HAND TREMORS	08MAR97	5, ..	-53 4 Days	20	CON	MOD	NO	REL	No	No
13MAR97			10, ..	-48 7 Days	20	CON	MIL	NO	REL	No	No	
04APR97			32, ..	-26 13 Days	20	CON	MIL	NO	PSR	No	No	
329.006.00038	Chest Pain	CHEST PAIN-APPROXIMATELY 3 OCCASIONS-INTENSE JAB THEN REMITS	27MAR95	41, ..	-16 3 Days	20	3	SEV	NO	PSR	No	No
			12APR95	57, ..	0 3 Days	20	CON	MOD	STP	UNR	No	No
			12APR95	57, ..	0 3 Days	20	CON	MOD	STP	UNR	No	No
			12APR95	57, ..	0 1 Days	20	1	SEV	STP	UNR	No	Yes

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.006.00038	Headache	HEADACHE	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR No	No
	Hostility	ANGRY (PATIENT NOTICED)	15MAR95	29, ., -28	8 Days	20	CON	MIL	NO	PSR No	No
	Myalgia	MUSCLE ACHE	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR No	No
	Myasthenia	MUSCLE WEAKNESS	12APR95	57, ., 0	3 Days	20	CON	MOD	STP	UNR No	No
	Sinusitis	COLD-SINUS SYMPTOMS	22FEB95	8, ., -49	10 Days	20	CON	MIL	NO	UNR No	No
329.006.00039	Asthenia	VERY TIRED	22MAR95	43, -19, -49	7 Days	20	CON	SEV	NO	PSR No	No
	Depression	MORE DEPRESSED	22MAR95	43, -19, -49	7 Days	20	CON	SEV	NO	PSR No	No
	Headache	HEADACHES-MORE SEVERE THAN USUAL	24APR95	76, 15, -16	5 Days	30	3	SEV	NO	PBU Yes	No
	Myoclonus	GRIMACING FACE WITH BLINKING EYES {TIC}	22MAR95	43, -19, -49	7 Days	20	CON	MIL	NO	PSR No	No
	Nervousness	IRRITABLE MOOD	22MAR95	43, -19, -49	7 Days	20	CON	MOD	NO	PSR No	No
	Trauma	SUPERFICIAL SCRATCHES	25FEB95	18, -44, -74	12 Days	20	CON	MIL	NO	PBU No	No
329.006.00260	Esophagitis	BURNING ACHE IN UPPER ESOPHAGUS REGION	05AUG96	19, -40, -135	5 Mins	20	3	MOD	NO	PSR No	No
		BURNING ACHE IN UPPER ESOPHAGUS REGION-BRIEF	07AUG96	21, -38, -133	45 Mins	20	1	MOD	NO	PSR No	No
	Headache	HEADACHE	23JUL96	6, -53, -148	45 Mins	20	1	MIL	NO	UNR Yes	No
		HEADACHE	24JUL96	7, -52, -147	01:00 Hrs	20	1	MOD	NO	UNR Yes	No
		HEADACHE	27JUL96	10, -49, -144	01:00 Hrs	20	1	MIL	NO	PBU Yes	No
HEADACHE	HEADACHE	28JUL96	11, -48, -143	01:00 Hrs	20	1	MIL	NO	PBU Yes	No	

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329.006.00260	Headache	HEADACHE	29JUL96	12, -47, -142	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			30JUL96	13, -46, -141	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
			11AUG96	25, -34, -129	45 Mins	20	1	MIL	NO	PBU	Yes	No
			20AUG96	34, -25, -120	30 Mins	30	1	MIL	NO	PBU	Yes	No
			26AUG96	40, -19, -114	40 Mins	30	1	MOD	NO	PBU	Yes	No
			02SEP96	47, -12, -107	30 Mins	30	1	MIL	NO	PBU	Yes	No
			06SEP96	51, -8, -103	45 Mins	30	1	MOD	NO	PBU	Yes	No
			08SEP96	53, -6, -101	45 Mins	30	1	SEV	NO	PBU	Yes	No
			11SEP96	56, -3, -98	30 Mins	30	1	MOD	NO	PBU	Yes	No
			16SEP96	61, 3, -93	02:00 Hrs	30	1	SEV	NO	PBU	Yes	No
			08OCT96	83, 25, -71	01:00 Hrs	30	1	MIL	NO	PBU	Yes	No
05NOV96	111, 53, -43	01:00 Hrs	30	1	MIL	NO	PBU	No	No			
329.006.00260	Respiratory Disorder	COLD {SYMPTOMS}	08OCT96	83, 25, -71	08:00 Hrs	30	1	MIL	NO	PBU	Yes	No
	Tooth Disorder	TOOTHACHE TOOTHACHE PAIN	06AUG96 25JUL96	20, -39, -134 8, -51, -146	30 Mins 09:00 Hrs	20 20	1 1	SEV MOD	NO NO	UNR	Yes	No
329.006.00261	Headache	HEADACHE	22JAN97	58, -1, -97	01:00 Hrs	30	1	MOD	NO	PBU	Yes	No
	Infection	SCABIES ON BOTH ARMS	18FEB97	85, 27, -70	44 Days	30	CON	MOD	NO	UNR	No	No
329.007.00140	Fungal Dermatitis	RINGWORM	13OCT95	29, -27, -40	21 Days	20	CON	MIL	NO	UNR	No	No
329.007.00142	Infection	FLU	01DEC95	45, ., -3	8 Days	40	1	MOD	NO	UNR	Yes	No
	Rhinitis	NASAL CONGESTION	30NOV95	44, ., -4	1 Days	40	1	MIL	NO	UNR	Yes	No
329.007.00145	Headache	HEADACHE	30APR96	111, 55, -115	16 Days	40	CON	SEV	DCR	PSR	Yes	No
	Hyperkinesia	AKATHISIA	02MAY96	113, 57, -113	29 Days	30	CON	MOD	DCR	REL	No	No
	Hypertension	HYPERTENSION	14MAY96	125, 69, -101	17 Days	20	CON	MOD	DCR	PSR	No	No

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Appendix D.2

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Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther	SAE
329.007.00145	Respiratory Disorder	FEVER, COLD SYMPTOMS, SORE THROAT	21AUG96	224, 168, -2	3 Days	20	CON	MIL	NO	UNR	Yes	No
	Rhinitis	NASAL CONGESTION	01FEB96	22, -35, -204	2 Days	20	1	MIL	NO	UNR	Yes	No
	Thrombocytopenia	THROMBOCYTOPENIA	30MAY96	141, 85, -85	29 Days	20	CON	MIL	NO	PSR	No	No
329.007.00268	Agitation	FIDGETY/PSYCHOMOTOR AGITATION	16SEP96	169, 110, -93	17 Days	40	CON	MIL	DCR	PSR	No	No
	Back Pain	NECK PAIN	26MAY96	56, -4, -206	5 Days	30	CON	MOD	NO	UNR	Yes	No
	Constipation	CONSTIPATION	19NOV96	233, 174, -29	02:00 Hrs	30	1	MOD	NO	UNR	Yes	No
	Diarrhea	DIARRHEA	03APR96	3, -57, -259	8 Days	20	CON	MIL	NO	PSR	No	No
	Headache	HEADACHE HEADACHES (DAILY)	26MAY96	56, -4, -206	5 Days	30	CON	MOD	NO	UNR	Yes	No
			01OCT96	184, 125, -78	38 Days	30	35	MIL	NO	PSR	Yes	No
	Insomnia	TERMINAL INSOMNIA	09SEP96	162, 103, -100	24 Days	40	12	MOD	DCR	PSR	No	No
	Myalgia	MUSCLE PAIN	07JUL96	98, 39, -164	124 Days	30	CON	MIL	NO	UNR	Yes	No
	Nausea	NAUSEA NAUSEA DUE TO RIDES AT AMUSEMENT PARK	27OCT96	210, 151, -52	10 Days	30	CON	MOD	NO	PBU	Yes	No
29APR96			29, -31, -233	01:00 Hrs	20	1	MOD	NO	UNR	Yes	No	
Otitis Media	EAR INFECTION LEFT EAR INFECTION	10APR96	10, -50, -252	5 Days	20	CON	MOD	NO	UNR	Yes	No	
		21JUN96	82, 23, -180	9 Days	30	CON	MOD	NO	UNR	Yes	No	

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Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE	
329.007.00268	Syncope	BLACKNESS IN FRONT OF EYES, LIGHTHEADED, SWEATING {PRE-SYNCO PAL EPISODE/HEAT EXPOSURE}	01AUG96	123, 64, -139	20 Mins	40	CON	MIL	NO	UNR	No	
	Trauma	HEADACHE DUE TO ACCIDENT	26MAY96	56, -4, -206	5 Days	30	CON	MOD	NO	UNR	Yes	No
		NECK PAIN DUE TO ACCIDENT	26MAY96	56, -4, -206	13 Days	30	CON	MOD	NO	UNR	Yes	No
		PATIENT ACCIDENTALLY THROWN FROM 3 WHEELER STRIKING HEAD AND A NUMBER OF ABRASIONS	26MAY96	56, -4, -206	5 Mins	30	1	SEV	NO	UNR	Yes	No
	Vestibular Disorder	LEFT INNER EAR INFECTION	01JUL96	92, 33, -170	10 Days	30	CON	MOD	NO	UNR	Yes	No
Weight Gain	WEIGHT GAIN	30SEP96	183, 124, -79	95 Days	30	CON	MOD	NO	PSR	Yes	No	
329.007.00294	Abdominal Pain	CRAMPS (ABDOMINAL)	07APR97	39, ., -3	02:00 Hrs	30	CON	MOD	NO	UNR	Yes	No
	Back Pain	BACKACHE	21MAR97	22, ., -20	3 Days	20	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHES (DAILY, 1-2X /DAY)	04MAR97	5, ., -37	Not Stated	20		MOD	NO	PSR	Yes	No
	Respiratory Disorder	UPPER RESPIRATORY INFECTION	02APR97	34, ., -8	6 Days	20	CON	MIL	NO	UNR	Yes	No
	Somnolence	DROWSINESS DURING DAY	28FEB97	1, ., -41	19 Days	20	CON	MIL	NO	PBU	No	No
329.007.00309	Abdominal Pain	STOMACH ACHE	27OCT96	105, 53, -150	3 Days	20	CON	MIL	NO	UNR	No	No
	Bronchitis	BRONCHITIS	13SEP96	61, 9, -194	7 Days	20	CON	MOD	NO	UNR	Yes	No

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Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther SAE
329.007.00309	Dizziness	DIZZINESS	17JUL96	3, -50, -252	2 Days	20	2	MIL	NO	PSR	No
	Dysmenorrhea	MENSTRUAL CRAMPS	16AUG96	33, -20, -222	4 Days	20	CON	MOD	NO	UNR	Yes
	Ear Pain	EARACHE	06JAN97	176, 124, -79	8 Days	20	CON	MIL	NO	UNR	Yes
	Fever	FEVER	04DEC96	143, 91, -112	3 Days	20	CON	MIL	NO	UNR	Yes
	Gingivitis	ABSCESSSED TOOTH	26SEP96	74, 22, -181	1 Days	20	CON	SEV	NO	UNR	Yes
	Headache	HEADACHE (CHANGE IN SEVERITY)	05DEC96	144, 92, -111	04:00 Hrs	20	CON	SEV	NO	PBU	No
		HEADACHES (DAILY)	14JAN97	184, 132, -71	30 Days	20	24	MOD	NO	PBU	Yes
		HEADACHES (INCREASED FREQUENCY)	24SEP96	72, 20, -183	19 Days	20	20	MOD	NO	PBU	Yes
	Infection	FLU (COUGH, HEAD CONGESTION, LOW-GRADE FEVER)	12DEC96	151, 99, -104	11 Days	20	CON	MOD	NO	UNR	No
	Nausea	NAUSEA	27OCT96	105, 53, -150	3 Days	20	CON	MIL	NO	UNR	No
			10MAR97	239, 187, -16	Not Stated	30	CON	MIL	NO	UNR	No
	Respiratory Disorder	UPPER RESPIRATORY ILLNESS	30AUG96	47, -6, -208	9 Days	20	CON	MOD	NO	UNR	Yes
		URI (UPPER RESPIRATORY INFECTION)	26JUL96	12, -41, -243	21 Days	20	CON	MIL	NO	UNR	No
	Rhinitis	CONGESTION {NOSE}	04DEC96	143, 91, -112	5 Days	20	CON	MOD	NO	UNR	Yes
	Tooth Disorder	TOOTHACHE (CUTTING WISDOM TEETH)	26AUG96	43, -10, -212	17 Days	20	CON	MOD	NO	UNR	Yes

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
329.007.00309	Tremor	TREMOR (HANDS, HEAD, TEETH)	15JUL96	1, -52,-254	47 Days	20	CON	MIL	NO	PSR	No	No
329.007.00310	Arthralgia	LEFT KNEE PAIN	14NOV96	50, -11,-221	Not Stated	20	CON	MOD	NO	UNR	Yes	No
	Gastrointestinal Disorder	FOOD POISONING	16NOV96	52, -9,-219	2 Days	20	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	17DEC96	83, 23,-188	3 Days	20	CON	SEV	NO	PBU	No	No
		MILD HEADACHE	14MAR97	170, 110,-101	10 Days	20	CON	MOD	NO	PBU	Yes	No
			17OCT96	22, -39,-249	03:00 Hrs	20	CON	MIL	NO	PSR	No	No
	Hypertonia	STIFF NECK	14MAR97	170, 110,-101	10 Days	20	CON	MOD	NO	UNR	Yes	No
	Infection	"FLU" HEADACHE, SORE THROAT AND WEAKNESS, FEVER, EARACHE	05OCT96	10, -51,-261	12 Days	20	CON	MOD	NO	PBU	No	No
		POSSIBLE STREP THROAT	17MAR97	173, 113, -98	12 Days	20	CON	MOD	NO	UNR	Yes	No
	Myalgia	PAIN IN NECK MUSCLES	07OCT96	12, -49,-259	9 Days	20	CON	MOD	NO	PBU	Yes	No
	Pharyngitis	SORE THROAT	19DEC96	85, 25,-186	11 Days	20	CON	MOD	NO	UNR	Yes	No
	Photosensitivity	SUNBURN	01MAY97	218, 158, -53	8 Days	20	CON	MOD	NO	UNR	Yes	No
	Rhinitis	NASAL CONGESTION	19DEC96	85, 25,-186	12 Days	20	CON	MOD	NO	UNR	Yes	No
	Sinusitis	SINUS CONGESTION	05OCT96	10, -51,-261	25 Days	20	CON	MOD	NO	PBU	Yes	No
329.008.00160	Breast Enlargement	INCREASE IN BREAST SIZE {FEMALE}	27NOV95	27, -40,-254	Not Stated	20	CON	MIL	NO	PSR	No	No
	Dyspnea	SHORTNESS OF BREATH	20NOV95	20, -47,-261	8 Days	20	CON	MIL	NO	UNR	Yes	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.008.00160	Nervousness	JITTERINESS	20NOV95	20, -47,-261	8 Days	20	1	MIL	NO	UNR	No
329.008.00188	Anxiety	ANXIETY ATTACKS	24FEB96	52, ., -3	30 Mins	40	1	MIL	NO	PBU	No
	Migraine	MIGRAINES	20FEB96	48, ., -7	04:00 Hrs	40	2	MOD	NO	UNR	No
	Nervousness	JITTERINESS	07JAN96	4, ., -51	Not Stated	20	12	MIL	NO	PSR	No
329.008.00271	Asthenia	DECREASED ENERGY/TIRED	07MAY96	58, -7,-197	Not Stated	40	CON	MIL	NO	PSR	No
	Concentration Impaired	DECREASED CONCENTRATION	11MAY96	62, -3,-193	4 Days	40	CON	MIL	NO	PSR	No
	Conjunctivitis	DRY ITCHY EYES	07APR96	28, -37,-227	2 Days	20	CON	MIL	NO	PSR	No
	Decreased Appetite	REDUCED APPETITE	18MAR96	8, -57,-247	24 Days	20	CON	MIL	NO	REL	No
	Dizziness	COLD CLAMMY LIGHTHEADEDNESS [LIGHTHEADEDNESS]	05APR96	26, -39,-229	15 Mins	20	1	MIL	DCR	PSR	No
		LIGHTHEADED LIGHTHEADED {WHEN STANDING}	03APR96 11MAY96	24, -41,-231 62, -3,-193	15 Mins Not Stated	20 40	2 CON	MIL MIL	DCR NO	PSR PSR	No No
	Dry Mouth	DRY MOUTH	06APR96	27, -38,-228	11 Days	20	CON	MIL	NO	PBU	No
	Headache	HEADACHE (DAILY)	07MAY96	58, -7,-197	6 Days	40		MIL	NO	PSR	Yes
	Hypertonia	STIFF NECK	07APR96	28, -37,-227	30 Mins	20	3	MIL	NO	PBU	No
	Nervousness	INCREASED IRRITABILITY	12MAY96	63, -2,-192	Not Stated	40	CON	MIL	NO	PSR	No
	Pharyngitis	SORE THROAT SWALLOWING	06APR96	27, -38,-228	11 Days	20	CON	MIL	NO	PBU	No

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.008.00271	Skin Disorder	COLD, CLAMMY LIGHTHEADEDNESS [COLD, CLAMMY]	05APR96	26, -39,-229	15 Mins	20	1	MIL	DCR	PSR No	No
	Somnolence	SOMNOLENCE DAYTIME	15MAR96	5, -60,-250	52 Days	20	CON	MIL	NO	PSR No	No
	Tremor	SHAKY SUBJECTIVE FEELINGS OF SHAKINESS	14MAY96	65, 1,-190	Not Stated	40	CON	MIL	NO	PSR No	No
			03APR96	24, -41,-231	14 Days	20	3	MIL	DCR	PSR No	No
	Vasodilatation	FEELING HOT	06MAR96	-5, -69,-259	61 Days	0		MIL	NO	PSR No	No
329.008.00275	Dizziness	DIZZINESS	25JUN96	49, -7,-174	9 Days	40	3	MIL	NO	REL No	No
			19JUL96	73, 18,-150	5 Days	30	3	MIL	NO	REL No	No
			10AUG96	95, 40,-128	3 Mins	30	1	MIL	NO	REL No	No
			08SEP96	124, 69,-99	3 Days	30	2	MIL	NO	REL No	No
			05JUN96	29, -27,-194	3 Days	30	2	MIL	NO	REL No	No
	Dry Mouth	DRY MOUTH	08MAY96	1, -55,-222	Not Stated	20	CON	MIL	NO	PSR No	No
			21JUL96	75, 20,-148	06:00 Hrs	30	1	MIL	NO	REL No	No
		12AUG96	97, 42,-126	9 Days	30	3	MIL	NO	REL No	No	
		03SEP96	119, 64,-104	2 Days	30	3	MIL	NO	REL No	No	
		04NOV96	181, 126,-42	26:00 Hrs	30	2	MIL	NO	REL No	No	
329.009.00130	Abdominal Pain	STOMACH ACHE	13SEP95	149, 93,-33	Not Stated	20		MIL	NO	PBU Yes	No
	Agitation	["HYPER"{AGITATION}]	19MAY95	32, -25,-150	26 Days	20	3	MOD	NO	PSR No	No
	Nausea	NAUSEA	23MAY95	36, -21,-146	3 Days	20	2	MIL	NO	PSR No	No
	Sinusitis	SINUS INFECTION SINUSITIS	04SEP95	140, 84,-42	10 Days	20	CON	MOD	NO	PBU Yes	No
25APR95			8, -49,-174	10 Days	20	CON	MOD	NO	PBU Yes	No	

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.009.00131	Acne	ACNE-FACIAL	30MAY95	29, -28, -89	Not Stated	20	CON	MOD	NO	PSR Yes	No
	Constipation	CONSTIPATION	20MAY95	19, -38, -99	3 Days	20	1	MOD	NO	PSR Yes	No
	Thrombocythemia	INCREASED PLATELET COUNT	27JUN95	57, 1, -61	29 Days	20	CON	MIL	NO	PBU No	No
329.009.00133	Diarrhea	LOOSE STOOLS	29JUN95	17, ., -28	Not Stated	20		MOD	NO	PSR Yes	No
	Nausea	NAUSEA	29JUN95	17, ., -28	Not Stated	20	CON	MOD	NO	PSR No	No
	Sweating	SWEATING INCREASED	07JUL95	25, ., -20	Not Stated	20	CON	MOD	NO	PSR No	No
	Tooth Disorder	WISDOM TOOTH EXTRACTION {TOOTH DISORDER}	14JUL95	32, ., -13	03:00 Hrs	30	CON	MIL	NO	UNR Yes	No
329.009.00170	Agitation	AGITATION	09JUL96	246, 189, 1	12:00 Hrs	20	CON	MOD	NO	PSR No	Yes
	Asthenia	FATIGUE	27JUN96	234, 177, -11	11 Days	20	CON	MOD	NO	PSR No	Yes
	Constipation	CONSTIPATION	07JUL96	244, 187, -1	Not Stated	20	CON	MIL	NO	UNR No	No
	Decreased Appetite	LOSS OF APPETITE	09NOV95	3, -55, -242	43 Days	20	CON	MIL	NO	PSR No	No
			21DEC95	45, -13, -200	14 Days	40	CON	MOD	DCR	PSR No	No
	Dysmenorrhea	DYSMENORRHEA	07JUL96	244, 187, -1	Not Stated	20	CON	MIL	NO	UNR Yes	No
	Increased Appetite	INCREASED APPETITE	01APR96	147, 90, -98	85 Days	30	CON	MIL	NO	PSR No	No
			30JUN96	237, 180, -8	9 Days	20	CON	MOD	NO	PSR No	No
Insomnia	MIDDLE INSOMNIA	23NOV95	17, -41, -228	6 Days	20	CON	MIL	NO	PSR No	No	
		28NOV95	22, -36, -223	37 Days	20	CON	MOD	NO	PSR No	No	
Nausea	NAUSEA	27JUN96	234, 177, -11	12 Days	20	CON	SEV	NO	REL Yes	Yes	

