

## **APPENDIX A**

### **SUMMARY TABLES OF HEALTHY VOLUNTEER ADVERSE EVENT DATA**

[Table 1](#): List of Phase I studies included in this Appendix

[Table 2](#): Group 1 - Percentage of Volunteers Reporting Adverse Events from Single Dose Studies.

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**Table 1 List of Phase I studies included in this Appendix**

**Group 1**

DFG310, DFG311, HP/80/102, HP/80/98, HP/80/99, HP/82/125, HP/82/14, HP/82/157, HP/82/22, HP/82/59, HP/82/86, HP/83/102, HP/83/76, HP/83/81, HP/83/88, HP/84/10, HP/84/121, HP/84/39, HP/84/54, HP/84/57, HP/84/74, HP/84/78, HP/85/2, HP/85/3, HP/85/33, HP/85/70, HP/86/63, HP/86/78, HP/87/88, HPG/04/85, HPG/26/84, HPG/34/84, HPG/37/84, HPG/50/82, HPG/19/83, HPG/19/84, HPG/242/84, HPG/25/83, HPG/282/86, HPG/20/84, HPG/33+35/83, HPG/51/82, HPG/1-01/85, HPG/1-10/85, HPG/2-250/85, MD/PAR/001, MD/PAR/001B, MD/PAR/001C, MD/PAR/011, MD/PAR/011A, MD/PAR/017B, MD/PAR/033, MD/PAR/048, MDUK/015, MDUK/015B, MDUK/PAR/051, MDUK/PAR/052, PAR08.01, PAR10.01, PAR12.01, PAR13.01, PAR14.01, PAR15.01, PAR16.01 **(TOTAL: 64 studies)**

**Group 2**

29060/294, 29060/360, 29060/418, 29060/440, 29060/663, 29060/664, 29060/105, 29060/110, 29060/113, 29060/243, 29060/125, 29060/303, 29060/374, 29060/419, 29060/533, 29060/486 **(TOTAL: 16 studies)**

**Group 3**

29060/452, 29060/472, 29060/473, 29060/474, 29060/480, 29060/485, 29060/505, 29060/539, 29060/563, 29060/564 **(TOTAL: 10 studies)**

**GRAND TOTAL: 90 studies**

**Table 2: Group 1 - Percentage of Volunteers Reporting Adverse Events from Single Dose Studies**

Number of subjects	Placebo 83	Paroxetine					
		15 mg 17	20 mg 25	30 mg 205	40 mg 29	50 mg 8	60 mg 28
<b>Nervous System</b>							
Reflexes increased	-	-	12	2	21	-	14
Anxiety	4	-	4	2	7	13	7
Dizziness	6	-	4	5	17	25	7
Insomnia	-	-	8	1	10	63	4
Myoclonus	-	-	8	2	17	-	11
Nervousness	-	-	4	1	3	-	4
Heel/Toe gait abnormality	-	-	8	1	14	-	11
Faciculations	-	-	8	1	10	-	18
Babinski sign positive	-	-	-	1	-	-	-
Agitation	-	-	-	1	-	25	-
Incoordination	-	-	-	1	-	-	4
Amnesia	-	-	-	1	-	-	-
CNS stimulation	-	-	-	1	-	-	-
Confusion	-	-	-	1	-	-	-
Euphoria	-	-	-	2	-	-	-
Emotional lability	-	-	-	1	-	-	4
Somnolence	10	-	-	13	3	-	14
Tremor	-	-	-	1	7	-	7
Speech disorder	-	-	-	1	-	-	-
Vertigo	-	-	-	1	-	-	18
Paraesthesia	-	-	-	1	-	13	4
Lack of emotion	-	-	-	2	-	-	-
Concentration impaired	1	-	-	3	3	-	7
Drugged feeling	-	-	-	2	-	13	-
Positive Romberg test	-	-	-	-	3	-	-
Depression	-	-	-	-	-	-	4
Dystonia	-	-	-	-	-	-	4

N.B – Indicate no event reported

**Table 2 (Cont.): Group 1 - Percentage of Volunteers Reporting Adverse Events from Single Dose Studies**

Number of subjects	Placebo 83	Paroxetine					
		15 mg 17	20 mg 25	30 mg 205	40 mg 29	50 mg 8	60 mg 28
<b>Digestive System</b>							
Nausea	2	6	4	18	24	25	46
Vomiting	4	6	-	-	14	-	21
Dyspepsia	-	-	4	1	7	-	-
Flatulence	1	-	4	4	-	-	7
Diarrhoea	4	-	12	17	24	38	29
Increased appetite	-	-	-	1	-	-	-
Decreased appetite	-	-	-	2	-	13	4
Dry mouth	5	-	-	3	-	25	14
Increased salivation	-	-	-	1	-	-	-
Dysphagia	-	-	-	2	-	-	-
Constipation	-	-	-	1	-	-	-
<b>Body as a Whole</b>							
Asthenia	6	-	4	16	-	50	36
Hyperthermia	-	-	4	-	3	-	7
Headache	12	-	12	18	14	-	29
Abdominal pain	1	-	4	2	14	-	7
Fever	-	-	-	1	3	-	4
Malaise	-	-	-	1	-	13	4
Pain	1	-	-	1	-	-	-
Neck pain	-	-	-	1	-	-	-
Chest pain	-	-	-	-	3	-	-
Chills	-	-	-	-	-	-	4
Flu syndrome	-	-	-	1	-	-	-

N.B – Indicate no event reported

**Table 2 (Cont.): Group 1 - Percentage of Volunteers Reporting Adverse Events from Single Dose Studies**

Number of subjects	Placebo 83	Paroxetine					
		15 mg 17	20 mg 25	30 mg 205	40 mg 29	50 mg 8	60 mg 28
<b>Cardiovascular system</b>							
Hypertension	-	-	4	1	10	-	11
Vasodilation	-	-	-	4	3	-	-
Syncope	-	-	-	-	-	13	-
Palpitation	-	-	-	-	-	-	4
Tachycardia	-	-	-	-	-	-	7
<b>Respiratory System</b>							
Yawn	-	-	-	1	-	25	11
Respiratory disorder	-	-	-	2	-	-	-
Epistaxis	-	-	-	1	-	-	-
Pharyngitis	1	-	-	-	-	-	-
<b>Skin and Appendages</b>							
Rash	-	-	16	2	24	-	11
Sweating	2	-	-	1	3	-	4
<b>Special Senses</b>							
Anisocoria	-	-	4	1	7	-	-
Mydriasis	-	-	8	1	21	-	11
Eye disorder	4	-	-	1	-	-	4
Eye pain	-	-	-	1	-	-	4
Intraocular pressure disorder	-	-	-	1	-	-	-
Taste peversion	-	-	-	1	-	25	-
Special senses disorder	-	-	-	1	-	-	-
Blurred vision	6	-	-	2	-	-	-
Pupillary disorder	-	-	-	-	3	-	-
<b>Urogenital System</b>							
Male genital disorder	-	-	-	1	-	-	-
<b>Metabolic and Nutritional Disorders</b>							
Thirst	-	-	-	1	-	-	-

N.B – Indicate no event reported

**Table 3: Group 1 - Percentage of Volunteers Reporting Adverse Events from Repeat Dose Studies**

	Placebo							Number of subjects	Paroxetine						
	Predose n=65	Wk 1 65	Wk 2 21	Wk 3 20	Wk 4 8	Wk 4+ 2	Follow-up 53		Predose 110	Wk 1 110	Wk 2 91	Wk 3 62	Wk 4 31	Wk 4+ 16	Follow-up 107
<b>Nervous System</b>								<b>Nervous System</b>							
Amnesia	-	2	-	-	-	-	-	Amnesia	-	7	1	-	-	-	2
CNS stimulation	-	3	5	5	-	-	-	CNS stimulation	1	6	1	-	-	-	6
Depersonalisation	-	3	5	-	-	-	-	Depersonalisation	-	6	1	3	-	-	5
Dizziness	-	11	-	5	-	-	-	Dizziness	-	25	6	5	10	-	18
Abnormal dreams	-	2	-	-	-	-	4	Abnormal dreams	-	-	-	2	-	-	15
Emotional lability	-	6	10	5	-	-	-	Emotional lability	1	10	3	2	3	-	8
Insomnia	-	12	5	15	-	-	2	Insomnia	3	25	11	5	10	6	17
Hyperonia	-	2	-	-	-	-	-	Hyperonia	-	-	-	-	-	-	-
Somnolence	-	25	10	5	25	-	2	Somnolence	1	38	19	13	7	6	13
Tremor	-	3	-	-	-	-	-	Tremor	-	15	4	5	3	-	6
Concentration impaired	-	15	10	-	13	-	2	Concentration impaired	-	19	6	2	3	-	11
Libido decreased	-	-	-	-	-	-	-	Libido decreased	-	2	-	-	-	-	-
Withdrawn	-	-	-	-	-	-	-	Withdrawn	-	2	-	-	-	-	-
Agitation	-	-	-	-	-	-	-	Agitation	-	11	1	3	-	-	3
Anxiety	-	-	-	-	-	-	-	Anxiety	-	3	-	-	-	-	4
Depression	-	-	-	-	-	-	-	Depression	-	2	-	-	-	-	1
Parasthesia	-	-	-	-	-	-	-	Parasthesia	-	2	-	-	-	-	2
Diplopia	-	-	-	-	-	-	-	Diplopia	-	1	-	2	-	-	-
Abnormal gait	-	-	-	-	-	-	-	Abnormal gait	-	-	1	-	-	-	1
Dyskinesia	-	-	-	-	-	-	-	Dyskinesia	-	-	-	2	-	-	-
Confusion	-	-	-	-	-	-	-	Confusion	-	-	-	-	-	-	1

- = No event reported

All dose levels of paroxetine totalled

**Table 3 (Cont.): Group 1 - Percentage of Volunteers Reporting Adverse Events from Repeat Dose Studies**

	Placebo							Number of subjects	Paroxetine						
	Predose n=65	Wk 1 65	Wk 2 21	Wk 3 20	Wk 4 8	Wk 4+ 2	Follow-up 53		Predose 110	Wk 1 110	Wk 2 91	Wk 3 62	Wk 4 31	Wk 4+ 16	Follow-up 107
<b>Digestive System</b>								<b>Digestive System</b>							
Dyspepsia	-	2	-	-	-	-	-	Dyspepsia	-	1	1	3	-	-	-
Flatulence	-	9	-	-	-	-	-	Flatulence	-	11	-	2	-	-	5
Nausea	-	6	-	-	-	-	-	Nausea	1	39	7	5	3.2	-	8
Decreased appetite	-	2	5	-	-	-	2	Decreased appetite	-	3	-	-	-	-	1
Dry mouth	-	6	-	-	-	-	-	Dry mouth	-	14	-	2	-	6	1
Constipation	-	2	-	-	-	-	-	Constipation	-	4	1	-	-	-	1
Diarrhoea	-	8	-	-	-	-	2	Diarrhoea	-	14	1	5	-	-	4
Glossitis	-	-	-	5	-	-	2	Glossitis	-	2	1	2	-	-	-
Eructation	-	-	-	-	-	-	-	Eructation	-	1	-	-	-	-	-
Increased appetite	-	-	-	-	-	-	-	Increased appetite	-	2	-	-	-	-	1
Gastrointestinal disorder	-	-	-	-	-	-	-	Gastrointestinal disorder	-	1	-	-	-	-	-
Vomiting	-	-	-	-	-	-	-	Vomiting	-	2	-	-	-	-	2
Gingivitis	-	-	-	-	-	-	-	Gingivitis	-	1	-	-	-	-	-
Mouth ulceration	-	-	-	-	-	-	-	Mouth ulceration	-	1	-	3	-	-	-
Increased salivation	-	-	-	-	-	-	-	Increased salivation	-	2	-	-	-	-	-
Bruxism	-	-	-	-	-	-	-	Bruxism	-	1	1	-	-	-	-
<b>Body as a Whole</b>								<b>Body as a Whole</b>							
Asthenia	2	11	14	5	-	-	2	Asthenia	-	22	6	2	3	-	5
Chills	2	2	5	-	-	-	2	Chills	-	6	2	3	3	-	1
Malaise	2	9	10	-	-	50	6	Malaise	-	14	9	5	7	-	9
Headache	5	25	19	10	25	-	4	Headache	-	31	17	18	3	-	17
Pain	-	2	-	5	-	-	-	Pain	-	4	-	2	3	-	1
Chest pain	-	5	5	-	-	50	-	Chest pain	-	2	-	-	3	-	-
Abdominal pain	-	3	5	-	-	-	2	Abdominal pain	-	6	1	-	-	-	2
Back pain	-	2	-	-	-	-	-	Back pain	-	-	-	-	-	-	1
Abdominal disorder	-	-	-	-	-	-	-	Abdominal disorder	-	1	-	-	-	-	-
Flu syndrome	-	-	-	-	-	-	-	Flu syndrome	-	-	-	-	-	-	1

- = No event reported

All dose levels of paroxetine totalled

**Table 3 (Cont.): Group 1 - Percentage of Volunteers Reporting Adverse Events from Repeat Dose Studies**

	Placebo							Number of subjects	Paroxetine						
	Predose n=65	Wk 1 65	Wk 2 21	Wk 3 20	Wk 4 8	Wk 4+ 2	Follow-up 53		Predose 110	Wk 1 110	Wk 2 91	Wk 3 62	Wk 4 31	Wk 4+ 16	Follow-up 107
<b>Cardiovascular System</b>								<b>Cardiovascular System</b>							
Vasodilation	2	8	-	-	-	-	-	Vasodilation	-	10	3	-	-	-	4
Palpitation	-	3	-	-	-	-	-	Palpitation	-	1	-	-	-	-	1
<b>Respiratory System</b>								<b>Respiratory System</b>							
Sputum increased	11	3	-	5	-	-	-	Sputum increased	-	4	3	2	-	-	1
Cough increased	15	6	5	5	-	50	2	Cough increased	-	3	4	2	-	-	2
Dyspnoea	3	-	-	-	-	-	-	Dyspnoea	-	3	3	-	-	-	1
Respiratory disorder	5	-	-	5	-	-	-	Respiratory disorder	-	1	-	-	-	-	-
Pharyngitis	2	2	5	5	-	50	2	Pharyngitis	-	1	2	2	-	-	2
Asthma	2	-	5	-	-	-	-	Asthma	-	2	-	-	-	-	1
Rhinitis	-	3	5	-	-	50	2	Rhinitis	-	9	4	-	-	-	2
Respiratory flu	-	2	5	-	-	-	-	Respiratory flu	-	-	1	-	-	-	3
Yawn	-	-	-	-	-	-	-	Yawn	-	9	1	-	-	-	-
Epistaxis	-	-	-	-	-	-	-	Epistaxis	-	1	-	-	-	-	-
<b>Skin and Appendages</b>								<b>Skin and Appendages</b>							
Sweating	-	9	-	-	-	-	-	Sweating	-	5	2	3	3	-	4
Pruritis	-	-	-	-	-	-	-	Pruritis	-	2	-	-	-	-	1
Dry skin	-	-	-	-	-	-	-	Dry skin	-	1	-	2	-	-	-
Rash	-	-	-	-	-	-	-	Rash	-	2	1	-	-	-	1

- = No event reported

All dose levels of paroxetine totalled



**Table 3 (Cont.): Group 1 - Percentage of Volunteers Reporting Adverse Events from Repeat Dose Studies**

	Placebo							Number of subjects	Paroxetine						
	Predose n=65	Wk 1 65	Wk 2 21	Wk 3 20	Wk 4 8	Wk 4+ 2	Follow-up 53		Predose 110	Wk 1 110	Wk 2 91	Wk 3 62	Wk 4 31	Wk 4+ 16	Follow-up 107
<b>Special Senses</b>								<b>Special Senses</b>							
Taste peversion	2	6	5	5	-	-	-	Taste peversion	-	8	2	2	-	-	2
Eye disorder	-	-	-	-	-	-	-	Eye disorder	-	1	-	-	-	-	-
Eye pain	-	-	-	-	-	-	-	Eye pain	-	1	-	-	-	-	1
Conjunctivitis	-	-	-	-	-	-	-	Conjunctivitis	-	1	-	-	-	-	-
Hearing disorder	-	-	-	-	-	-	-	hearing disorder	-	1	-	2	-	-	-
Eye appendage disorders	-	-	-	-	-	-	-	Eye appendage disorders	-	-	1	-	-	-	-
Blurred Vision	-	-	-	-	-	-	-	Blurred Vision	-	8	2	-	-	-	-
Ear Disorder	-	-	-	-	-	-	-	Ear Disorder	-	-	-	-	-	-	1
<b>Urogenital System</b>								<b>Urogenital System</b>							
Urination Impaired	-	2	-	-	-	-	-	Urination Impaired	-	4	1	-	-	-	-
Urine Abnormality	-	3	-	-	-	-	-	Urine Abnormality	-	1	-	-	-	-	-
Dysmenorrhea	-	2	-	-	-	-	-	Dysmenorrhea	-	-	-	-	-	-	-
Abnormal Ejaculation	-	-	-	-	-	-	-	Abnormal Ejaculation	1	5	3	-	-	-	-
Male Genital Disorders	-	-	-	-	-	-	-	Male Genital Disorders	-	9	10	-	-	-	1
Female Genital Disorders	-	-	-	-	-	-	-	Female Genital Disorders	-	-	1	-	-	-	-
Urinary Frequency	-	-	-	-	-	-	-	Urinary Frequency	-	-	-	2	-	-	1
Polyuria	-	-	-	-	-	-	-	Polyuria	-	-	-	-	-	-	1
<b>Endocrine System</b>								<b>Endocrine System</b>							
Testes disorder	-	-	-	-	-	-	-	Testes disorder	-	-	1	-	-	-	-
<b>Metabolic and Nutritional Disorders</b>								<b>Metabolic and Nutritional Disorders</b>							
Thirst	2	6	5	5	13	-	-	Thirst	-	5	1	3	3	6	6
<b>Musculo-Skeletal System</b>								<b>Musculo-Skeletal System</b>							
Arthralgia	2	2	-	-	-	-	-	Arthralgia	-	1	1	-	3	-	1