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.009.00170	Somnolence	DROWSY	27JUN96	234, 177, -11	11 Days	20	CON	MOD	NO	PSR No	Yes
		SLEEPINESS WHEN TAKING EVENING MEDS	21DEC95	45, -13, -200	14 Days	40	CON	MOD	NO	PSR No	No
	Tremor	SHAKY TREMORS	27JUN96	234, 177, -11	2 Days	20	CON	MOD	NO	PSR No	Yes
	Vomiting	VOMITING	01JUL96	238, 181, -7	6 Days	20	CON	SEV	NO	REL Yes	No
329.009.00173	Weight Loss	WEIGHT LOSS	21DEC95	45, -13, -200	14 Days	40	CON	MIL	NO	PBU No	No
		Asthenia	FATIGUE	01JAN96	43, -21, -57	Not Stated	30	CON	MOD	NO	PSR No
	Insomnia	INSOMNIA	15JAN96	57, -7, -43	Not Stated	20	CON	MOD	NO	PSR No	No
	Nervousness	RESTLESSNESS	29DEC95	40, -24, -60	18 Days	30	CON	MOD	DCR	PSR No	No
329.009.00193	Somnolence	INCREASED DAYTIME SLEEPINESS SOMNOLENCE	13DEC95	24, -40, -76	Not Stated	20	CON	MOD	NO	PSR No	No
		Nervousness	RESTLESSNESS	01DEC95	4, ., -67	12 Days	20	CON	MIL	NO	PSR No
	Respiratory Disorder	COLD SYNDROME (URI) {UPPER RESPIRATORY INFECTION}	10DEC95	13, ., -58	18 Days	20	CON	MOD	NO	UNR Yes	No
329.009.00196	Asthma	ASTHMA	29JAN96	43, ., -27	Not Stated	30	CON	SEV	NO	UNR Yes	No
		Constipation	CONSTIPATION	20DEC95	3, ., -67	Not Stated	20	7	MIL	NO	PBU No
	Decreased Appetite	DECREASED APPETITE	19DEC95	2, ., -68	21 Days	20	CON	MIL	NO	PBU No	No
	Dry Mouth	DRY MOUTH	03JAN96	17, ., -53	6 Days	20	CON	MIL	NO	PSR No	No

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Corrective Therapy [Corr Ther]
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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.009.00196	Dyspepsia	HEARTBURN	27JAN96	41, ..	-29 Not Stated	30	CON	MIL	NO	PBU	Yes No
	Insomnia	INSOMNIA (INITIAL)	19DEC95	2, ..	-68 21 Days	20	CON	MIL	NO	PBU	No No
	Nausea	NAUSEA	19DEC95	2, ..	-68 21 Days	20	CON	MIL	NO	PSR	No No
	Sinusitis	SINUS INFECTION	29JAN96	43, ..	-27 Not Stated	30	CON	MOD	NO	PBU	Yes No
329.009.00201	Agitation	AGITATION	03APR96	58, ..	-1 Not Stated	20	CON	SEV	STP	PSR	No Yes
	Hostility	AGGRESSIVE ASSAULTIVE BEHAVIOR	03APR96	58, ..	-1 Not Stated	20	CON	SEV	STP	PSR	Yes Yes
	Infection	TONSILLITIS (STREP PHARYNGITIS)	01APR96	56, ..	-3 Not Stated	30	CON	MIL	NO	UNR	Yes No
	Insomnia	INITIAL INSOMNIA	28FEB96	23, ..	-36 Not Stated	20	CON	MOD	NO	PSR	No No
	Nausea	NAUSEA	07MAR96	31, ..	-28 1 Days	20	CON	MIL	NO	PBU	No No
	Paranoid Reaction	PARANOIA	03APR96	58, ..	-1 Not Stated	20	CON	MOD	STP	PSR	No Yes
	Rhinitis	NASAL CONGESTION	07APR96	62, ..	3 3 Days	20	CON	MOD	NO	UNR	Yes No
	Somnolence	SOMNOLENCE	26MAR96	50, ..	-9 Not Stated	30	CON	MIL	NO	PSR	No No
	Vomiting	VOMITING	07MAR96	31, ..	-28 1 Days	20		MIL	NO	UNR	No No
	Weight Gain	WEIGHT GAIN {11LBS}[WEIGHT GAIN]	02APR96	57, ..	-2 Not Stated	20	CON	MOD	NO	PSR	No No
329.009.00204	Nausea	NAUSEA	26MAR96	8, -49,-203	22 Days	20	CON	MIL	NO	PSR	No No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther SAE
329.009.00235	Arrhythmia	SINUS ARRHYTHMIA (PER EKG)	17MAR97	90, 36, -40	Not Stated	20	CON	MIL	NO	UNR	No No
	Dry Mouth	DRY MOUTH	30DEC96	13, -42, -117	43 Days	20	CON	MIL	NO	PSR	No No
	Headache	HEADACHE	17MAR97	90, 36, -40	29 Days	20	CON	MIL	NO	PSR	No No
	Insomnia	INSOMNIA (INITIAL)	03FEB97	48, -7, -82	8 Days	20	CON	MIL	NO	UNR	No No
	Nausea	NAUSEA	27JAN97	41, -14, -89	50 Days	20	CON	MIL	NO	PSR	No No
	Tachycardia	ELEVATED PULSE	06JAN97	20, -35, -110	36 Days	20	CON	MIL	NO	REL	No No
329.009.00240	Concentration Impaired	ATTENTION DEFICIT HYPERACTIVITY DISORDER	26MAR97	72, ., 21	Not Stated	0	CON	MOD	NO	UNR	Yes No
	Depression	WORSENING OF DEPRESSION	02MAR97	48, ., -3	Not Stated	30	CON	SEV	STP	UNR	Yes Yes
	Insomnia	WORSENING OF SLEEP DISTURBANCE	05MAR97	51, ., 0	Not Stated	30	CON	SEV	NO	PSR	Yes Yes
	Rash	BILATERAL ERYTHEMATOUS EYELIDS	11FEB97	29, ., -22	8 Days	20	CON	MIL	NO	UNR	No No
	Sinusitis	SINUS CONGESTION	11FEB97	29, ., -22	14 Days	20	CON	MIL	NO	UNR	No No
329.009.00303	Allergic Reaction	SEASONAL ALLERGIES	29APR96	28, -29, -237	1 Days	20	CON	MIL	NO	UNR	No No
329.009.00304	Headache	HEADACHE (WORSENING FROM BASELINE)	21MAY96	43, -14, -167	8 Days	30	CON	MOD	NO	PSR	No No
	Postural Hypotension	ORTHOSTATIC HYPOTENSION	21MAY96	43, -14, -167	30 Mins	30	CON	MIL	NO	PSR	No No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.009.00304	Somnolence	DAYTIME SLEEPINESS	14MAY96	36, -21, -174	15 Days	30	CON	MOD	NO	PSR No	No
	Weight Gain	WEIGHT GAIN {10 LBS} [WEIGHT GAIN]	30JUL96	113, 57, -97	Not Stated	30	CON	MIL	NO	PSR No	No
329.009.00324	Abnormal Dreams	INCREASED DREAMING NIGHTMARES	25NOV96 11NOV96	29, .. -44 15, .. -58	Not Stated 15 Days	20 20	CON CON	MIL MIL	NO NO	PSR No PSR No	No No
	Decreased Appetite	DECREASED APPETITE	16DEC96	50, .. -23	31 Days	20	CON	MIL	NO	PSR No	No
	Insomnia	INSOMNIA	11NOV96	15, .. -58	8 Days	20	CON	MIL	NO	PSR No	No
	Nausea	NAUSEA	29OCT96	2, .. -71	21 Days	20	CON	MIL	NO	PSR No	No
	Rash	RASH	27DEC96	61, .. -12	20 Days	20	CON	MOD	STP	REL No	No
	Respiratory Disorder	COLD {SYMPTOMS}	09DEC96	43, .. -30	8 Days	20	CON	MIL	NO	UNR No	No
	Depression	WORSENING OF DEPRESSION	12NOV96	35, .. -35	22 Days	20	CON	MOD	NO	PBU No	No
329.009.00329	Dizziness	DIZZINESS IN AM	14OCT96	6, .. -64	10 Days	20	CON	MIL	NO	REL No	No
	Somnolence	SLEEPINESS IN AM	14OCT96	6, .. -64	16 Days	20	CON	MIL	NO	REL No	No
329.010.00182	Headache	HEADACHE	28DEC95	10, .. -22	1 Days	20	CON	MIL	NO	PSR Yes	No
329.010.00278	Abdominal Pain	ABDOMINAL PAIN (PRESENT PREVIOUSLY)	22MAR96	43, -14, -197	5 Days	40	CON	SEV	NO	PBU Yes	No
	Dry Mouth	DRY MOUTH	29MAR96	50, -7, -190	6 Days	40	CON	MIL	NO	REL No	No
	Infection	MONONUCLEOSIS	01SEP96	206, 150, -34	Not Stated	40	CON	SEV	NO	PBU Yes	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE	
329.010.00278	Larynx Disorder	LARYNGITIS	01MAR96	22, -35, -218	4 Days	20	1	MIL	NO	UNR	No	
	Nervousness	RESTLESSNESS	03MAR96	24, -33, -216	5 Days	20	CON	MIL	NO	PSR	No	
329.010.00280	Acne	ACNE	16JUN96	31, -25, -43	Not Stated	20	CON	MIL	NO	PSR	No	
	Dizziness	LIGHT-HEADED (X2 MINUTES)	10JUL96	55, -1, -19	2 Mins	40	1	MIL	NO	PSR	No	
	Headache	HEADACHE	25JUN96	40, -16, -34	60 Mins	30	1	MIL	NO	PSR	Yes	No
			27JUN96	42, -14, -32	60 Mins	40	1	MIL	NO	PSR	Yes	No
	Rhinitis	CONGESTION (NASAL)	15MAY96	-2, -57, -75	2 Days	0	1	MIL	NO	UNR	Yes	No
Urine Abnormality	ABNORMAL URINALYSIS	21AUG96	97, 42, 23	Not Stated	0	CON	MIL	NO	UNR	No	No	
329.011.00283	Headache	HEADACHE	25FEB96	18, -40, -40	01:00 Hrs	20	1	MIL	NO	PBU	No	No
			11MAR96	33, -25, -25	01:00 Hrs	20	1	MIL	NO	PBU	Yes	No
	Tremor	"SHAKINESS"	05MAR96	27, -31, -31	6 Days	20	6	MIL	NO	PSR	No	No
329.011.00288	Cough Increased	COUGH	26JUL96	2, ., -41	Not Stated	20	CON	MIL	NO	UNR	Yes	No
329.012.00025	Abdominal Pain	DISCOMFORT ACROSS ALL OF ABDOMEN	06NOV95	14, ., -59	02:00 Hrs	20	1	MOD	NO	PBU	No	No
	Asthenia	FATIGUE	16NOV95	24, ., -49	Not Stated	20	CON	MOD	NO	REL	No	No
	Insomnia	INITIAL AND MIDDLE INSOMNIA	24OCT95	1, ., -72	Not Stated	20	CON	MOD	NO	PSR	No	No
	Nausea	NAUSEA	06NOV95	14, ., -59	02:00 Hrs	20	1	MOD	NO	PBU	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
329.012.00025	Somnolence	DROWSINESS	16NOV95	24, ., -49	20 Days	20	CON	MOD	NO	REL	No	No
	Tremor	SHAKINESS OF WHOLE BODY	24OCT95	1, ., -72	02:00 Hrs	20	CON	MIL	NO	PSR	No	No
	Urinary Tract Infection	[URINARY INFECTION QUESTIONABLE]	19DEC95	57, ., -16	9 Days	40	CON	MIL	NO	UNR	No	No
329.012.00220	Abnormal Vision	BLURRED VISION	25JUN96	9, -52, -150	2 Days	20	CON	MIL	NO	REL	No	No
	Bronchitis	BRONCHITIS	26SEP96	102, 42, -57	37 Days	30	CON	MOD	NO	PBU	Yes	No
	Dizziness	DIZZINESS	25JUN96	9, -52, -150	3 Days	20	CON	MOD	NO	REL	No	No
	Nausea	NAUSEA	13SEP96	89, 29, -70	04:00 Hrs	30	1	MIL	NO	PBU	No	No
329.012.00222	Cystitis	BLADDER INFECTION	18JUL96	21, -43, -65	4 Days	20	CON	MIL	NO	UNR	Yes	No
329.012.00226	Av Block	PR PROLONGATION CARDIAC CONDUCTION DELAY	20DEC96	18, ., 0	4 Days	20	CON	MOD	STP	PSR	No	No
	Nausea	NAUSEA	12DEC96	10, ., -8	12 Days	20	CON	MIL	NO	PBU	No	No
	Respiratory Disorder	COLD SYMPTOMS (SORE THROAT, COUGH)	30NOV96	-3, ., -20	24 Days	0	CON	MIL	NO	UNR	No	No
329.012.00228	Dry Mouth	DRY MOUTH	20MAR97	2, ., -2	4 Days	20	CON	MIL	NO	PBU	No	No
	Insomnia	INITIAL INSOMNIA	20MAR97	2, ., -2	4 Days	20	CON	MIL	NO	PBU	No	No
329.012.00231	Conjunctivitis	ITCHY EYES	23APR97	48, -14, -117	4 Days	20	CON	MIL	NO	PBU	No	No
	Dizziness	DIZZINESS	25MAY97	80, 19, -85	10 Days	30	4	MIL	NO	PBU	No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PAROXETINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther SAE
329.012.00231	Dry Mouth	DRY MOUTH	20MAR97	14, -48, -151	41 Days	20	CON	MIL	NO	PBU	No No
	Headache	HEADACHE	18APR97	43, -19, -122	2 Days	20	CON	MOD	NO	PBU	No No
			24APR97	49, -13, -116	02:00 Hrs	20	CON	MOD	NO	PBU	Yes No
		MODERATE HEADACHE	28APR97	53, -9, -112	Not Stated	30		MIL	NO	PBU	Yes No
			28APR97	53, -9, -112	Not Stated	30		MOD	NO	PSR	Yes No
	Nausea	NAUSEA	25MAY97	80, 19, -85	10 Days	30	4	MIL	NO	PBU	No No

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Appendix D.2

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Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----												
Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act-Int ion	Inv Corr-Rel Ther	SAE		
329.001.00061	Concentration Impaired	DECREASE CONCENTRATION	30JUL94	2, ..	-46 27 Days	50	CON	MOD NO	REL No	No		
			01SEP94	35, ..	-13 Not Stated	200	CON	MIL NO	PBU No	No		
	Dizziness	DIZZINESS UPON GETTING UP SUDDENLY	06AUG94	9, ..	-39 20 Days	100	CON	MIL NO	REL No	No		
	Dry Mouth	DRY MOUTH	11AUG94	14, ..	-34 Not Stated	150	CON	MIL NO	REL No	No		
	Dysphagia	DIFFICULTY SWALLOWING 1 HOUR DURATION AFTER AWAKENING	28AUG94	31, ..	-17 Not Stated	200	3	MIL NO	PSR No	No		
	Insomnia	INSOMNIA MIDDLE	18AUG94	21, ..	-27 Not Stated	200	7	MIL NO	REL No	No		
	Pharyngitis	SORE THROAT 1 HOUR DURATION AFTER AWAKENING	28AUG94	31, ..	-17 Not Stated	200	3	MIL NO	PSR No	No		
	Qt Interval Prolonged	WIDENED CORRECTED QT {INTERVAL} QRS	01SEP94	35, ..	-13 Not Stated	200	CON	MIL STP	REL No	No		
	Tremor	HAND TREMORS	25AUG94	28, ..	-20 Not Stated	200	4	MIL NO	REL No	No		
329.001.00066	Abnormal Vision	BLURRED VISION WHEN READING LONG TIME	02DEC94	11, ..	-11 Not Stated	100	3	MIL NO	PSR No	No		
	Decreased Appetite	DECREASE APPETITE	23NOV94	2, ..	-20 Not Stated	50	CON	MIL NO	PSR No	No		
	Dizziness	DIZZY	02DEC94	11, ..	-11 5 Mins	100	1	MIL NO	PSR No	No		
	Headache	HEADACHE	23NOV94	2, ..	-20 5 Days	50	2	MIL NO	PSR No	No		
	Nausea	NAUSEA	23NOV94	2, ..	-20 13 Days	50	CON	MIL NO	PSR No	No		

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Intent-to-Treat Population

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.001.00066	Tachycardia	INCREASED HEART RATE	05DEC94	14, ., -8	Not Stated	100	CON	MOD	STP	REL No	No
329.001.00067	Dizziness	FAINTNESS	30NOV94	9, ., -13	Not Stated	100	CON	MOD	STP	PSR No	No
	Postural Hypotension	POSTURAL HYPOTENSION	30NOV94	9, ., -13	Not Stated	100	CON	MOD	STP	PSR No	No
	Somnolence	HYPERSOMNIA	30NOV94	9, ., -13	Not Stated	100	5	MIL	NO	PSR No	No
329.001.00070	Agitation	INCREASE AGITATION	28FEB95	7, ., -24	Not Stated	100	CON	MIL	NO	PBU No	No
	Dry Mouth	DRY MOUTH	08MAR95	15, ., -16	Not Stated	150	CON	MIL	NO	REL No	No
	Insomnia	MIDDLE INSOMNIA TERMINAL INSOMNIA	22FEB95 11MAR95	1, ., -30 18, ., -13	16 Days Not Stated	50 150	CON CON	MIL MIL	NO NO	PBU PBU	No No
	Nausea	NAUSEA	23FEB95	2, ., -29	Not Stated	50	CON	MIL	NO	PSR No	No
	Syncope	FAINTNESS UPON STANDING	10MAR95	17, ., -14	Not Stated	150	3	MIL	NO	PSR No	No
	Tachycardia	PULSE {INCREASED} 2 CONSECUTIVE WEEKS	08MAR95	15, ., -16	Not Stated	150	CON	SEV	STP	REL No	No
	Tremor	HAND TREMORS	23FEB95	2, ., -29	Not Stated	50	CON	MIL	NO	PSR No	No
	Vasodilatation	HOT FLASHES	01MAR95	8, ., -23	Not Stated	100	2	MIL	NO	PBU No	No
329.001.00122	Amnesia	MORE FORGETFUL	11JUL95	22, -36, -160	15 Days	200	CON	MIL	NO	PSR No	No
	Constipation	CONSTIPATION	05JUL95 14JUL95	16, -42, -166 25, -33, -157	4 Days 19 Days	150 200	CON CON	MIL MIL	NO NO	PSR PSR	No No

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.001.00122	Extrasystoles	PVC'S ON EKG [PREMATURE VENTRICULAR CONTRACTIONS]	27JUN95	8, -50,-174	9 Days	100	CON	MIL	NO	PBU	No
	Hypesthesia	NUMBNESS IN HANDS AND ARMS WHEN AWAKES	18JUL95	29, -29,-153	30 Days	200	CON	MIL	NO	PBU	No
	Increased Appetite	INCREASED APPETITE	11OCT95	114, 57, -68	Not Stated	200	CON	MOD	NO	REL	No
	Myoclonus	MUSCLE TWITCH RIGHT EYE RIGHT KNEE TWITCH	14JUL95 14JUL95	25, -33,-157 25, -33,-157	19 Days 62 Days	200 200	CON CON	MIL MIL	NO NO	PSR REL	No No
	Rhinitis	CONGESTION BACK OF THROAT	07OCT95	110, 53, -72	8 Days	200	CON	MIL	NO	UNR	No
	Tachycardia	HEART RACING (BEATS HARD)	12SEP95	85, 28, -97	30 Days	200	2	MIL	NO	REL	No
	Tremor	HAND TREMORS RIGHT KNEE TREMOR	08AUG95 14JUL95	50, -8,-132 25, -33,-157	120 Days 62 Days	200 200	CON CON	MOD MIL	NO NO	REL REL	No No
	Weight Gain	WEIGHT GAIN	11OCT95	114, 57, -68	Not Stated	200	CON	MOD	NO	REL	No
329.002.00050	Cough Increased	COUGHING	23MAR95	1, ., -34	12 Days	50	CON	MIL	NO	PBU	Yes
	Fever	FEVER	23MAR95	1, ., -34	6 Days	50	CON	MOD	NO	PBU	Yes
	Headache	HEADACHE	23MAR95	1, ., -34	5 Days	50	CON	MIL	NO	PBU	Yes
	Pharyngitis	SORE THROAT	23MAR95	1, ., -34	6 Days	50	CON	MOD	NO	PBU	Yes
	Postural Hypotension	DIZZINESS WITH ORTHOSTATIC HYPOTENSION	30MAR95	8, ., -27	6 Days	100	CON	MIL	STP	PSR	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.002.00050	Tachycardia	HEART RATE INCREASE	23MAR95	1, ., -34	22 Days	50	CON	MOD	STP	PSR No	No
	Urination Impaired	URINARY HESITANCY	30MAR95	8, ., -27	6 Days	100	CON	MIL	STP	PSR No	No
329.002.00056	Tachycardia	INCREASED HEART RATE	02AUG94	15, ., -21	22 Days	150	CON	MIL	STP	PSR No	No
329.002.00057	Hyperkinesia	SENSATION OF RESTLESSNESS IN LEGS NO OBSERVABLE TREMORS	27SEP94	20, -38, -109	45 Mins	150	CON	MIL	NO	PBU No	No
	Unintended Pregnancy	PREGNANCY NAUSEA VOMITING	10DEC94	94, 37, -35	Not Stated	300	CON	MOD	STP	UNR No	No
	Vomiting	NAUSEA, VOMITING	06OCT94	29, -29, -100	20 Mins	250	CON	MIL	NO	UNR No	No
329.002.00098	Constipation	CONSTIPATION	02MAR95	59, ., -14	Not Stated	250	CON	MIL	DCR	PSR No	No
	Dry Mouth	DRY MOUTH	10JAN95	8, ., -65	Not Stated	100	CON	MOD	DCR	PSR No	No
	Headache	HEADACHES	21FEB95	50, ., -23	9 Days	250	CON	MOD	DCR	PSR No	No
	Tremor	SHAKING	14FEB95	43, ., -30	Not Stated	250	CON	MOD	DCR	PSR No	No
329.002.00100	Dizziness	DIZZINESS"OFF AND ON"	14APR95	39, -20, -46	15 Mins	250	15	MIL	NO	PSR No	No
	Dry Mouth	DRY MOUTH	14APR95	39, -20, -46	10 Mins	250	12	MIL	NO	PSR No	No
329.002.00103	Abdominal Pain	STOMACH ACHE	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR No	No
		STOMACH ACHE FOLLOWING INGESTION OF MEDS	21APR95	2, -55, -126	21 Days	50	14	MIL	NO	PSR No	No
		STOMACH ACHE FOLLOWING INGESTION OF STUDY MEDS	20JUN95	62, 6, -66	52 Days	250	2	MIL	NO	PSR No	No