- = No event reported

All dose levels of paroxetine totalled

**Table 4: Group 2 - Single Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Paroxetine Treatment Group							
Preferred Term	Body System	Severity	20mg		30mg		40mg		All	
			N	%	N	%	N	%	N	%
	Total Subject Sessions		96	100.0	57	100.0	97	100.0	250	100.0
	Subject Sessions with one or more AEs		52	54.2	42	73.7	81	83.5	175	70.0
Headache	Central and Peripheral Nervous System	Mild	19	19.8	11	19.3	19	19.6	49	19.6
		Moderate	5	5.2	9	15.8	10	10.3	24	9.6
		Severe	1	1.0	-	-	-	-	1	0.4
		All	25	26.0	20	35.1	29	29.9	74	29.6
Diarrhoea	Gastrointestinal System	Mild	3	3.1	19	33.3	23	23.7	45	18.0
		Moderate	-	-	6	10.5	16	16.5	22	8.8
		Severe	-	-	4	7.0	3	3.1	7	2.8
		All	3	3.1	29	50.9	42	43.3	74	29.6
Nausea	Gastrointestinal System	Mild	7	7.3	10	17.5	24	24.7	41	16.4
		Moderate	-	-	2	3.5	8	8.2	10	4.0
		All	7	7.3	12	21.1	32	33.0	51	20.4
Fatigue	Body as a Whole General	Mild	9	9.4	1	1.8	11	11.3	21	8.4
		Moderate	2	2.1	-	-	2	2.1	4	1.6
		All	11	11.5	1	1.8	13	13.4	25	10.0
Dizziness	Central and Peripheral Nervous System	Mild	3	3.1	5	8.8	7	7.2	15	6.0
		Moderate	-	-	-	-	1	1.0	1	0.4
		Severe	-	-	-	-	1	1.0	1	0.4
		All	3	3.1	5	8.8	9	9.3	17	6.8
Upper Resp. Tract Infection	Resistance Mechanism	Mild	12	12.5	1	1.8	1	1.0	14	5.6
		Moderate	-	-	-	-	1	1.0	1	0.4
		All	12	12.5	1	1.8	2	2.1	15	6.0

**Table 4 (Cont.): Group 2 - Single Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Paroxetine Treatment Group							
Preferred Term	Body System	Severity	20mg		30mg		40mg		All	
			N	%	N	%	N	%	N	%
Pharyngitis	Respiratory System	Mild	3	3.1	1	1.8	3	3.1	7	2.8
		Moderate	-	-	-	-	2	2.1	2	0.8
		Severe	-	-	-	-	1	1.0	1	0.4
		All	3	3.1	1	1.8	6	6.2	10	4.0
Vomiting	Gastrointestinal System	Mild	1	1.0	2	3.5	3	3.1	6	2.4
		Moderate	-	-	-	-	1	1.0	1	0.4
		All	1	1.0	2	3.5	4	4.1	7	2.8
Depersonalisation	Psychiatric	Mild	-	-	-	-	6	6.2	6	2.4
		All	-	-	-	-	6	6.2	6	2.4
Insomnia	Psychiatric	Mild	1	1.0	2	3.5	1	1.0	4	1.6
		Moderate	-	-	1	1.8	1	1.0	2	0.8
		All	1	1.0	3	5.3	2	2.1	6	2.4
Flatulence	Gastrointestinal System	Mild	-	-	2	3.5	2	2.1	4	1.6
		Moderate	-	-	1	1.8	-	-	1	0.4
		All	-	-	3	5.3	2	2.1	5	2.0
Tremor	Central and Peripheral Nervous System	Mild	2	2.1	-	-	2	2.1	4	1.6
		All	2	2.1	-	-	2	2.1	4	1.6
Anorexia	Gastrointestinal System	Mild	-	-	-	-	3	3.1	3	1.2
		Moderate	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	4	4.1	4	1.6
Somnolence	Psychiatric	Mild	-	-	-	-	2	2.1	2	0.8
		Moderate	-	-	-	-	2	2.1	2	0.8
		All	-	-	-	-	4	4.1	4	1.6
Sweating Increased	Autonomic Nervous System	Mild	-	-	1	1.8	2	2.1	3	1.2
		All	-	-	1	1.8	2	2.1	3	1.2

**Table 4 (Cont.): Group 2 - Single Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Paroxetine Treatment Group							
Preferred Term	Body System	Severity	20mg		30mg		40mg		All	
			N	%	N	%	N	%	N	%
Abdominal Pain	Gastrointestinal System	Mild	-	-	-	-	2	2.1	2	0.8
		Severe	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	3	3.1	3	1.2
Concentration Impaired	Psychiatric	Mild	-	-	-	-	2	2.1	2	0.8
		Moderate	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	3	3.1	3	1.2
Dystonia	Central and Peripheral Nervous System	Mild	-	-	-	-	2	2.1	2	0.8
		All	-	-	-	-	2	2.1	2	0.8
Confusion	Psychiatric	Mild	1	1.0	-	-	1	1.0	2	0.8
		All	1	1.0	-	-	1	1.0	2	0.8
Mouth Dry	Autonomic Nervous System	Mild	1	1.0	1	1.8	-	-	2	0.8
		All	1	1.0	1	1.8	-	-	2	0.8
Mydriasis	Vision	Mild	-	-	-	-	2	2.1	2	0.8
		All	-	-	-	-	2	2.1	2	0.8
Dyspepsia	Gastrointestinal System	Mild	-	-	-	-	1	1.0	1	0.4
		Moderate	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	2	2.1	2	0.8
Rhinitis	Respiratory System	Mild	2	2.1	-	-	-	-	2	0.8
		All	2	2.1	-	-	-	-	2	0.8
Malaise	Body as a Whole General	Mild	-	-	-	-	2	2.1	2	0.8
		All	-	-	-	-	2	2.1	2	0.8

**Table 4 (Cont.): Group 2 - Single Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Paroxetine Treatment Group							
Preferred Term	Body System	Severity	20mg		30mg		40mg		All	
			N	%	N	%	N	%	N	%
Injury	Body as a Whole General	Mild	-	-	-	-	2	2.1	2	0.8
		All	-	-	-	-	2	2.1	2	0.8
Rash Erythematous	Skin and Appendages	Mild	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4
Injection Site Pain	Application Site	Mild	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4
Stupor	Central and Peripheral Nervous System	Mild	1	1.0	-	-	-	-	1	0.4
		All	1	1.0	-	-	-	-	1	0.4
Constipation	Gastrointestinal System	Mild	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4
Flushing	Autonomic Nervous System	Mild	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4
Vision Abnormal	Vision	Mild	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4
Dysphagia	Gastrointestinal System	Mild	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4
Tooth Disorder	Gastrointestinal System	Mild	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4
Purpura	Platelet Bleeding and Clotting	Mild	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4

**Table 4 (Cont.): Group 2 - Single Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Paroxetine Treatment Group							
Preferred Term	Body System	Severity	20mg		30mg		40mg		All	
			N	%	N	%	N	%	N	%
Polyuria	Urinary System	Mild	1	1.0	-	-	-	-	1	0.4
		All	1	1.0	-	-	-	-	1	0.4
Asthenia	Body as a Whole General	Mild	1	1.0	-	-	-	-	1	0.4
		All	1	1.0	-	-	-	-	1	0.4
Chest Pain	Body as a Whole General	Mild	1	1.0	-	-	-	-	1	0.4
		All	1	1.0	-	-	-	-	1	0.4
Pain	Body as a Whole General	Mild	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4
Edema Periorbital	Body as a Whole General	Mild	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4
Gastrointestinal Disorder Nos		Mild	-	-	1	1.8	-	-	1	0.4
		All	-	-	1	1.8	-	-	1	0.4
Hematoma	Platelet Bleeding and Clotting	Mild	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4
Asthma	Respiratory System	Mild	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4
Ejaculation Failure	Reproductive male	Moderate	-	-	2	3.5	-	-	2	0.8
		Severe	-	-	-	-	1	1.0	1	0.4
		All	-	-	2	3.5	1	1.0	3	1.2
Hypertonia	Central and Peripheral Nervous System	Moderate	1	1.0	-	-	-	-	1	0.4
		All	1	1.0	-	-	-	-	1	0.4
Yawning	Psychiatric	Moderate	1	1.0	-	-	-	-	1	0.4
		All	1	1.0	-	-	-	-	1	0.4

**Table 4 (Cont.): Group 2 - Single Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Paroxetine Treatment Group							
Preferred Term	Body System	Severity	20mg		30mg		40mg		All	
			N	%	N	%	N	%	N	%
Back Pain	Musculoskeletal System	Moderate	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4
Rigors	Body as a Whole General	Moderate	-	-	1	1.8	-	-	1	0.4
		All	-	-	1	1.8	-	-	1	0.4
Infection Viral	Resistance Mechanism	Moderate	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4
Tooth Ache	Gastrointestinal System	Moderate	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4
Hot Flushes	Body as a Whole General	Severe	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4
Influenza-like Symptoms	Body as a Whole General	Severe	-	-	-	-	1	1.0	1	0.4
		All	-	-	-	-	1	1.0	1	0.4

**Table 5: Group 2 - Repeat Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group											
Preferred Term	Body System	Severity	Active Only		Active + Other		Placebo Only		Placebo + Other		Other Only		All	
			N	%	N	%	N	%	N	%	N	%	N	%
	Total Subject Sessions		381	100.0	68	100.0	18	100.0	13	100.0	59	100.0	539	100.0
	Subject Sessions with one or more AEs		241	63.3	9	13.2	3	16.7	3	23.1	4	6.8	260	48.2
Diarrhoea	Gastrointestinal System	Mild	85	22.3	-	-	-	-	-	-	-	-	85	15.8
		Moderate	7	1.8	-	-	2	11.1	-	-	-	-	9	1.7
		All	92	24.1	-	-	2	11.1	-	-	-	-	94	17.4
Headache	Central and Peripheral Nervous System	Mild	69	18.1	-	-	-	-	-	-	-	-	69	12.8
		Moderate	16	4.2	-	-	1	5.6	-	-	-	-	17	3.2
		Severe	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	87	22.8	-	-	1	5.6	-	-	-	-	88	16.3
Fatigue	Body as a Whole General	Mild	82	21.5	-	-	-	-	-	-	-	-	82	15.2
		Moderate	4	1.0	-	-	-	-	-	-	-	-	4	0.7
		Severe	-	-	-	-	1	5.6	-	-	-	-	1	0.2
		All	86	22.6	-	-	1	5.6	-	-	-	-	87	16.1
Nausea	Gastrointestinal System	Mild	37	9.7	1	1.5	-	-	-	-	-	-	38	7.1
		Moderate	4	1.0	1	1.5	-	-	-	-	-	-	5	0.9
		Severe	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	42	11.0	2	2.9	-	-	-	-	-	-	44	8.2
Dizziness	Central and Peripheral Nervous System	Mild	30	7.9	1	1.5	-	-	-	-	-	-	31	5.8
		Moderate	2	0.5	1	1.5	-	-	-	-	-	-	3	0.6
		All	32	8.4	2	2.9	-	-	-	-	-	-	34	6.3
Upper Resp. Tract Infection	Resistance Mechanism	Mild	17	4.5	-	-	-	-	-	-	-	-	17	3.2
		All	17	4.5	-	-	-	-	-	-	-	-	17	3.2
Active only	Paroxetine		Active + other				Paroxetine + other co-administered drugs							
Placebo + other	Placebo + other co-administered drugs		Other only				Other drugs given alone							