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329.002.00103	Abnormal Vision	BLURRED VISION WHEN STANDS QUICKLY	08JUN95	50, -7, -78	36 Days	250	10	MIL	NO	PSR	No
	Chills	CHILLS / GOOSE BUMPS WHILE EXERCISING (1X) FEELING HOT/COLD	08MAY95	19, -38, -109	2 Mins	150	CON	MIL	NO	PSR	No
			23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No
	Dizziness	DIZZINESS DIZZINESS (WHEN GOING FROM SIT TO STAND)	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No
			10AUG95	113, 57, -15	16 Days	250		MIL	NO	PSR	No
	Dry Mouth	DRY MOUTH	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No
Nausea	NAUSEA	23MAY95	34, -23, -94	8 Days	200	CON	MOD	NO	PSR	No	
Rash	RED SPOTS / BLOTCHES ON SKIN ARMS, THROAT, CHEST	11MAY95	22, -35, -106	35 Days	200			MIL	NO	PSR	No
329.002.00104	Dizziness	DIZZINESS	24MAY95	21, -36, -238	133 Days	150	CON	MIL	NO	REL	No
	Dry Mouth	DRY MOUTH	11MAY95	8, -49, -251	76 Days	100	CON	MOD	NO	REL	No
	Infection	STREP THROAT	21DEC95	232, 176, -27	11 Days	300	1	MOD	NO	UNR	Yes
	Urination Impaired	DIFFICULTY INITIATING URINATION	04MAY95	1, -56, -258	8 Days	50	2	MIL	NO	REL	No
	Vomiting	NAUSEA AND VOMITING DURING DOWN TITRATION VOMITING WHEN FORGOT DOSE	10JAN96	252, 196, -7	6 Days	100	1	MOD	NO	PSR	No
25JUL95			83, 27, -176	1 Days	300	1	MOD	NO	REL	No	
329.002.00243	Abdominal Pain	STOMACH ACHES	21MAR96	8, ., -15	Not Stated	100	CON	MIL	NO	REL	No

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
329.002.00243	Asthenia	TIREDFNESS AND DROWSINESS	14MAR96	1, ..	-22 Not Stated	50	CON	MOD NO	PSR No	No
	Constipation	CONSTIPATION	04APR96	22, ..	-1 Not Stated	150	CON	SEV NO	PSR No	No
	Nausea	NAUSEA	21MAR96	8, ..	-15 Not Stated	100	CON	MIL NO	REL No	No
	Postural Hypotension	ORTHOSTATIC HYPOTENSION	28MAR96	15, ..	-8 Not Stated	150	CON	MIL NO	PSR No	No
	Rash	ITCHING AND RASH TO RIGHT FOREARM AND BOTH CALVES	17MAR96	4, ..	-19 6 Days	50	CON	MOD NO	UNR Yes	No
	Trauma	DIZZINESS - (HIT HEAD DURING FALL)	17MAR96	4, ..	-19 Not Stated	50	CON	MOD STP	PSR No	No
	Tremor	(WORSENING) ENTIRE BODY SHAKES AND SHAKY HAND	22MAR96	9, ..	-14 Not Stated	100	CON	MOD NO	PSR No	No
329.002.00244	Asthenia	FEELS MORE TIRED AFTER TAKING MEDS	22MAR96	2, -56, -82	14 Days	50	CON	MIL NO	PSR No	No
	Depersonalization	"SPACEY" 1X	23MAR96	3, -55, -81	02:00 Hrs	50	7	MIL NO	PSR No	No
	Dizziness	DIZZINESS UPON STANDING {1-2X/DAILY}	29MAR96	9, -49, -75	24 Days	100	48	MOD NO	PSR No	No
	Dry Mouth	DRY THROAT, MOUTH	29MAR96	9, -49, -75	61 Days	100	CON	MOD NO	PSR No	No
	Thirst	INCREASED THIRST	29MAR96	9, -49, -75	61 Days	100	CON	MOD NO	PBU No	No

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE	
329.002.00321	Hostility	PSYCHIATRIC HOSPITALIZATION FOLLOWING ASSAULTIVE BEHAVIOR	02JUN96	11, .. -1	Not Stated	50	1	SEV	STP	UNR No	Yes	
329.002.00322	Abdominal Pain	STOMACH ACHE STOMACH ACHE, RE-OCCURRING	21JAN97 06FEB97	13, .. -33 29, .. -17	02:00 Hrs Not Stated	100 200	1	MOD MIL	NO NO	PBU No PSR No	No No	
	Arrhythmia	ORTHOSTATIC CHANGES [IRREGULAR PULSE]	13FEB97	36, .. -10	Not Stated	200	CON	MOD	STP	PSR No	No	
	Dizziness	DIZZINESS ORTHOSTATIC CHANGES [DIZZINESS]	11JAN97 13FEB97	3, .. -43 36, .. -10	Not Stated Not Stated	50 200	CON CON	MOD MOD	STP STP	PBU No PSR No	No No	
329.003.00073	Gastrointestinal Disorder	NAUSEA, VOMITING HEADACHES, DIARRHEA (GASTROINTESTINAL ILLNESS)	23FEB95	36, .. -9	Not Stated	250	CON	MOD	NO	UNR No	No	
	Postural Hypotension	ORTHOSTATIC SYMPTOMS {ORTHOSTATIC HYPOTENSION}	03FEB95	16, .. -29	Not Stated	150	CON	MOD	NO	PSR No	No	
	Vomiting	VOMITING	04MAR95	45, .. 0	Not Stated	250	CON	SEV	STP	PSR Yes	No	
329.003.00076	Dizziness	DIZZINESS	06AUG95	188, 133, -52	66 Days	200	CON	MIL	NO	PBU No	No	
	Dry Mouth	DRY MOUTH	01FEB95	2, -54, -238	48 Days	50	CON	MIL	NO	PSR No	No	
329.003.00079	Insomnia	INSOMNIA (FREQUENT AWAKENING)	11MAY95	9, .. -8	Not Stated	100	CON	MOD	NO	PSR No	No	

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act-Int ion	Inv Corr Rel Ther	SAE
329.003.00079	Pharyngitis	SORE THROAT	17MAY95	15, .. -2	Not Stated	100	CON	MIL NO	PBU Yes	No
329.003.00082	Dizziness	DIZZY	03JAN96	24, .. -14	Not Stated	150	CON	MIL NO	PSR No	No
	Dry Mouth	DRY MOUTH	17JAN96	38, .. 0	Not Stated	250	CON	MIL NO	PSR No	No
	Headache	HEADACHE	02JAN96 17JAN96	23, .. -15 38, .. 0	04:00 Hrs Not Stated	100 250	1 CON	MOD NO MIL NO	PSR No PSR No	No No
329.003.00088	Abnormal Vision	BLURRED VISION	14MAR95	15, .. -26	Not Stated	100	CON	MIL NO	PSR No	No
	Constipation	CONSTIPATION	14MAR95	15, .. -26	Not Stated	100	CON	MIL NO	PSR No	No
	Dizziness	DIZZINESS	14MAR95	15, .. -26	764 Days	100	CON	MIL NO	PBU No	No
	Dry Mouth	DRY MOUTH	21MAR95	22, .. -19	Not Stated	200	CON	MIL NO	PSR No	No
	Postural Hypotension	ORTHOSTATIC HYPOTENSION	12MAR95	13, .. -28	1 Days	100	1	MIL NO	PSR No	No
	Taste Perversion	BAD TASTE	10MAR95	11, .. -30	21 Days	100	CON	MIL NO	PSR No	No
	Urinary Retention	URINARY RETENTION	14MAR95	15, .. -26	Not Stated	100	CON	SEV STP	REL No	No
329.003.00090	Constipation	CONSTIPATION	26APR95 02MAY95	44, .. -25 50, .. -19	6 Days Not Stated	250 200	CON CON	SEV DCR MOD NO	PSR Yes PSR Yes	No No
	Dizziness	DIZZINESS	28MAR95 09MAY95	15, .. -54 57, .. -12	29 Days Not Stated	100 200	CON CON	MIL NO MIL NO	PSR No PSR No	No No
	Dry Mouth	DRY MOUTH	28MAR95	15, .. -54	15 Days	100	CON	MIL NO	PSR No	No
	Dyspepsia	HEARTBURN INDIGESTION	02MAY95 26APR95	50, .. -19 44, .. -25	Not Stated 6 Days	200 250	CON CON	MIL NO MOD DCR	PSR Yes PSR No	No No

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329.003.00090	Dyspepsia	INDIGESTION	02MAY95	50, .. -19	Not Stated	200	CON	MIL NO	PSR Yes	No
	Headache	HEADACHE HEADACHES	16MAR95 11APR95 26APR95 05MAY95	3, .. -66 29, .. -40 44, .. -25 53, .. -16	13 Days 15 Days 9 Days 1 Days	50 200 250 200	CON CON CON 3	SEV DCR MIL NO MOD DCR MIL NO	PSR Yes PSR Yes PSR Yes PSR Yes	No No No No
	Taste Perversion	BAD TASTE	16MAR95	3, .. -66	5 Days	50	CON	MIL DCR	PSR No	No
329.003.00092	Abdominal Pain	STOMACH ACHE STOMACH CRAMPS	22DEC95 21MAY95 10JUN95	234, 176, -27 19, -40, -242 39, -20, -222	02:00 Hrs 30 Mins 1 Days	200 150 200	1 2 1	MIL NO MIL NO MOD NO	PBU No PBU No PBU Yes	No No No
	Dry Mouth	DRY MOUTH	04MAY95	2, -57, -259	146 Days	50	CON	MIL NO	PSR No	No
	Gastrointestinal Disorder	STOMACH PROBLEMS	22OCT95	173, 115, -88	2 Days	0		MOD DCR	PBU Yes	No
	Pharyngitis	SORE THROAT	01MAY95	-2, -60, -262	16 Days	0	CON	MIL NO	UNR No	No
	Somnolence	DROWSINESS	17MAY95	15, -44, -246	16 Days	150	CON	MIL NO	PSR No	No
329.003.00093	Dizziness	DIZZINESS	08AUG95	49, -15, -31	20 Mins	300	1	MIL NO	PBU No	No
	Dry Mouth	DRY MOUTH	20JUN95	-1, -64, -80	106 Days	0	CON	MIL NO	PSR No	No
329.003.00247	Asthenia	TIRED	30APR96	90, 36, -21	1 Days	200	1	MIL NO	UNR No	No
	Dizziness	DIZZINESS WHEN WAKING UP IN AM	10FEB96	10, -45, -101	32 Days	100		MIL NO	PSR No	No
	Dry Mouth	DRY MOUTH	10FEB96 07MAR96	10, -45, -101 36, -19, -75	23 Days 15 Days	100 200	CON CON	MIL NO MIL NO	PSR No PSR No	No No

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329.003.00247	Nervousness	IRRITABLE EDGY BURNT SELF WITH CIGARETTE	16MAR96	45, -10, -66	11 Days	200	1	MIL DCR	PSR No	No
	Postural Hypotension	DIZZINESS WHEN STANDING UP ORTHOSTATIC HYPOTENSION	09FEB96	9, -46, -102	33 Days	100	CON	MIL NO	PSR No	No
	Respiratory Disorder	COLD {SYMPTOMS}	05MAR96	34, -21, -77	3 Days	200	CON	MOD NO	UNR Yes	No
329.003.00249	Dizziness	DIZZINESS	15APR96	40, .., -22	1 Mins	300	1	MIL NO	PSR No	No
		DIZZINESS (ORTHOSTATIC)	16APR96	41, .., -21	2 Mins	300	CON	MIL NO	PSR No	No
		LIGHT HEADEDNESS	20MAR96	14, .., -48	14 Days	150	CON	MIL NO	PSR No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	13APR96	38, .., -24	3 Days	300		MIL NO	UNR Yes	No
	Headache	HEADACHE	07MAR96	1, .., -61	3 Days	50	2	MIL NO	PSR Yes	No
Respiratory Disorder	COLD {SYMPTOMS}	23APR96	48, .., -14	8 Days	300		MIL NO	UNR Yes	No	
329.003.00289	Anemia	ANEMIA	11OCT96	227, 171, -11	Not Stated	150	CON	MIL NO	UNR No	No
	Dry Mouth	DRY MOUTH	11MAR96	13, -44, -225	31 Days	100		MIL NO	PSR No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	24APR96	57, 1, -181	Not Stated	200	6	MIL NO	UNR No	No
	Headache	HEADACHES	28FEB96	1, -56, -237	85 Days	50		MIL NO	PBU No	No
	Insomnia	INSOMNIA	13MAR96	15, -42, -223	129 Days	150		MIL NO	PBU No	No
329.003.00290	Dry Mouth	DRY MOUTH	12MAR96	2, .., -10	24:00 Hrs	50	1	MIL NO	PBU No	No
	Hypertension	HIGH BLOOD PRESSURE	20MAR96	10, .., -2	15 Days	100	CON	MIL STP	PSR No	No

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329.003.00290	Tachycardia	TACHYCARDIA	20MAR96	10, ., -2	Not Stated	100	CON	MIL STP	PSR No	No
329.003.00314	Dizziness	DIZZINESS LIGHT HEADED	17DEC96 24OCT96	57, ., -20 3, ., -74	Not Stated 13 Days	200 50	CON CON	MIL NO MIL NO	PSR No PSR No	No No
	Dry Mouth	DRY MOUTH	14NOV96	24, ., -53	Not Stated	200	1	MIL NO	PSR No	No
	Dyspepsia	HEARTBURN	04DEC96	44, ., -33	48:00 Hrs	200	1	MIL NO	UNR No	No
	Ear Pain	EARACHE	20DEC96	60, ., -17	24:00 Hrs	250	1	MIL NO	UNR Yes	No
	Infection	FLU	15NOV96	25, ., -52	3 Days	200	1	MIL NO	UNR Yes	No
	Insomnia	INSOMNIA	23OCT96	2, ., -75	3 Days	50	3	MOD NO	PSR No	No
329.003.00317	Allergic Reaction	ALLERGY	14JAN97	27, ., -43	24:00 Hrs	200	CON	MIL NO	PBU Yes	No
	Back Pain	BACKACHE	07JAN97	20, ., -50	27 Days	150	3	MIL NO	PSR No	No
	Dizziness	DIZZINESS ORTHOSTATIC	07JAN97	20, ., -50	29 Days	150	4	MIL NO	PSR No	No
	Headache	HEADACHES	19DEC96	1, ., -69	48 Days	50	7	MIL NO	PSR Yes	No
	Respiratory Disorder	COLD {COMMON}	14JAN97	27, ., -43	24:00 Hrs	200	CON	MIL NO	PBU Yes	No
329.004.00013	Abnormal Vision	VISUAL BRIGHT SPOTS	20JUL94	2, -58, -246	5 Days	50	8	MIL NO	REL No	No
	Dizziness	DIZZINESS	20JUL94	2, -58, -246	5 Days	50	CON	MOD NO	REL No	No
	Dry Mouth	DRY MOUTH	30JUL94	12, -48, -236	Not Stated	100	CON	MOD NO	REL No	No
	Headache	HEADACHES	20JUL94	2, -58, -246	5 Days	50	CON	SEV NO	REL No	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
329.004.00013	Somnolence	SLEEPINESS	20JUL94	2, -58, -246	3 Days	50	2	MIL NO	REL No	No
	Sweating	SWEATING	20JUL94	2, -58, -246	3 Days	50	CON	MIL NO	REL No	No
	Tinnitus	RINGING IN EARS-5-10 MINUTES IN A.M.	03AUG94	16, -44, -232	8 Days	150	7	MIL NO	REL No	No
	Tremor	TREMBLING OF HANDS	07AUG94	20, -40, -228	4 Days	150	2	MIL NO	REL No	No
329.004.00014	Constipation	CONSTIPATED	02DEC94	4, ., -11	Not Stated	50	CON	MOD NO	REL No	No
	Dysphagia	LUMP IN THE THROAT	29NOV94	1, ., -14	11 Days	50	7	MOD NO	REL No	No
	Nausea	NAUSEA	05DEC94	7, ., -8	3 Days	100	1	MOD NO	PSR No	No
			07DEC94	9, ., -6	Not Stated	100	18	SEV NO	PSR No	No
			05DEC94	7, ., -8	Not Stated	100	21	MOD STP	PSR No	No
	Polyuria	POLYURIA	05DEC94	7, ., -8	1 Days	100		MIL NO	PSR No	No
Respiratory Disorder	COMMON COLD	24NOV94	-5, ., -19	6 Days	0	1	MIL NO	UNR Yes	No	
329.004.00211	Dizziness	DIZZINESS	19FEB96	18, ., -31	18 Days	150	CON	MIL NO	REL No	No
	Dry Mouth	DRY MOUTH	05FEB96	4, ., -45	14 Days	50	CON	MIL NO	PSR No	No
			19FEB96	18, ., -31	15 Days	150	CON	SEV NO	REL No	No
			05MAR96	33, ., -16	14 Days	200	CON	MOD NO	REL No	No
			19MAR96	47, ., -2	Not Stated	200	CON	SEV STP	REL No	No
	Gastroenteritis	BACTERIAL GASTROENTERITIS	21MAR96	49, ., 0	3 Days	200	CON	SEV STP	UNR Yes	No
	Headache	HEADACHE	23FEB96	22, ., -27	Not Stated	200	CON	MOD NO	PBU Yes	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.004.00211	Hypertonia	STIFF NECK	23FEB96	22, .. -27	18 Days	200	CON	MIL	NO	PBU	No
	Postural Hypotension	ORTHOSTATIC HYPOTENSION	12FEB96	11, .. -38	7 Days	100	CON	MIL	NO	PSR	No
			19FEB96	18, .. -31	15 Days	150	CON	MOD	NO	REL	No
			05MAR96	33, .. -16	Not Stated	200	CON	MIL	NO	REL	No
	Trauma	MOUTH CUTS	20MAR96	48, .. -1	Not Stated	200	CON	SEV	STP	REL	Yes
Tremor	TREMORS	19FEB96	18, .. -31	22 Days	150	CON	MIL	NO	PSR	No	
Ulcerative Stomatitis	MOUTH SORES	20MAR96	48, .. -1	Not Stated	200	CON	SEV	STP	REL	Yes	
329.004.00215	Abnormal Dreams	NIGHTMARES	25APR97	37, .. -3	7 Days	200	CON	MOD	STP	REL	No
	Arthralgia	JOINT PAINS	30APR97	42, .. 2	Not Stated	200	CON	MIL	STP	REL	Yes
	Asthenia	WEAKNESS	30APR97	42, .. 2	Not Stated	200	CON	MOD	STP	REL	No
	Dizziness	DIZZINESS	04APR97	16, .. -24	2 Days	150	CON	MIL	NO	REL	No
			25APR97	37, .. -3	Not Stated	200	CON	MOD	STP	REL	No
	Dry Mouth	DRY MOUTH	28MAR97	9, .. -31	Not Stated	100	CON	MOD	NO	REL	No
	Esophagitis	ESOPHAGEAL IRRITATION	09APR97	21, .. -19	3 Days	150	CON	MIL	NO	PSR	No
	Hallucinations	VISUAL HALLUCINATIONS	25APR97	37, .. -3	7 Days	200	CON	SEV	STP	REL	Yes
	Headache	HEADACHE	25MAR97	6, .. -34	2 Days	50	1	MIL	NO	UNR	No
HEADACHES		01APR97	13, .. -27	30 Days	100	CON	MIL	NO	PSR	No	
		01MAY97	43, .. 3	Not Stated	200	CON	SEV	STP	REL	Yes	
Nausea	NAUSEA	30APR97	42, .. 2	Not Stated	200	CON	SEV	STP	REL	Yes	

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.004.00215	Nervousness	IRRITABILITY	25APR97	37, ., -3	7 Days	200	CON	SEV	STP	REL No	Yes
	Pharyngitis	SORE THROAT	25MAR97	6, ., -34	5 Days	50	CON	MIL	NO	UNR Yes	No
	Postural Hypotension	ORTHOSTATIC HYPOTENSION	01APR97	13, ., -27	21 Days	100	CON	MOD	NO	REL No	No
			22APR97	34, ., -6	11 Days	200	CON	MIL	NO	REL No	No
	Rhinitis	RHINITIS	26MAR97	7, ., -33	4 Days	50	CON	MIL	NO	UNR Yes	No
Vomiting	VOMITING	30APR97	42, ., 2	Not Stated	200	CON	SEV	STP	REL Yes	No	
329.005.00003	Dizziness	DIZZINESS	27SEP94	8, ., -7	10 Days	100	CON	MOD	NO	PSR No	No
	Headache	HEADACHE	23SEP94	4, ., -11	03:00 Hrs	50	1	MOD	NO	PSR No	No
	Sweating	SWEATINESS	22SEP94	3, ., -12	6 Days	50	CON	MOD	NO	PSR No	No
	Tachycardia	"RACING HEART" RACING HEARTBEAT	23SEP94	4, ., -11	12 Days	50	4	MOD	NO	PBU No	No
			30SEP94	11, ., -4	5 Days	100	2	MOD	STP	REL No	No
Tremor	SHAKINESS	27SEP94	8, ., -7	10 Days	100	CON	MOD	NO	PSR No	No	
329.005.00006	Dizziness	DIZZINESS WHEN GETTING OUT OF BED IN AM	11NOV94	8, -53, -167	25 Days	50	CON	MIL	NO	REL No	No
	Dry Mouth	DRY MOUTH	09NOV94	6, -55, -169	Not Stated	50	CON	MOD	NO	REL No	No
	Dyspepsia	UPSET STOMACH	26NOV94	23, -38, -152	64 Days	150	CON	MOD	NO	UNR Yes	No
	Increased Appetite	CRAVINGS: CEREALS, PASTAS, CARBOHYDRATES	24NOV94	21, -40, -154	41 Days	150	CON	MOD	NO	PSR No	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.005.00006	Infection	STREP THROAT/FEVER/SORE THROAT	26NOV94	23, -38, -152	5 Days	150	CON	SEV	NO	UNR Yes	No
	Nausea	NAUSEA	26NOV94	23, -38, -152	64 Days	150	CON	MOD	NO	UNR Yes	No
	Neurosis	OBSESSIVE THOUGHTS	27FEB95	116, 56, -59	Not Stated	300	CON	MOD	STP	PBU No	No
	Pyuria	URINALYSIS - WBC'S {INCREASED}	28APR95	176, 116, 1	Not Stated	50		MIL	NO	UNR No	No
329.005.00007	Abnormal Dreams	NIGHTMARES	02APR95	145, 82, -47	15 Days	250	10	SEV	NO	UNR No	No
	Convulsion	SEIZURE	24MAY95	197, 134, 5	5 Mins	250	CON	SEV	STP	UNR Yes	No
	Dehydration	DEHYDRATION	18MAY95	191, 128, -1	8 Days	250	CON	SEV	STP	PBU Yes	No
	Dry Mouth	DRY MOUTH	20DEC94	42, -22, -150	151 Days	250	CON	MOD	NO	REL No	No
	Headache	HEADACHE	07MAY95	180, 117, -12	03:30 Hrs	250	CON	MOD	NO	UNR Yes	No
	Infection	GI VIRUS-NAUSEA, VOMITING AND DIARRHEA	10DEC94	32, -32, -160	4 Days	200	CON	SEV	NO	UNR No	No
		NAUSEA, VOMITING, DIARRHEA, FLU	30DEC94	52, -12, -140	2 Days	250	CON	SEV	NO	UNR No	No
	Myalgia	LEG CRAMPS AND ACHES	28JAN95	81, 18, -111	Not Stated	250	CON	MOD	NO	PSR Yes	No
	Postural Hypotension	DIZZINESS-POSTURAL HYPOTENSION (ONLY IN GYM CLASSES)	01DEC94	23, -41, -169	14 Days	150	1	MOD	NO	REL No	No
	Rash	RASH-BILATERAL FOREARMS	10NOV94	2, -62, -190	5 Days	50	CON	MOD	STP	PBU Yes	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----												
Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE	
329.005.00007	Tremor	HAND TREMORS	20DEC94	42, -22, -150	6 Days	250	CON	MIL	NO	REL No	No	
			26DEC94	48, -16, -144	3 Days	300	CON	MOD	DCR	REL No	No	
			29DEC94	51, -13, -141	142 Days	250	CON	MIL	NO	REL No	No	
	Urticaria	HIVES-BILATERAL FOREARMS	10NOV94	2, -62, -190	5 Days	50	CON	MOD	NO	PBU Yes	No	
329.005.00009	Dry Mouth	DRY MOUTH	16DEC94	5, .. -68	Not Stated	50	CON	MOD	NO	REL No	No	
			09JAN95	29, .. -44	Not Stated	200	CON	MOD	NO	REL No	No	
		Dysmenorrhea	MENSTRUAL CRAMPS	20JAN95	40, .. -33	5 Days	300	CON	SEV	NO	UNR No	No
	Dyspepsia	HEARTBURN UPSET STOMACH/INDIGESTION	09JAN95	29, .. -44	03:00 Hrs	200	1	MOD	NO	PBU No	No	
			17DEC94	6, .. -67	Not Stated	50	6	MIL	NO	PSR No	No	
		Haematuria	[URINE OCCULT BLOOD]	07DEC94	-5, .. -77	1 Days	0	1	MIL	NO	UNR No	No
	Headache	HEADACHE	16DEC94	5, .. -68	4 Days	50	3	MOD	NO	PSR Yes	No	
			01JAN95	21, .. -52	04:00 Hrs	150	1	SEV	NO	PSR Yes	No	
			22DEC94	11, .. -62	6 Days	100	3	SEV	NO	PSR Yes	No	
		Hyperglycemia	GLUCOSE ELEVATED	08FEB95	59, .. -14	1 Days	250	1	SEV	NO	UNR No	No
	Leukocytosis	NEUTROPHILS, SEGS {INCREASED}	07DEC94	-5, .. -77	1 Days	0	1	MIL	NO	UNR No	No	
	Leukopenia	LYMPHOCYTES {DECREASED}	07DEC94	-5, .. -77	1 Days	0	1	MIL	NO	UNR No	No	
Tremor	HAND TREMORS		12JAN95	32, .. -41	Not Stated	250	CON	MIL	NO	REL No	No	
			15JAN95	35, .. -38	10 Days	250	CON	MIL	NO	REL No	No	
			24JAN95	44, .. -29	8 Days	300	CON	SEV	DCR	REL No	No	
329.005.00110	Dizziness	DIZZINESS	15JAN95	5, .. -4	5 Mins	50	CON	MIL	NO	PSR No	No	

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Corrective Therapy [Corr Ther]

Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int ion	Act- ion	Inv Corr Rel Ther	SAE
329.005.00110	Unintended Pregnancy	POSITIVE PREGNANCY TEST RESULT	21JAN95	11, ., 2	1 Days	100	CON	SEV	STP	UNR No	No
329.005.00113	Abnormal Vision	BLURRED VISION	06FEB95	8, ., -24	Not Stated	50	10	MIL	NO	REL No	No
	Dizziness	DIZZINESS	06FEB95	8, ., -24	Not Stated	50	9	MIL	NO	REL No	No
	Dry Mouth	DRY MOUTH	05FEB95	7, ., -25	Not Stated	50	CON	MOD	NO	REL No	No
	Emotional Lability	SUICIDAL IDEATION	02MAR95	32, ., 0	1 Days	200	CON	MOD	STP	UNR No	No
	Headache	HEADACHE	31JAN95	2, ., -30	03:45 Hrs	50	1	SEV	NO	UNR Yes	No
	Palpitation	HEART WAS POUNDING	19FEB95	21, ., -11	30 Mins	150	1	MOD	NO	REL No	No
	Tachycardia	QUESTIONABLE INCREASED HEART RATE QUESTIONABLE TACHYCARDIA	19FEB95	21, ., -11	30 Mins	150	1	MOD	NO	REL No	No
	Tremor	HAND TREMORS	06FEB95	8, ., -24	Not Stated	50	CON	MIL	NO	REL No	No
329.005.00117	Chills	CHILLS-INCREASED AND DECREASED BACK AND ARMS-NO FEVER	18MAR95	1, ., -69	31 Days	50	11	MOD	NO	PSR No	No
	Diarrhea	DIARRHEA	19MAR95	2, ., -68	3 Days	50	1	MOD	NO	PSR No	No
	Epistaxis	NOSEBLEEDS	14APR95	28, ., -42	15 Mins	200	2	MIL	NO	PBU No	No
	Gastritis	GASTRITIS	27APR95	41, ., -29	Not Stated	200	CON	MOD	NO	PBU Yes	No
	Headache	HEADACHE	25APR95	39, ., -31	Not Stated	200	CON	SEV	NO	PBU No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther	SAE
329.005.00117	Nervousness	INCREASED IRRITABILITY	15APR95	29, ., -41	Not Stated	200	CON	MOD	NO	PBU	No	No
	Pruritus	ITCHING-WITHOUT HIVES	19MAR95	2, ., -68	3 Days	50	1	MIL	NO	PSR	No	No
	Tachycardia	INCREASED HEART RATE	10APR95	24, ., -46	22 Days	200	CON	MOD	NO	PSR	No	No
	Tooth Disorder	PAIN DUE TO WISDOM TOOTH EXTRACTION	08MAY95	52, ., -18	8 Days	200	CON	MOD	NO	UNR	Yes	No
	Vasodilatation	FLUSHED FACE-NO HIVES	18MAR95	1, ., -69	4 Days	50	3	MIL	NO	PSR	No	No
	Vomiting	NAUSEATED AND VOMITING	07APR95	21, ., -49	Not Stated	150	CON	SEV	NO	PBU	No	No
329.005.00118	Dizziness	LIGHT-HEADEDNESS	23MAY95	7, ., -43	23 Days	50	5	MIL	NO	PSR	No	No
	Headache	HEADACHE	09JUN95	24, ., -26	02:00 Hrs	200	2	MOD	NO	PBU	No	No
	Migraine	MIGRAINE HEADACHE	20MAY95	4, ., -46	04:00 Hrs	50	CON	SEV	NO	UNR	No	No
	Pharyngitis	SORE THROAT	20MAY95	4, ., -46	4 Days	50	CON	MOD	NO	UNR	Yes	No
	Respiratory Disorder	CHEST CONGESTION AND COUGH	19MAY95	3, ., -47	6 Days	50	CON	MOD	NO	UNR	Yes	No
329.005.00153	Back Pain	BACK PAIN	23JAN96	-2, -58, -237	04:00 Hrs	0	1	MIL	NO	UNR	Yes	No
	Decreased Appetite	DECREASED APPETITE	25JAN96	1, -56, -235	42 Days	50	CON	MOD	NO	PSR	No	No
	Dizziness	LIGHTHEADED	25JAN96	1, -56, -235	29 Days	50	7	MIL	NO	PSR	No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	31JAN96	7, -50, -229	12:00 Hrs	50	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	10FEB96	17, -40, -219	05:00 Hrs	150	CON	MIL	NO	PBU	Yes	No

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

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Intent-to-Treat Population

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE		
329.005.00153	Headache	HEADACHE	21FEB96	28, -29, -208	03:00 Hrs	200	CON	MIL	NO	PBU	Yes	No	
			02MAR96	38, -19, -198	03:30 Hrs	250	CON	MIL	NO	UNR	Yes	No	
			21MAR96	57, 1, -179	28 Days	250		3	MOD	NO	UNR	Yes	No
			17APR96	84, 28, -152	57 Days	300		9	MIL	NO	UNR	Yes	No
			12JUN96	140, 84, -96	55 Days	300		3	MIL	NO	UNR	Yes	No
			02FEB96	9, -48, -227	9 Days	100			MIL	NO	PSR	No	No
329.005.00255	Abdominal Pain	STOMACH ACHE	05MAR96	2, .. -69	04:00 Hrs	50		1	MOD	NO	PBU	No	No
			15APR96	43, .. -28	8 Days	250		15	SEV	DCR	REL	No	No
			29APR96	57, .. -14	Not Stated	200	CON	MOD	NO	PBU	No	No	
			04MAR96	1, .. -70	22 Days	50		16	MOD	NO	PSR	Yes	No
329.005.00255	Abnormal Vision	BLURRED VISION	24MAR96	21, .. -50	9 Days	150		4	MOD	NO	PBU	No	No
			29APR96	57, .. -14	Not Stated	200			MOD	NO	PSR	No	No
			29APR96	57, .. -14	Not Stated	200			MOD	NO	PSR	No	No
329.005.00255	Eosinophilia	EOSINOPHILS ELEVATED	29APR96	57, .. -14	Not Stated	200	CON	MOD	NO	PBU	No	No	
			04MAR96	1, .. -70	22 Days	50		16	MOD	NO	PSR	Yes	No
329.005.00255	Headache	HEADACHES	24MAR96	21, .. -50	9 Days	150		4	MOD	NO	PBU	No	No
			29APR96	57, .. -14	Not Stated	200			MOD	NO	PSR	No	No
329.005.00255	Somatic Complaint	SOMATIC COMPLAINT HEADACHE	29APR96	57, .. -14	Not Stated	200			MOD	NO	PSR	No	No
			29APR96	57, .. -14	Not Stated	200			MOD	NO	PSR	No	No
329.005.00255	Nausea	SOMATIC COMPLAINT NAUSEA	29APR96	57, .. -14	Not Stated	200			MOD	NO	PSR	No	No
			29APR96	57, .. -14	Not Stated	200			MOD	NO	PSR	No	No
329.005.00255	Pharyngitis	SORE THROAT	14APR96	42, .. -29	4 Days	300	CON	MIL	NO	PBU	No	No	
			14APR96	42, .. -29	4 Days	300	CON	MIL	NO	PBU	No	No	
329.005.00255	Tremor	"SHAKINESS"	05MAR96	2, .. -69	4 Days	50	CON	MOD	NO	PSR	No	No	
			05APR96	33, .. -38	19 Days	250	CON	MOD	DCR	REL	No	No	

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.005.00255	Vaginal Moniliasis	YEAST INFECTION (VAGINAL)	19APR96	47, .. -24	5 Days	250	CON	MOD	NO	PBU Yes	No
	Vasodilatation	FLUSHED FACE	11MAR96	8, .. -63	04:00 Hrs	100	1	MOD	NO	PSR No	No
329.005.00256	Back Pain	BACKACHE	17MAR96	13, -44, -122	4 Days	100	CON	MOD	NO	UNR Yes	No
	Dizziness	DIZZINESS UPON STANDING	04APR96	31, -26, -104	13 Days	250	4	MIL	NO	REL No	No
	Dry Mouth	DRY MOUTH	30MAR96	26, -31, -109	33 Days	200	CON	MOD	NO	PSR No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	20MAR96	16, -41, -119	2 Days	100	CON	MOD	NO	UNR Yes	No
	Dyspepsia	GI UPSET	11JUL96	129, 73, -6	Not Stated	50	CON	MOD	NO	UNR Yes	No
	Fever	FEVER	05MAR96	1, -56, -134	2 Days	50	1	MOD	NO	PBU No	No
	Headache	HEADACHE	05MAR96 17MAR96	1, -56, -134 13, -44, -122	3 Days 4 Days	50 100	1 CON	MOD MOD	NO NO	PBU Yes UNR Yes	No No
	Nausea	NAUSEA	05MAR96	1, -56, -134	3 Days	50	1	MOD	NO	PBU No	No
	Pharyngitis	SORE THROAT	28MAR96	24, -33, -111	5 Days	200	CON	MOD	NO	UNR Yes	No
	Vasodilatation	HOT FLASHES	23MAR96	19, -38, -116	3 Days	150	2	MOD	NO	PSR No	No
329.005.00295	Chest Pain	CHEST PAIN	15APR96	19, .. -50	2 Days	150	2	MOD	NO	PSR No	No
	Dizziness	DIZZINESS	04MAY96	38, .. -31	2 Days	200	4	MIL	NO	PSR No	No
	Dry Mouth	DRY MOUTH	07APR96	11, .. -58	55 Days	100	CON	MOD	NO	REL No	No

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
329.005.00295	Emotional Lability	SUICIDAL THREAT WITH SCISSORS	19APR96	23, .. -46	1 Days	200	1	MOD NO	PBU No	No
	Headache	HEADACHE	18APR96	22, .. -47	03:30 Hrs	200	CON	MIL NO	PBU No	No
		HEADACHES	05MAY96	39, .. -30	04:30 Hrs	200	CON	MOD NO	PSR No	No
			21MAR96	-7, .. -75	1 Days	0	1	MOD NO	UNR Yes	No
	Hostility	HOMICIDAL TENDENCIES TOWARDS PARENTS	18MAY96	52, .. -17	04:30 Hrs	250	CON	SEV STP	PSR No	No
	Nausea	NAUSEA	05MAY96	39, .. -30	02:00 Hrs	200	CON	MIL NO	PSR No	No
	Vomiting	VOMITING	15MAY96	49, .. -20	30 Mins	250	CON	MOD NO	PBU No	No
329.005.00297	Dyspepsia	HEARTBURN	24APR96	6, .. -20	04:00 Hrs	50	CON	MOD NO	UNR No	No
	Headache	HEADACHE	10MAY96	22, .. -4	02:00 Hrs	150	2	MOD NO	PSR Yes	No
	Respiratory Disorder	HEADCOLD AND NASAL CONGESTION	14APR96	-5, .. -30	3 Days	0	CON	MOD NO	UNR Yes	No
329.005.00332	Dizziness	DIZZINESS IN GYM CLASS X1	20DEC96	9, .. -63	5 Mins	100	CON	MIL NO	PSR No	No
	Dry Mouth	DRY MOUTH	03JAN97	23, .. -49	4 Days	200	CON	MIL NO	REL No	No
	Headache	HEADACHE - AFTER GYM CLASS OR EXERCISE	16DEC96	5, .. -67	30 Mins	50	CON	MIL NO	PSR No	No
329.005.00335	Diarrhea	UPSET STOMACH WITH DIARRHEA	10MAR97	11, .. -57	2 Days	100	CON	SEV NO	UNR No	No
	Dizziness	DIZZINESS	01MAR97	2, .. -66	4 Days	50	CON	MIL NO	REL No	No

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Listing of Adverse Experiences by Treatment Group and Patient
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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
329.005.00335	Dizziness	DIZZINESS	05MAR97	6, .. -62	01:00 Hrs	50	CON	SEV	NO	REL	No	No
	Dry Mouth	DRY MOUTH	08MAR97	9, .. -59	Not Stated	100	CON	MOD	NO	REL	No	No
	Electrocardiogram Abnormal	EKG CHANGE	03APR97	35, .. -33	1 Days	200	CON	MOD	DCR	REL	No	No
	Headache	HEADACHE	27FEB97	-1, .. -68	03:30 Hrs	0	CON	MOD	NO	PBU	Yes	No
			10MAR97	11, .. -57	03:30 Hrs	100	CON	MIL	NO	UNR	No	No
			17MAR97	18, .. -50	4 Days	150	6	MOD	NO	UNR	No	No
			21MAR97	22, .. -46	6 Days	200	5	MOD	NO	UNR	No	No
			30MAR97	31, .. -37	4 Days	250	3	MOD	NO	UNR	No	No
			11APR97	43, .. -25	04:00 Hrs	200	CON	SEV	NO	PBU	Yes	No
			22APR97	54, .. -14	03:30 Hrs	200	CON	MOD	NO	PBU	Yes	No
	Tremor	HAND TREMORS	01MAR97	2, .. -66	4 Days	50	CON	MIL	NO	REL	No	No
			05MAR97	6, .. -62	12:00 Hrs	50	CON	SEV	NO	REL	No	No
			06MAR97	7, .. -61	14 Days	50	CON	MOD	NO	REL	No	No
			01APR97	33, .. -35	5 Days	250	CON	MOD	NO	REL	No	No
06APR97			38, .. -30	4 Days	200	CON	MIL	NO	REL	No	No	
329.006.00040	Asthenia	FATIGUE	22FEB95	7, .. -7	8 Days	50	CON	SEV	STP	REL	No	No
	Constipation	CONSTIPATION	22FEB95	7, .. -7	8 Days	50	CON	MOD	STP	REL	No	No
	Dizziness	DIZZINESS	22FEB95	7, .. -7	8 Days	50	CON	MOD	STP	REL	No	No
	Dyspepsia	INDIGESTION	22FEB95	7, .. -7	8 Days	50	CON	MOD	STP	PSR	No	No
	Mydriasis	EYE DILATION	22FEB95	7, .. -7	8 Days	50	CON	MOD	STP	REL	No	No
	Nervousness	IRRITABLE MOOD	22FEB95	7, .. -7	8 Days	50	CON	MOD	STP	REL	No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther SAE
329.006.00040	Tachycardia	ELEVATED HEART RATE	01MAR95	14, ., 0	14 Days	50	CON	MOD	STP	REL No	No
	Urinary Retention	URINARY RETENTION	22FEB95	7, ., -7	8 Days	50	CON	MOD	STP	REL No	No
329.006.00041	Headache	HEADACHE	23AUG95	141, 77, -104	1 Days	300	1	SEV	NO	PBU Yes	No
	Insomnia	INSOMNIA	16AUG95	134, 70, -111	8 Days	300	6	MOD	NO	UNR No	No
	Nervousness	IRRITABLE MOOD	16APR95	12, -53, -233	3 Days	100	1	MOD	NO	UNR No	No
	Nocturia	NOCTURIA	24MAY95	50, -15, -195	8 Days	250	CON	MIL	NO	PSR No	No
	Pharyngitis	SORE THROAT	16APR95	12, -53, -233	3 Days	100	1	MOD	NO	PBU Yes	No
	Respiratory Disorder	COLD SYMPTOMS	22AUG95	140, 76, -105	3 Days	300	CON	MOD	NO	UNR Yes	No
	Syncope	LIGHTHEADED FAINT SYNCOPE	22APR95	18, -47, -227	1 Mins	150	1	MIL	NO	PSR No	No
	Vomiting	EMESIS	22AUG95	140, 76, -105	1 Days	300	2	MIL	NO	UNR No	No
329.007.00139	Chest Pain	CHEST PAIN	17MAY95	10, ., -8	8 Days	50	4	MOD	STP	PSR No	No
	Dyspnea	SHORTNESS OF BREATH	17MAY95	10, ., -8	8 Days	50	CON	MIL	STP	PSR No	No
329.007.00143	Acne	ACNE	15NOV95	7, ., -16	Not Stated	50	CON	MOD	STP	PSR No	No
329.007.00146	Anxiety	ANXIETY	14JUL96	172, 119, -69	04:00 Hrs	200	CON	MIL	NO	UNR Yes	No
	Diarrhea	DIARRHEA	04JUL96	162, 109, -79	02:00 Hrs	200	CON	MOD	NO	UNR Yes	No
	Dyspepsia	UPSET STOMACH	22MAR96	58, 5, -183	04:00 Hrs	200	CON	MOD	NO	PBU Yes	No

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----														
Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE			
329.007.00146	Myalgia	LEFT KNEE MUSCLE SPASMS	18SEP96	238, 185, -3	06:00 Hrs	50	CON	MIL	NO	UNR	Yes	No		
	Respiratory Disorder	COLD SYMPTOMS	20JUL96	178, 125, -63	3 Days	200	CON	MIL	NO	UNR	Yes	No		
329.007.00269	Electrocardiogram Abnormal	LOW OR NEGATIVE T WAVES	18APR96	8, ., -7	15 Days	100	CON	MIL	STP	REL	No	No		
	Nausea	NAUSEA	16APR96	6, ., -9	1 Days	50	CON	MIL	NO	PSR	No	No		
	Tachycardia	TACHYCARDIA	18APR96	8, ., -7	15 Days	100	CON	MIL	STP	REL	No	No		
329.007.00270	Chest Pain	FOOT PAIN{INJURY}	21APR96	11, ., -4	2 Days	100	CON	MIL	NO	UNR	Yes	No		
		CHEST PAIN, CHEST TIGHTNESS	19JUN96	42, ., -1	03:00 Hrs	200	1	SEV	STP	PSR	No	Yes		
		Contact Dermatitis	POISON IVY	17MAY96	9, ., -34	3 Days	100	CON	MOD	NO	UNR	Yes	No	
		Diarrhea	DIARRHEA	19JUN96	42, ., -1	30 Mins	200	CON	MIL	NO	UNR	No	No	
				24JUN96	47, ., 4	2 Days	200	CON	MIL	NO	UNR	No	No	
		Dry Mouth	DRY MOUTH	23MAY96	15, ., -28	15 Days	150	CON	MIL	NO	PSR	No	No	
		Dyspnea	SHORTNESS OF BREATH	19JUN96	42, ., -1	03:00 Hrs	200	1	SEV	STP	PSR	No	Yes	
		Fungal Dermatitis	RINGWORM	30MAY96	22, ., -21	17 Days	200	CON	MIL	NO	UNR	Yes	No	
		Headache	HEADACHE	24JUN96	47, ., 4	2 Days	200	CON	MOD	NO	UNR	No	No	
		Postural Hypotension	ORTHOSTATIC HYPOTENSION	01JUN96	24, ., -19	4 Days	200	5	MIL	NO	PSR	No	No	
329.007.00307	Dry Mouth	DRY MOUTH	18MAY96	3, ., -33	39 Days	50	CON	MIL	NO	REL	No	No		

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Appendix D.2

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Intent-to-Treat Population

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329.007.00307	Headache	HEADACHES	04JUL96	50, ., 14	Not Stated	0	20	MOD	NO	UNR	No	No
	Maculopapular Rash	MORBILLIFORM "MEASLES LIKE" ERUPTION, GENERALIZED SIMILAR TO TRICYCLIC RASH, ON TRUNK, BACK, EXTREMITIES, CHEST, BUTTOCKS, TORSO/FRONT AND BACK, AND LOWER NECK	16JUN96	32, ., -4	10 Days	200	CON	MOD	STP	REL	Yes	Yes
	Sinusitis	SINUSITIS	02JUN96 23JUL96	18, ., -18 69, ., 33	6 Days Not Stated	150 0	CON CON	MIL MOD	NO NO	UNR UNR	Yes Yes	No No
329.007.00308	Tremor	TREMORS	30MAY96	15, ., -21	25 Days	150	CON	MIL	NO	REL	No	No
	Nausea	NAUSEA	30JUN96	-2, ., -11	01:00 Hrs	0	CON	MIL	NO	PSR	Yes	No
	Vomiting	VOMITING	30JUN96	-2, ., -11	01:00 Hrs	0	CON	MIL	NO	PSR	No	No
329.008.00159	Dizziness	DIZZINESS	24OCT95	42, -21, -92	9 Days	250		MIL	NO	REL	No	No
	Dry Mouth	DRY MOUTH	04OCT95	22, -41, -112	29 Days	200	CON	MIL	NO	PSR	No	No
	Insomnia	TROUBLE GETTING TO SLEEP AND EARLY AWAKENING	29OCT95	47, -16, -87	8 Days	250	CON	MIL	NO	PSR	No	No
329.008.00161	Dry Mouth	DRY MOUTH	16NOV95	1, -55, -55	4 Days	50	CON	MIL	NO	REL	No	No
	Hostility	INTENSE ANGER	24DEC95	39, -17, -17	30 Mins	200		2 MOD	NO	PSR	No	No
	Insomnia	POOR SLEEP	16NOV95	1, -55, -55	4 Days	50	CON	MIL	NO	REL	No	No