**Table 5 (Cont.): Group 2 - Repeat Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group											
Preferred Term	Body System	Severity	Active Only		Active + Other		Placebo Only		Placebo + Other		Other Only		All	
			N	%	N	%	N	%	N	%	N	%	N	%
Insomnia	Psychiatric	Mild	13	3.4	-	-	-	-	-	-	-	-	13	2.4
		Moderate	1	0.3	-	-	-	-	1	7.7	-	-	2	0.4
		All	14	3.7	-	-	-	-	1	7.7	-	-	15	2.8
Somnolence	Psychiatric	Mild	10	2.6	-	-	-	-	-	-	-	-	10	1.9
		Moderate	1	0.3	1	1.5	-	-	1	7.7	-	-	3	0.6
		All	11	2.9	1	1.5	-	-	1	7.7	-	-	13	2.4
Ejaculation Disorder	Reproductive Male	Mild	11	2.9	-	-	-	-	-	-	-	-	11	2.0
		Moderate	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		Severe	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	13	3.4	-	-	-	-	-	-	-	-	13	2.4
Anorexia	Gastrointestinal System	Mild	12	3.1	-	-	-	-	-	-	-	-	12	2.2
		All	12	3.1	-	-	-	-	-	-	-	-	12	2.2
Vomiting	Gastrointestinal System	Mild	9	2.4	-	-	-	-	-	-	-	-	9	1.7
		Moderate	3	0.8	-	-	-	-	-	-	-	-	3	0.6
		All	12	3.1	-	-	-	-	-	-	-	-	12	2.2
Ejaculation Failure	Reproductive Male	Mild	5	1.3	-	-	-	-	-	-	2	3.4	7	1.3
		Moderate	2	0.5	1	1.5	1	5.6	-	-	-	-	4	0.7
		All	7	1.8	1	1.5	1	5.6	-	-	2	3.4	11	2.0
Mouth Dry	Autonomic Nervous System	Mild	10	2.6	1	1.5	-	-	-	-	-	-	11	2.0
		All	10	2.6	1	1.5	-	-	-	-	-	-	11	2.0
Sweating Increased	Autonomic Nervous System	Mild	8	2.1	-	-	-	-	-	-	-	-	8	1.5
		Moderate	-	-	1	1.5	-	-	-	-	-	-	1	0.2
		Severe	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	9	2.4	1	1.5	-	-	-	-	-	-	10	1.9
Active only	Paroxetine	Active + other	Paroxetine + other co-administered drugs											
Placebo + other	Placebo + other co-administered drugs	Other only	Other drugs given alone											

**Table 5 (Cont.): Group 2 - Repeat Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group											
Preferred Term	Body System	Severity	Active Only		Active + Other		Placebo Only		Placebo + Other		Other Only		All	
			N	%	N	%	N	%	N	%	N	%	N	%
Abdominal Pain	Gastrointestinal System	Mild	9	2.4	-	-	-	-	-	-	-	-	9	1.7
		Moderate	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	10	2.6	-	-	-	-	-	-	-	-	10	1.9
Nervousness	Psychiatric	Mild	8	2.1	-	-	-	-	-	-	-	-	8	1.5
		All	8	2.1	-	-	-	-	-	-	-	-	8	1.5
Paroniria	Psychiatric	Mild	8	2.1	-	-	-	-	-	-	-	-	8	1.5
		All	8	2.1	-	-	-	-	-	-	-	-	8	1.5
Concentration Impaired	Psychiatric	Mild	6	1.6	-	-	-	-	-	-	-	-	6	1.1
		Moderate	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	7	1.8	-	-	-	-	-	-	-	-	7	1.3
Tremor	Central and Peripheral Nervous System	Mild	5	1.3	-	-	-	-	-	-	-	-	5	0.9
		Moderate	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	6	1.6	-	-	-	-	-	-	-	-	6	1.1
Impotence	Reproductive male	Mild	3	0.8	1	1.5	-	-	-	-	-	-	4	0.7
		Moderate	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		Severe	-	-	1	1.5	-	-	-	-	-	-	1	0.2
		All	4	1.0	2	2.9	-	-	-	-	-	-	6	1.1
Pharyngitis	Respiratory System	Mild	4	1.0	-	-	-	-	-	-	1	1.7	5	0.9
		Moderate	-	-	1	1.5	-	-	-	-	-	-	1	0.2
		All	4	1.0	1	1.5	-	-	-	-	1	1.7	6	1.1
Constipation	Gastrointestinal System	Mild	5	1.3	-	-	-	-	-	-	-	-	5	0.9
		All	5	1.3	-	-	-	-	-	-	-	-	5	0.9
Active only	Paroxetine		Active + other		Paroxetine + other co-administered drugs									
Placebo + other	Placebo + other co-administered drugs		Other only		Other drugs given alone									

**Table 5 (Cont.): Group 2 - Repeat Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group											
Preferred Term	Body System	Severity	Active Only		Active + Other		Placebo Only		Placebo + Other		Other Only		All	
			N	%	N	%	N	%	N	%	N	%	N	%
Flatulence	Gastrointestinal System	Mild	5	1.3	-	-	-	-	-	-	-	-	5	0.9
		All	5	1.3	-	-	-	-	-	-	-	-	5	0.9
Coughing	Respiratory System	Mild	5	1.3	-	-	-	-	-	-	-	-	5	0.9
		All	5	1.3	-	-	-	-	-	-	-	-	5	0.9
SGPT Increased	Liver ad Biliary System	Mild	4	1.0	-	-	-	-	-	-	-	-	4	0.7
		All	4	1.0	-	-	-	-	-	-	-	-	4	0.7
Asthenia	Body as a Whole General	Mild	4	1.0	-	-	-	-	-	-	-	-	4	0.7
		All	4	1.0	-	-	-	-	-	-	-	-	4	0.7
Tooth Ache	Gastrointestinal System	Mild	3	0.8	-	-	-	-	-	-	-	-	3	0.6
		Moderate	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	4	1.0	-	-	-	-	-	-	-	-	4	0.7
Aggressive Reaction	Psychiatric	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		Moderate	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	3	0.8	-	-	-	-	-	-	-	-	3	0.6
Euphoria	Psychiatric	Mild	3	0.8	-	-	-	-	-	-	-	-	3	0.6
		All	3	0.8	-	-	-	-	-	-	-	-	3	0.6
Vision Abnormal	Vision	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		Moderate	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	3	0.8	-	-	-	-	-	-	-	-	3	0.6
SGOT Increased	Liver and Biliary System	Mild	3	0.8	-	-	-	-	-	-	-	-	3	0.6
		All	3	0.8	-	-	-	-	-	-	-	-	3	0.6
Active only	Paroxetine		Active + other		Paroxetine + other co-administered drugs									
Placebo + other	Placebo + other co-administered drugs		Other only		Other drugs given alone									

**Table 5 (Cont.): Group 2 - Repeat Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group											
Preferred Term	Body System	Severity	Active Only		Active + Other		Placebo Only		Placebo + Other		Other Only		All	
			N	%	N	%	N	%	N	%	N	%	N	%
Epistaxis	Respiratory System	Mild	-	-	1	1.5	-	-	-	-	1	1.7	2	0.4
		Moderate	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	1	1.5	-	-	-	-	1	1.7	3	0.6
Anorgasmia Female	Reproductive Female	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		Moderate	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	3	0.8	-	-	-	-	-	-	-	-	3	0.6
Arthralgia	Musculoskeletal System	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	2	0.5	-	-	-	-	-	-	-	-	2	0.4
Myalgia	Musculoskeletal System	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		Moderate	-	-	-	-	-	-	1	7.7	-	-	1	0.2
		All	1	0.3	-	-	-	-	1	7.7	-	-	2	0.4
Agitation	Psychiatric	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	2	0.5	-	-	-	-	-	-	-	-	2	0.4
Depression	Psychiatric	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	2	0.5	-	-	-	-	-	-	-	-	2	0.4
Emotional Lability	Psychiatric	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	2	0.5	-	-	-	-	-	-	-	-	2	0.4
Hallucination	Psychiatric	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	2	0.5	-	-	-	-	-	-	-	-	2	0.4
Yawning	Psychiatric	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	2	0.5	-	-	-	-	-	-	-	-	2	0.4
Active only	Paroxetine		Active + other		Paroxetine + other co-administered drugs									
Placebo + other	Placebo + other co-administered drugs		Other only		Other drugs given alone									