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Appendix D.2

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329.008.00161	Nervousness	RESTLESSNESS	16NOV95	1, -55, -55	4 Days	50	CON	MIL	NO	REL	No
329.008.00187	Acne	INCREASED ACNE (FACE, CHEST, BACK)	30NOV95	2, .., -71	Not Stated	50	CON	MIL	NO	PSR	No
	Dry Mouth	DRY MOUTH	30NOV95	2, .., -71	Not Stated	50	CON	MIL	NO	PSR	No
	Dyspnea	SHORTNESS OF BREATH (WITH EXERCISE)	07JAN96	40, .., -33	Not Stated	200	CON	MIL	NO	PSR	No
	Nausea	INFREQUENTLY NAUSEA	10DEC95	12, .., -61	Not Stated	100	CON	MIL	NO	PSR	No
	Photophobia	LIGHT SENSITIVITY	18DEC95	20, .., -53	Not Stated	150	CON	MIL	NO	REL	No
	Somnolence	SEDATION	22DEC95	24, .., -49	Not Stated	200	CON	MOD	NO	REL	No
	Sweating	EPISODIC CALOR AND PERSPIRATION	10DEC95	12, .., -61	Not Stated	100	CON	MIL	NO	PSR	No
	Taste Perversion	BITTER TASTE IN MOUTH	30NOV95	2, .., -71	Not Stated	50	CON	MIL	NO	PSR	No
329.008.00192	Dizziness	LIGHTHEADEDNESS	26MAR96	22, .., -16	Not Stated	200	CON	MIL	DCR	PBU	No
	Dry Mouth	DRY MOUTH	26MAR96	22, .., -16	Not Stated	200	CON	MIL	DCR	PBU	No
	Dyspepsia	HEARTBURN	30MAR96	26, .., -12	Not Stated	200	CON	MIL	DCR	PSR	No
	Somnolence	DROWSINESS	26MAR96	22, .., -16	Not Stated	200	CON	MIL	DCR	PBU	No
329.008.00272	Asthenia	FATIGUE	04APR96	2, -55, -167	Not Stated	50	CON	MIL	NO	PSR	No
	Somnolence	DROWSINESS	24JUL96	113, 57, -56	Not Stated	200	CON	MIL	NO	REL	No

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329.008.00273	Accidental Overdose	TRICYCLIC TOXICITY	09SEP96	116, 53, 0	8 Days	300		SEV STP	REL No	Yes
329.009.00127	Chest Pain	CHEST PAIN WHEN TAKING MEDS	17APR95	8, ., -39	45 Days	100	CON	MIL NO	PBU No	No
	Dizziness	DIZZINESS	24APR95	15, ., -32	38 Days	150		MOD NO	REL No	No
	Headache	OCCASIONAL HEADACHE	12APR95	3, ., -44	Not Stated	50		MIL NO	PSR No	No
	Insomnia	INITIAL INSOMNIA	17APR95	8, ., -39	45 Days	100	CON	MOD NO	PSR No	No
	Nausea	NAUSEA	24APR95	15, ., -32	38 Days	150		MOD STP	REL No	No
	Somnolence	DAYTIME DROWSINESS	12APR95	3, ., -44	Not Stated	50	CON	MIL NO	PSR No	No
329.009.00132	Headache	HEADACHE	18JUN95	27, -31, -140	3 Days	200	CON	MIL NO	UNR No	No
	Nausea	NAUSEA	18JUN95 24AUG95	27, -31, -140 94, 37, -73	3 Days 62 Days	200 200		MIL NO MIL NO	UNR No PSR No	No No
	Vomiting	VOMITING	19JUN95	28, -30, -139	06:00 Hrs	200		MIL NO	UNR No	No
329.009.00134	Asthenia	FATIGUE	10JUL95	5, ., -61	65 Days	50	CON	MIL NO	PSR No	No
	Dizziness	DIZZINESS	11AUG95	37, ., -29	33 Days	200	CON	MOD STP	REL No	No
	Dry Mouth	DRY MOUTH	27JUL95	22, ., -44	48 Days	200	CON	MIL NO	PSR No	No
	Headache	HEADACHE(OCCASIONAL)	12AUG95	38, ., -28	Not Stated	200		MIL NO	PSR Yes	No
	Postural Hypotension	POSTURAL HYPOTENSION	11AUG95	37, ., -29	33 Days	200	3	MOD NO	PSR No	No

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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----												
Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther	SAE
329.009.00134	Qt Interval Prolonged	INCREASED QT/{CORRECTED}QTC RATIO	29AUG95	55, ., -11	15 Days	150	CON	MOD	STP	REL	No	No
	Somnolence	HYPERSOMNOLENCE	10JUL95	5, ., -61	65 Days	50	CON	MOD	NO	PSR	No	No
	Sweating	INCREASED SWEATING	27JUL95	22, ., -44	48 Days	200	CON	MIL	NO	PSR	No	No
	Syncope	BLACKOUTS	11AUG95	37, ., -29	33 Days	200	3	MOD	NO	PSR	No	No
	Tachycardia	TACHYCARDIA	11AUG95	37, ., -29	33 Days	200		MOD	NO	PSR	No	No
329.009.00137	Asthenia	FATIGUE	14NOV95	36, ., -32	22 Days	200	CON	MOD	NO	PSR	No	No
	Headache	HEADACHE	17NOV95	39, ., -29	4 Days	200		MIL	NO	PSR	No	No
	Somnolence	SOMNOLENCE	25OCT95	16, ., -52	42 Days	150	CON	MOD	NO	PSR	No	No
	Urinary Frequency	INCREASED URINATION	17OCT95	8, ., -60	8 Days	100	CON	MIL	NO	PBU	No	No
329.009.00171	Maculopapular Rash	RASH{FINE MACULAR ON FACE, INSIDE ELBOWS, BACK}	10NOV95	4, ., -4	Not Stated	50	CON	SEV	STP	PBU	No	No
	Pharyngitis	SORE THROAT	14NOV95	8, ., 0	Not Stated	50	CON	MIL	NO	PBU	No	No
	Sinusitis	SINUS CONGESTION	14NOV95	8, ., 0	Not Stated	50	CON	MIL	NO	PBU	No	No
329.009.00172	Abnormal Dreams	NIGHTMARES	18DEC95	36, -22, -215	52 Days	200		MOD	NO	PSR	No	No
	Diarrhea	DIARRHEA	18JUL96	249, 192, -2	2 Days	50	CON	MIL	NO	PBU	No	No
	Dizziness	DIZZINESS	03DEC95	21, -37, -230	233 Days	150	CON	MOD	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	05DEC95	23, -35, -228	231 Days	200	CON	MOD	NO	PSR	No	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.009.00172	Insomnia	INITIAL INSOMNIA	10JUN96	211, 154, -40	29 Days	200	CON	MIL	NO	PBU No	No
	Nausea	NAUSEA	18JUL96	249, 192, -2	2 Days	50	CON	MIL	NO	PBU No	No
	Somnolence	SOMNOLENCE	29NOV95	17, -41, -234	6 Days	150	CON	MOD	NO	PSR No	No
	Tachycardia	TACHYCARDIA	14NOV95	2, -56, -249	14 Days	50	2	MIL	NO	PBU No	No
	Thinking Abnormal	RACING THOUGHTS	22DEC95	40, -18, -211	13 Days	200		MIL	NO	PBU No	No
	Tinnitus	RINGING IN EARS	03DEC95	21, -37, -230	30 Days	150		MIL	NO	PSR No	No
	Urinary Retention	URINARY RETENTION	09JAN96	58, 1, -193	8 Days	200	CON	MOD	NO	PBU No	No
	Urination Impaired	HARD TO INITIATE URINATION	09JAN96	58, 1, -193	8 Days	200	CON	MOD	NO	PBU No	No
329.009.00194	Abdominal Pain	STOMACH ACHE	19DEC95	15, -42, -169	181 Days	150	CON	MOD	NO	REL Yes	No
	Abnormal Dreams	INCREASED DREAMING NIGHTMARES	07DEC95	3, -54, -181	34 Days	50		MOD	NO	PSR No	No
			07DEC95	3, -54, -181	13 Days	50	1	MOD	NO	PSR No	No
	Insomnia	INITIAL INSOMNIA	27FEB96	85, 29, -99	64 Days	200	CON	MIL	NO	PSR No	No
	Nausea	NAUSEA	16JAN96	43, -14, -141	153 Days	200	CON	MOD	STP	PSR No	No
	Respiratory Disorder	COLD SYNDROME UPPER RESPIRATORY TRACT INFECTION(URI)	02JAN96	29, -28, -155	15 Days	200	CON	MIL	NO	UNR Yes	No
329.009.00195	Chest Pain	CHEST PAIN	02APR96	120, 64, -64	76 Days	200	CON	MIL	NO	PSR No	No
			04JAN96	21, ., -15	19 Days	200	2	MOD	NO	PSR No	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----												
Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE	
329.009.00195	Dizziness	DIZZINESS	04JAN96	21, .. -15	19 Days	200	CON	MOD	NO	PSR	No	No
	Extrasystoles	CARIDAC ARRHYTHMIA [PREMATURE VENTRICULAR CONTRACTIONS]	08JAN96	25, .. -11	15 Days	150	CON	MOD	STP	REL	No	No
	Headache	HEAD PAIN	02JAN96	19, .. -17	21 Days	200	20	MOD	NO	PSR	No	No
	Sweating	SWEATING	25DEC95	11, .. -25	29 Days	100	CON	MOD	NO	PSR	No	No
	Vasodilatation	FACIAL FLUSHING	25DEC95	11, .. -25	29 Days	100	CON	MOD	NO	PSR	No	No
	Weight Loss	WEIGHT LOSS	27DEC95	13, .. -23	13 Days	150	CON	MIL	NO	PSR	No	No
329.009.00199	Dizziness	DIZZINESS	17JAN96	2, .. -69	Not Stated	50	CON	MOD	NO	PSR	No	No
	Dry Mouth	DRY MOUTH	24JAN96	9, .. -62	15 Days	100	CON	MIL	NO	PSR	No	No
	Headache	HEADACHES	13MAR96	58, .. -13	Not Stated	200	5	MIL	NO	PBU	No	No
	Nausea	NAUSEA	17JAN96 28FEB96	2, .. -69 44, .. -27	42 Days 15 Days	50 250	CON CON	MOD MIL	NO NO	PSR PSR	No No	No No
329.009.00203	Av Block	1ST DEGREE AV BLOCK	26MAR96	23, .. -10	Not Stated	150	CON	MOD	STP	REL	No	No
	Nausea	NAUSEA WHEN TAKING PM MEDS	05MAR96	2, .. -31	Not Stated	50	CON	MIL	NO	PSR	No	No
	Palpitation	PALPITATIONS	24MAR96	21, .. -12	Not Stated	150	CON	MOD	NO	PSR	No	No
	Qt Interval Prolonged	PROLONGED QT-QUANTITATIVE TIP CULTURES	26MAR96	23, .. -10	Not Stated	150	CON	MOD	STP	REL	No	No

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Corrective Therapy [Corr Ther]
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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.009.00203	Thirst	INCREASED THIRST	24MAR96	21, ., -12	Not Stated	150	CON	MIL	NO	PSR No	No
	Vasodilatation	HOT FLASHES (FACIAL FLUSHING)	24MAR96	21, ., -12	Not Stated	150	CON	MOD	NO	PSR No	No
329.009.00236	Dizziness	DIZZINESS	20JAN97	22, ., -19	Not Stated	200	CON	MOD	STP	REL No	No
	Insomnia	MIDDLE INSOMNIA	15JAN97	17, ., -24	6 Days	150	CON	MIL	NO	PSR No	No
	Somnolence	DAYTIME SEDATION	20JAN97	22, ., -19	Not Stated	200	CON	MOD	STP	REL No	No
329.009.00239	Bradycardia	SINUS BRADYCARDIA PER EKG	12MAY97	175, 118, 28	Not Stated	0	CON	MIL	NO	PBU No	No
	Dry Mouth	DRY MOUTH	09DEC96	21, -37, -126	8 Days	200	CON	MIL	NO	PSR No	No
			06JAN97	49, -9, -98	10 Days	200	CON	MIL	NO	PSR No	No
	Dry Skin	DRY FINGERTIPS	17MAR97	119, 62, -28	Not Stated	200	CON	MIL	NO	PSR Yes	No
	Dysphagia	DIFFICULTY SWALLOWING PILL	16DEC96	28, -30, -119	8 Days	200	CON	MIL	NO	REL No	No
	Headache	HEADACHE	18FEB97	92, 35, -55	Not Stated	200	CON	MIL	NO	PSR No	No
	Insomnia	MIDDLE INSOMNIA	30DEC96	42, -16, -105	8 Days	200	CON	MIL	NO	PSR Yes	No
	Nausea	NAUSEA	26DEC96	38, -20, -109	5 Days	200	CON	MOD	NO	PBU No	No
	Respiratory Disorder	HEAD COLD	06JAN97	49, -9, -98	10 Days	200	CON	MIL	NO	UNR No	No
	Sinusitis	SINUS CONGESTION	18FEB97	92, 35, -55	28 Days	200	CON	MIL	NO	UNR Yes	No
Somnolence	DAYTIME SOMNOLENCE	09DEC96	21, -37, -126	22 Days	200	CON	MIL	NO	PSR No	No	

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
329.009.00239	Tachycardia	ELEVATED PULSE	25NOV96	7, -51,-140	141 Days	100	CON	MIL	NO	REL	No	No
	Vomiting	VOMITING	26DEC96	38, -20,-109	5 Days	200	CON	MOD	NO	PBU	Yes	No
329.009.00262	Av Block	INCREASED PR INTERVAL (PER EKG)	07MAR97	19, ., -50	11 Days	200	CON	MIL	NO	PSR	No	No
	Cough Increased	COUGH	15MAR97	27, ., -42	2 Days	200	CON	MIL	NO	PBU	Yes	No
	Dry Mouth	DRY MOUTH	24FEB97	8, ., -61	64 Days	100	CON	MIL	NO	REL	No	No
	Ear Pain	EARACHE	03MAR97	15, ., -54	5 Days	150	CON	MIL	NO	PBU	No	No
	Eye Disorder	EYE INFECTION (LEFT AND RIGHT EYE)	10FEB97	-7, ., -75	57 Days	0	CON	MOD	NO	UNR	Yes	No
	Heart Malformation	POSSIBLE RIGHT ATRIAL ENLARGEMENT (PER EKG)	17MAR97	29, ., -40	15 Days	200	CON	MIL	NO	PSR	No	No
	Postural Hypotension	MILD OTHOSTATIC STATE (1X) (DUE TO BLOOD DRAW) {ORTHOSTATIC HYPOTENSION}	14APR97	57, ., -12	5 Mins	200	CON	MIL	NO	PSR	No	No
	Somnolence	DAYTIME SOMNOLENCE	24FEB97	8, ., -61	8 Days	100	CON	MIL	NO	PSR	No	No
329.009.00264	Agitation	AGITATION	11NOV96	11, ., -54	8 Days	150	CON	MOD	NO	PSR	No	No
	Electrocardiogram Abnormal	NONSPECIFIC T-WAVE ABNORMALITY (PER EKG) BASELINE ARTIFACT	23DEC96	53, ., -12	Not Stated	200	CON	MIL	NO	PSR	No	No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.009.00264	Insomnia	DECREASED SLEEP (INITIAL, MIDDLE)	11DEC96	41, ., -24	6 Days	200	CON	MIL	NO	PSR	No
	Somnolence	DAYTIME SOMNOLENCE	08NOV96	8, ., -57	25 Days	100	CON	MOD	NO	PSR	No
			16DEC96	46, ., -19	Not Stated	200	CON	MOD	NO	PSR	No
Tachycardia	INCREASED HEART RATE SINUS TACHYCARDIA	11NOV96	11, ., -54	Not Stated	150	CON	MIL	NO	PSR	No	
		23DEC96	53, ., -12	Not Stated	200	CON	MIL	NO	PSR	No	
329.009.00301	Dizziness	DIZZINESS	09APR96	22, -35, -75	1 Days	150	CON	MIL	NO	PBU	No
	Infection	INCREASED SWEATING (VIRAL SYNDROME) NAUSEA (VIRAL SYNDROME) VOMITING (VIRAL SYNDROME)	09APR96	22, -35, -75	20 Mins	150	CON	MIL	NO	PBU	No
			09APR96	22, -35, -75	1 Days	150	CON	MIL	NO	PBU	No
			09APR96	22, -35, -75	1 Days	150	CON	MIL	NO	PBU	No
	Tachycardia	INCREASE IN PULSE (SECONDARY TO ALUPENT)	23APR96	36, -21, -61	15 Mins	200	CON	MOD	NO	PBU	No
329.009.00305	Abnormal Vision	BLURRED VISION	03JUL96	58, 1, -203	35 Days	200	CON	MIL	NO	PSR	No
	Dizziness	DIZZINESS	14MAY96	8, -50, -253	15 Days	100	CON	MOD	NO	PSR	No
			28MAY96	22, -36, -239	71 Days	200	CON	MIL	NO	PSR	No
			09SEP96	126, 69, -135	142 Days	200	CON	MIL	NO	PSR	No
	Dry Mouth	DRY MOUTH	14MAY96	8, -50, -253	22 Days	100	CON	MOD	NO	PSR	No
			03JUL96	58, 1, -203	35 Days	200	CON	MIL	NO	PSR	No
			09SEP96	126, 69, -135	142 Days	200	CON	MIL	NO	PSR	No
Electrocardiogram Abnormal	POSITIVE/NEGATIVE RIGHT AXIS DEVIATION (BKG)	10JAN97	249, 192, -12	19 Days	200	CON	MIL	NO	PBU	No	

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE		
329.009.00305	Nausea	NAUSEA	14MAY96	8, -50, -253	15 Days	100	CON	MOD	NO	PSR	No	No		
			28MAY96	22, -36, -239	23 Days	200	CON	MIL	NO	PSR	No	No		
			02JUL96	57, -1, -204	1 Days	200	CON	MOD	NO	UNR	Yes	No		
329.009.00325	Abnormal Dreams	INCREASED DREAMING	30SEP96	35, -21, -89	11 Days	200	CON	MIL	NO	PSR	No	No		
			Chills	CHILLS	10OCT96	45, -11, -79	40 Days	200	CON	MOD	NO	UNR	Yes	No
			Cough Increased	COUGH	10OCT96	45, -11, -79	40 Days	200	CON	MOD	NO	UNR	Yes	No
			Dizziness	DIZZINESS	01SEP96	6, -50, -118	16 Days	50	CON	MOD	NO	PSR	No	No
					17SEP96	22, -34, -102	Not Stated	200	CON	MIL	NO	PSR	No	No
			Dry Mouth	DRY MOUTH	23SEP96	28, -28, -96	8 Days	200	CON	MIL	NO	PSR	No	No
			Dyspnea	SHORTNESS OF BREATH	01SEP96	6, -50, -118	16 Days	50	CON	MIL	NO	PSR	No	No
			Headache	HEADACHES	10OCT96	45, -11, -79	40 Days	200	CON	MOD	NO	PBU	Yes	No
			Keratoconjunctivitis	IRRITATION IN EYES (DRY EYES)	09SEP96	14, -42, -110	8 Days	150	CON	MIL	NO	PSR	No	No
			Nausea	NAUSEA	06SEP96	11, -45, -113	11 Days	100	CON	MIL	NO	PSR	No	No
					23SEP96	28, -28, -96	8 Days	200	CON	MIL	NO	PSR	No	No
			Rhinitis	NASAL CONGESTION	10OCT96	45, -11, -79	40 Days	200	CON	MOD	NO	UNR	Yes	No
Syncope	DIZZINESS WITH SYNCOPE	01SEP96	6, -50, -118	1 Days	50	CON	MIL	NO	PSR	No	No			
Tachycardia	TACHYCARDIA	23OCT96	58, 3, -66	27 Days	200		MOD	NO	PSR	No	No			
329.009.00326	Dizziness	DIZZINESS	14OCT96	40, -14, -75	4 Days	200	CON	MIL	NO	PSR	No	No		

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther	SAE
329.009.00326	Hyperkinesia	AKATHISIA	30SEP96	26, -28, -89	18 Days	200	CON	MIL	NO	PSR	No	No
	Nausea	NAUSEA	14OCT96	40, -14, -75	4 Days	200	CON	MIL	NO	PSR	No	No
	Tachycardia	TACHYCARDIA	30SEP96	26, -28, -89	Not Stated	200	CON	MIL	NO	PSR	No	No
329.010.00279	Abdominal Pain	STOMACH PAIN	02OCT96	195, 139, -51	6 Days	300	5	MOD	DCR	PBU	No	No
		STOMACH PAINS	30SEP96	193, 137, -53	02:00 Hrs	300	CON	MIL	NO	PSR	Yes	No
	Acne	ACNE	15JUN96	86, 30, -160	Not Stated	300	CON	MOD	NO	PBU	Yes	No
	Contact Dermatitis	POISON IVY	09JUL96	110, 54, -136	11 Days	300	CON	MIL	NO	UNR	Yes	No
			23AUG96	155, 99, -91	51 Days	300	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	01APR96	11, -46, -235	03:00 Hrs	100	1	MOD	NO	PBU	Yes	No
	Infection	FLU	01MAY96	41, -16, -205	3 Days	300	CON	MIL	NO	PBU	No	No
	Nausea	NAUSEA	01OCT96	194, 138, -52	03:00 Hrs	300	CON	MIL	NO	PSR	No	No
			02OCT96	195, 139, -51	6 Days	300	5	MOD	DCR	PBU	No	No
	Respiratory Disorder	COLD - RUNNY NOSE, CONGESTION	08MAY96	48, -9, -198	4 Days	300	CON	MIL	NO	PBU	No	No
Thinking Abnormal	"STRANGE THOUGHTS"	23APR96	33, -24, -213	2 Days	250	1	MIL	NO	PBU	No	No	
Tooth Disorder	MOLAR ERUPTING	07AUG96	139, 83, -107	02:00 Hrs	300	CON	MOD	NO	UNR	Yes	No	
Ulcerative Stomatitis	MOUTH SORES	03OCT96	196, 140, -50	Not Stated	300	CON	MOD	NO	PBU	No	No	
329.010.00281	Abdominal Pain	STOMACH ACHE	18DEC96	146, 85, -32	2 Days	300	CON	MIL	NO	PBU	No	No