**Table 5 (Cont.): Group 2 - Repeat Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group											
Preferred Term	Body System	Severity	Active Only		Active + Other		Placebo Only		Placebo + Other		Other Only		All	
			N	%	N	%	N	%	N	%	N	%	N	%
Eye Pain	Vision	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	2	0.5	-	-	-	-	-	-	-	-	2	0.4
NPN Increased	Metabolic and Nutritional	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	2	0.5	-	-	-	-	-	-	-	-	2	0.4
Heart Disorder	Cardiovascular General	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	2	0.5	-	-	-	-	-	-	-	-	2	0.4
Rhinitis	Respiratory System	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	2	0.5	-	-	-	-	-	-	-	-	2	0.4
Leukocytosis	White Cell and Reticulo-endothelial System	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	2	0.5	-	-	-	-	-	-	-	-	2	0.4
Pyuria	Urinary System	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	2	0.5	-	-	-	-	-	-	-	-	2	0.4
Influenza-like Symptoms	Body as a Whole General	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	2	0.5	-	-	-	-	-	-	-	-	2	0.4
Gastrointestinal Disorder Nos		Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	2	0.5	-	-	-	-	-	-	-	-	2	0.4
Gamma-GT Increased	Liver and Biliary System	Mild	2	0.5	-	-	-	-	-	-	-	-	2	0.4
		All	2	0.5	-	-	-	-	-	-	-	-	2	0.4
Acne	Skin and Appendages	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Active only	Paroxetine		Active + other				Paroxetine + other co-administered drugs							
Placebo + other	Placebo + other co-administered drugs		Other only				Other drugs given alone							

**Table 5 (Cont.): Group 2 - Repeat Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group											
Preferred Term	Body System	Severity	Active Only		Active + Other		Placebo Only		Placebo + Other		Other Only		All	
			N	%	N	%	N	%	N	%	N	%	N	%
Rash Erythematous	Skin and Appendages	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Arthritis	Musculoskeletal System	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Confusion	Psychiatric	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Dysphonia	Central and Peripheral Nervous System	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Hypertonia	Central and Peripheral Nervous System	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Neuropathy	Central and Peripheral Nervous System	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Paresthesia	Central and Peripheral Nervous System	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Stupor	Central and Peripheral Nervous System	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Anxiety	Psychiatric	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Apathy	Psychiatric	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Active only	Paroxetine		Active + other				Paroxetine + other co-administered drugs							
Placebo + other	Placebo + other co-administered drugs		Other only				Other drugs given alone							

**Table 5 (Cont.): Group 2 - Repeat Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group											
Preferred Term	Body System	Severity	Active Only		Active + Other		Placebo Only		Placebo + Other		Other Only		All	
			N	%	N	%	N	%	N	%	N	%	N	%
Tenesmus	Gastrointestinal System	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Conjunctivitis	Vision	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Tinnitus	Hearing and Vestibular	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Taste Peversion	Special Senses Other	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Gastroenteritis	Gastrointestinal System	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Hyperuricemia	Metabolic and Nutritional	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Phosphatase Alkaline Increased	Metabolic and Nutritional	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Purpura	Platelet Bleeding and Clotting	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Sinusitis	Respiratory System	Mild	-	-	1	1.5	-	-	-	-	-	-	1	0.2
		All	-	-	1	1.5	-	-	-	-	-	-	1	0.2
Albuminuria	Urinary System	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Active only	Paroxetine		Active + other				Paroxetine + other co-administered drugs							
Placebo + other	Placebo + other co-administered drugs		Other only				Other drugs given alone							

**Table 5 (Cont.): Group 2 - Repeat Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group											
Preferred Term	Body System	Severity	Active Only		Active + Other		Placebo Only		Placebo + Other		Other Only		All	
			N	%	N	%	N	%	N	%	N	%	N	%
Cystitis	Urinary System	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Micturition Disorder	Urinary System	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Urethral Disorder	Urinary System	Mild	-	-	-	-	-	-	-	-	1	1.7	1	0.2
		All	-	-	-	-	-	-	-	-	1	1.7	1	0.2
Fever	Body as a Whole General	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Rigors	Body as a Whole General	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Creatine Phosphokinase Increased	Metabolic and Nutritional	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Herpes Simplex	Resistance Mechanism	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Cramps Legs	Vascular Extracardiac	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Ejaculation Premature	Reproductive Male	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Ear Disorder Nos	Hearing and Vestibular	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Active only	Paroxetine		Active + other				Paroxetine + other co-administered drugs							
Placebo + other	Placebo + other co-administered drugs		Other only				Other drugs given alone							



**Table 5 (Cont.): Group 2 - Repeat Dose Studies: Treatment Emergent Adverse Experience Summary**

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group											
Preferred Term	Body System	Severity	Active Only		Active + Other		Placebo Only		Placebo + Other		Other Only		All	
			N	%	N	%	N	%	N	%	N	%	N	%
Hypertriglyceridemia	Metabolic and Nutritional	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Injury	Body as a Whole General	Mild	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Infection Viral	Resistance Mechanism	Moderate	1	0.3	-	-	-	-	1	7.7	-	-	2	0.4
		All	1	0.3	-	-	-	-	1	7.7	-	-	2	0.4
Migraine	Central and Peripheral Nervous System	Moderate	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Depersonalisation	Psychiatric	Moderate	-	-	1	1.5	-	-	-	-	-	-	1	0.2
		All	-	-	1	1.5	-	-	-	-	-	-	1	0.2
Dysphagia	Gastrointestinal System	Moderate	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Enteritis	Gastrointestinal System	Moderate	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Thrombophlebitis Arm	Vascular Extracardiac	Moderate	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Thrombophlebitis	Vascular Extracardiac	Severe	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Pregnancy Unintended	Reproductive Female	Severe	1	0.3	-	-	-	-	-	-	-	-	1	0.2
		All	1	0.3	-	-	-	-	-	-	-	-	1	0.2
Active only	Paroxetine		Active + other				Paroxetine + other co-administered drugs							
Placebo + other	Placebo + other co-administered drugs		Other only				Other drugs given alone.							

**Table 6: Group 3 - Single Dose and Repeat Dose CR Studies: Treatment Emergent Adverse Experience Summary**

Paroxetine CR Prototypes category = Un-coated Geomatrix Paroxetine; DS and DV Geomatrix Paroxetine.

Paroxetine CR EC Geomatrix = Enteric-coated paroxetine CR.

In clinical pharmacology studies (Phase I), the incidence of AEs was calculated by dosing subject session, rather than by subject. For example in a two-way crossover study, if a subject reported the same AE on several occasions within a single dosing session, that AE was counted only once; whereas, if a subject reported the same AE in two different dosing sessions, the AE would be counted twice.

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary - All Studies

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group								ALL	
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo			
			N	%	N	%	N	%	N	%		
Preferred Term	Body System	SEVERITY										
	TOTAL SUBJECT SESSIONS		168	100.0	660	100.0	184	100.0	120	100.0	1,132	100.0
	SUBJECT SESSIONS WITH ONE OR MORE AES		120	71.4	387	58.6	146	79.3	61	50.8	714	63.1
NAUSEA	GASTROINTESTINAL SYSTEM	MILD	47	28.0	77	11.7	49	26.6	16	13.3	189	16.7
		MODERATE	17	10.1	36	5.5	24	13.0	.	.	77	6.8
		SEVERE	1	0.6	4	0.6	6	3.3	.	.	11	1.0
		All	65	38.7	117	17.7	79	42.9	16	13.3	277	24.5
HEADACHE	CENTRAL AND PERIPHERAL NERVOUS SYSTEM	MILD	24	14.3	99	15.0	22	12.0	14	11.7	159	14.0
		MODERATE	7	4.2	51	7.7	21	11.4	8	6.7	87	7.7
		SEVERE	4	2.4	3	0.5	2	1.1	.	.	9	0.8
		All	35	20.8	153	23.2	45	24.5	22	18.3	255	22.5

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group									
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo		ALL	
			N	%	N	%	N	%	N	%	N	%
Preferred Term	Body System	SEVERITY										
FATIGUE	BODY AS A WHOLE GENERAL	MILD	29	17.3	64	9.7	48	26.1	9	7.5	150	13.3
		MODERATE	7	4.2	13	2.0	6	3.3	3	2.5	29	2.6
		SEVERE	.	.	.	.	.	.	1	0.8	1	0.1
		All	36	21.4	77	11.7	54	29.3	13	10.8	180	15.9
DIARRHEA	GASTROINTESTINAL SYSTEM	MILD	18	10.7	73	11.1	20	10.9	8	6.7	119	10.5
		MODERATE	10	6.0	22	3.3	2	1.1	.	.	34	3.0
		SEVERE	2	1.2	2	0.3	1	0.5	.	.	5	0.4
		All	30	17.9	97	14.7	23	12.5	8	6.7	158	14.0
DIZZINESS	CENTRAL AND PERIPHERAL NERVOUS SYSTEM	MILD	14	8.3	41	6.2	20	10.9	6	5.0	81	7.2
		MODERATE	6	3.6	6	0.9	4	2.2	.	.	16	1.4
		SEVERE	.	.	1	0.2	1	0.5	.	.	2	0.2
		All	20	11.9	48	7.3	25	13.6	6	5.0	99	8.7