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Action Taken on Study Medication [Action] : DCR = Dose Decreased, INC = Dose Increased, NO = None, STP = Drug Stopped
Investigator Relationship [Inv Rel]: PBU = Probably Unrelated, PSR = Possibly Related, REL = Related, UNR = Not Related
Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.010.00281	Asthenia	FATIGUE	05DEC96	133, 72, -45	20 Days	300	CON	MOD	NO	PSR No	No
			24DEC96	152, 91, -26	30 Days	300	CON	SEV	STP	PSR No	No
	Bundle Branch Block	PROLONGED QRS DURATION	18SEP96	55, -7, -123	15 Days	300	CON	MIL	NO	REL No	No
	Headache	HEADACHE	03SEP96	40, -22, -138	16:00 Hrs	250	1	MOD	NO	PSR Yes	No
			18DEC96	146, 85, -32	2 Days	300	CON	MIL	NO	PBU Yes	No
329.011.00163	Dizziness	DIZZINESS	28NOV95	4, .., -24	18:00 Hrs	50	1	MIL	NO	PBU No	No
	Headache	HEADACHE	23NOV95	-2, .., -29	04:00 Hrs	0	1	MIL	NO	UNR Yes	No
			28NOV95	4, .., -24	18:00 Hrs	50	1	MOD	NO	PBU Yes	No
	Nausea	NAUSEA	28NOV95	4, .., -24	18:00 Hrs	50	1	MIL	NO	PBU No	No
			17DEC95	23, .., -5	5 Days	150	CON	MIL	NO	PBU No	No
			22DEC95	28, .., 0	Not Stated	200	CON	MOD	STP	PSR No	No
			23DEC95	29, .., 1	Not Stated	200	CON	MOD	STP	PSR No	No
Pharyngitis	SORE THROAT	30NOV95	6, .., -22	20:00 Hrs	50	CON	MIL	NO	UNR Yes	No	
Rash	RASH	21NOV95	-4, .., -31	Not Stated	0	CON	MIL	NO	UNR Yes	No	
Vomiting	VOMITING	22DEC95	28, .., 0	4 Days	200	4	MOD	STP	PSR No	No	
329.011.00208	Abdominal Pain	STOMACH ACHE	16SEP96	11, -49, -68	03:00 Hrs	100	1	MIL	NO	UNR No	No
			20SEP96	15, -45, -64	3 Days	150	6	MIL	NO	PBU No	No
	Abnormal Laboratory Value	TOXIC IMIPRAMINE LEVEL	07NOV96	63, 4, -16	Not Stated	300		MIL	STP	REL No	No
Constipation	CONSTIPATION	12OCT96	37, -23, -42	13 Days	300	CON	MIL	NO	PSR No	No	
329.011.00209	Rhinitis	RUNNY NOSE	30SEP96	20, -43, -80	4 Days	150	CON	MIL	NO	UNR Yes	No

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Corrective Therapy [Corr Ther]
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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.011.00284	Constipation	CONSTIPATION	22APR96	32, -25, -106	11 Days	200	CON	MIL	NO	PSR No	No
	Diarrhea	DIARRHEA	08JUN96	79, 23, -59	03:00 Hrs	250	3	MIL	NO	PBU No	No
	Dysuria	DYSURIA	09JUN96	80, 24, -58	2 Days	250	3	MOD	NO	PBU No	No
	Headache	HEADACHE	21APR96 07JUN96	31, -26, -107 78, 22, -60	01:00 Hrs 01:00 Hrs	200 250	1 CON	MOD MIL	NO NO	PBU Yes PBU Yes	No No
	Leukopenia	LOW NEUTROPHILS LOW WHITE CELL COUNT	16MAY96 16MAY96	56, -1, -82 56, -1, -82	Not Stated Not Stated	250 250	CON CON	MOD MOD	NO NO	PBU No PBU No	No No
	Nausea	NAUSEA	21MAR96	-1, -57, -138	13 Days	0	4	MIL	NO	PSR No	No
	Pharyngitis	SORE THROAT	30MAR96	9, -48, -129	4 Days	100	CON	MIL	NO	UNR Yes	No
329.012.00221	Constipation	CONSTIPATION	14OCT96	112, 49, -20	19 Days	200	CON	MOD	NO	UNR Yes	No
	Dizziness	DIZZINESS	02AUG96	39, -25, -93	8 Days	200	5	MOD	NO	PBU No	No
	Dry Mouth	DRY MOUTH	30AUG96	67, 4, -65	52 Days	200	CON	MOD	NO	PSR No	No
	Emotional Lability	OVERDOSE {INTENTIONAL}	03NOV96	132, 69, 0	19:30 Hrs	200	CON	SEV	STP	UNR No	Yes
	Euphoria	MILD ELATION AND DISINHIBITION	24JUL96	30, -34, -102	13 Days	250	CON	MIL	DCR	PSR No	No
	Headache	HEADACHES (SEVERE)	10SEP96	78, 15, -54	06:00 Hrs	200	1	SEV	NO	PBU Yes	No
	Insomnia	INSOMNIA	15AUG96	52, -12, -80	39 Days	200	MOD	NO	UNR Yes	No	
329.012.00223	Depression	MAJOR DEPRESSION	29SEP96	31, ., -13	Not Stated	200	CON	MOD	NO	UNR No	Yes

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Corrective Therapy [Corr Ther]
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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE	
329.012.00223	Emotional Lability	SELF MUTILATION	29SEP96	31, .. -13	Not Stated	200	CON	MOD	NO	UNR No	Yes	
		SUICIDAL IDEATION	24SEP96	26, .. -18	10 Days	200	1	MOD	NO	UNR No	No	
	Hypertension	HYPERTENSION	30SEP96	32, .. -12	Not Stated	200	CON	MOD	NO	UNR No	Yes	
329.012.00227	Drug Dependence	CANNABIS USE	18JAN97	32, -38, -228	1 Days	200	1	MIL	NO	UNR No	No	
	Dry Mouth	DRY MOUTH	17JAN97	31, -39, -229	Not Stated	200	CON	MIL	NO	PBU No	No	
		SEVERE DRY MOUTH	25APR97	129, 60, -131	128 Days	300	CON	SEV	NO	PSR No	No	
	Headache	MODERATE HEADACHE	05JAN97	19, -51, -241	52 Days	100	5	MOD	NO	PSR No	No	
		SEVERE HEADACHES	24DEC96	7, -63, -253	07:00 Hrs	50	2	SEV	NO	PSR No	No	
	Hypertension	HYPERTENSION	25APR97	129, 60, -131	117 Days	300		MOD	NO	PBU No	No	
	Insomnia	TERMINAL INSOMNIA	07FEB97	52, -18, -208	Not Stated	200		MIL	INC	PBU No	No	
	Myalgia	MUSCLE SPASMS IN RIBS	09MAY97	143, 74, -117	11:00 Hrs	300	CON	MOD	NO	PBU No	No	
	Pharyngitis	PHARYNGITIS	06JAN97	20, -50, -240	36 Days	150	CON	MOD	NO	PBU Yes	No	
SORE THROAT		10FEB97	55, -15, -205	11 Days	200	CON	MIL	NO	PBU No	No		
Respiratory Disorder	COMMON COLD	05MAY97	139, 70, -121	18 Days	300	CON	MIL	NO	UNR Yes	No		
Syncope	SYNCOPE	23MAR97	96, 27, -164	161 Days	300		MIL	NO	PBU No	No		
329.012.00230	Cystitis	FEELING BLADDER FULL AFTER URINATING	01MAY97	63, -7, -25	28 Days	200	CON	MIL	NO	PBU Yes	No	
	Dizziness	DIZZINESS	12MAR97	13, -57, -75	3 Days	100		2	MIL	NO	PBU No	No
	Dry Mouth	DRY MOUTH	11MAR97	12, -58, -76	77 Days	100	CON	MOD	NO	PSR No	No	

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=IMIPRAMINE -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
329.012.00230	Dyspepsia	HEARTBURN	14MAR97	15, -55, -73	74 Days	150		MIL NO	PBU Yes No	
	Headache	HEADACHE	31MAR97	32, -38, -56	1 Days	200	CON	MIL NO	PBU Yes No	
	Nausea	NAUSEA	18APR97 07MAY97	50, -20, -38 69, -1, -19	7 Days 14:00 Hrs	200 250	CON	MOD NO MIL NO	UNR No No UNR Yes No	
	Postural Hypotension	ORTHOSTATIC HYPOTENSION	18APR97	50, -20, -38	19 Days	200		MIL NO	PBU No No	
	Tooth Disorder	PAIN RE: 4 IMPACTED WISDOM TEETH EXTRACTED UNDER GENERAL ANESTHETIC	18APR97	50, -20, -38	1 Days	200	CON	MOD NO	UNR Yes No	

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Corrective Therapy [Corr Ther]
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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PLACEBO -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
329.001.00062	Back Pain	BACK AND NECK ACHES	31OCT94	12, ., -15	19 Days	0		MOD NO	PSR No	No
	Dizziness	DIZZINESS WHEN RIDING IN ELEVATOR OR ESCALATOR	10NOV94	22, ., -5	9 Days	0		MIL NO	UNR No	No
	Dry Mouth	DRY MOUTH	04NOV94	16, ., -11	Not Stated	0	CON	MIL NO	PSR No	No
	Increased Appetite	INCREASED APPETITE	23OCT94	4, ., -23	Not Stated	0	CON	MOD NO	PSR No	No
329.001.00064	Abdominal Pain	STOMACH ACHE	23NOV94 01DEC94	14, -41, -138 22, -33, -130	03:00 Hrs 8 Days	0 0	1 2	MIL NO MIL NO	PSR No PSR No	No No
	Albuminuria	URINE 1+PROTEIN	28MAR95	139, 85, -13	Not Stated	0	CON	MIL NO	PBU No	No
	Cough Increased	CONGESTED COUGH	24DEC94	45, -10, -107	18 Days	0	CON	MIL NO	UNR No	No
	Diarrhea	DIARRHEA	23NOV94 31JAN95	14, -41, -138 83, 29, -69	03:00 Hrs 2 Days	0 0	2 CON	MIL NO MIL NO	PSR No UNR No	No No
	Dizziness	DIZZY UPON POSITION CHANGE	12NOV94	3, -52, -149	6 Days	0	5	MIL NO	PSR No	No
	Headache	HEADACHE	26JAN95	78, 24, -74	6 Days	0	2	MIL NO	PBU No	No
	Nausea	NAUSEA	31JAN95	83, 29, -69	2 Days	0	CON	MIL NO	UNR No	No
	Rhinitis	NASAL CONGESTION	24DEC94	45, -10, -107	18 Days	0	CON	MIL NO	UNR No	No
	Trauma	FRACTURED LEFT INDEX FINGER SPRAINED ANKLE	25JAN95 04JAN95	77, 23, -75 56, 2, -96	35 Days 18 Days	0 0	CON CON	MOD NO MOD NO	UNR No UNR No	No No
	329.001.00069	Albuminuria	URINE 1+PROTEIN	13APR95	57, ., -5	Not Stated	0	CON	MIL NO	PBU No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PLACEBO -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.001.00069	Decreased Appetite	ANOREXIA	18MAR95	31, .. -31	21 Days	0	CON	MIL	NO	PSR	No
	Dyspepsia	STOMACH UPSET	22MAR95	35, .. -27	17 Days	0	2	MIL	NO	PSR	No
	Nausea	NAUSEA NAUSEA AM	21FEB95	6, .. -56	02:30 Hrs	0	1	MIL	NO	PSR	No
			22MAR95	35, .. -27	17 Days	0	2	MIL	NO	PSR	No
	Pharyngitis	SORE THROAT	09MAR95	22, .. -40	8 Days	0	CON	MIL	NO	UNR	No
	Respiratory Disorder	UPPER RESPIRATORY CONGESTION	09MAR95	22, .. -40	12 Days	0	CON	MIL	NO	UNR	No
	Syncope	FAINT UPON STANDING	17MAR95	30, .. -32	22 Days	0	CON	MIL	NO	PSR	No
329.001.00071	Lymphadenopathy	SWOLLEN LYMPH NODES IN NECK	13MAR95	19, .. -52	4 Days	0	CON	MIL	NO	UNR	No
	Myalgia	ARM AND LEG MUSCLE ACHES	21MAR95	27, .. -44	5 Days	0	CON	MIL	NO	PBU	No
	Nausea	NAUSEA	04APR95	41, .. -30	23 Days	0	CON	MIL	NO	PSR	No
	Pharyngitis	SORE THROAT	13MAR95	19, .. -52	15 Days	0	CON	MOD	NO	UNR	No
	Respiratory Disorder	UPPER RESPIRATORY INFECTION	13MAR95	19, .. -52	15 Days	0	CON	MOD	NO	UNR	No
329.001.00123	Bronchitis	BRONCHITIS WITH BRONCHOSPASMS	13JAN96	10, .. -39	13 Days	0	CON	MOD	NO	UNR	Yes
	Cough Increased	DRY COUGH	07JAN96	4, .. -45	19 Days	0	CON	MOD	NO	UNR	No
	Depression	WORSENING OF DEPRESSION	18FEB96	46, .. -3	Not Stated	0	CON	SEV	STP	REL	No

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Corrective Therapy [Corr Ther]
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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PLACEBO -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
329.001.00123	Emotional Lability	SUICIDAL THOUGHTS	18FEB96	46, .. -3	Not Stated	0	CON	SEV STP	REL No	Yes
	Headache	HEADACHE	21FEB96	49, .. 0	Not Stated	0	CON	MOD NO	PSR Yes	No
		HEADACHES	21JAN96	18, .. -31	8 Days	0	CON	MIL NO	UNR No	No
	Nausea	NAUSEA	22JAN96	19, .. -30	7 Days	0	CON	MIL NO	UNR No	No
		NAUSEA (POST TAKING MEDS)	21FEB96	49, .. 0	Not Stated	0	CON	MIL NO	PSR No	No
			05JAN96	2, .. -47	04:30 Hrs	0	2	MIL NO	PSR No	No
			29JAN96	26, .. -23	5 Days	0	CON	MIL NO	PSR No	No
	Pain	BODY ACHES	22JAN96	19, .. -30	7 Days	0	CON	MIL NO	UNR No	No
Tremor	HAND TREMORS	04FEB96	32, .. -17	Not Stated	0	3	MIL NO	PSR No	No	
329.001.00207	Abdominal Pain	STOMACH CRAMPS	03MAR96	5, .. -53	23:00 Hrs	0	CON	MIL NO	UNR No	No
	Cough Increased	STOMACH CRAMPS (SINCE STARTING BIAXIN)	24APR96	57, .. -1	3 Days	0	CON	MIL NO	UNR No	No
		COUGH	05APR96	38, .. -20	7 Days	0	CON	MIL NO	UNR No	No
	Decreased Appetite	DECREASED APPETITE	21MAR96	23, .. -35	15 Days	0	CON	MIL NO	PBU No	No
	Diarrhea	DIARRHEA	03MAR96	5, .. -53	15:00 Hrs	0	3	MOD NO	UNR No	No
		06APR96	39, .. -19	13:00 Hrs	0	4	MIL NO	PBU No	No	
			24APR96	57, .. -1	3 Days	0	CON	MIL NO	UNR No	No
	Headache	HEADACHE	18APR96	51, .. -7	8 Days	0	CON	MOD NO	PBU Yes	No
	Pain	BODY ACHES	18APR96	51, .. -7	7 Days	0	CON	MIL NO	UNR No	No
	Pharyngitis	SORE THROAT	10APR96	43, .. -15	2 Days	0	CON	MIL NO	UNR No	No

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 Corrective Therapy [Corr Ther]
 Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PLACEBO -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.001.00207	Rhinitis	STUFFY NOSE	05APR96	38, ., -20	7 Days	0	CON	MIL	NO	UNR	No
	Sinusitis	HEAD CONGESTION	22MAR96	24, ., -34	4 Days	0	CON	MIL	NO	UNR	No
		SINUS INFECTION	05APR96	38, ., -20	7 Days	0	CON	MIL	NO	UNR	No
			18APR96	51, ., -7	15 Days	0	CON	MOD	NO	UNR	Yes
329.002.00049	Headache	HEADACHE	25MAR95	17, ., -57	3 Days	0	3	MIL	NO	PSR	Yes
329.002.00097	Abdominal Pain	STOMACH ACHE	23MAR95	80, 22, -181	20 Mins	0	3	MIL	NO	PSR	No
	Abnormal Vision	BLURRING VISION	18JAN95	16, -43, -245	126 Days	0	99	MOD	NO	PSR	No
	Dizziness	DIZZINESS (WHEN STANDS QUICKLY)	23MAR95	80, 22, -181	1 Mins	0	3	MIL	NO	PSR	No
	Infection	FLU SYMPTOMS	16JAN95	14, -45, -247	3 Days	0	CON	MIL	NO	UNR	Yes
	Sweating	SWEATY HANDS	17JAN95	15, -44, -246	127 Days	0		MIL	NO	PBU	No
	Vasodilatation	HOT FLASHES	25JAN95	23, -36, -238	5 Mins	0	4	MIL	NO	PSR	No
	329.002.00101	Drug Dependence	POSITIVE MARIJUANA URINE SCREEN (PROTOCOL DEVIATION)	22JUN95	87, 29, -19	1 Days	0	CON	MOD	NO	UNR
329.002.00107	Dizziness	DIZZINESS (WHEN STANDING)	25AUG96	214, 158, -44	Not Stated	0	CON	MIL	NO	PSR	No
	Infection	STREP THROAT	16SEP96	236, 180, -22	46 Days	0	CON	MOD	NO	UNR	Yes
	Pharyngitis	TONSILLITIS	16SEP96	236, 180, -22	46 Days	0	CON	MOD	NO	UNR	Yes
	Wbc Abnormality	ELEVATED ATYPICAL LYMPHS	16SEP96	236, 180, -22	46 Days	0	CON	MOD	NO	UNR	Yes

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PLACEBO -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
329.002.00241	Cough Increased	COUGH	09APR96	64, 8, -44	22 Days	0	CON	MOD NO	UNR Yes	No
	Emotional Lability	PT. HOSPITALIZED FOR SUICIDAL IDEATION	23MAY96	108, 52, 0	Not Stated	0	CON	SEV STP	PBU Yes	Yes
	Hostility	PT. HOSPITALIZED FOR HOMICIDAL IDEATION	23MAY96	108, 52, 0	Not Stated	0	CON	SEV STP	PBU No	Yes
	Vomiting	NAUSEA AND VOMITING	03MAR96	27, -30, -81	3 Days	0	2 MIL	NO	PBU No	No
329.002.00246	Abdominal Pain	STOMACH ACHES (IF TAKES MEDS WITHOUT FOOD)	20MAY96	33, ., -39	Not Stated	0	MIL	NO	PSR No	No
	Asthenia	FATIGUE	25APR96	8, ., -64	Not Stated	0	CON	MIL NO	PSR No	No
	Dizziness	DIZZINESS	23MAY96	36, ., -36	7 Days	0	CON	MIL NO	PSR No	No
	Dry Mouth	DRY MOUTH	25APR96	8, ., -64	Not Stated	0	CON	MIL NO	REL No	No
	Headache	HEADACHES (WORSENING)	10MAY96	23, ., -49	Not Stated	0	MIL	NO	PSR Yes	No
	Herpes Zoster	VARICELLA	12JUN96	56, ., -16	5 Days	0	MOD	NO	UNR No	No
	Trauma	CAR ACCIDENT (NO INJURIES)	15MAY96	28, ., -44	1 Days	0	CON	MIL NO	UNR No	No
		FALL FROM ROPE RESULTING IN DIZZINESS, HEADACHES, AND FATIGUE	26MAY96	39, ., -33	5 Days	0	MOD	NO	UNR No	No
	Vomiting	VOMITING	02MAY96	15, ., -57	2 Days	0	2 MIL	NO	PBU No	No
329.002.00320	Back Pain	BACK PAIN	17SEP96	125, 64, -21	Not Stated	0	CON	MOD NO	UNR No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PLACEBO -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.002.00320	Dizziness	FAINTING	03SEP96	111, 50, -35	Not Stated	0	CON	MOD	NO	UNR No	No
	Dry Mouth	DRY MOUTH	14JUN96	30, -32, -116	11 Days	0	CON	MIL	NO	PSR No	No
	Otitis Media	EAR INFECTION	09SEP96	117, 56, -29	11 Days	0	1	MOD	NO	UNR Yes	No
	Trauma	SHOULDER TRAUMA	16JUN96	32, -30, -114	1 Days	0	CON	MOD	NO	UNR Yes	No
329.002.00323	Asthenia	FATIGUE	04MAR97	113, 55, -114	Not Stated	0	CON	MIL	NO	PSR No	No
	Dizziness	DIZZINESS (ESPECIALLY DURING AEROBICS AND HEAVY LIFTING)	19NOV96	8, -51, -219	37 Days	0	CON	MOD	NO	PSR No	No
	Headache	HEADACHE HEADACHES	01FEB97	82, 24, -145	4 Days	0	1	MIL	NO	PSR No	No
			30DEC96	49, -10, -178	11 Days	0	CON	MIL	NO	PSR Yes	No
	Pharyngitis	PHARYNGITIS	11APR97	151, 93, -76	8 Days	0	1	MIL	NO	UNR Yes	No
	Somnolence	FALLING ASLEEP IN THE AFTERNOON	15NOV96	4, -55, -223	42 Days	0	CON	MOD	NO	PSR No	No
Thirst	INCREASED THIRST	26NOV96	15, -44, -212	10 Days	0	CON	MIL	NO	REL No	No	
329.003.00074	Constipation	CONSTIPATION	18FEB95	25, -32, -249	12 Days	0	CON	MIL	NO	PSR No	No
	Headache	HEADACHES	09FEB95	16, -41, -258	01:30 Hrs	0	2	MIL	NO	PSR No	No
329.003.00080	Asthenia	FATIGUE	04JAN96	39, ., -36	Not Stated	0	CON	SEV	NO	PBU No	No
	Dizziness	DIZZINESS	04JAN96	39, ., -36	Not Stated	0	CON	MIL	NO	PSR No	No
	Dry Mouth	DRY MOUTH	04JAN96	39, ., -36	Not Stated	0	CON	MIL	NO	PSR No	No