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group								ALL	
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo			
			N	%	N	%	N	%	N	%		
Preferred Term	Body System	SEVERITY										
INSOMNIA	PSYCHIATRIC	MILD	11	6.5	19	2.9	15	8.2	1	0.8	46	4.1
		MODERATE	1	0.6	8	1.2	1	0.5	1	0.8	11	1.0
		SEVERE	.	.	.	.	1	0.5	.	.	1	0.1
		All	12	7.1	27	4.1	17	9.2	2	1.7	58	5.1
SOMNOLENCE	PSYCHIATRIC	MILD	4	2.4	22	3.3	6	3.3	4	3.3	36	3.2
		MODERATE	2	1.2	2	0.3	3	1.6	.	.	7	0.6
		SEVERE	1	0.6	.	.	1	0.5	.	.	2	0.2
		All	7	4.2	24	3.6	10	5.4	4	3.3	45	4.0
VOMITING	GASTROINTESTINAL SYSTEM	MILD	4	2.4	14	2.1	7	3.8	.	.	25	2.2
		MODERATE	3	1.8	9	1.4	3	1.6	.	.	15	1.3
		SEVERE	1	0.6	2	0.3	1	0.5	.	.	4	0.4
		All	8	4.8	25	3.8	11	6.0	.	.	44	3.9

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group								ALL	
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo			
			N	%	N	%	N	%	N	%		
Preferred Term	Body System	SEVERITY										
ABDOMINAL PAIN	GASTROINTESTINAL SYSTEM	MILD	3	1.8	23	3.5	2	1.1	2	1.7	30	2.7
		MODERATE	.	.	2	0.3	1	0.5	.	.	3	0.3
		SEVERE	.	.	1	0.2	1	0.5	.	.	2	0.2
		All	3	1.8	26	3.9	4	2.2	2	1.7	35	3.1
MOUTH DRY	AUTONOMIC NERVOUS SYSTEM	MILD	5	3.0	13	2.0	8	4.3	2	1.7	28	2.5
		MODERATE	.	.	3	0.5	1	0.5	.	.	4	0.4
		All	5	3.0	16	2.4	9	4.9	2	1.7	32	2.8
TREMOR	CENTRAL AND PERIPHERAL NERVOUS SYSTEM	MILD	5	3.0	9	1.4	10	5.4	.	.	24	2.1
		MODERATE	2	1.2	1	0.2	1	0.5	.	.	4	0.4
		All	7	4.2	10	1.5	11	6.0	.	.	28	2.5
ANOREXIA	GASTROINTESTINAL SYSTEM	MILD	3	1.8	14	2.1	8	4.3	.	.	25	2.2
		MODERATE	.	.	1	0.2	.	.	.	.	1	0.1

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group								ALL	
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo			
			N	%	N	%	N	%	N	%		
Preferred Term	Body System	SEVERITY										
ANOREXIA	GASTROINTESTINAL SYSTEM	All	3	1.8	15	2.3	8	4.3	.	.	26	2.3
SWEATING INCREASED	AUTONOMIC NERVOUS SYSTEM	MILD	6	3.6	6	0.9	5	2.7	1	0.8	18	1.6
		MODERATE	.	.	4	0.6	1	0.5	.	.	5	0.4
		SEVERE	.	.	1	0.2	.	.	.	.	1	0.1
		All	6	3.6	11	1.7	6	3.3	1	0.8	24	2.1
YAWNING	PSYCHIATRIC	MILD	1	0.6	7	1.1	6	3.3	.	.	14	1.2
		MODERATE	.	.	2	0.3	1	0.5	.	.	3	0.3
		All	1	0.6	9	1.4	7	3.8	.	.	17	1.5
FLATULENCE	GASTROINTESTINAL SYSTEM	MILD	2	1.2	10	1.5	2	1.1	1	0.8	15	1.3
		MODERATE	.	.	1	0.2	.	.	.	.	1	0.1
		All	2	1.2	11	1.7	2	1.1	1	0.8	16	1.4
NERVOUSNESS	PSYCHIATRIC	MILD	2	1.2	7	1.1	4	2.2	.	.	13	1.1

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group									
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo		ALL	
			N	%	N	%	N	%	N	%	N	%
Preferred Term	Body System	SEVERITY										
NERVOUSNESS	PSYCHIATRIC	Moderate	.	.	1	0.2	.	.	.	.	1	0.1
		All	2	1.2	8	1.2	4	2.2	.	.	14	1.2
PHARYNGITIS	RESPIRATORY SYSTEM	MILD	.	.	4	0.6	2	1.1	1	0.8	7	0.6
		Moderate	.	.	3	0.5	.	.	.	.	3	0.3
		SEVERE	1	0.6	.	.	1	0.5	.	.	2	0.2
		All	1	0.6	7	1.1	3	1.6	1	0.8	12	1.1
CONCENTRATION IMPAIRED	PSYCHIATRIC	MILD	3	1.8	2	0.3	5	2.7	1	0.8	11	1.0
		Moderate	.	.	.	.	1	0.5	.	.	1	0.1
		All	3	1.8	2	0.3	6	3.3	1	0.8	12	1.1
UPPER RESP TRACT INFECTION	RESISTANCE MECHANISM	MILD	2	1.2	5	0.8	.	.	1	0.8	8	0.7
		Moderate	.	.	1	0.2	.	.	.	.	1	0.1
		SEVERE	.	.	1	0.2	.	.	.	.	1	0.1

(CONTINUED)



Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group									
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo		ALL	
			N	%	N	%	N	%	N	%	N	%
Preferred Term	Body System	SEVERITY										
UPPER RESP TRACT INFECTION	RESISTANCE MECHANISM	All	2	1.2	7	1.1	.	.	1	0.8	10	0.9
DYSPEPSIA	GASTROINTESTINAL SYSTEM	MILD	2	1.2	3	0.5	2	1.1	.	.	7	0.6
		MODERATE	1	0.6	.	.	.	.	.	.	1	0.1
		All	3	1.8	3	0.5	2	1.1	.	.	8	0.7
EJACULATION DISORDER	REPRODUCTIVE MALE	MILD	.	.	6	0.9	.	.	.	.	6	0.5
		MODERATE	1	0.6	.	.	1	0.5	.	.	2	0.2
		All	1	0.6	6	0.9	1	0.5	.	.	8	0.7
MYALGIA	MUSCULOSKELETAL SYSTEM	MILD	1	0.6	2	0.3	.	.	2	1.7	5	0.4
		MODERATE	1	0.6	1	0.2	.	.	.	.	2	0.2
		All	2	1.2	3	0.5	.	.	2	1.7	7	0.6
CONFUSION	PSYCHIATRIC	MILD	.	.	6	0.9	.	.	.	.	6	0.5
		MODERATE	.	.	1	0.2	.	.	.	.	1	0.1

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group									
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo		ALL	
			N	%	N	%	N	%	N	%	N	%
Preferred Term	Body System	SEVERITY										
CONFUSION	PSYCHIATRIC	All	.	.	7	1.1	.	.	.	.	7	0.6
EUPHORIA	PSYCHIATRIC	MILD	1	0.6	1	0.2	4	2.2	.	.	6	0.5
		MODERATE	1	0.6	.	.	.	.	.	.	1	0.1
		All	2	1.2	1	0.2	4	2.2	.	.	7	0.6
DYSPHAGIA	GASTROINTESTINAL SYSTEM	MILD	2	1.2	4	0.6	1	0.5	.	.	7	0.6
		All	2	1.2	4	0.6	1	0.5	.	.	7	0.6
RHINITIS	RESPIRATORY SYSTEM	MILD	1	0.6	3	0.5	1	0.5	1	0.8	6	0.5
		MODERATE	1	0.6	.	.	.	.	.	.	1	0.1
		All	2	1.2	3	0.5	1	0.5	1	0.8	7	0.6
ASTHENIA	BODY AS A WHOLE GENERAL	MILD	1	0.6	2	0.3	3	1.6	1	0.8	7	0.6
		All	1	0.6	2	0.3	3	1.6	1	0.8	7	0.6

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group									
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo		ALL	
			N	%	N	%	N	%	N	%	N	%
Preferred Term	Body System	SEVERITY										
HYPERKINESIA	CENTRAL AND PERIPHERAL NERVOUS SYSTEM	MILD	1	0.6	1	0.2	2	1.1	1	0.8	5	0.4
		MODERATE	.	.	1	0.2	.	.	.	.	1	0.1
		All	1	0.6	2	0.3	2	1.1	1	0.8	6	0.5
PARESTHESIA	CENTRAL AND PERIPHERAL NERVOUS SYSTEM	MILD	2	1.2	1	0.2	2	1.1	.	.	5	0.4
		SEVERE	1	0.6	.	.	.	.	.	.	1	0.1
		All	3	1.8	1	0.2	2	1.1	.	.	6	0.5
CONSTIPATION	GASTROINTESTINAL SYSTEM	MILD	.	.	3	0.5	1	0.5	.	.	4	0.4
		MODERATE	.	.	1	0.2	.	.	1	0.8	2	0.2
		All	.	.	4	0.6	1	0.5	1	0.8	6	0.5
VISION ABNORMAL	VISION	MILD	.	.	6	0.9	.	.	.	.	6	0.5
		All	.	.	6	0.9	.	.	.	.	6	0.5
MICTURITION FREQUENCY	URINARY SYSTEM	MILD	.	.	3	0.5	2	1.1	1	0.8	6	0.5

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group								ALL	
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo			
			N	%	N	%	N	%	N	%		
Preferred Term	Body System	SEVERITY										
MICTURITION FREQUENCY	URINARY SYSTEM	All	.	.	3	0.5	2	1.1	1	0.8	6	0.5
BACK PAIN	MUSCULOSKELETAL SYSTEM	MILD	.	.	2	0.3	.	.	.	.	2	0.2
		MODERATE	.	.	2	0.3	2	1.1	.	.	4	0.4
		All	.	.	4	0.6	2	1.1	.	.	6	0.5
MALAISE	BODY AS A WHOLE GENERAL	MILD	.	.	4	0.6	1	0.5	.	.	5	0.4
		MODERATE	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	5	0.8	1	0.5	.	.	6	0.5
INJECTION SITE PAIN	APPLICATION SITE	MILD	1	0.6	1	0.2	2	1.1	.	.	4	0.4
		MODERATE	.	.	1	0.2	.	.	.	.	1	0.1
		All	1	0.6	2	0.3	2	1.1	.	.	5	0.4
ANXIETY	PSYCHIATRIC	MILD	1	0.6	.	.	1	0.5	1	0.8	3	0.3
		MODERATE	1	0.6	1	0.2	.	.	.	.	2	0.2

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group									
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo		ALL	
			N	%	N	%	N	%	N	%	N	%
Preferred Term	Body System	SEVERITY										
ANXIETY	PSYCHIATRIC	All	2	1.2	1	0.2	1	0.5	1	0.8	5	0.4
APPETITE INCREASED	GASTROINTESTINAL SYSTEM	MILD	1	0.6	1	0.2	3	1.6	.	.	5	0.4
		All	1	0.6	1	0.2	3	1.6	.	.	5	0.4
MYDRIASIS	VISION	MILD	.	.	2	0.3	1	0.5	.	.	3	0.3
		MODERATE	.	.	1	0.2	1	0.5	.	.	2	0.2
		All	.	.	3	0.5	2	1.1	.	.	5	0.4
DYSMENORRHEA	REPRODUCTIVE FEMALE	MILD	.	.	1	0.2	1	0.5	.	.	2	0.2
		MODERATE	.	.	3	0.5	.	.	.	.	3	0.3
		All	.	.	4	0.6	1	0.5	.	.	5	0.4
RASH	SKIN AND APPENDAGES	MILD	.	.	2	0.3	1	0.5	.	.	3	0.3
		MODERATE	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	3	0.5	1	0.5	.	.	4	0.4

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group									
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo		ALL	
			N	%	N	%	N	%	N	%	N	%
Preferred Term	Body System	SEVERITY										
DEPERSONALIZATION	PSYCHIATRIC	MILD	1	0.6	2	0.3	.	.	.	.	3	0.3
		MODERATE	.	.	1	0.2	.	.	.	.	1	0.1
		All	1	0.6	3	0.5	.	.	.	.	4	0.4
TASTE PERVERSION	SPECIAL SENSES OTHER	MILD	2	1.2	1	0.2	1	0.5	.	.	4	0.4
		All	2	1.2	1	0.2	1	0.5	.	.	4	0.4
BILIRUBINEMIA	LIVER AND BILIARY SYSTEM	MILD	.	.	2	0.3	1	0.5	1	0.8	4	0.4
		All	.	.	2	0.3	1	0.5	1	0.8	4	0.4
URINARY TRACT INFECTION	URINARY SYSTEM	MILD	.	.	3	0.5	.	.	.	.	3	0.3
		MODERATE	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	4	0.6	.	.	.	.	4	0.4
HOT FLUSHES	BODY AS A WHOLE GENERAL	MILD	.	.	.	.	1	0.5	1	0.8	2	0.2
		MODERATE	.	.	2	0.3	.	.	.	.	2	0.2

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group									
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo		ALL	
			N	%	N	%	N	%	N	%	N	%
Preferred Term	Body System	SEVERITY										
HOT FLUSHES	BODY AS A WHOLE GENERAL	All	.	.	2	0.3	1	0.5	1	0.8	4	0.4
INFECTION VIRAL	RESISTANCE MECHANISM	MILD	.	.	1	0.2	1	0.5	.	.	2	0.2
		MODERATE	.	.	2	0.3	.	.	.	.	2	0.2
		All	.	.	3	0.5	1	0.5	.	.	4	0.4
INJURY	BODY AS A WHOLE GENERAL	MILD	.	.	3	0.5	.	.	.	.	3	0.3
		MODERATE	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	4	0.6	.	.	.	.	4	0.4
HYPERTONIA	CENTRAL AND PERIPHERAL NERVOUS SYSTEM	MILD	.	.	3	0.5	.	.	.	.	3	0.3
		All	.	.	3	0.5	.	.	.	.	3	0.3
DEPRESSION	PSYCHIATRIC	MILD	.	.	.	.	2	1.1	1	0.8	3	0.3
		All	.	.	.	.	2	1.1	1	0.8	3	0.3
SLEEP DISORDER	PSYCHIATRIC	MILD	.	.	1	0.2	2	1.1	.	.	3	0.3

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group									
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo		ALL	
			N	%	N	%	N	%	N	%	N	%
Preferred Term	Body System	SEVERITY										
SLEEP DISORDER	PSYCHIATRIC	All	.	.	1	0.2	2	1.1	.	.	3	0.3
THINKING ABNORMAL	PSYCHIATRIC	MILD	.	.	1	0.2	1	0.5	.	.	2	0.2
		MODERATE	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	2	0.3	1	0.5	.	.	3	0.3
PHOTOPHOBIA	VISION	MILD	.	.	.	.	3	1.6	.	.	3	0.3
		All	.	.	.	.	3	1.6	.	.	3	0.3
SGOT INCREASED	LIVER AND BILIARY SYSTEM	MILD	.	.	1	0.2	2	1.1	.	.	3	0.3
		All	.	.	1	0.2	2	1.1	.	.	3	0.3
PYURIA	URINARY SYSTEM	MILD	.	.	.	.	2	1.1	1	0.8	3	0.3
		All	.	.	.	.	2	1.1	1	0.8	3	0.3
RIGORS	BODY AS A WHOLE GENERAL	MILD	1	0.6	.	.	2	1.1	.	.	3	0.3
		All	1	0.6	.	.	2	1.1	.	.	3	0.3

(CONTINUED)



Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group								ALL	
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo			
			N	%	N	%	N	%	N	%		
Preferred Term	Body System	SEVERITY										
INFLUENZA-LIKE SYMPTOMS	BODY AS A WHOLE GENERAL	MILD	.	.	1	0.2	1	0.5	.	.	2	0.2
		MODERATE	.	.	.	.	1	0.5	.	.	1	0.1
		All	.	.	1	0.2	2	1.1	.	.	3	0.3
HYPESTHESIA	CENTRAL AND PERIPHERAL NERVOUS SYSTEM	MILD	.	.	2	0.3	.	.	.	.	2	0.2
		All	.	.	2	0.3	.	.	.	.	2	0.2
MUSCLE CONTRACTIONS INVOLUNTARY	CENTRAL AND PERIPHERAL NERVOUS SYSTEM	MILD	1	0.6	1	0.2	.	.	.	.	2	0.2
		All	1	0.6	1	0.2	.	.	.	.	2	0.2
AGITATION	PSYCHIATRIC	MILD	1	0.6	1	0.2	.	.	.	.	2	0.2
		All	1	0.6	1	0.2	.	.	.	.	2	0.2
IMPOTENCE	REPRODUCTIVE MALE	MILD	.	.	2	0.3	.	.	.	.	2	0.2
		All	.	.	2	0.3	.	.	.	.	2	0.2
LIBIDO DECREASED	PSYCHIATRIC	MILD	.	.	1	0.2	1	0.5	.	.	2	0.2

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group								ALL	
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo			
			N	%	N	%	N	%	N	%		
Preferred Term	Body System	SEVERITY										
LIBIDO DECREASED	PSYCHIATRIC	All	.	.	1	0.2	1	0.5	.	.	2	0.2
FLUSHING	AUTONOMIC NERVOUS SYSTEM	MILD	2	1.2	.	.	.	.	.	.	2	0.2
		All	2	1.2	.	.	.	.	.	.	2	0.2
SYNCOPE	CARDIOVASCULAR GENERAL	MODERATE	.	.	.	.	1	0.5	.	.	1	0.1
		SEVERE	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	1	0.5	.	.	2	0.2
THIRST	METABOLIC AND NUTRITIONAL	MILD	2	1.2	.	.	.	.	.	.	2	0.2
		All	2	1.2	.	.	.	.	.	.	2	0.2
PURPURA	PLATELET BLEEDING AND CLOTTING	MILD	.	.	2	0.3	.	.	.	.	2	0.2
		All	.	.	2	0.3	.	.	.	.	2	0.2
COUGHING	RESPIRATORY SYSTEM	MILD	1	0.6	1	0.2	.	.	.	.	2	0.2
		All	1	0.6	1	0.2	.	.	.	.	2	0.2

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group									
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo		ALL	
			N	%	N	%	N	%	N	%	N	%
Preferred Term	Body System	SEVERITY										
EPISTAXIS	RESPIRATORY SYSTEM	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		MODERATE	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	2	0.3	.	.	.	.	2	0.2
HEMATURIA	URINARY SYSTEM	MILD	1	0.6	.	.	1	0.5	.	.	2	0.2
		All	1	0.6	.	.	1	0.5	.	.	2	0.2
NOCTURIA	URINARY SYSTEM	MILD	.	.	2	0.3	.	.	.	.	2	0.2
		All	.	.	2	0.3	.	.	.	.	2	0.2
MENSTRUAL DISORDER	REPRODUCTIVE FEMALE	SEVERE	.	.	.	.	1	0.5	1	0.8	2	0.2
		All	.	.	.	.	1	0.5	1	0.8	2	0.2
PREGNANCY UNINTENDED	REPRODUCTIVE FEMALE	All	1	0.6	.	.	.	.	1	0.8	2	0.2
		NONE	1	0.6	.	.	.	.	1	0.8	2	0.2
GASTROESOPHAGEAL REFLUX	GASTROINTESTINAL SYSTEM	MILD	.	.	1	0.2	1	0.5	.	.	2	0.2