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Intent-to-Treat Population

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329.003.00080	Headache	HEADACHES	03JAN96	38, .. -37	Not Stated	0	CON	MIL	NO	PSR No	No	
	Respiratory Disorder	COLD SYMPTOMS	23DEC95	27, .. -48	12 Days	0	1	MIL	NO	UNR No	No	
329.003.00085	Dry Mouth	DRY MOUTH	22DEC94	45, .. -26	4 Days	0	1	MIL	NO	PSR No	No	
329.003.00086	Dizziness	DIZZINESS	12DEC94	15, -43, -264	Not Stated	0	CON	MIL	NO	PBU No	No	
	Dry Mouth	DRY MOUTH	01DEC94	4, -54, -275	Not Stated	0	CON	MIL	NO	PSR No	No	
	Fever	FEVER	02JAN95	36, -22, -243	02:00 Hrs	0		MIL	NO	UNR Yes	No	
	Rash	RASH ON BACK	13FEB95	78, 21, -201	72 Days	0	CON	MOD	NO	PSR Yes	No	
	Respiratory Disorder	COLD {SYMPTOMS}	12DEC94 15MAY95	15, -43, -264 169, 112, -110	3 Days 5 Days	0 0	CON CON	MIL MIL	NO NO	UNR UNR	Yes Yes	No No
329.003.00094	Asthenia	WEAKNESS	11DEC95 12DEC95	49, .. -24 50, .. -23	02:00 Hrs Not Stated	0 0	1 CON	MOD MIL	NO NO	PSR PBU	No No	No No
	Dizziness	DIZZINESS	11DEC95	49, .. -24	02:00 Hrs	0	1	MOD	NO	PSR No	No	
	Dyspepsia	STOMACH ACIDITY	24NOV95	32, .. -41	Not Stated	0	CON	MIL	NO	PSR Yes	No	
	Headache	HEADACHE	11DEC95 12DEC95	49, .. -24 50, .. -23	02:00 Hrs Not Stated	0 0	1 CON	MOD MIL	NO NO	PSR PSR	No No	No No
	Rash	RASH {MINOR OF UNKNOWN CAUSES}	28OCT95	5, .. -68	24:00 Hrs	0	1	MIL	NO	PBU No	No	
329.003.00252	Asthenia	FATIGUE	25APR96	16, .. -54	20 Days	0	CON	MIL	NO	PSR No	No	
	Dizziness	DIZZINESS	29APR96	20, .. -50	1 Mins	0	1	MIL	NO	PSR No	No	

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.003.00252	Dyspnea	SHORTNESS OF BREATH	21MAY96	42, .. -28	30 Mins	0	1	MIL	DCR	PSR No	No
	Headache	HEADACHE	30APR96	21, .. -49	30 Mins	0	5	MIL	NO	PSR No	No
			18MAY96	39, .. -31	02:00 Hrs	0	1	MOD	DCR	PSR Yes	No
	Nausea	NAUSEA	30APR96	21, .. -49	30 Mins	0	5	MIL	NO	PSR No	No
	Nervousness	IRRITABILITY	16MAY96	37, .. -33	13 Days	0	CON	MOD	DCR	PSR No	No
329.003.00291	Abdominal Pain	STOMACH PAINS	09JUL96	7, -59, -113	01:00 Hrs	0	2	MIL	NO	PSR No	No
	Arrhythmia	SINUS-ARRHYTHMIA	02OCT96	92, 27, -28	29 Days	0	1	MIL	NO	PBU No	No
	Constipation	CONSTIPATION	21AUG96	50, -16, -70	Not Stated	0	1	MIL	NO	PBU No	No
	Dizziness	DIZZINESS	07AUG96	36, -30, -84	8 Days	0	1	MIL	NO	PBU No	No
	Dry Mouth	DRY MOUTH	28AUG96	57, -9, -63	8 Days	0	CON	MIL	NO	UNR No	No
	Headache	HEADACHE	14JUL96	12, -54, -108	01:00 Hrs	0	1	MOD	NO	PSR No	No
329.003.00315	Respiratory Disorder	COLD {SYMPTOMS}	18NOV96	7, .. -53	3 Days	0	1	MIL	NO	UNR Yes	No
329.003.00316	Thrombocythemia	ELEVATED PLATELETS	11FEB97	57, .. -7	Not Stated	0	CON	MIL	NO	PBU No	No
329.004.00016	Abdominal Pain	STOMACH CRAMPS	28MAR95	16, .. -22	3 Days	0	CON	MOD	NO	UNR Yes	No
	Allergic Reaction	COUGHING DUE TO ALLERGIES	30MAR95	18, .. -20	Not Stated	0	CON	MIL	NO	UNR Yes	No
		HEADACHES DUE TO ALLERGIES	24MAR95	12, .. -26	Not Stated	0	CON	MOD	NO	UNR Yes	No
		SNEEZING DUE TO ALLERGIES	24MAR95	12, .. -26	Not Stated	0	CON	MOD	NO	UNR Yes	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PLACEBO -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther	SAE
329.004.00016	Allergic Reaction	STUFFED SINUSES DUE TO ALLERGIES	24MAR95	12, .. -26	Not Stated	0	CON	MOD	NO	UNR	Yes	No
329.004.00018	Abnormal Vision	BLURRY VISION	20JUN95	49, .. -24	21 Days	0	CON	MOD	NO	PSR	No	No
	Allergic Reaction	RHINITIS, SNEEZING, ITCHY EYES (POLLEN ALLERGY)	12MAY95	10, .. -63	7 Days	0	CON	MOD	NO	UNR	Yes	No
	Anxiety	TENSION {ANXIOUS FEELING POST CONFRONTATION NON-MEDICATION RELATED}	28MAY95	26, .. -47	1 Days	0	1	SEV	NO	UNR	Yes	No
	Dry Mouth	DRY MOUTH	20JUN95	49, .. -24	21 Days	0	CON	SEV	NO	PSR	No	No
	Headache	HEADACHE HEADACHES	24MAY95 22JUN95	22, .. -51 51, .. -22	02:00 Hrs Not Stated	0 0	1 CON	SEV MOD	NO NO	UNR PSR	Yes Yes	No No
	Insomnia	INSOMNIA (WORSENING)	07MAY95	5, .. -68	20 Days	0	CON	SEV	NO	REL	No	No
	Nausea	NAUSEA	09MAY95	7, .. -66	5 Days	0	CON	MOD	NO	REL	No	No
	Vomiting	NAUSEA-VOMITING	01JUN95	30, .. -43	38 Days	0	CON	MIL	NO	PSR	No	No
329.004.00020	Nausea	NAUSEA	12NOV95	4, .. -12	3 Days	0	CON	MOD	NO	UNR	No	No
329.004.00213	Abdominal Pain	STOMACH ACHES	03AUG96 11AUG96	2, -53, -239 10, -45, -231	8 Days 192 Days	0 0	CON CON	MIL MOD	NO NO	PSR UNR	No Yes	No No
	Back Pain	BACKACHE	02AUG96	1, -54, -240	8 Days	0	CON	MIL	NO	UNR	No	No
	Constipation	CONSTIPATION	08AUG96	7, -48, -234	5 Days	0	2	MIL	NO	PSR	No	No

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Intent-to-Treat Population

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329.004.00213	Constipation	CONSTIPATION	10AUG96	9, -46, -232	13 Days	0	CON	MIL	NO	UNR	No	
	Diarrhea	DIARRHEA	07AUG96	6, -49, -235	4 Days	0	4	MIL	NO	PSR	No	
			09FEB97	192, 138, -49	31 Days	0	CON	MIL	NO	UNR	No	
	Dry Mouth	DRY MOUTH	14SEP96	44, -11, -197	Not Stated	0	CON	MIL	NO	PSR	No	
	Headache	HEADACHES	04AUG96	3, -52, -238	227 Days	0	CON	MIL	NO	UNR	Yes	No
	Rash	RASH	20DEC96	141, 87, -100	8 Days	0	CON	MIL	NO	PBU	No	No
	Respiratory Disorder	UPPER RESPIRATORY INFECTION (COLD)	12AUG96	11, -44, -230	19 Days	0	CON	MIL	NO	UNR	Yes	No
Trauma	HEAD INJURY WITH LACERATION TO SCALP (4 STITCHES) NO LOSS OF CONSCIOUSNESS (PUSHED ONTO SUBWAY TRACK)	05OCT96	65, 11, -176	5 Mins	0	1	MOD	NO	UNR	No	No	
329.005.00005	Asthenia	SLIGHTLY TIRED	03NOV94	3, ., -6	14 Days	0	5	MIL	NO	PSR	No	No
	Dizziness	SLIGHTLY DIZZY	03NOV94	3, ., -6	14 Days	0	4	MIL	NO	PSR	No	No
	Tachycardia	ELEVATED HEART RATE	08NOV94	8, ., -1	2 Days	0	2	MOD	STP	PSR	No	No
329.005.00010	Dizziness	DIZZINESS	22DEC94	10, -48, -245	6 Days	0	4	MIL	NO	PSR	No	No
			20JAN95	39, -19, -216	24:00 Hrs	0	CON	MIL	NO	PSR	No	No
	Infection	FLU-NAUSEA, CRAMPS DIARRHEA, STOMACH ACHE	18JAN95	37, -21, -218	3 Days	0	CON	SEV	NO	UNR	No	No

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329.005.00010	Menstrual Disorder	2 MENSTRUAL CYCLES IN JULY-2 WEEKS APART	03JUL95	203, 146, -52	6 Days	0	CON	MOD	NO	PBU No	No
			18JUL95	218, 161, -37	7 Days	0	CON	MOD	NO	PBU No	No
	Trauma	FOOT/ANKLE (RUN OVER BY CAR INJURY-PAIN)	13APR96	488, 431, 233	3 Days	0	CON	MOD	NO	UNR Yes	No
	Urticaria	HIVES	02MAR95	80, 23, -175	6 Days	0	CON	MOD	NO	UNR Yes	No
329.005.00012	Dry Mouth	DRY MOUTH (1/2 HOUR AFTER TAKING MEDICATION)	22DEC94	4, -56, -161	13 Days	0	CON	MIL	NO	REL No	No
			22DEC94	4, -56, -161	13 Days	0	CON	MIL	NO	REL No	No
	Headache	HEADACHE	24JAN95	37, -23, -128	04:30 Hrs	0	CON	MOD	NO	PSR Yes	No
	Infection	STOMACH FLU- (HEADACHE, NAUSEA/VOMITING AND DIARRHEA)	31DEC94	13, -47, -152	4 Days	0	CON	SEV	NO	UNR No	No
			TOXOPLASMOSIS	01JUN95	165, 106, 0	Not Stated	0	CON	MOD	STP	UNR Yes
329.005.00111	Allergic Reaction	"PUFFY", ITCHY, WATERY EYES {ALLERGIES}	04MAR95	53, -4, -57	9 Days	0	CON	SEV	NO	PBU No	No
			31JAN95	21, -36, -89	8 Days	0	CON	MIL	NO	PSR No	No
	Back Pain	BACKACHE	07JAN95	-4, -60, -113	39 Days	0	12	MOD	NO	PBU Yes	No
	Fever	FEVER	15FEB95	36, -21, -74	6 Days	0	CON	MOD	NO	UNR Yes	No
	Headache	HEADACHE	07JAN95 14APR95	-4, -60, -113 94, 38, -16	39 Days 2 Days	0 0	12 CON	MOD SEV	NO NO	PBU UNR	Yes Yes

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329.005.00111	Headache	HEADACHE	16APR95	96, 40, -14	2 Days	0	CON	SEV	NO	UNR	Yes No
	Nausea	NAUSEA	15FEB95	36, -21, -74	4 Days	0	CON	MIL	NO	PSR	No No
			16MAR95	65, 9, -45	2 Days	0	CON	MIL	NO	PBU	No No
	Pain	FACE PAIN	14APR95	94, 38, -16	2 Days	0	CON	SEV	NO	UNR	Yes No
	Pharyngitis	SORE THROAT	15FEB95	36, -21, -74	6 Days	0	CON	MOD	NO	UNR	Yes No
			16MAR95	65, 9, -45	2 Days	0	CON	SEV	NO	UNR	Yes No
			16APR95	96, 40, -14	2 Days	0	CON	SEV	NO	UNR	Yes No
	Rash	RASH ON BOTH FOREARMS	30JAN95	20, -37, -90	6 Days	0	CON	MOD	NO	PBU	No No
	Rhinitis	NASAL STUFFINESS NOSE PAIN	16FEB95	37, -20, -73	49 Days	0	CON	SEV	NO	PBU	Yes No
			14APR95	94, 38, -16	2 Days	0	CON	SEV	NO	UNR	Yes No
Sinusitis	SINUS INFECTION SINUS STUFFINESS	17APR95	97, 41, -13	Not Stated	0	CON	SEV	STP	UNR	Yes No	
		16FEB95	37, -20, -73	49 Days	0	CON	SEV	NO	PBU	Yes No	
Tooth Disorder	TEETH PAIN	14APR95	94, 38, -16	2 Days	0	CON	SEV	NO	UNR	Yes No	
Vomiting	VOMITING DRY HEAVES	17APR95	97, 41, -13	20:00 Hrs	0	CON	SEV	NO	UNR	No No	
329.005.00114	Infection	STREP THROAT SORE THROAT AND FEVER	04FEB95	5, -53, -93	11 Days	0	CON	SEV	NO	UNR	Yes No
	Tremor	HAND TREMORS	01MAR95	30, -28, -68	22 Days	0	CON	MIL	NO	REL	No No
329.005.00115	Dry Mouth	DRY MOUTH	08FEB95	3, -69, -72	6 Days	0	CON	MIL	NO	REL	No No
	Headache	HEADACHE HEADACHES	12FEB95	7, -65, -68	02:30 Hrs	0	CON	MIL	NO	PSR	No No
			14MAR95	37, -35, -38	02:00 Hrs	0	7	MIL	NO	PSR	No No

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329.005.00115	Sinusitis	TOOTHACHE/QUESTIONABLE SINUS INFECTION	23FEB95	18, -54, -57	26 Days	0	CON	SEV	NO	UNR Yes	No
	Wbc Abnormality	ATYPICAL LYMPHS	18APR95	72, 1, -3	1 Days	0	1	MIL	NO	PBU No	No
	Weight Loss	WEIGHT LOSS (12 POUNDS)	10APR95	64, -8, -11	9 Days	0	CON	SEV	NO	UNR No	No
329.005.00120	Cough Increased	COUGH COUGHING	12SEP95 23OCT95	14, .. -44 55, .. -3	8 Days Not Stated	0 0	CON CON	MOD MIL	NO NO	UNR Yes UNR Yes	No No
	Eosinophilia	INCREASED EOSINOPHILS	22AUG95 26OCT95	-8, .. -65 58, .. 0	Not Stated Not Stated	0 0	CON CON	MIL MIL	NO NO	UNR No UNR No	No No
	Euphoria	LAUGHING A LOT {EUPHORIA}	19SEP95	21, .. -37	17 Days	0	3	MOD	NO	UNR No	No
	Headache	HEADACHE	14SEP95	16, .. -42	30 Mins	0	1	MIL	NO	UNR No	No
	Hyperglycemia	INCREASED GLUCOSE	22AUG95 26OCT95	-8, .. -65 58, .. 0	Not Stated Not Stated	0 0	CON CON	MIL MIL	NO NO	UNR No UNR No	No No
	Kidney Function Abnormal	DECREASED UREA NITROGEN	22AUG95	-8, .. -65	66 Days	0	CON	MIL	NO	UNR No	No
	Nervousness	NERVOUS	19SEP95 21SEP95	21, .. -37 23, .. -35	2 Days 8 Days	0 0	MIL CON	NO MIL	NO NO	UNR No UNR No	No No
	Rhinitis	RUNNY NOSE	12SEP95	14, .. -44	7 Days	0	CON	MIL	NO	UNR Yes	No
329.005.00253	Headache	HEADACHE	02FEB96 26FEB96 27FEB96 23MAR96	-6, .. -61 19, .. -37 20, .. -36 45, .. -11	04:00 Hrs 05:00 Hrs 03:30 Hrs 04:30 Hrs	0 0 0 0	2 CON CON CON	MIL MIL MIL MIL	NO NO NO NO	UNR Yes UNR Yes UNR Yes UNR Yes	No No No No

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Corrective Therapy [Corr Ther]
Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PLACEBO -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.005.00253	Infection	CHLAMYDIA	04MAR96	26, ., -30	9 Days	0	CON	MIL	NO	UNR	Yes No
329.005.00254	Abdominal Pain	STOMACH ACHE	28FEB96	14, -42,-244	03:00 Hrs	0	CON	MOD	NO	UNR	No No
	Arthralgia	SHOULDER PAIN IN AM	18MAR96	33, -23,-225	3 Days	0	3	MOD	NO	UNR	No No
	Asthenia	TIRED	16MAR96	31, -25,-227	Not Stated	0	CON	MIL	NO	PSR	No No
	Chest Pain	CHEST PAIN	28FEB96	14, -42,-244	03:00 Hrs	0	CON	MIL	NO	UNR	No No
	Dysmenorrhea	MENSTRUAL CRAMPS	09MAR96 28MAY96	24, -32,-234 104, 49,-154	12:00 Hrs 06:30 Hrs	0 0	CON CON	SEV SEV	NO NO	UNR UNR	Yes Yes No No
	Headache	HEADACHE	11FEB96 16FEB96 24FEB96 08MAR96 07APR96 02SEP96 03SEP96	-4, -59,-261 2, -54,-256 10, -46,-248 23, -33,-235 53, -3,-205 201, 146, -57 202, 147, -56	03:00 Hrs 5 Days 1 Days 02:00 Hrs 02:30 Hrs 02:00 Hrs 04:00 Hrs	0 0 0 0 0 0 0	CON 3 2 CON CON CON CON	MIL MIL MIL SEV MOD MOD MOD	NO NO NO NO NO NO NO	UNR PSR PBU UNR PBU UNR UNR	Yes No No Yes Yes Yes Yes No No No No No No No
329.005.00293	Acne	ACNE	26MAR97	15, ., -42	Not Stated	0	CON	MIL	NO	UNR	No No
	Headache	HEADACHE	06APR97 19APR97 06MAY97	26, ., -31 39, ., -18 56, ., -1	03:30 Hrs 01:00 Hrs 45 Mins	0 0 0	1 1 1	MOD MOD MOD	NO NO NO	PBU PBU PBU	Yes Yes No No No
	Respiratory Disorder	RESPIRATORY CONGESTION	18MAR97	7, ., -50	8 Days	0	CON	MOD	NO	PBU	Yes No
329.005.00298	Back Pain	BACK ACHE BACK PAIN (OLD SOCCER INJURY)	12SEP96 23JUN96	114, 58,-134 33, -24,-215	3 Days 03:00 Hrs	0 0	CON CON	MOD MOD	NO NO	UNR UNR	No Yes No No

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Serious AE as Judged according to SB Criteria by Investigator [SAE]

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PLACEBO -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther SAE
329.005.00298	Diarrhea	STOMACH ACHE WITH DIARRHEA	18MAY96	-4, -60,-251	4 Days	0	CON	SEV	NO	UNR	No No
	Dizziness	DIZZINESS WHEN STANDING UP	09DEC96	202, 146, -46	3 Days	0	3	MIL	NO	PBU	No No
	Dysmenorrhea	MENSTRUAL CRAMPS	06JUL96 04NOV96 07DEC96 07JAN97	46, -11,-202 167, 111, -81 200, 144, -48 231, 175, -17	2 Days 24:00 Hrs 3 Days 3 Days	0 0 0 0	CON CON CON CON	MOD SEV MOD MOD	NO NO NO NO	UNR UNR UNR UNR	Yes Yes Yes Yes No No No No
	Epistaxis	NOSEBLEEDS	06JAN97	230, 174, -18	7 Days	0	8	SEV	NO	PSR	No No
	Headache	HEADACHE	06NOV96	169, 113, -79	02:30 Hrs	0	CON	MOD	NO	UNR	No No
	Hypertonia	STIFF NECK	29JUN96	39, -18,-209	04:00 Hrs	0	CON	MOD	NO	UNR	Yes No
	Respiratory Disorder	COLD SYMPTOMS:STUFFY NOSE, SORE THROAT, FEVER	08DEC96	201, 145, -47	12 Days	0	CON	MOD	NO	UNR	Yes No
	Sinusitis	SINUS CONGESTION	30JUN96 28AUG96	40, -17,-208 99, 43,-149	2 Days 8 Days	0 0	CON CON	MOD MOD	NO NO	UNR UNR	Yes No No No
		SINUS HEADACHE AND CONGESTION	02JUN96	12, -45,-236	4 Days	0	CON	MOD	NO	UNR	Yes No
	Trauma	CHARLEY HORSE LEFT LEG-THIGH	01OCT96	133, 77,-115	4 Days	0	CON	MOD	NO	UNR	Yes No
		KNEE INJURY (SOCCER RELATED)	15JUL96	55, -2,-193	3 Days	0	CON	MOD	NO	UNR	Yes No
		PAIN IN RIGHT LEG (FOLLOWING AUTOMOBILE ACCIDENT)	16JUN96	26, -31,-222	04:30 Hrs	0	CON	MOD	NO	UNR	Yes No