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group								ALL	
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo			
			N	%	N	%	N	%	N	%		
Preferred Term	Body System	SEVERITY										
GASTROESOPHAGEAL REFLUX	GASTROINTESTINAL SYSTEM	All	.	.	1	0.2	1	0.5	.	.	2	0.2
ANISOCORIA	VISION	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		MODERATE	1	0.6	.	.	.	.	.	.	1	0.1
		All	1	0.6	1	0.2	.	.	.	.	2	0.2
DREAMING ABNORMAL	PSYCHIATRIC	MILD	.	.	1	0.2	1	0.5	.	.	2	0.2
		All	.	.	1	0.2	1	0.5	.	.	2	0.2
GASTROINTESTINAL DISORDER NOS	GASTROINTESTINAL SYSTEM	MILD	.	.	.	.	2	1.1	.	.	2	0.2
		All	.	.	.	.	2	1.1	.	.	2	0.2
ASTHMA	RESPIRATORY SYSTEM	MODERATE	.	.	1	0.2	.	.	1	0.8	2	0.2
		All	.	.	1	0.2	.	.	1	0.8	2	0.2
PRURITUS	SKIN AND APPENDAGES	MODERATE	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group									
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo		ALL	
			N	%	N	%	N	%	N	%	N	%
Preferred Term	Body System	SEVERITY										
RASH ERYTHEMATOUS	SKIN AND APPENDAGES	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
RASH MACULO-PAPULAR	SKIN AND APPENDAGES	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
DERMATITIS CONTACT	APPLICATION SITE	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
INJECTION SITE INFLAMMATION	APPLICATION SITE	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
INJECTION SITE REACTION	APPLICATION SITE	MILD	1	0.6	.	.	.	.	.	.	1	0.1
		All	1	0.6	.	.	.	.	.	.	1	0.1
COORDINATION ABNORMAL	CENTRAL AND PERIPHERAL NERVOUS SYSTEM	MILD	1	0.6	.	.	.	.	.	.	1	0.1
		All	1	0.6	.	.	.	.	.	.	1	0.1

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group									
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo		ALL	
			N	%	N	%	N	%	N	%	N	%
Preferred Term	Body System	SEVERITY										
DYSKINESIA	CENTRAL AND PERIPHERAL NERVOUS SYSTEM	MILD	1	0.6	.	.	.	.	.	.	1	0.1
		All	1	0.6	.	.	.	.	.	.	1	0.1
DYSPHONIA	CENTRAL AND PERIPHERAL NERVOUS SYSTEM	MODERATE	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
GAIT ABNORMAL	CENTRAL AND PERIPHERAL NERVOUS SYSTEM	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
MIGRAINE	CENTRAL AND PERIPHERAL NERVOUS SYSTEM	MILD	.	.	.	.	1	0.5	.	.	1	0.1
		All	.	.	.	.	1	0.5	.	.	1	0.1
PARESIS	CENTRAL AND PERIPHERAL NERVOUS SYSTEM	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
APATHY	PSYCHIATRIC	MILD	1	0.6	.	.	.	.	.	.	1	0.1
		All	1	0.6	.	.	.	.	.	.	1	0.1

(CONTINUED)

## Number (%) of Subject Sessions with Treatment Emergent Adverse Events

## Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group									
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo		ALL	
			N	%	N	%	N	%	N	%	N	%
Preferred Term	Body System	SEVERITY										
EMOTIONAL LABILITY	PSYCHIATRIC	MODERATE	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
PARANOID REACTION	PSYCHIATRIC	MODERATE	.	.	.	.	1	0.5	.	.	1	0.1
		All	.	.	.	.	1	0.5	.	.	1	0.1
PALPITATION	HEART RATE AND RHYTHM	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
EYE ABNORMALITY	VISION	MODERATE	.	.	.	.	1	0.5	.	.	1	0.1
		All	.	.	.	.	1	0.5	.	.	1	0.1
ERUCTATION	GASTROINTESTINAL SYSTEM	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
GLOSSITIS	GASTROINTESTINAL SYSTEM	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group									
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo		ALL	
			N	%	N	%	N	%	N	%	N	%
Preferred Term	Body System	SEVERITY										
TONGUE DISORDER	GASTROINTESTINAL SYSTEM	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
EDEMA PERIPHERAL	BODY AS A WHOLE GENERAL	MILD	.	.	.	.	1	0.5	.	.	1	0.1
		All	.	.	.	.	1	0.5	.	.	1	0.1
HEMORRHAGE NOS	VASCULAR EXTRACARDIAC	MILD	1	0.6	.	.	.	.	.	.	1	0.1
		All	1	0.6	.	.	.	.	.	.	1	0.1
PHLEBITIS	VASCULAR EXTRACARDIAC	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
THROMBOPHLEBITIS	VASCULAR EXTRACARDIAC	MILD	1	0.6	.	.	.	.	.	.	1	0.1
		All	1	0.6	.	.	.	.	.	.	1	0.1
LARYNGITIS	RESPIRATORY SYSTEM	MILD	.	.	.	.	.	.	1	0.8	1	0.1
		All	.	.	.	.	.	.	1	0.8	1	0.1

(CONTINUED)



## Number (%) of Subject Sessions with Treatment Emergent Adverse Events

## Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group								ALL	
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo			
			N	%	N	%	N	%	N	%		
Preferred Term	Body System	SEVERITY										
RESPIRATORY DISORDER	RESPIRATORY SYSTEM	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
ANEMIA	RED BLOOD CELL	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
EOSINOPHILIA	WHITE CELL AND RETICULOENDOTHELIAL SYSTEM	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
GRANULOCYTOPENIA	WHITE CELL AND RETICULOENDOTHELIAL SYSTEM	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
LYMPHADENOPATHY	WHITE CELL AND RETICULOENDOTHELIAL SYSTEM	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
CYSTITIS	URINARY SYSTEM	MODERATE	.	.	.	.	.	.	1	0.8	1	0.1
		All	.	.	.	.	.	.	1	0.8	1	0.1

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group								ALL	
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo			
			N	%	N	%	N	%	N	%		
Preferred Term	Body System	SEVERITY										
DYSURIA	URINARY SYSTEM	MILD	.	.	.	.	.	.	1	0.8	1	0.1
		All	.	.	.	.	.	.	1	0.8	1	0.1
MENORRHAGIA	REPRODUCTIVE FEMALE	SEVERE	.	.	.	.	1	0.5	.	.	1	0.1
		All	.	.	.	.	1	0.5	.	.	1	0.1
ALLERGIC REACTION	BODY AS A WHOLE GENERAL	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
CHEST PAIN	BODY AS A WHOLE GENERAL	SEVERE	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
PAIN	BODY AS A WHOLE GENERAL	MILD	1	0.6	.	.	.	.	.	.	1	0.1
		All	1	0.6	.	.	.	.	.	.	1	0.1
INFECTON	RESISTANCE MECHANISM	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group								ALL	
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo			
			N	%	N	%	N	%	N	%		
Preferred Term	Body System	SEVERITY										
INFECTION FUNGAL	RESISTANCE MECHANISM	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
MONILIASIS	RESISTANCE MECHANISM	MODERATE	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
HERPES SIMPLEX	RESISTANCE MECHANISM	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
THERAPEUTIC RESPONSE INCREASED	BODY AS A WHOLE GENERAL	MILD	.	.	1	0.2	.	.	.	.	1	0.1
		All	.	.	1	0.2	.	.	.	.	1	0.1
TEETH-GRINDING	PSYCHIATRIC	MILD	.	.	.	.	1	0.5	.	.	1	0.1
		All	.	.	.	.	1	0.5	.	.	1	0.1
EAR DISORDER NOS	HEARING AND VESTIBULAR	MODERATE	1	0.6	.	.	.	.	.	.	1	0.1
		All	1	0.6	.	.	.	.	.	.	1	0.1

(CONTINUED)

Number (%) of Subject Sessions with Treatment Emergent Adverse Events  
 Treatment Emergent Adverse Experience Summary

Number of Subject Sessions where Signs and Symptoms were reported			Treatment Group										
			Paroxetine CR Prototypes		Paroxetine CR EC Geomatrix		Paroxetine IR		Placebo		ALL		
			N	%	N	%	N	%	N	%	N	%	
Preferred Term	Body System	SEVERITY											
GAMMA-GT INCREASED	LIVER AND BILIARY SYSTEM	MODERATE	.	.	.	.	.	.	1	0.8	1	0.1	
		All	.	.	.	.	.	.	1	0.8	1	0.1	
HEPATIC ENZYMES INCREASED	LIVER AND BILIARY SYSTEM	MILD	1	0.6	.	.	.	.	.	.	1	0.1	
		All	1	0.6	.	.	.	.	.	.	1	0.1	
HEMATOMA	PLATELET BLEEDING AND CLOTTING	MODERATE	.	.	1	0.2	.	.	.	.	1	0.1	
		All	.	.	1	0.2	.	.	.	.	1	0.1	
THROMBOSIS VENOUS ARM	VASCULAR EXTRACARDIAC	MILD	.	.	1	0.2	.	.	.	.	1	0.1	
		All	.	.	1	0.2	.	.	.	.	1	0.1	
TOOTH ACHE	GASTROINTESTINAL SYSTEM	MILD	.	.	.	.	.	.	1	0.8	1	0.1	
		All	.	.	.	.	.	.	1	0.8	1	0.1	