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Intent-to-Treat Population

----- Treatment Group=PLACEBO -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Act- Int ion	Inv Corr Rel Ther	SAE
329.005.00298	Trauma	PULLED MUSCLE - LEFT SHIN (SOCCER INJURY)	17OCT96	149, 93, -99	06:00 Hrs	0	CON	MOD NO	UNR Yes	No
329.005.00331	Back Pain	BACKACHE	20DEC96	30, .. -27	6 Days	0	CON	MIL NO	UNR No	No
			07JAN97	48, .. -9	2 Days	0	CON	MIL NO	UNR No	No
	Depersonalization	"SPACED OUT" FEELING	08DEC96	18, .. -39	5 Days	0	CON	MIL DCR	PSR No	No
	Dizziness	DIZZINESS DIZZINESS IN AM	19DEC96	29, .. -28	5 Mins	0	CON	MIL NO	PBU No	No
			09DEC96	19, .. -38	4 Days	0	3	MIL NO	PBU No	No
	Dry Mouth	DRY MOUTH	23NOV96	3, .. -54	5 Days	0	CON	MIL NO	REL No	No
	Headache	HEADACHE	21NOV96	1, .. -56	4 Days	0	4	MOD NO	REL Yes	No
			23NOV96	3, .. -54	1 Days	0	2	MIL NO	PSR No	No
			24NOV96	4, .. -53	1 Days	0	CON	MIL NO	PSR No	No
			30NOV96	10, .. -47	2 Days	0	2	MOD NO	REL Yes	No
26DEC96			36, .. -21	02:30 Hrs	0	CON	MOD NO	UNR Yes	No	
09JAN97			50, .. -7	02:30 Hrs	0	CON	MIL NO	PBU No	No	
Nervousness	FIDGETINESS	23NOV96	3, .. -54	10:00 Hrs	0	CON	MIL NO	PSR No	No	
Sinusitis	SINUS INFECTION	17DEC96	27, .. -30	11 Days	0	CON	SEV NO	UNR Yes	No	
329.005.00334	Albuminuria	ABNORMAL URINALYSIS POSITIVE PROTEIN MODERATE BACTERIA [ABNORMAL URINALYSIS POSITIVE PROTEIN]	27MAR97	56, .. 0	1 Days	0	CON	MOD NO	UNR No	No
	Back Pain	BACK ACHE BACKACHE	19MAR97	48, .. -8	24:00 Hrs	0	CON	MOD NO	UNR Yes	No
			20FEB97	21, .. -35	04:00 Hrs	0	CON	MOD NO	UNR No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PLACEBO -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther	SAE
329.005.00334	Fever	FEVER - 102 DEGREES [FEVER]	19MAR97	48, ., -8	24:00 Hrs	0	CON	MOD	NO	UNR	Yes	No
	Gastrointestinal Disorder	FOOD POISONING	18MAR97	47, ., -9	3 Days	0	CON	SEV	NO	UNR	No	No
	Headache	HEADACHE	03MAR97	32, ., -24	02:30 Hrs	0	CON	MIL	NO	PBU	Yes	No
			12MAR97	41, ., -15	05:00 Hrs	0	CON	SEV	NO	PBU	Yes	No
	Pharyngitis	SORE THROAT	03FEB97	4, ., -52	8 Days	0	CON	MOD	NO	UNR	Yes	No
	Pyuria	ABNORMAL URINALYSIS POSITIVE PROTEIN MODERATE BACTERIA [ABNORMAL URINALYSIS MODERATE BACTERIA]	27MAR97	56, ., 0	1 Days	0	CON	MOD	NO	UNR	No	No
Tooth Disorder	{TOOTH DISORDER}	29JAN97	-2, ., -57	01:00 Hrs	0	CON	SEV	NO	UNR	No	No	
329.006.00037	Bronchitis	BRONCHITIS	06FEB95	10, ., -15	8 Days	0	CON	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	06FEB95	10, ., -15	Not Stated	0	CON	MOD	NO	REL	No	No
	Insomnia	INSOMNIA	06FEB95	10, ., -15	Not Stated	0	CON	MOD	NO	REL	No	No
	Nausea	NAUSEA	15FEB95	19, ., -6	Not Stated	0	CON	MIL	NO	REL	No	No
329.006.00042	Dyspepsia	INDIGESTION (MEXICAN SPICY FOOD)	31DEC95	25, -33, -213	3 Days	0	3	MOD	NO	UNR	No	No
		UPSET STOMACH	07JAN96	32, -26, -206	22:00 Hrs	0	1	MOD	NO	UNR	Yes	No
	Headache	HEADACHE	23MAR96 24APR96	108, 51, -130 140, 83, -98	30 Mins 01:30 Hrs	0 0	1 1	MOD MOD	NO NO	PBU PBU	Yes Yes	No No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PLACEBO -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE	
329.006.00042	Headache	HEADACHE	09JUL96	216, 159, -22	01:00 Hrs	0	1	MOD	NO	UNR	Yes	No
			11JUL96	218, 161, -20	06:00 Hrs	0	1	SEV	NO	UNR	Yes	No
			13JUL96	220, 163, -18	01:00 Hrs	0	1	MIL	NO	UNR	Yes	No
		HEADACHES	28DEC95	22, -36, -216	6 Days	0	7	MIL	NO	UNR	No	No
	Myalgia	MUSCLE ACHE	07JAN96	32, -26, -206	34:00 Hrs	0	1	MIL	NO	UNR	No	No
	Nausea	NAUSEA	07JAN96	32, -26, -206	22:00 Hrs	0	1	MOD	NO	UNR	Yes	No
	Palpitation	HEART PALPITATION {ONE TIME ONLY}	18MAY96	164, 107, -74	1 Mins	0	1	MIL	NO	PBU	No	No
329.007.00141	Sinusitis	SINUS HEADACHE	07JAN96	32, -26, -206	5 Days	0	CON	MOD	NO	UNR	No	No
	Tooth Disorder	ORTHODONTIC PAIN	02JUL96	209, 152, -29	5 Days	0	CON	SEV	NO	UNR	Yes	No
	Vomiting	EMESIS	07JAN96	32, -26, -206	1 Mins	0	1	MOD	NO	UNR	No	No
	Angina Pectoris	ANGINA ON EXERTION	13SEP95	-8, ., -29	30 Days	0	2	MOD	STP	PBU	No	No
	Headache	HEADACHE	14JAN96	39, -18, -18	2 Days	0	1	MIL	NO	PSR	Yes	No
329.007.00266	Headache	HEADACHE	08MAR96	2, ., -69	04:00 Hrs	0	1	SEV	NO	PSR	No	No
	Hyperkinesia	AKATHISIA	11MAR96	5, ., -66	46 Days	0	CON	MIL	NO	REL	No	No
	Nausea	NAUSEA	08MAR96	2, ., -69	04:00 Hrs	0	1	MIL	NO	PSR	No	No
	Pharyngitis	SORE THROAT	27APR96	52, ., -19	13 Days	0	CON	MOD	NO	UNR	Yes	No
329.007.00267	Abdominal Pain	STOMACH ACHE,NO VOMITING	16MAY96	71, ., 15	04:00 Hrs	0	CON	MOD	NO	PBU	No	No
	Headache	HEADACHE	06MAR96	-1, ., -56	01:00 Hrs	0	1	MOD	NO	PSR	No	No

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Appendix D.2

Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

----- Treatment Group=PLACEBO -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Rel	Corr Ther	SAE
329.007.00311	Abdominal Pain	ABDOMINAL PAIN	09OCT96	7, -54,-197	01:00 Hrs	0	CON	MIL	NO	UNR	Yes	No
	Arthralgia	KNEE PAIN (RIGHT KNEE)	18NOV96	47, -14,-157	5 Days	0	CON	MOD	NO	UNR	Yes	No
	Bronchitis	BRONCHITIS BRONCHITIS SYMPTOMS: CONGESTION, COUGH	17MAR97	166, 106, -38	15 Days	0	CON	MOD	NO	UNR	Yes	No
			22OCT96	20, -41,-184	12 Days	0	CON	MOD	NO	UNR	Yes	No
	Diarrhea	DIARRHEA	18OCT96	16, -45,-188	02:00 Hrs	0	1	MIL	NO	UNR	No	No
			23JAN97	113, 53, -91	2 Days	0	12	MOD	NO	UNR	Yes	No
	Infection	FLU SYMPTOMS	23JAN97	113, 53, -91	2 Days	0	CON	MOD	NO	UNR	Yes	No
	Nausea	NAUSEA	18OCT96	16, -45,-188	02:00 Hrs	0	1	MIL	NO	UNR	No	No
Sinusitis	SINUS CONGESTION SINUSITIS	26DEC96	85, 25,-119	2 Days	0	CON	MIL	NO	UNR	Yes	No	
		23OCT96	21, -40,-183	31 Days	0	CON	MIL	NO	UNR	Yes	No	
Vomiting	VOMITING	23JAN97	113, 53, -91	2 Days	0	12	MOD	NO	UNR	Yes	No	
329.008.00158	Breast Pain	BREAST SORENESS {FEMALE}	12SEP95	-1, -63,-106	16 Days	0		MIL	NO	UNR	No	No
329.008.00162	Asthenia	DROP IN ENERGY	20DEC95	50, -16,-210	8 Days	0	1	MIL	INC	PSR	No	No
	Bronchitis	BRONCHITIS	29NOV95	29, -37,-231	11 Days	0	1	MIL	NO	UNR	No	No
	Eye Disorder	EYE INFECTION	07DEC95	37, -29,-223	11 Days	0	1	MIL	NO	UNR	No	No
	Insomnia	DROP IN SLEEP	20DEC95	50, -16,-210	8 Days	0	1	MIL	INC	PSR	No	No
329.008.00191	Decreased Appetite	APPETITE DOWN	03FEB96	3, -59,-131	Not Stated	0	CON	MIL	NO	PSR	No	No
	Nervousness	RESTLESS AND JUMPY	28FEB96	28, -34,-106	Not Stated	0	CON	MIL	NO	PSR	No	No

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Listing of Adverse Experiences by Treatment Group and Patient
Intent-to-Treat Population

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Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.008.00191	Somnolence	SLEEPINESS	03FEB96	3, -59, -131	Not Stated	0	CON	MOD	NO	PSR No	No
329.009.00128	Bundle Branch Block	RIGHT BUNDLE BRANCH BLOCK	18APR95	8, ., -14	Not Stated	0	CON	MIL	STP	PSR No	No
329.009.00135	Diarrhea	DIARRHEA	21OCT95	20, ., -29	1 Days	0	CON	MIL	NO	UNR No	No
	Nausea	NAUSEA	21OCT95	20, ., -29	2 Days	0	CON	MIL	NO	UNR No	No
	Postural Hypotension	ORTHOSTATIC HYPOTENSION	30OCT95	29, ., -20	21 Days	0	CON	MIL	NO	PSR No	No
	Vomiting	VOMITING	21OCT95	20, ., -29	2 Days	0	CON	MIL	NO	UNR No	No
329.009.00136	Contact Dermatitis	CONTACT DERMATITIS LOWER AND UPPER HIP	10OCT95	8, ., -62	15 Days	0	CON	MIL	NO	PBU No	No
	Headache	HEADACHE	04NOV95	33, ., -37	11 Days	0	3	MIL	NO	PBU Yes	No
	Thirst	INCREASE IN THIRST	10OCT95	8, ., -62	15 Days	0	CON	MIL	NO	PSR No	No
329.009.00169	Dizziness	SLIGHT DIZZINESS WHEN TAKING MEDS	19DEC95	50, -16, -47	Not Stated	0	CON	MOD	NO	PSR No	No
	Infection	SCABIES	03DEC95	34, -32, -63	13 Days	0	CON	MOD	NO	UNR Yes	No
	Insomnia	MILD INITIAL INSOMNIA	12DEC95	43, -23, -54	Not Stated	0	CON	MIL	NO	PSR No	No
	Manic Reaction	HYPOMANIA	02JAN96	64, -2, -33	Not Stated	0	CON	SEV	STP	REL No	No
	Somnolence	DAYTIME SLEEPINESS	22NOV95	23, -43, -74	17 Days	0		MIL	NO	PSR No	No
329.009.00174	Constipation	CONSTIPATION	10DEC95	20, -38, -65	Not Stated	0		MIL	NO	PSR No	No

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----- Treatment Group=PLACEBO -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel	Ther SAE
329.009.00174	Headache	HEADACHE	03DEC95	13, -45, -72	Not Stated	0		MOD	NO	PSR	Yes No
	Infection	FLU (STOMACH ACHE)	03DEC95	13, -45, -72	5 Days	0	CON	MIL	NO	UNR	Yes No
329.009.00197	Dizziness	DIZZY	18JAN96	21, -34, -227	1 Days	0	CON	MIL	NO	PBU	No No
	Nausea	NAUSEA	20AUG96	236, 182, -12	4 Days	0		MOD	NO	UNR	No No
	Trauma	SCALP LACERATIONS (TOP OF HEAD)	17JUN96	172, 118, -76	2 Days	0	CON	MOD	NO	UNR	Yes No
	Vomiting	VOMITING	20AUG96	236, 182, -12	4 Days	0		3 MIL	NO	UNR	No No
329.009.00198	Abnormal Dreams	NIGHTMARE	03JAN96	2, ., -66	7 Days	0		6 MOD	NO	PSR	No No
	Asthenia	FATIGUE	03JAN96	2, ., -66	Not Stated	0	CON	MOD	NO	PSR	No No
	Nausea	NAUSEA	08JAN96	7, ., -61	13 Days	0	CON	MIL	NO	PSR	No No
	Nervousness	RESTLESSNESS	16JAN96	15, ., -53	8 Days	0	CON	MIL	NO	PSR	No No
	Trauma	FACIAL CUTS {LEFT CHEEK}	18FEB96	48, ., -20	1 Days	0	CON	MOD	NO	UNR	Yes No
329.009.00200	Av Block	SINUS ARRHYTHMIA (MOBITZ I)	06FEB96	15, ., -42	43 Days	0		2 MIL	NO	PBU	No No
	Nausea	NAUSEA	20FEB96	29, ., -28	9 Days	0	CON	MIL	NO	PSR	No No
	Rash	NON PAPULAR RASH (UPPER TORSO AND BACK)	19MAR96	57, ., 0	Not Stated	0	CON	MIL	NO	PBU	No No
	Thirst	INCREASE IN THIRST	12FEB96	21, ., -36	3 Days	0	CON	MIL	NO	PSR	No No

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Intent-to-Treat Population

----- Treatment Group=PLACEBO -----

Patient ID	Preferred Term	Verbatim Term	AE Onset Date	Relative Days *	Duration	Onset Dose (mg)	No. Epi	Inv Int	Act- ion	Inv Corr Rel Ther	SAE
329.009.00202	Abdominal Pain	STOMACH ACHES IN AM	08MAR96	18, ..	-18 12 Days	0	CON	MOD	NO	PSR No	No
		STOMACH CRAMPS (VIRAL)	22FEB96	3, ..	-33 3 Days	0	CON	MIL	NO	PBU No	No
	Diarrhea	DIARRHEA (VIRAL)	22FEB96	3, ..	-33 3 Days	0	CON	MIL	NO	PBU No	No
329.009.00238	Abnormal Dreams	VIVID DREAMING	26NOV96	15, ..	-54 8 Days	0	CON	MIL	NO	PSR No	No
	Av Block	SERIAL INCREASE PR INTERVAL	26NOV96	15, ..	-54 15 Days	0	CON	MIL	NO	PSR No	No
	Cough Increased	COUGH	23DEC96	42, ..	-27 9 Days	0	CON	MIL	NO	UNR Yes	No
	Headache	INCREASE HEADACHE	03DEC96	22, ..	-47 Not Stated	0	CON	MOD	NO	PSR Yes	No
	Nausea	NAUSEA	03DEC96	22, ..	-47 Not Stated	0	CON	MIL	NO	PSR No	No
	Pharyngitis	SORE THROAT	23DEC96	42, ..	-27 9 Days	0	CON	MIL	NO	UNR Yes	No
	Rhinitis	CONGESTION {NOSE}	23DEC96	42, ..	-27 9 Days	0	CON	MIL	NO	UNR Yes	No
329.009.00276	Decreased Appetite	DECREASED APPETITE	18MAR97	57, ..	-14 Not Stated	0	CON	MIL	NO	PSR No	No
	Fever	FEVER	13MAR97	52, ..	-19 6 Days	0	CON	MIL	NO	PBU Yes	No
	Headache	HEADACHES	04FEB97	15, ..	-56 15 Days	0	CON	MIL	NO	PSR No	No
	Infection	STOMACH VIRUS	31MAR97	70, ..	-1 2 Days	0	CON	MIL	NO	PSR Yes	No
	Nausea	NAUSEA	04FEB97	15, ..	-56 29 Days	0	CON	MIL	NO	PSR No	No
	Pharyngitis	SORE THROAT	20FEB97 13MAR97	31, .. 52, ..	-40 -19	12:00 Hrs 6 Days	0 0	CON CON	MIL MIL	NO NO	PBU No PBU Yes

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329.009.00276	Weight Loss	WEIGHT LOSS	13MAR97	52, .. -19	20 Days	0	CON	MIL	NO	PSR No	No
329.009.00302	Maculopapular Rash	RASH ON WRIST ELBOWS, ANKLE, (MACULOPAPULAR)	03APR96	8, .. -7	Not Stated	0	CON	MOD	STP	PSR No	No
	Nodal Arrhythmia	JUNCTIONAL ESCAPE PATTERN (EKG)	03APR96	8, .. -7	Not Stated	0	CON	MIL	NO	PSR No	No
329.009.00306	Anemia	ANEMIA	03JUN96	-8, .. -77	Not Stated	0	CON	MIL	NO	UNR Yes	No
	Vasodilatation	HOT FLASHES	02JUL96	22, .. -48	50 Days	0	CON	MIL	NO	PSR No	No
329.009.00312	Back Pain	BACKACHES	06JAN97	64, .. -14	15 Days	0	CON	MIL	NO	PBU No	No
	Headache	INCREASE IN HEADACHES	27DEC96	54, .. -24	Not Stated	0		MOD	NO	PSR Yes	No
329.009.00330	Bradycardia	SINUS BRADYCARDIA	28OCT96	8, .. -7	8 Days	0	CON	MIL	NO	PSR No	No
	Dizziness	DIZZINESS	21OCT96	1, .. -14	Not Stated	0	CON	MOD	STP	REL No	No
	Heart Malformation	POSSIBLE LEFT VENTRICULAR HYPERTROPHY	28OCT96	8, .. -7	8 Days	0	CON	MIL	NO	PSR No	No
	Nausea	NAUSEA	21OCT96	1, .. -14	Not Stated	0	CON	MOD	STP	REL No	No
	Supraventricular Extrasystoles	OCCASIONAL PREMATURE ATRIAL COMPLEXES	28OCT96	8, .. -7	8 Days	0	CON	MIL	NO	PSR No	No
	Vomiting	VOMITING	01NOV96	12, .. -3	2 Days	0		2 MIL	STP	PSR No	No

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329.010.00263	Abdominal Pain	STOMACH ACHE HEADACHE {SIMULTANEOUS} [STOMACH ACHE]	08SEP96	31, .. -41	10 Mins	0	1	MIL	NO	PSR	No
	Arthralgia	SHOULDER PAIN RIGHT SHOULDER	11SEP96	34, .. -38	12:00 Hrs	0	1	MIL	NO	UNR	No
	Back Pain	BACK ACHE	07SEP96	30, .. -42	06:00 Hrs	0	1	MIL	NO	UNR	No
	Headache	HEADACHE	14AUG96	6, .. -66	03:00 Hrs	0	1	MIL	NO	PBU	Yes
			17AUG96	9, .. -63	02:00 Hrs	0	1	MIL	NO	PBU	Yes
			04SEP96	27, .. -45	15 Mins	0	1	MIL	NO	PBU	No
		STOMACH ACHE HEADACHE {SIMULTANEOUS} [HEADACHE]	08SEP96	31, .. -41	10 Mins	0	1	MIL	NO	PSR	No
	Pain	SIDE ACHE LEFT SIDE	10SEP96	33, .. -39	01:30 Hrs	0	1	MIL	NO	UNR	Yes
	Respiratory Disorder	COLD AND CONGESTION	22SEP96	45, .. -27	8 Days	0	CON	MIL	NO	UNR	Yes
	Ulcerative Stomatitis	MOUTH SORES	06OCT96	59, .. -13	8 Days	0	CON	MIL	NO	UNR	No
329.010.00277	Headache	HEADACHE	06AUG96	159, 103, 46	02:00 Hrs	0	1	MIL	NO	UNR	Yes
329.010.00282	Back Pain	BACKACHE	15AUG96	21, .. -58	12 Days	0	CON	MIL	NO	UNR	Yes
	Diarrhea	DIARRHEA	19SEP96	56, .. -23	6 Days	0	20	MOD	NO	PSR	No
	Dysmenorrhea	CRAMPS (MENSTRUAL)	19SEP96	56, .. -23	12:00 Hrs	0	CON	MIL	NO	PBU	Yes
	Headache	HEADACHE	02SEP96	39, .. -40	30 Mins	0	1	MOD	NO	PBU	Yes

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329.011.00164	Back Pain	BACKACHE	11JAN96	21, ., -15	01:00 Hrs	0	1	MIL	NO	UNR	Yes No
	Dizziness	DIZZINESS	24JAN96	34, ., -2	06:00 Hrs	0	7	MIL	NO	PSR	No No
	Headache	HEADACHE	11JAN96	21, ., -15	01:00 Hrs	0	1	MIL	NO	PBU	Yes No
329.011.00210	Arrhythmia	SINUS ARRHYTHMIA	24OCT96	27, -40, -40	40 Days	0	2	MIL	NO	PBU	No No
	Asthenia	FATIGUE	24OCT96	27, -40, -40	12 Days	0	CON	MIL	NO	PSR	No No
	Chest Pain	CHEST PAIN	03OCT96	6, -61, -61	20 Mins	0	1	MIL	NO	PBU	No No
	Headache	HEADACHE	03OCT96	6, -61, -61	20 Mins	0	1	MIL	NO	PBU	No No
329.011.00285	Tooth Disorder	TOOTHACHE	04JUN96	18, ., -57	Not Stated	0	CON	MOD	NO	UNR	Yes No
329.012.00027	Anxiety	ANXIETY	21DEC95	16, ., -21	Not Stated	0	CON	MOD	NO	PBU	Yes No
	Back Pain	NECK SPASM	21DEC95	16, ., -21	Not Stated	0	CON	MOD	NO	PBU	Yes No
	Otitis Media	OTITIS MEDIA (EAR INFECTION)	26NOV95	-10, ., -46	12 Days	0	CON	MOD	NO	UNR	Yes No
	Respiratory Disorder	COMMON COLD	15DEC95	10, ., -27	13 Days	0	CON	SEV	NO	UNR	Yes No
329.012.00217	Asthma	RECURRENT ASTHMA	15JUN96	26, ., 1	5 Days	0	CON	MOD	NO	UNR	Yes No
	Depression	DEPRESSION (WORSENING)	19JUN96	30, ., 5	8 Days	0	CON	SEV	NO	UNR	Yes Yes
	Infection	FLU	13JUN96	24, ., -1	7 Days	0	CON	MOD	STP	UNR	Yes No
	Respiratory Disorder	COMMON COLD	03JUN96	14, ., -11	10 Days	0	CON	MIL	NO	UNR	Yes No

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329.012.00218	Headache	HEADACHE (MODERATE)	08JUN96	-8, -66, -115	02:00 Hrs	0	1	MOD	NO	UNR	Yes	No
			11JUL96	26, -33, -82	01:00 Hrs	0	1	MOD	NO	UNR	Yes	No
329.012.00224	Arthralgia	LEFT KNEE PAIN	03OCT96	18, -49, -149	18:00 Hrs	0	CON	MIL	NO	UNR	No	No
	Dysmenorrhea	MENSTRUAL CRAMPS	09OCT96	24, -43, -143	Not Stated	0		MOD	NO	UNR	Yes	No
	Infection	STREP THROAT	08DEC96	84, 18, -83	11 Days	0	CON	MIL	NO	UNR	Yes	No
	Insomnia	DIFFICULTY FALLING TO SLEEP	01JAN97	108, 42, -59	1 Days	0	1	MIL	NO	PBU	Yes	No
	Respiratory Disorder	COLD SYMPTOMS	22SEP96	7, -60, -160	11 Days	0	CON	MIL	NO	UNR	No	No
	Tooth Disorder	TOOTHACHE	01OCT96	16, -51, -151	1 Days	0	CON	MIL	NO	UNR	Yes	No
329.012.00225	Asthma	BRONCHOSPASM	29MAR97	124, 60, -134	11 Days	0	CON	MOD	NO	UNR	Yes	No
	Hypesthesia	NUMB LEFT UPPER LEG	20MAR97	115, 51, -143	1 Days	0	1	MIL	NO	PBU	No	No
	Lymphadenopathy	SLIGHTLY ENLARGED NON-TENDER LEFT JUGULO-DIGASTRIC NODE	04APR97	130, 66, -128	59 Days	0	1	MIL	NO	UNR	No	No
	Otitis Media	EAR INFECTION LEFT	29MAR97	124, 60, -134	11 Days	0	CON	MOD	NO	UNR	Yes	No
	Trauma	SPRAINED WRIST LEFT	15JUL97	232, 168, -26	Not Stated	0	CON	MIL	NO	UNR	Yes	No

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